North American Association of Central Cancer Registries, Inc.

Standards for Cancer Registries

Laboratory Electronic Pathology Reporting Guidelines

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Comments and Suggestions:

Comments and suggestions on this and other North American Association of Central Cancer Registries (NAACCR) standards documents are welcome and can be forwarded to an editor or to any member of the NAACCR Board of Directors.

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Preface

The earliest version of pathology laboratory electronic reporting guidelines was only one chapter in the North American Association of Central Cancer Registries (NAACCR) Standards for Cancer Registries Data Standards and Data Dictionary, Version 10, Chapter VI, "Pathology Laboratory Electronic Reporting." Over the years, these guidelines have evolved into a standalone document. *Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting Version 2.0* documents recommended message and format standards for electronic transmission of reports (pathology, cytology, and hematology) from pathology laboratories to central cancer registries. NAACCR Standards Volume V Version 2.1 evolved from modifications made to Version 2.0 as pathology laboratories and central cancer registries developed tools to transmit electronic laboratory reports to cancer registries. In Standards Volume V Version 3.0, the Health Level Seven (HL7) section was upgraded to HL7 Version 2.5.1, which includes more robust guidance for handling specimen information. Standards Volume V Version 4.0, Chapter 3, "Synoptic Reporting," was expanded to include additional guidance on the transmission format of synoptic cancer pathology reports and complex cancer pathology reports examples. Standards Volume V Version 5.0 was revised to capture more information from multiple types of reports originating from the same specimen, to gather and group anatomical and additional reports as pathology reporting continues to evolve. NAACCR Laboratory Electronic Pathology Reporting Version 5.1 includes extensive document editing, revision, and correction made to previously published examples, modified date datatype, and inclusion of additional forward adopted HL7 elements, making Version 5.1 a stepping-stone between HL7 and HL7 FHIR. The purpose of this manual is to describe guidelines for electronic pathology reporting, including capture of biomarker information from a pathology laboratory to a cancer registry.

This document retains the standard specifications for electronic pathology reporting using HL7 Version 2.5.1, as it did in the previous version (Version 5.0). Although HL7 has released Version 2.6 through Version 2.9 as approved American National Standards Institute (ANSI) standards prior to the date of this publication, national standards organizations are recommending HL7 Version 2.5.1. The older version, HL7 Version 2.3.1, does not contain the robustness to handle the specimen-specific information required by cancer registries today. For this reason, the NAACCR Pathology Reporting Workgroup decided to define this standard using HL7 Version 2.5.1, the first version of HL7 to introduce the SPM (specimen) segment, in 2003. Unlike Volume V Version 4.0, in which the SPM segment was considered optional, beginning with version 5.0 of NAACCR Volume V, the SPM segment is required to correctly track identifiers in modern laboratory analyses. With the implementation of version 5.1 of this document, the name of the document has changed to the NAACCR Standards for Cancer Registries: Laboratory Electronic Pathology Reporting Guidelines (formerly known as the NAACCR Standards for Cancer Registries Volume V: Laboratory Electronic Reporting for Pathology).

It is the hope of the NAACCR Pathology Reporting Workgroup that making these consensus standards available to the community will make it easier and less costly for pathology laboratories, central cancer registries, and software vendors to implement uniform, standard methods for the transmission and receipt of electronic pathology reports. Ultimately, our goal is to develop resources that will support current and future initiatives toward standardization through the recommended communication protocols that will assure the collection of reliable, accurate, and timely pathology reports of cancer specimens examined by pathology laboratories. The content of this document will assist pathology laboratories in transmitting electronic reports to cancer registries by utilizing the recommended format standard. It is not intended to be the final revision of the standard, which will evolve over time as more is learned about laboratory technology, electronic reporting, new information technologies, vocabulary and codes, reporting regulations, and confidentiality.

1. Introduction

1.1. BACKGROUND

"Public health surveillance is the systematic, ongoing collection, management, analysis, and interpretation of data followed by the dissemination of these data to public health programs."[1] This broad definition also applies to *cancer* surveillance, where the monitoring and tracking of *cancer* occurrence—be that at the state, provincial/territorial, or national level—provides invaluable information for cancer screening, prevention, diagnosis, treatment, and cancer research. In addition, cancer surveillance may initiate cancer cluster investigations, facilitate trend monitoring, contribute to evaluations of the effectiveness of prevention measures, and guide public health policy. Because most cancers are definitively diagnosed by histology, cancer surveillance programs use pathology reports to identify new cases and to collect information on previously reported cases.

Each state, province, and territory have requirements for cancer registries to conduct population-based cancer surveillance. Cancer registries often rely on pathology laboratories to report certain findings. In the past, these reports were handwritten or printed in a format unique to each registry or laboratory. Today, laboratories send reportable data to cancer registries electronically. The development of this Guide facilitates the implementation of a standard message format for the transmission of electronic pathology reports, including how to incorporate results from genomic tests into the Health Level Seven (HL7) message. The North American Association of Central Cancer Registries (NAACCR) Pathology Reporting Work Group led the development of this Guide, with technical assistance from Klein Consulting and the Association of Public Health Laboratories.

This guide contains the specifications for sending reportable cancers and benign/borderline intracranial and central nervous system (CNS) tumors to appropriate hospital, state, provincial, and territorial cancer registries using HL7 messages. The message is specific to any potentially reportable cancer or benign/borderline intracranial and CNS tumor diagnosis and is applicable for most laboratory-reportable findings as defined by NAACCR. This guide specifies the electronic communication of these tumors, consistent with recommended reporting of reportable conditions from laboratories to cancer registries, using HL7 Version 2.5.1. The Implementation Guide follows the specifications described in the HL7 Standard Version 2.5.1 and focuses on one type of HL7 message, the Observational Report – Unsolicited (ORU). The Guide provides (1) a description of the utility and requirement of each data field in the ORU message, (2) examples of complete messages, and (3) tables of recommended codes.

1.2. PROBLEM STATEMENT, GOALS, AND SCOPE OF THIS DOCUMENT

1.2.1. The Problem

In many instances, sometimes as a result of precision medicine, tumor specimens are being analyzed by multiple laboratories, with each lab transmitting a unique report to the Central Cancer Registry. For central cancer registries, as receivers of such information, this expansion of players involved in the specimen journey highlights the need for interoperability within and across systems that store pathology and genomic findings. The struggle to assemble relevant information on the patient at the tumor/specimen level—including how to carry institutional and provider identifiers in one message transmission—is exacerbated by the lack of a standardized system for reporting.

1.2.2. The Proposed Solution

The Pathology Reporting Work Group has developed this document as a recommended approach for pathology laboratories to report electronically to central cancer registries. HL7 Version 2.5.1 is the

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[1] Porta M, ed. *Dictionary of Epidemiology, 5th Edition.* International Epidemiological Association. New York, NY: Oxford University Press; 2008.

recommended data format for transmitting electronic pathology laboratory reports. A standard pathology laboratory data set, data dictionary, and HL7 transmission format were developed to enhance the completeness, timeliness, consistency, and efficiency with which cancer data are transmitted by pathology laboratories and received and processed by central cancer registries.

1.2.3. Goals of the Standards for Cancer Registries Volume V: Laboratory Electronic Reporting for Pathology

The goals of this document are to define the data standards for cancer registration as used by cancer registries, pathology laboratories, vendors, and other groups, and to provide guidelines for the implementation of these standards.

1.2.4. Scope of This Document

The scope of this document is limited to standards and guidelines to transmit cancer information from laboratories to cancer registries and describes data items, data item definitions, and transmission specifications. In addition, the use of HL7 as the primary recommended clinical data interchange standard will provide a cost-effective solution to addressing data exchange in the 21st century.

Although this Guide describes in detail a data exchange protocol for submitting anatomical pathology reports (traditional narrative and synoptic) for reportable tumors (cancers and selected benign/borderline intracranial and CNS tumors) to hospital and central cancer registries, it is not an HL7 or an interfacing tutorial. The reader is expected to have a basic understanding of interface concepts, HL7 messaging standards, and electronic laboratory-based reporting of public health information.

This document is an update to NAACCR *Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 5.0,* which consists of an HL7 Version 2.5.1 implementation guide. Any user-defined variations from the standard are described, and electronic copies of this document are available on the NAACCR website (www.naaccr.org). Reporting requirements may vary by hospital, state, district, territory, or province. Reportable tumor definitions are available from the state/provincial cancer registries.

1.3. STANDARDS AND GUIDELINES FOR ELECTRONIC TRANSMISSION OF REPORTS FROM PATHOLOGY LABORATORIES TO CENTRAL CANCER REGISTRIES

This document refers to the Health Level Seven (HL7) Version 2.5.1 format for transmitting electronic pathology laboratory reports to central cancer registries. The use of this format is recommended by NAACCR and is fully described within this guide. Laboratories that have demonstrated the inability to report using HL7 may be provided an exception and permitted to report using the pipe-delimited format that is described in NAACCR Volume V, Version 2.2. The use of the pipe-delimited format is not recommended, and its use is only approved on a case-by-case basis, with the expectation that the reporter will upgrade to the recommended format within an agreed upon timeframe.

1.3.1. Implementation Guide for Transmission of Laboratory-Based Reports to Cancer Registries Using Version 2.5.1 of the HL7 Standards Protocol

These chapters are for electronic communication of reportable cancers and benign/borderline intracranial and CNS tumors, consistent with recommended reporting of reportable conditions from laboratories to cancer registries using HL7 Version 2.5.1. The Implementation Guide follows the specifications described in the HL7 Standard Version 2.5.1 and focuses on one type of HL7 message, the ORU.

1.4.   HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Within the United States, the Health Insurance Portability and Accountability Act (HIPAA, or the Act), P.L. 104-191, enacted on August 21, 1996, includes provisions related to insurance coverage and a section that is relevant to electronic reporting of health care information. HIPAA requires that standards be adopted for certain uniform financial and administrative transactions, data elements, and security of electronic health information systems. It also includes provisions for adopting standards for the privacy of health information. The Act preempts state laws and imposes civil monetary penalties and prison terms for certain violations.

HIPAA also imposes changes in the membership and duties of the National Committee on Vital and Health Statistics (NCVHS). It includes a provision that the NCVHS will make recommendations and legislative proposals to the Secretary of the U.S. Department of Health and Human Services on the adoption of uniform data standards for patient medical record information and the electronic exchange of such information.

HIPAA addresses state regulatory reporting by stating, "[N]othing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification."[2]

For public health authorities, HIPAA states, "Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention."[3] Covered entities that are named in the HIPAA legislation are "health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in Section 1173(a) of the Act."[4] The regulation implementing the HIPAA privacy provisions allows public health exemptions for disclosure without patient consent of individually identifiable health information for the purposes quoted above.

Under HIPAA, state cancer registries qualify as public health authorities operating as agencies authorized by law to "collect or receive such information for the purposes of preventing or controlling disease… and for the conduct of public health surveillance, public health investigations, and public health interventions" (45 CFR 164.512). As such, public health reporting to state agencies from pathology laboratories is exempt from HIPAA privacy rules. Pathology laboratories, as covered entities, may report this public health information to state cancer registries using the HL7 Standard as described here; HIPAA provisions will not alter these reports.

At a state level, an example of recent changes to electronic pathology reporting can be seen in California's passage of AB 2325. This state law, signed September 14, 2016, requires all pathologists diagnosing cancer to report cancer diagnoses to the California Cancer Registry (CCR) via electronic means beginning on January 1, 2019. For further information, see the CCR website at www.ccrcal.org/AB2325.shtml.

Within Canada, the Canada Health Act (CHA or the Act) is Canada's federal legislation for publicly funded health care insurance. The Act sets out the primary objective of Canadian health care policy, which is "to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers."[5] The CHA establishes

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[2] The Health Insurance Portability and Accountability Act, 42 U.S.C. 1320d–7.

[3] *Ibid.*

[4] Association of American Physicians and Surgeons, Inc., https://www.aapsonline.org/confiden/1173.htm, accessed April 13, 2020.

[5] Canada Health Act, r.S.C., 1985, c. C-6.

criteria and conditions related to insured health services and extended health care services that the provinces and territories must fulfill.

Provinces and Territories enact pathology reporting requirements through independent cancer surgery agreements with hospitals, laboratories, and other health care agencies and also legislate the collection, use, and disclosure of personal health information.

At a provincial level, one example is that Ontario collects pathology cancer data pursuant to section 23(a) of O.Reg 965, of the Public Hospitals Act and pursuant to the cancer registries' authority as a Prescribed Entity under section 45 of the Personal Health Information Protection Act, 2004.

1.5.   PATHOLOGY REPORT DESCRIPTIONS AND DEFINITIONS

This section identifies the formal names and terms that are used throughout this Guide. Pathology data currently are captured, formatted, and transmitted to cancer registries in a variety of ways.

There are many styles of pathology reports, with great variation in the level of pathological detail, use of narrative versus structured layouts, use of tables and images, use of terminology encoding, and use of electronic transmission. These reports can be structured such that the information captured from the pathologist allows free-text narrative or question-answer pairs with predefined answer selection that may or may not have unique identifiers assigned to every question and answer.

The narrative message style refers to the way pathology information is transmitted in the HL7 message. The message style will depend greatly on how information is captured and stored in the system. If the pathology report structure allows the pathologist to write a narrative response, then the message style will be narrative. A narrative message may be submitted as unstructured free-text data or as structured text that is organized and reported in discrete sections.

A synoptic message style will have very specific question-and-answer sets for the pathologist to complete. Ideally, each answer will be stored in a discrete field that uses a coded value for the answer (in electronic Cancer Protocol message format, or eCP); however, when this is not the case, the information may be stored as a block of text (synoptic summary format). Depending on how the data are stored in the system, the synoptic message style will be transmitted as either a fully encoded eCP message format or a synoptic segmented message format. The fully encoded eCP message format structure includes a template identifier for the form and unique identifiers for both the questions and answers. The synoptic message format includes the questions and answers as formatted text so that the questions and their associated answers appear on separate lines.

The relationship between the different concepts outlined below is shown graphically in Section 2.2.1, Registry Reporting Domain Model, below.

1.5.1.   Kinds of Pathology Reports

Many kinds of reports may be transmitted to cancer registries, depending on jurisdictional rules and local customary practice. In addition to the pathology study report itself, there may be supplemental reports on additional cancers, special studies, other laboratory procedures, supporting clinical information, etc. The most common kinds of reports sent to registries are described below.

1.5.1.1. Primary Report

This is the principal pathology report that contains all of the pathologic and prognostic information associated with the patient's surgical case (specimen(s)).

1.5.1.2. Supplemental Reports

Some kinds of supplemental reports have specific Logical Observation Identifiers Names and Codes (LOINC) codes, and others may not. **The use of LOINC code 22639-9 is deprecated and should not be**

included in any new or updated interfaces. The LOINC code 35265-8 [Addendum] should be used instead.

1.5.1.3. Addenda

An addendum report is a type of ancillary report that contains additional information, typically the results of ancillary diagnostic studies completed after the original pathology report has been released. These reports contain additional information attached to the pathology report, generally after the original report has been issued[6], and may address subsequent testing or stains, comparison with previous specimens, second opinions from other pathologists or laboratories, or a change in diagnosis resulting from re-examining the specimen(s) or sampling new areas within the specimen. Reports from prognostic tests could be considered reportable to the central cancer registry, depending on the individual state law. If these reports mention any clinical history of cancer, then the report may be deemed reportable.

1.5.1.4. Amendments

Amended reports are created to correct errors or discrepancies in the original final report. Typical reasons to create an amended report include correction of typographical errors, modification of the final diagnosis, or documentation of the resolution of a specimen-labeling discrepancy. Note that no special LOINC code is required for Amendments. The LOINC code selected is the code for the report that is being amended, whatever kind the report is, and whatever style the amendment is, with a Result Status (OBR-25) of "C" indicating that the message contains a correction to the previously transmitted report; this differentiates them from the original sent, which carries the Result Status of "F" for Final. Note that preliminary reports (Result Status "P") should not be sent to the registry.

1.5.1.5. Consultation Notes (consults)

A consultation report is a report that provides advice or guidance by a second or additional expert or a deliberation by pathologists on a diagnosis and/or interpretation of diagnostic test results. This may be a second opinion of the specimen diagnosis.

1.5.1.6. Autopsy Report

This is a pathology report that contains all clinical and pathologic information obtained at the time of death and at a postmortem examination[7].

1.5.1.7. Pathology Report Collection

Sometimes several kinds of reports are transmitted together in a single HL7 message (preferred method). These are grouped together as a comprehensive collection, as they often need to be interpreted together as a set. When multiple reports from multiple facilities are included in a single HL7 message as components of the Pathology Report Collection, the Filler Order Number (and Laboratory ID) that is identified in the OBR containing the LOINC code for the collection (60567-5 Comprehensive pathology report panel) should be used to identify the overall case. When applicable, the earliest specimen collection date should be used when reporting a comprehensive pathology report panel for the overall case. NOTE: If Cancer Registry operations do not have a date of diagnosis provided from any other reporting source (e.g., hospital, ambulatory provider, etc.), then the specimen collection date is often used as a date of diagnosis.

For a more complete description of this structure, see Section 2.2.1, Registry Reporting Domain Model.

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[6] Goldsmith JD, Siegal GP, Suster S, Wheeler TM, Brown RW. "Reporting guidelines for clinical laboratory reports in surgical pathology." *Arch Pathol Lab Med.* 132 2008;(10):1608–16.

[7] Edge S, Byrd DR, Compton CC, Fritz AG, Greene FL, Trotti A, eds. *AJCC Cancer Staging Manual 7th Edition.* American Joint Committee on Cancer. New York, NY: Springer; 2010, p. 13.

1.5.2. Pathology Report Formatting

Pathology reports can be grouped *by content* into reports for biopsies, resections, biomarkers, and many other ancillary studies. All of these reports can be submitted in a message layout that is narrative, structured, or a combination of both. Standards are available for most types of primary resection reports in the form of the CAP Cancer Protocols (CCPs). The College of American Pathologists (CAP) standards are also available for some cancer biomarkers in the form of the CAP Biomarker Reporting Templates. The resection standards are in common use, especially in laboratories accredited by CAP and/or the American College of Surgeons' Commission on Cancer (CoC). At present, CAP templates for cancer biomarkers and biopsies are less commonly used. Even when the CAP standards are used, the format of the pathology report may not necessarily follow the original CCP format.

Structured narrative style comments are commonly used for clinical history, gross descriptions, and microscopic descriptions. However, structured narrative style reports are not a substitute for electronically structured synoptic reporting, described in Chapter 3.

This section describes five (5) possible message formats that have been used to structure electronic pathology reports for cancer registry reporting:

a. **Unstructured Narrative** pathology report (also known as a Text Blob). The laboratory is not able to separate the pathology report text into sections such as Clinical History, Gross Observation, Microscopic Observation, Final Dx, Final Dx Text/Path Report Text using LOINC codes (or other codes). See Appendix E for sample message.

b. **Structured Narrative** pathology message text in which LOINC codes are used to submit (any or all) the following path report sections: Clinical History, Nature of Specimen, Gross Observation, Microscopic Observation, Final Dx, Comments, Supplemental Reports, etc. See Appendix E for sample message.

c. **Synoptic Reports,** which include CAP case summaries and/or biomarker templates. These reports should be transmitted using one of the following message styles (see Appendix E for sample messages):

- **Synoptic Summary message** format involves all question-and-answer pairs reported on separate lines sent in one single Observation/Result (OBX) segment. The Report Template Source will be reported as Synoptic Summary. If report template information is available, see Chapter 3 for encoding the first 3 OBX rows.

- **Synoptic Segmented message** format involves question-and-answer pairs sent in separate OBX segments. The Report Template Source will be reported as Synoptic Segmented. If report template information is available, see Chapter 3 for encoding the first 3 OBX rows.

- **Synoptic eCP message** format involves question-and-answer pairs in separate OBX segments. See Chapter 3 rules for reporting eCP templates. Each OBX segment in a synoptic eCP message contains one or more identifiers derived from the XML template. This format is sometimes referred to as a "fully encoded" message style.

1.5.2.1. Unstructured Narrative

Unstructured narrative cancer pathology reports are provided in a paragraph-based or narrative-style format, with specific pathologic findings contained in the narrative text. These reports generally are dictated by a pathologist and then transcribed by a transcriptionist. For unstructured narrative reports in which sections cannot be split into discrete segments and are reported as one paragraph of text, the OBR-4 would be LOINC code 11529-5 (Surgical pathology study), and OBX-3 would be LOINC code 33746-9 (Pathologic Findings).

1.5.2.2. Structured Narrative

A structured narrative report is defined as a report that is generally narrative and formally divided into labeled sections, with each section having a designated LOINC code. Refer to OBR-4 guidance and the LOINC table to identify the appropriate LOINC code to include in OBR-4. The individual sections of the pathology report and their LOINC codes (for use in OBX-3) are listed in Table 1 and described below.

Table 1: Structured Narrative NAACCR Item to LOINC Component Mapping

NAACCR Item Name	NAACCR Item #	LOINC Code	LOINC Component Name
Path–Final Diagnosis	7450	22637-3	Path report.final diagnosis
Path–Text Diagnosis	7400	33746-9	Pathologic findings
Path–Clinical History	7410	22636-5	Pathology report.relevant Hx
Path–Nature of Specimen	7420	22633-2	Pathology report.site of origin
Path–Gross Pathology	7430	22634-0	Pathology report gross observation
Path–Micro Pathology	7440	22635-7	Path report.microscopic observation
Path–Comment Section	7460	22638-1	Pathology report.comments
*Path–Suppl Reports	7470	*22639-9	Pathology report.supplemental reports
Path–Addendum		35265-8	Path report.addendum

* This code (#22639-9) was used for supplemental reports, but since there are explicit LOINC codes for consult reports and addendum, the use of this code is deprecated and should not be included in any new or updated interfaces. LOINC code 35265-8 should be used for narrative supplemental reports, and LOINC code 60569-1 should be used in OBR-4.1 for CAP synoptic checklists that are specific to tumor marker/biomarker tests.

Final Diagnosis Section
LOINC code: 22637-3 Path report.final diagnosis
The final diagnosis section is generally a summation of the "final word" on pathologic and prognostic findings by the pathologist. This section is used in narrative reports. Note that this section does not exist as a separate section in synoptic reports; rather, multiple single items describe it (site, histology, grade, laterality, etc.).

Pathologic Findings Section
LOINC code: 33746-9 Pathologic findings
In general, the text diagnosis section contains all the information that pertains to the pathologic diagnosis of each specimen submitted during one surgical procedure.

Clinical History Section (may also contain Reason for Study)
LOINC code: 22636-5 Pathology report.relevant Hx
The clinical history section provides a brief account of the patient's past and present state of health that is relevant to the tissue sample the pathologist is examining. Note that this section often exists as a separate section in synoptic reports, in addition to specific structured history items in the synoptic template itself.

Site of Origin Section (Nature of Specimen)
LOINC code: 22633-2 Pathology report.site of origin Spec
Describes the site(s) and laterality of the specimen(s). If more than one specimen is included on the pathology report, each is generally assigned an identifying letter or numeral.

Gross Observation Section
LOINC code: 22634-0 Pathology report.gross observation
The gross/macroscopic description section contains the written description (e.g., size, weight, color, etc.) of all removed tissue or foreign materials received by the surgical pathology laboratory.

Microscopic Observation Section
LOINC code: 22635-7 Path report.microscopic observation
The microscopic description section describes the salient histopathologic findings of the case. Specific attributes that the pathologist may look for and report in the microscopic section include histologic grade, tumor margins, assigning of TNM pathological staging, etc. These attributes are typically contained within specific synoptic templates, and so generally are included as a unit only in structured narrative reports.

Comments/Notes Section
LOINC code: 22638-1 Pathology report.comments
The comments/notes field is optional and typically includes additional information that provides further clarification on the clinical findings and/or diagnosis contained within the body of the report. Synoptic templates have structured components for pathology comments, and this separate section typically is used only in narrative reports.

Supplemental Reports Section
LOINC code: 22639-9 Pathology report.supplemental reports
This code (#22639-9) was used for supplemental reports, but because there are explicit LOINC codes for consult reports and addendum, the use of this code is deprecated and should not be included in any new or updated interfaces. If no specific LOINC code is available for the ancillary test, then the LOINC code 35265-8 for path report.addendum should be used.

Report Addendum Section
LOINC code: 35265-8 Path report.addendum
The addendum report section is a type of ancillary report that contains additional information, typically the results of ancillary diagnostic studies completed after the original pathology report has been released. By definition, addendum reports provide additional information that may come, for example, from flow cytometry and immunohistochemistry. This additional information does not result in a change to the final diagnosis of the original pathology report.

1.5.2.3. Synoptic Report
A synoptic report is a narrative report that is formally divided into explicit items covering specific observations on a specimen and laid out in a predefined format. These reports include CAP case summaries and/or biomarker templates. The LOINC code should be Synoptic Report (60568-3) in OBR-4.

1.5.2.3.1. *Synoptic Summary Message*
A Synoptic Summary Message format is all question-and-answer pairs reported on separate lines sent in one single OBX. The Report Template Source should be reported as Synoptic Summary. If a template version is available, then report OBX using LOINC code 60574-1 (template version). If the report is based on a CAP Cancer Protocol, then format according to the instructions in Chapter 3.

1.5.2.3.2. *Synoptic Segmented Message*
The Synoptic Segmented Message format is question-and-answer pairs sent in separate OBXs. The Report Template Source should be Synoptic Segmented Message. See Chapter 3 for more information.

1.5.2.3.3.   CAP eCP Message
The CAP eCP message format is fully encoded question-and-answer pairs in separate OBX. See Chapter 3 for reporting from eCP-based reports.

1.5.3.   LOINC Coding for Reports

The kinds and styles of reports are labeled by a LOINC code contained in the report's HL7 message. This LOINC code is carried in the OBR-4 (Universal Service ID) for the report. See the OBR-4 table and discussion in section 2.7.3 for a summarized list of report types with associated LOINC codes for OBR-4, as well as the associated data element codes for NAACCR Data Item #7480 (Path Report Type 1).

Amended reports do not have any special LOINC codes; the code of the original report should be used, with a Result Status (OBR-25) of "C" indicating that the message contains a correction to the previously transmitted Report and Observation Result Status (OBX-11) should be reported as "C" to indicate the information in OBX-5 has been changed; this differentiates them from the original sent, which carries the Result Status of "F" for Final. Note that preliminary reports (Result Status "P") should not be sent to the registry.

Many supplemental reports may be custom laboratory studies or other types of reports. These should be reported with the LOINC code for the study done, carried in the OBR-4.

1.6.   SAMPLE PATHOLOGY REPORTS

The sample reports below illustrate many of the data items for which this guide provides encoding rules for HL7 Messages to Cancer Registries. For more examples of Synoptic Reports, see Chapter 3.

1.6.1.   Sample Traditional Unstructured Narrative Pathology Report

The anatomic pathology report example below is a typical simple report with content to be transmitted from a laboratory or hospital to a cancer registry. See Appendix E for an example of an ORU message that supports sending the data, as illustrated in the sample pathology report below.

PATHOLOGY REPORT

Report Identification		Patient Information			
Facility ID:	33D1234567	Chart/MRN:	**00466144**	Address:	**495 East Overshoot Drive**
Requisition ID:	7654098				
Accession ID:	97 810430	SSN/SIN:	**123456789**		
Specimen ID:	3567829				
Report Date:	2004-07-28	Surname:	**CANE**	City/Town:	**Delmar**
Report Type:	Final	Given Name:	**CANDY**	State/Prov:	**NY**
Requester ID:	594110NY	Sex:	**F**	Zip/Post Code:	**12054**
Requester:	CARING, CAREN M.D. Albany Medical Center, 43 New Scotland Ave. NY, Albany 12208	Date of Birth:	**1957-07-06**	Country:	
Procedure Date:	2004-07-20	Age:	**47** (at procedure date)		
Surgeon ID:	123456	Insurer:	**USHC**		
Surgeon:	MYELOMUS, JOHN	Insurance No:	**3270686987**		
Pathologist ID:	109771	Race:	**White**		
Pathologist:	GLANCE, JUSTIN	Ethnicity:			

Clinical Dx/ Comment	Carcinoma of breast. Post-operative diagnosis: same.
Clinical History	47-year old white female with (L) UOQ breast mass
Tissue Submitted	left breast biopsy apical axillary tissue contents of left radical mastectomy
Gross Pathology	Part #1 is labeled "left breast biopsy" and is received fresh after frozen section preparation. It consists of a single firm nodule measuring 3 cm in circular diameter and 1.5 cm in thickness, surrounded by adherent fibrofatty tissue. On section, a pale gray, slightly mottled appearance is revealed. Numerous sections are submitted for permanent processing. Part #2 is labeled "apical left axillary tissue" and is received fresh. It consists of two amorphous fibrofatty tissue masses without grossly discernible lymph nodes therein. Both pieces are rendered into numerous sections and submitted in their entirety for history. Part #3 is labeled "contents of left radical mastectomy" and is received fresh. It consists of a large ellipse of skin overlying breast tissue, the ellipse measuring 20 cm in length and 14 cm in height. A freshly sutured incision extends 3 cm directly lateral from the areola, corresponding to the closure for removal of part #1. Abundant amounts of fibrofatty connective tissue surround the entire beast and the deep aspect includes an 8 cm length of pectoralis minor and a generous mass of overlying pectoralis major muscle. Incision from the deepest aspect of the specimen beneath the tumor mass reveals tumor extension gross to within 0.5 cm of muscle. Sections are submitted according to the following code: DE – deep surgical resection margins; SU, LA, INF, ME – full- thickness radial samplings from the center of the tumor superiorly, laterally, inferiorly, and medially, respectively: NI – nipple and subjacent tissue. Lymph nodes dissected free from axillary fibrofatty tissue from Levels I, II, and III will be labeled accordingly.
Microscopic	Sections of part #1 confirm frozen section diagnosis of infiltrating duct carcinoma. It is to be noted that the tumor cells show considerable pleomorphism, and mitotic figures are frequent (as many as 4 per high-power field). Many foci of calcification are present within the tumor. Part #2 consists of fibrofatty tissue and a single tiny lymph node free of disease. Part #3 includes 18 lymph nodes, three from Level III, two from Level II, and 13 from Level I. All lymph nodes are free of disease, with the exception of one Level I lymph node, which contains several masses of metastatic carcinoma. All sections taken radially from the superficial center of the resection site fail to include tumor, indicating the tumor to have originated deep within the breast parenchyma. Similarly, there is no malignancy in the nipple region, or in the lactiferous sinuses. Sections of deep surgical margin demonstrate diffuse tumor infiltration of deep fatty tissues; however, there is no invasion of muscle. Total size of primary tumor is estimated to be 4cm in greatest dimension.
Final Dx	1. Infiltrating duct carcinoma, left breast. 2. Lymph node, no pathologic diagnosis, left axilla. 3. Ext. of tumor into deep fatty tissue. Metastatic carcinoma, left axillary lymph node (1) Level I. Free of disease 17 of 18 lymph nodes – Level I (12), Level II (2), and Level III (3).
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1.6.2.　　Sample Structured Narrative Pathology Report

The anatomic pathology report example below is a typical simple report with content to be transmitted from a laboratory or hospital to a cancer registry. See Appendix E for an example of an ORU message that supports the sending of the data as illustrated in the sample pathology report below.

Report Identification		Patient Information			
Facility ID:	33D1234567	Chart/MRN:	**00466144**	Address	**495 East Overshoot Drive**
Requisition ID:	7654098				
Accession ID:	97 810430	SSN/SIN:	**123456789**		
Specimen ID:	3567829				
Report Date:	2004-07-28	Surname:	**CANE**	City/Town:	**Delmar**
Report Type:	Final	Given Name:	**CANDY**	State/Prov:	**NY**
Requester ID:	594110NY	Sex:	**F**	Zip/Post Code:	**12054**
Requester:	CARING, CAREN M.D. Albany Medical Center, 43 New Scotland Ave. NY, Albany 12208	Date of Birth:	**1957-07-06**	Country:	

Procedure Date:	2004-07-20	Age:	**47** (at procedure date)		
Surgeon ID:	123456	Insurer:	**USHC**		
Surgeon:	MYELOMUS, JOHN	Insurance No:	**3270686987**		
Pathologist ID:	109771	Race:	**White**		
Pathologist:	GLANCE, JUSTIN	Ethnicity:			
Clinical Dx/ Comment	Carcinoma of breast. Post-operative diagnosis: same.				
Clinical History	47 year old white female with (L) UOQ breast mass				
Tissue Submitted	Left breast lesion – short stitch superior. Long stitch lateral.				

Gross Pathology	SPECIMEN SITE DESCRIBED ON CONTAINER: left breast lesion
	SPECIMEN DESCRIPTION
	    Tissue/s: consistent with breast lumpectomy, with attached skin ellipse
	        Handling Prior to Receipt in Lab: specimen received intact
	        Clinical Orientation: attached short suture, described on requisition as
	"superior" and attached long suture, described as "lateral" – used for the orientation of the
	specimen (below) Resection Margins:
	        inked:
	        red medial and lateral
	        blue superior
	        green inferior
	        black deep
	    Other Handling in Lab: sectioned and left for overnight fixation
	        Approximate Fixation Time: > 48 hours / < 7 days
	        Specimen Size: breast $7.1 \times 6.2 \times 2.5$ cm in greatest dimensions; skin ellipse 3.3×0.6 cm
	    Diagnostic Imaging for Identification of Suspect Area/s: not required
	    Breast Tumor: present – see below
	        Size: difficult to measure accurately; a 0.6 cm area of hemorrhage immediately adjacent tumor, obscuring tumor margin approximately 2.0×1.2 cm in greatest dimensions
	    Location: 11 o'clock – as per prior clinical history Appearance: spiculated, ill-defined, firm, grey-white Evidence of Spread or Complications: none
	        Resection Lines: 0.3 cm from the closest resection margin – the deep 0.8 cm from the next closest resection margin – the junction of the superior and inferior (superficially) 1.2 cm from all remaining resection margins, the next closest being the medial
	    Other Breast: moderately fibrous centrally, and surrounding tumor
	    Nipple: not applicable – not included with specimen
	    Skin: normal
	    Lymph Nodes: none seen
	        Axillary Tissue: not applicable – none included with specimen
	        Other Abnormalities/Comments: none
	
	MATERIAL SUBMITTED FOR HISTOLOGY: entire tumor, and other representative sections
	
	BLOCKS SUBMITTED TO HISTOLOGY:
	
	A,B complete cross-section of tumor, in its largest dimension – split in two
	C tumor including closest (deep) resection margin
	D-G ? tumor including deep margin
	H fibrous breast, including inferior resection margin
	I breast, including lateral resection margin
	J breast, including medial resection margin section immediately superficial but perpendicular to that in A,B, including superior margin and skin ellipse				

Microscopic	Neoadjuvant Treatment: unknown – not provided clinically
	Specimen Type: lumpectomy
	Lymph Node Sampling: sentinel lymph node biopsy
	    Specimen Size:
	    Greatest Dimension (cm): 7.1				

	Comments: as described grossly
	Laterality: left
	Comments: as described clinically
	Features of Malignancy:
	Tumor Site: not specified clinically
	Comments: described as "11 o'clock" in the Clinical History for a previous core biopsy
	(S*-*****) – likely the same site as the tumor in the specimen here
	Invasive Carcinoma: present
	Histologic Type: invasive ductal carcinoma
	Comments: with prominent lobular differentiation; for instance, the carcinoma spreads as
	individual cells and small groups of cells at the edge of the main tumor mass
	Tumor Distribution: single focus only
	Comments: seen in the area described grossly
	Size of Invasive Component:
	Greatest Dimension (cm): 1.1
	Comments: exact size difficult to be certain of, because of the effect of previous biopsy,
	but appearing greater than 1.0 cm in largest dimension, from the microscopic slides
	Histologic Grade:
	Tubule Formation: 3/3
	Nuclear Pleomorphism: 2/3
	Mitotic Count (40x): 1/3
	Modified Nottingham Grade: Grade II/III – moderately differentiated
	Skin Involvement: absent
	Chest Wall Involvement: not applicable – none included with the specimen
	Venous/Lymphatic Invasion: absent
	Block(s) for Receptor Studies: being sent to: LHO
	Blocks Submitted: G
	In Situ Carcinoma: absent
	Comments: except in some very minute foci in and around the invasive tumor
	Lymph Nodes:
	Lymph Nodes Present: yes
	Number Examined: 1
	Number Involved: 0
	AJCC Staging:
	Additional pTNM Descriptors: not applicable
	Primary Tumor (pT): pT1c – tumor more than 1.0 cm but not more
	than 2.0 cm in greatest dimension
	Distant Metastasis (pM): pMx – cannot be assessed
	Resection Margin(s):
	Involvement by Invasive Carcinoma: absent
	Closest Margin(s): deep, in a number of slides – and particularly
	close in Slide G
	Distance to Closest Margin (mm): 1
	Comments: (0.1 cm)
	Correlation with IOC: not applicable
	Additional Pathologic Findings: reactive fibrosis around the carcinoma
	changes around the carcinoma consistent with the effect of previous
	biopsy some immunohistochemistry will be ordered to confirm
	some of the findings above – that will be reported in an Addendum
	Report to follow fibrocystic change in the background reactive
	changes in the lymph node
Final Dx	SKIN ELLIPSE AND UNDERLYING BREAST AND ADIPOSE TISSUE (LEFT),
	LUMPECTOMY: INVASIVE DUCTAL CARCINOMA
	– ADDENDUM AND CONSULTATION REPORTS WITH RECEPTORSTATUS TO FOLLOW
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1.6.3.   Sample Synoptic Pathology Report

The supplemental breast biomarker report example below is a typical simple report with content to be transmitted from a laboratory or hospital to a cancer registry. See Appendix E, for an example of an ORU message that supports sending the data, as illustrated in the sample pathology report below.

Breast Biomarker Report		Patient Information			
Facility ID:	33D1234567	Chart/MRN:	**00466144**	Address	**495 East Overshoot Drive**
Requisition ID:	7654098				
Accession ID:	97 810430	SSN/SIN:	**123456789**		
Report Date:	2004-07-28	Surname:	**CANE**	City/Town:	**Delmar**
Report Type:	Final	Given Name:	**CANDY**	State/Prov:	**NY**
Requester ID:	594110NY	Sex:	**F**	Zip/Post Code:	**12054**
Requester:	CARING, CAREN M.D. Albany Medical Center, 43 New Scotland Ave. NY, Albany 12208	Date of Birth:	**1957-07-06**	Country:	
Procedure Date:	2004-07-20	Age:	**47** (at procedure date)		
Surgeon ID:	123456	Insurer:	**USHC**		
Surgeon:	MYELOMUS, JOHN	Insurance No:	**3270686987**		
Pathologist ID:	109771	Race:	**White**		
Pathologist:	GLANCE, JUSTIN	Ethnicity:			

	Test(s) Performed
	Test(s) Performed: Estrogen Receptor (ER) Status (Note A), Progesterone Receptor (PgR) Status (Note A) **ER Results:** Negative (less than 1%) **ER Test Control Status:** Internal control cells present and stain as expected **Test Type:** Laboratory-developed test **Primary Antibody:** SP1 **PgR Results:** Negative (less than 1%) **PgR Test Control Status:** Internal control cells present and stain as expected **Test Type:** Laboratory-developed test **Primary Antibody:** 312 **Cold Ischemia and Fixation Times:** Do not meet requirements specified in latest version of the ASCO/CAP Guidelines **Fixative:** Formalin **Comment(s):** These results apply to both the invasive component and DCIS (both components are negative). CAP eCP August 2019 Preview
Clinical Dx/ Comment	
Clinical History	
Tissue Submitted	
Gross Pathology	
Microscopic	
Final Dx	
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1.7. SPECIMEN WORKFLOW AND IDENTIFIER ASSIGNMENT

Specimens are usually pieces of tissue. Each of these has one or more identifiers associated with it. This is due to workflow and IT-system requirements/limitations. Each facility that handles a specimen may assign its own identifier to the specimen. The points below provide details about this process.

Specimen Identifiers:

- During a surgical procedure, multiple specimen containers may be used and sent to the pathology lab or labs. In general, a surgical facility assigns a unique identifier to each container that holds patient tissue. This identifier will be called the **originally assigned identifier.** The tissue inside the container may be a single specimen, or the container may hold multiple specimens – e.g., multiple lymph nodes from a single region/zone.

- When a container bearing the **originally assigned identifier** is received by a pathology lab, the lab often will record this identifier. In many cases, the lab also will assign a new identifier to the tissue in that container.

- In general, most pathology labs will assign a single case identifier, "surg/path id," to group these specimen containers under a single identifier. In these cases, the "surg/path id" refers to all tissues received during that surgical specimen collection.

- In the pathology lab, each specimen container may contain multiple specimens. In addition, each piece of tissue ("specimen") may be subdivided and assigned its own identifier.

- Each specimen may be divided into sub-specimens. Each sub-specimen may receive its own identifier. For example, a specimen may be divided into multiple blocks, and a block may be divided into multiple slides. Each block and slide may be assigned its own identifier. The division of tissue for processing purposes is also common to molecular and other types of studies.

1.8. WORKFLOW BETWEEN MULTIPLE FACILITIES

A specimen sent to other facilities often has new identifiers assigned at that facility. A receiving facility often does not record the identifiers of the sending facility in its system, reports, or data transmissions. This problem is compounded by inconsistent use of terminology for specimens and their identifiers. Figure 1 below depicts an example of a complex workflow between multiple facilities. Reporting to central cancer registries may occur at any point in this process, not necessarily including original identifiers from other facilities.

Figure 1: Multiple Facility Workflow

2. Implementation Guide for Transmission of Laboratory-Based Reports to Cancer Registries Using Version 2.5.1 of the HL7 Standard Protocol

2.1. REGISTRY MESSAGING USING HL7

Electronic transmission of cancer pathology reports will flow to cancer registries using the Health Level Seven (HL7) standard protocol. This guide remains true to the HL7 Version 2.5.1 Final Standard, which was accepted as an American National Standards Institute (ANSI) standard on February 21, 2007 (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144). The entries described below are derived from that Standard for use with electronic laboratory reporting, with a few exceptions where the guide is forward-adopting elements from HL7 Version 2.9. Below is a list of data items that have been forward adopted:

Field Name	Comment
General Acknowledgement (ACK) Message Structure	Optional, if cancer registry is not using.
Segment Group for synoptic	Used to report CAP eCPs

2.1.1. Data Types Referred To in this Implementation

All fields that carry data in NAACCR messaging (defined in the Static Model) are associated with an HL7 data type, which defines the internal structure and data layout of the field. Although some fields are simple unformatted strings or numbers, most are complex composites with components that are delimited.

Only a subset of the data types defined in the HL7 Version 2.5.1 Standard is used for NAACCR Cancer Registry Messaging. Data types that are referred to in the Static Model definitions are listed here. For the complete definitions and all of the details of these data types, please see Appendix C, Detailed HL7 Data Type Specifications. Please also note that the data types for elements that are not supported in NAACCR messaging are not included here; for details on those data types, please refer to the HL7 Version 2.5.1 Standard, Chapter 2A.

CE – coded element
CF – coded element with formatted values
CNE – coded with no exceptions
CNN – composite ID number and name
CQ – composite quantity with units
CWE – coded with extensions
CX – extended composite ID with check digit
DLD – discharge to location and date
DR – date/time range
DT – date
DTM – date/time
ED – encapsulated data
EI – entity identifier
EIP – entity identifier pair
ELD – error location and description
ERL – error location
FN – family name
FT – formatted text data
HD – hierarchic designator
ID – coded value for HL7-defined tables
IS – coded value for user-defined tables

MSG – message type
NDL – name with date and location
NM – numeric
PL – person location
PRL – parent result link
PT – processing type
SI – sequence ID
SN – structured numeric
SPS – specimen source
ST – string data
TM – time
TS – time stamp
TX – text data
VID – version identifier
XAD – extended address
XCN – extended composite ID number and name for persons
XON – extended composite name and identification number for organizations
XPN – extended person name
XTN – extended telecommunication number

Please note that a number of data types (such as PN) that were used in the Version 2.3.1 specification have been removed from HL7 Version 2.5.1. These obsolete data types are:

CK – composite ID with check digit   PN – person name
CM – composite   TN telephone number

Please refer to HL7 Standard Version 2.3.1 for details on these obsolete data types.

2.1.2.   Most Commonly Used Identifiers

A few fields in the message have default values, meaning that senders of messages must populate the field with the default value if they do not have a case-specific value for that field. Non-required fields that are left empty by senders if they do not have data for the field will have the default value applied when the message is processed at the central cancer registry. This applied default value is used for quality control monitoring purposes. Table 3 lists the defined default values for these fields.

Table 3: HL7 Fields

Most Commonly Used Identifiers Fields			
Field ID	**Field Name**	**Identifiers**	**Comment**
MSH-21	Message Profile Identifier	VOL_V_50_ORU_R01^NAACCR _CP	Identifies the profile for the ORU^R01 message in this Specification
PID-3.4	Patient ID.Assigning authority	HD	
PID-3.4.1	Assigning authority. Namespace ID	IS	CLIA or NPI Table 0363
PID-3.4.2	Assigning authority. Universal ID	ST	CLIA or NPI
PID-3.4.3	Assigning authority. Universal ID type	ID	CLIA or NPI Table 0301
PID-3.5	Patient ID.Identifier Type Code	MR	When the repetition contains a Medical Record #
PID-3.5	Patient ID.Identifier Type Code	SS	When the repetition contains a Social Security #
PID-3.5	Patient ID.Identifier Type Code	PI	When the repetition contains a Patient Internal Identifier
PID-3.5	Patient ID.Identifier Type Code	MC	When the repetition contains a Medicare Beneficiary Identifier
PID-3.6	Patient ID.Assigning facility	HD	
PID-3.6.1	Assigning facility. Namespace ID	IS	CLIA or NPI Table 0363
PID-3.6.2	Assigning facility. Universal ID	ST	CLIA or NPI
PID-3.6.3	Assigning facility. Universal ID type	ID	CLIA or NPI Table 0301
PID-10.1	Identifier	ST	Table 0005

2.1.3.   Identifiers in HL7 Pathology Report Messages

A number of real-world entities are referred to in cancer registry messaging, many of which have persistent unique identifiers. These include clinicians, facilities, instances of reports in laboratory systems, specimens, and patients, among other things.

A large number of different identifiers are in wide use for individual providers and provider organizations. The use of NPI (National Provider ID) is encouraged, if available, to reduce variability in the ways providers are identified to registries. Note that NPIs are assigned at the individual level, as well as the organizational level, and they should be used according to the requirements associated with the

HL7 field. Note also that the use of UPIN (unique physician identifier) as the national identifier for physicians was discontinued in June 2007 and has since been replaced by NPI, which is encouraged for cancer registry messaging. UPIN is not recommended for use.

Because there are a variety of identifiers, the Identifier Type Code must be included when sending one of these identifiers. In most cases, a national or jurisdiction-wide identifier will be available; it is preferable to use one of these, rather than local identifiers, to identify providers.

Laboratories typically assign an identifier to the information recorded for the analysis requested on a received specimen(s) when the specimen(s) arrive at the laboratory. This identifier is specific to the laboratory; when part or the entire specimen is sent out for additional or supplemental analysis to another laboratory, a new identifier will be assigned by the supplemental laboratory. To maintain the traceability of these identifiers when data from multiple laboratories are sent in a single message, the identifier assigned by the laboratory sending the message should be populated in OBR-3 Filler Order Number (see Section 2.7.2, Observation Request Segment) of the OBR for the pathology report collection; and the OBR-3 value for each of the contained reports should contain the identifier assigned by the laboratory that created that report.

The identifier contained on the pathology study requisition form, commonly referred to as the requisition number, should be reported in the registry message in the OBR-2 Placer Order Number.

The specimen at a laboratory typically is identified with the same number as the overall report record in the Anatomic Pathology Laboratory Information System (APLIS), and the case itself—the accession number— generated when the requisition and specimen arrive and are accepted at the laboratory. However, in some circumstances, there will be multiple specimens, and the different specimens may end up generating different reports (see the complex use cases described in Appendix E). In such circumstances, it is recommended that identifiers of the different specimens be reported in the SPM-2; the message style includes a SPM segment, with each block of the message starting with an observation request (OBR).

Note that on rare occasions different specimen IDs may be associated with various components of a large multi- specimen case, such as the example in Appendix E with eight different types of tissue included. If this circumstance occurs and the additional specimen identifiers are to be transmitted in the message, then the field SPM-31 should be used for this purpose; do not send the additional specimen identifiers in

Observation/Result (OBX) segments. If multiple accession numbers from the same laboratory are to be sent as part of a single report (with a single OBR segment), then the SPM-30 should be used to carry these extra accession numbers. This implementation guide supports one to many relations, for example in the case of two tumors in a single organ that have different laboratory results.

Table 4 lists the identifier types commonly used in XCN, XON and NDL data types when identifying providers, either individual clinicians or organizations (hospitals and laboratories). The HL7 fields in which the type of identifiers are used most commonly are listed in the first column.

Identifiers: Table 4 lists a number of fields in the message that contain such identifiers and notes the NAACCR item name and numbers for these. The identifier types listed in the third column of the table are directly mapped to specific NAACCR data items; otherwise, the identifier type column contains "Others," which indicates that all other identifier types not listed in the table below are mapped to a specific NAACCR item.

Note that NAACCR item numbers 7000 and higher in Table 4 (and referenced elsewhere in this Guide) were specifically added to the NAACCR set in support of HL7 messaging as defined in this Volume V. See Appendix F for a complete list of NAACCR data item names and numbers and their relation to the

NAACCR Data Standards and Data Dictionary. Note also that "N/A" in any of the cells in the table indicates "Not Applicable."

Table 4: Identifiers in HL7 Pathology Report Messages

HL7 Field	HL7 Field Name	Identifier Type	NAACCR Item Name	NAACCR Item #	Comments
PID-3	Patient identifier list	SS	Social Security Number	2320	Patient SSN
PID-3	Patient identifier list	MR	Medical Record Number	2300	Patient MRN
PID-3	Patient identifier list	<Other code>	Path Patient ID Canadian	7570	Any other types of patient identifiers, including provincial/territorial health card number
PID-3	Patient identifier list	<Other code>	Path Patient ID Other	7578	Other types of Patient identifiers, including a Patient ID local to the laboratory
PV1-7	Attending Doctor	<Other code>	Physician Managing Other	7580	Other types of individual provider IDs
PV1-7	Attending Doctor	NPI	NPI Physician Managing	2465	National Provider ID
PV1-7	Attending Doctor	MD	Physician Managing	2460	**State Medical license number
PV1-8	Referring Doctor	MD	Physician Follow-up	2470	**State Medical license number
PV1-8	Referring Doctor	NPI	NPI Physician Follow-up	2475	National Provider ID
PV1-8	Referring Doctor	<Other code>	Physician Follow-up Other	7590	Other types of individual provider IDs
PV1-9	Consulting Doctor	MD	Physician 3	2490	**State Medical license number
PV1-9	Consulting Doctor	NPI	NPI Physician 3	2495	National Provider ID
PV1-9	Consulting Doctor	<Other code>	Path Physician 3	7600	Other types of individual provider IDs
PV1-17	Admitting Doctor	<Other code>	No NAACCR item	N/A	Other types of individual provider IDs
PV1-17	Admitting Doctor	NPI	No NAACCR item	N/A	National Provider ID
ORC-21	Ordering Facility Name	NPI	Path Ordering Facility Number NPI	7195	National Provider ID (in the U.S.)
ORC-21	Ordering Facility Name	<Other code>	Path Ordering Facility Number Other	7190	Other types of Facility identifiers (outside the U.S.)
OBR-2	Placer Order Number	N/A	Path Number Hosp	7610	Requisition number or Surgical Pathology Number (from Hospital)
OBR-3	Filler Order Number	N/A	Path Report Number	7090	Laboratory Report Number
OBR-3	Filler Order Number	N/A	No NAACCR item	N/A	Accession Number
OBR-10	Collector identifier	<Other code>	Physician Primary Surg Other	7620	Other types of individual provider IDs
OBR-10	Collector identifier	MD	Physician Primary Surg	2480	**State Medical license number
OBR-10	Collector identifier	NPI	NPI Physician Primary Surg	2485	National Provider ID
OBR-16	Ordering Provider	<Other code>	Ordering Client/Phys—Lic No Other	7108	Other types of individual provider IDs
OBR-16	Ordering Provider	MD	Ordering Client/Phys—Lic No	7100	**State Medical license number
OBR-16	Ordering Provider	NPI	Ordering Client/Phys—Lic No NPI	7105	National Provider ID

HL7 Field	HL7 Field Name	Identifier Type	NAACCR Item Name	NAACCR Item #	Comments
OBR-32	Principal Result Interpreter	<Other code>	Pathologist Lic Number Other	7308	Other types of individual provider IDs
OBR-32	Principal Result Interpreter	MD	Pathologist Lic Number	7300	**State Medical license number
OBR-32	Principal Result Interpreter	NPI	Pathologist Lic Number NPI	7305	National Provider ID
OBX-15	Producer's Reference	CLIA	Producer ID	7515	Clinical Laboratory Improvement Amendments (CLIA) number
OBX-16	Responsible observer	MD	Path Responsible Observer	7630	**State Medical license number
OBX-16	Responsible observer	NPI	Path Responsible Observer NPI	7635	National Provider ID
OBX-16	Responsible observer	<Other code>	Path Responsible Observer Other	7638	Other types of individual provider IDs
OBX-23	Performing Organization Name	<Other code>	Path Performing Organization Name	7640	Other types of organizational provider IDs
SPM-2	Specimen ID	N/A	No NAACCR item	N/A	Specimen Identifier or Accession Number
SPM-3	Specimen Parent ID	N/A	No NAACCR item	7091	
SPM-5	Specimen Type Modifier	<Other code>	No NAACCR item	N/A	Provides the precision required to fully describe the specimen
SPM-30	Accession ID	<Other code>	No NAACCR item	N/A	Accession Number
SPM-31	Other Specimen ID	<Other code>	No NAACCR item	N/A	Other types of specimen identifiers

** State Medical license number should be reported in the format of state (two letters) or province code (up to four letters) before the state license number (MD) (e.g. "xy_PHYSICIANLICENSE").

2.1.4. NAACCR Conformance Usage Rules

The following format is used in this document for listing and defining message segments and fields. First, the message segment's use is defined, and a segment attribute table is shown that lists all fields defined in the segment. In the segment attribute table, the following attributes are given for each field: sequence number within the segment, length of field, data type, and the HL7 Conformance criteria. This defines whether the field, for HL7 Version 2.5.1, is required (R), optional (O), or conditional (C) or uses (B) for backward compatibility.

Following this, the applicable table number for values, the field item number, and the field name are shown. The last columns in the table identify the NAACCR conformance specifics for the constrainable conformance type and define NAACCR usage as required (R), required or empty (RE), optional (O), conditional (C), or conditional or empty (CE). Note that the conformance criterion of RE (required or empty) indicates that if a sending system has the data, it must be transmitted, and all receiving systems must be able to process the data. All HL7 backward-compatible fields are constrained as either in or out for this conformance type. The NAACCR cardinality field defines the minimum and maximum number of repetitions that can populate a data field.

The conformance usage rules for the "NAACCR Usage" column are interpreted as described in Table 5.

Table 5: Conformance Rules for "NAACCR Usage"

Value	Description	Comment
R	Required	A conforming sending application shall populate all "R" elements with a non-empty value. A conforming receiving application shall process (save/print/archive/etc.) or ignore the information conveyed by required elements. A conforming receiving application must not raise an error due to the presence of a required element but may raise an error due to the absence of a required element. Any element designated as required in a standard HL7 message definition shall also be required in all HL7 message profiles of that standard message.
RE	Required but may be empty	The element may be missing from the message but must be sent by the sending application if there is relevant data. A conforming sending application must be **capable** of providing all "RE" elements. If the conforming sending application knows the required values for the element, then it must send that element. If the conforming sending application does not know the required values, then that element will be omitted. Receiving applications will be expected to process (save/print/archive/etc.) or ignore data contained in the message and must be able to successfully process the message if the element is omitted (no error message should be generated because the element is missing).
C	Conditional	This usage has an associated condition predicate. (See the HL7 Version 2.5.1 Standard Chapter 2 Section *2.12.6.6 Condition Predicate.*) **If the predicate is satisfied—** A conformant sending application must always send the element. A conformant receiving application must process or ignore data in the element. It may raise an error if the element is not present. **If the predicate is NOT satisfied—** A conformant sending application must NOT send the element. A conformant receiving application must NOT raise an error if the condition predicate is false and the element is not present, although it may raise an error if the element IS present.
CE	Conditional but it may be empty	This usage has an associated condition predicate. (See the HL7 Version 2.5.1 Standard Chapter 2 Section *2.12.6.6 Condition Predicate.*) **If the predicate is satisfied—** If the conformant sending application knows the required values for the element, then the application must send the element. If the conformant sending application does not know the values required for this element, then the element shall be omitted. The conformant sending application must be **capable** of knowing the element (when the predicate is true) for all "CE" elements. If the element is present, the conformant receiving application shall process (display/print/archive/etc.) or ignore the values of that element. If the element is not present, the conformant receiving application shall **not** raise an error due to the presence or absence of the element. **If the predicate is not satisfied—** The conformant sending application shall not populate the element. The conformant receiving application may raise an application error if the element is present.
B	Backward compatible	Left in for backward compatibility with previous versions of HL7. The field definitions following the segment attribute table should denote the optionality of the field for prior versions.

Value	Description	Comment
O	Optional	The inclusion of the element is optional. (O is only used in constrainable specifications, and the NAACCR Laboratory Electronic Pathology Reporting Guidelines must be further constrained for an operational implementation.)
X	Not supported	For conformant sending applications, the element MAY not be sent. Conformant receiving applications MAY ignore the element if it is sent and SHALL NOT raise an application error.

The following key words are used in the requirements to specify the level of requirement:

SHALL/REQUIRED: An absolute requirement of the specification.

SHALL NOT: An absolute prohibition of the specification.

SHOULD/RECOMMENDED: Valid reasons may exist in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

SHOULD NOT/NOT RECOMMENDED: Valid reasons may exist in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

MAY/OPTIONAL: An item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product, while another vendor may omit the same item. An implementation that does not include a particular option SHALL be prepared to interoperate with another implementation that does include the option, although perhaps with reduced functionality.

Similarly, an implementation that does include a particular option SHALL be prepared to interoperate with another implementation that does not include the option (except, of course, for the feature the option provides).

2.2.   CANCER REGISTRY MESSAGE DEFINITION

The transmitted reports sent to cancer registries may be of different kinds, may arrive at different times from different sending facilities and institutions, and may be formatted and/or encoded using different styles of reporting. The message definition in this Guide is designed to support all these permutations in an unambiguous and straightforward manner.

The different kinds of reports that arrive at a registry relating to the same patient and specimen are linked and consolidated at a registry, regardless of whether they arrive together in a single message or arrive at different times in different HL7 messages. There is a primary cancer report, but there may also be any number of supplemental reports, or even additional reports. These contain additional information attached to the pathology report, and often are transmitted after the original report has been issued. These reports may address subsequent testing or stains, comparison with previous specimens, second opinions from other pathologists or laboratories, a change in diagnosis resulting from re-examining the specimen(s) or sampling new areas within the specimen, autopsy reports, etc. These reports may be encoded using any of the styles discussed above in Section 1.5.2. For example, an addendum to a primary report in narrative message format style could also be in traditional narrative message format style or could be encoded using synoptic message format style. These supplemental reports may be called Addenda, Consult Notes, Amendments, Supporting Studies, Second Opinion Notes, or by other local vernacular. These concepts are not mutually exclusive.

The overall *logical* structure of the complete package of information, regardless of whether it is transmitted to the registry in one or several messages, can be conceptualized as described in Table 6.

Table 6: Cancer Registry Structure Message Definitions

Pathology Report Collection	This may or may not be present; when present, it functions as a "container" or "collector" of the several separate documents making up the overall reported data collection. This is a similar structure to a laboratory test panel. Each of the contained reports is a report document. This item is reported in OBR-4 of the message with a LOINC code of 60567-5 Comprehensive pathology report panel. This is particularly useful for transmitting the same pathology report in multiple styles in one message, such as both a narrative and a synoptic message format of the same report. It is used only in a message in which more than one document on the same patient for the same analysis is sent in a single message, such as a main report plus addenda and consults, or if the report is transmitted in different styles of reporting. When this code is used in OBR-4, the earliest date of the specimen collection must be populated in OBR-7.
Primary Report	This type of report would be submitted with OBR-4 of the message identified with a LOINC code of "11529-5 Surgical pathology study." This report represents the findings generated by the Pathologist for the tumor.
Consult Report	The Consult Report is identified in OBR-4 of the message with a LOINC code of "60570-9 Consultation note" when the message style is narrative, and with a LOINC code of "60571-7 Consultation note.synoptic" when the report is synoptically structured or encoded
Addendum	The Addendum is identified in OBR-4 of the message with a LOINC code of "35265-8 Pathology report addendum in Specimen Narrative" when the Addendum is narrative text. The LOINC code "60569-1 Report addendum.synoptic" is used if the addendum is being reported as a synoptically structured message. Additional Supplemental Report(s) include the "18743-5 Autopsy note," or an additional and essentially duplicate copy of the primary pathology report but encoded at a different reporting level, a pathology report that identifies multiple cancers or secondary tumors, amendments to reports issued at an earlier time, or other kinds of reports.

For a simple example of an HL7 Cancer Registry message, see Appendix E, Section E.1, Simplest Narrative Report Examples.

2.2.1.   Registry Reporting Domain Model

The overall high-level model of the collection of reports that may be contained in the registry message is shown in Figure 2. Note that this domain model covers the subset of cancer pathology studies and reporting that involves collection and construction of the information set to be transmitted to registries using HL7 as per this Guide.

Figure 2: Registry Reporting Domain Model
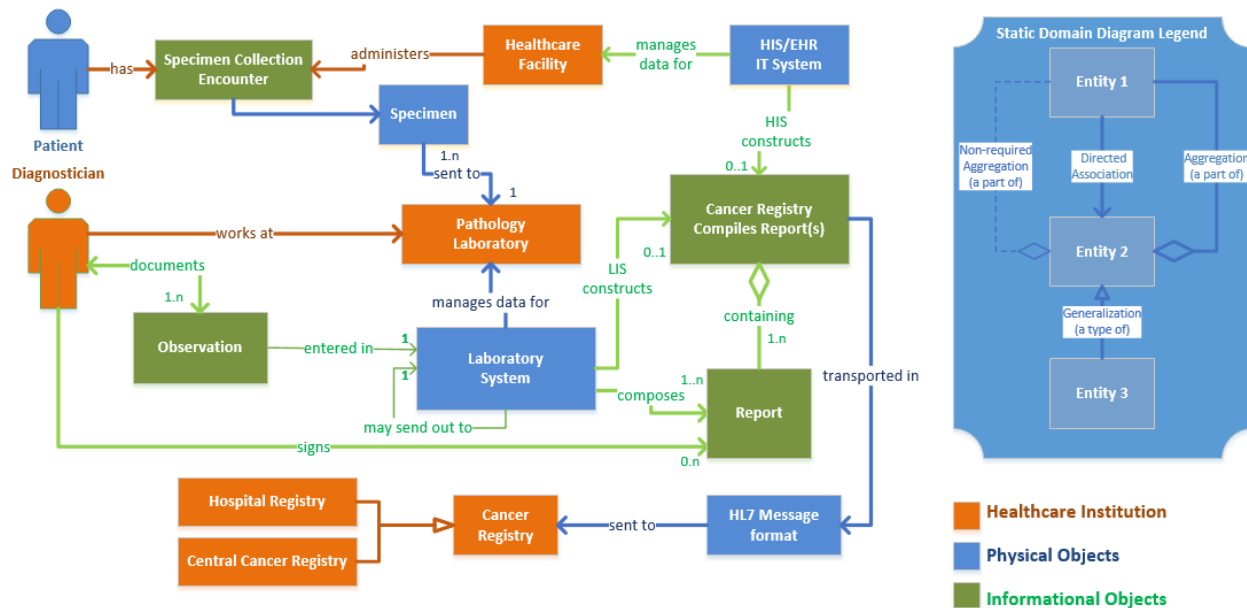
Descriptions of Entities in Domain Model

Patient: A person who requires or has required medical care. The person may be waiting for this care, may be receiving it, or may already have received it. This is the person from whom a specimen is collected and for whom the diagnostic study is being performed.

Specimen Collection Encounter: This is the event in which a clinician interacts with a patient to obtain a specimen for the pathology study.

Health Care Facility: This can also be thought of as the Ordering Facility. This may be a surgical department, or a hospital that manages a patient and collects specimens for pathological analysis for cancer. It also refers to the Surgical System and/or the Patient Records System at the facility in which a surgical center that collects specimens is housed. The system receives results and, in many cases, also is capable of sending results.

Specimen: A specimen is a sample taken from a patient. A specimen is a portion or quantity of material for use in testing, examination, or study.

Pathologist (Diagnostician): This is the physician specialist/pathologist who examines and analyzes the specimen(s), identifying and recording observations and findings for the prepared specimen. The Diagnostician/Pathologist also records findings for the case overall, which may not be specimen-specific in a multispecimen case.

Pathology Laboratory: This is the pathology laboratory organizational entity (stand-alone, or in-hospital department) that handles the specimen and prepares it for the pathology study. In most cases it also incorporates an AP (Anatomic Pathology System) and/or LIS (Laboratory Information System) that assigns specimen and accession numbers, and may send and receive HL7 messages. This organization physically handles the specimen, treating and preparing it for analysis.

Laboratory System: This is the computer system at a pathology laboratory that is used for workflow, and to capture from the clinicians the information that will be contained in the pathology report(s).

The AP or LIS system at a pathology laboratory must be capable of sending results; some also are capable of receiving results.

Observation: This is information that is collected and supplied by the pathologist/diagnostician.

Pathology Report Collection: This is a "container" for various report documents—e.g., primary report, addendum report, supplemental reports—when the different kinds of reports are transmitted together in a single HL7 message. These are grouped together as a comprehensive collection because they often need to be interpreted together as a set.

HL7 Message Format: A message is the entire unit of data transferred between systems in a single transmission. It is a series of segments in a defined sequence, with a message type and a trigger event. It contains the information making up the report(s) and is formatted as specified in this Guide.

Primary Report: This is the principal pathology report that contains all of the pathologic and prognostic information associated with the patient's surgical case (specimen(s)). Typically, the primary pathology report is broken into general headings: clinical history, final diagnosis, macroscopic or gross description, microscopic description, and comments.

Cancer Registry: This is the organization that receives detailed pathology results in which cancer is identified, as per statutory regulation.

Central Cancer Registry: A type of cancer registry that has all state/provincial/territorial or even national data that can be used for population-based cancer surveillance.

Hospital Cancer Registry: A type of cancer registry that has data specific to that community.

2.2.2. Static Domain Model

The overall high-level model of report types and styles that may be contained in the registry message is shown in Figure 3.

Figure 3: Static Domain Model
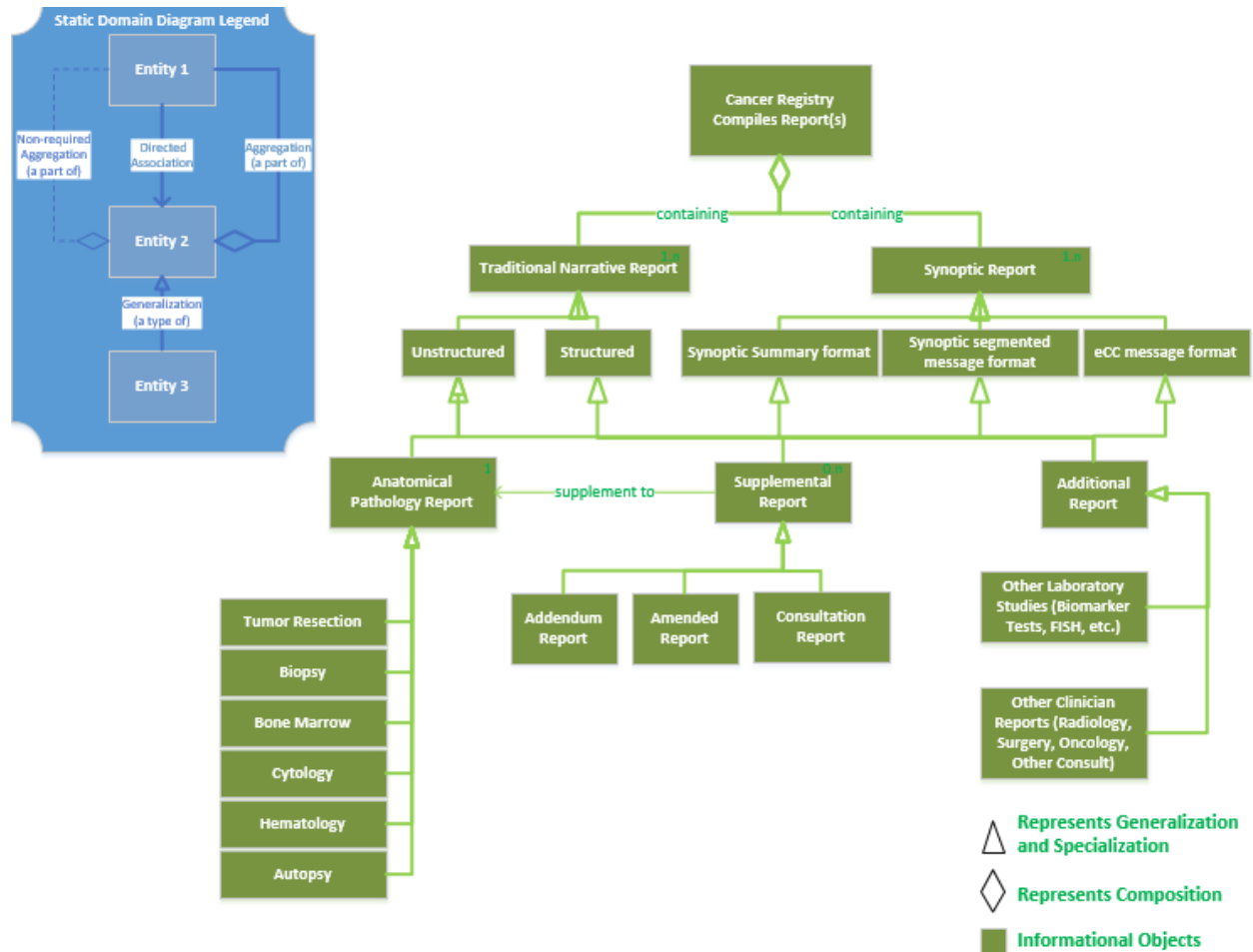
Anatomic Pathology Report: This is the report that contains all the pathologic and prognostic information associated with the patient's surgical case (specimen(s)). Typically, a pathology report is broken into general headings: clinical history, final diagnosis, macroscopic or gross description, microscopic description, and comments.

Supplemental Report: This refers to additional information attached to the pathology report, often after the original report has been issued. These reports may address subsequent testing or stains, comparison with previous specimens, second opinions from other pathologists or laboratories, or a change in diagnosis resulting from re-examining the specimen(s) or sampling new areas within the specimen. These reports may occur within any of the format styles or levels discussed in the prior section, e.g., an addendum could be in a traditional narrative format or a synoptic format. The general LOINC code 22639-9 is deprecated and should not be used in any new or updated interfaces. The LOINC code 35265-8 [Addendum] should be used when a more specific LOINC code is not available. **Note:** A supplemental report is identified by a specific LOINC code in the OBR-4 field, see Section 1.5.3 above for details.

Addendum Report: An addendum report is a type of ancillary report that contains additional information, typically the results of ancillary diagnostic studies completed after the original pathology report has been released. By definition, addendum reports provide additional information that may come from flow cytometry and immunohistochemistry, as examples. This additional information does

not result in a change to the final diagnosis of the original pathology report. If the intent of this ancillary report is to change a previously rendered diagnosis or to change other content, then the report should be titled ''Amended Report'' (see below). These reports may be appended to the original pathology report and resubmitted to the cancer registry. **Note:** An addendum report is identified by a specific LOINC code in the OBR-4 field, see Section 1.5.3 above for details.

Note: Any type of report may be amended. Corrections are flagged in the OBR-25 and OBX-11 fields (C=Corrected; F=Final).

Amended Report: Amended reports are created to correct errors or discrepancies in the original final report. Typical reasons to create an amended report include correction of typographical errors, modification of the final diagnosis, or documentation of the resolution of a specimen-labeling discrepancy. Any identified type of report may be amended, no special LOINC code is available for Amended Reports. The LOINC code selected is the code for the report that is being amended. **Note: Any type of report may be amended, corrections are flagged in the OBR-25 and OBX-11 fields (C=Corrected; F=Final).**

Consultation Report: A consultation report is a report that provides advice or guidance by a second or additional expert; or a deliberation by pathologists on a diagnosis and/or interpretation of diagnostic test results. This may be a second opinion on the specimen diagnosis. **Note:** A consultation report is identified by a specific LOINC code in the OBR-4 field, see Section 1.5.3 above for details.

Unstructured Narrative Report (also known as a **Text Blob**): The laboratory is not able to separate the pathology report text into sections using LOINC codes (or other codes), such as Clinical History, Gross Observation, Microscopic Observation, Final Dx, Final Dx Text/Path Report Text.

Structured Narrative Report: A cancer pathology report message text in which LOINC codes are used to submit (any or all) of the following pathology report sections: Clinical History, Nature of Specimen, Gross Observation, Microscopic Observation, Final Dx, Comments, Supplemental Reports, etc.

Synoptic Report: A synoptic report includes CAP case summaries and/or biomarker templates. The LOINC code should be Synoptic Report (60568-3) in OBR-4.

Synoptic Summary Message: A synoptic summary message is all question-and-answer pairs reported on separate lines sent in one single OBX Report Template Source=Synoptic Summary. If a template version is available, then report OBX using LOINC 60574-1 (template version).

Synoptic Segmented Message Format: The synoptic segmented message format is question-and-answer pairs sent in a separate OBX Report Template Source=Synoptic Segmented Message. If a template version is available, then report OBX using LOINC 60574-1 (template version).

eCP message Format: eCP message format is fully encoded question-and-answer pairs in separate OBX. See Chapter 3 for rules for reporting eCP templates.

2.2.3. Use Case Model

The overall high-level model of actors and processes involved in cancer data reporting is shown in Figure 4.

Figure 4: Use Case Model
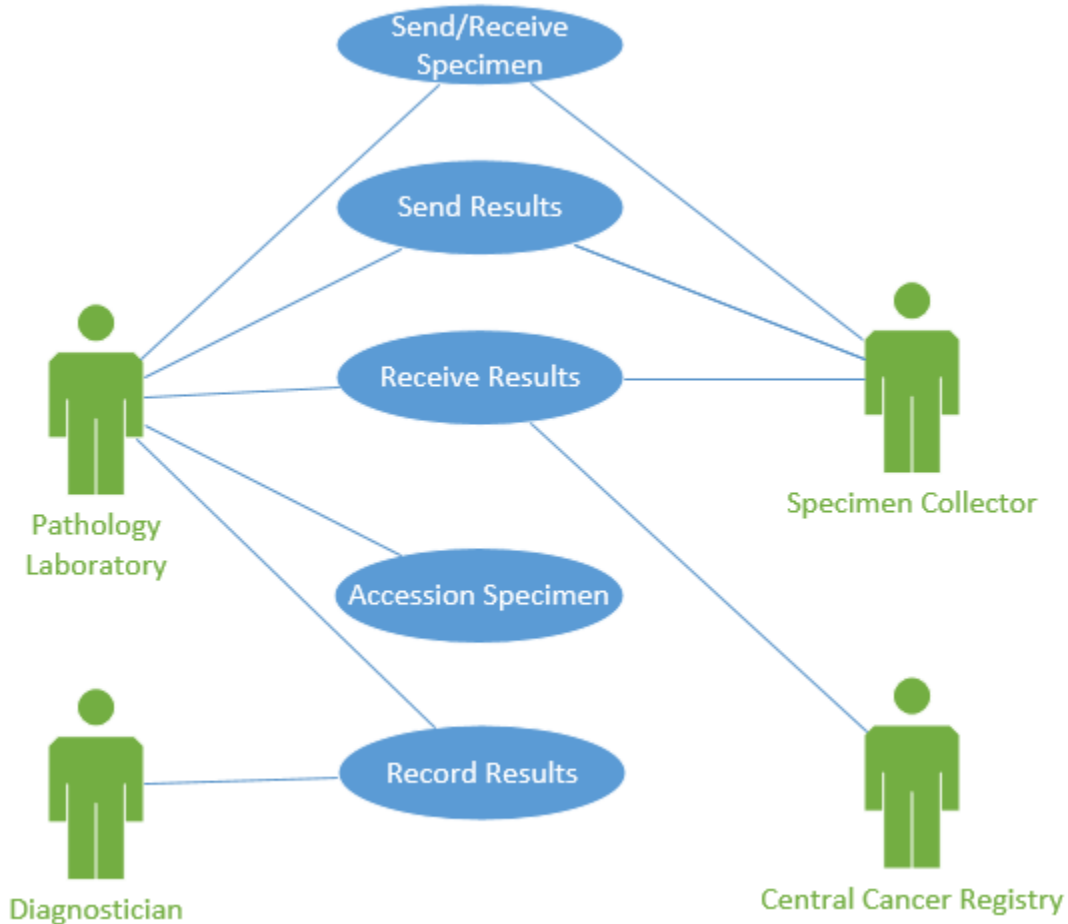
2.2.3.1. Processes

Send/Receive Specimen: The collected specimen, or specimens, are sent by surgery or other collectors, and received by the pathology lab for a pathology study, along with various identification and labeling information. This process also includes the processing and physical preparation of the specimen blocks and slides.

Accession Specimen: The collected specimen(s) are received for the pathology study, and the identification and labeling information is recorded for later use when sending the results. This process also includes processing the specimen to prepare slides to be read by the pathologist.

Record Results: The observations and findings made by the pathologist and other specialists who participate in the pathology study are captured so they can be incorporated into messages to be generated. This involves both the origination of new results and the revision of existing results.

Send Results: The observations and findings that result from the pathology study are sent and received by the pathology laboratory, the cancer registry, and the originating surgery (hospital and/or clinicians), using the format and encoding rules for the HL7 ORU_R01 message specified in this document.

Receive Results: The HL7 message containing the results is received by a system and optionally acknowledged. It is then processed and stored in the local data store.

2.2.3.2. Use Case Storyboard
Within the health care setting, various business rules are in place that outline the requirements for the sending of clinical information to central cancer registries when cancers are discovered. In general, one or more specimens are collected from a patient and sent to one or more laboratories to be analyzed; the findings are returned to the setting where the study was initiated before the finalized results are reported to the cancer registry. Two use cases are detailed in this section to illustrate different workflows implementing this basic process and the handling of identifiers and reporting for these workflows.

2.2.3.2.1.   *Single Hospital Specimen Processing and Reporting*
A surgical center collects one or more specimens from a patient and sends the specimen(s) to a pathology laboratory, where they are accessioned (labeled with identifiers) and prepared for analysis by the pathologist and other clinicians. The findings from the clinicians are recorded and sent electronically to the cancer registry and back to the surgical center using the message format described in Section 1.5.2. The messages have sufficient (if not complete) labeling information such that both the surgical center and the cancer registry can understand all the pertinent details of the pathology study.

2.2.3.2.2.   *Multiple Hospital Processing and Reporting with Consults*
A surgical center collects one or more specimens from a patient and sends the specimen(s) to a pathology laboratory, where they are accessioned (labeled with identifiers) and prepared for analysis by the pathologist and other clinicians. The findings from the clinicians are recorded and sent electronically to the cancer registry and back to the surgical center using the message format described in Section 1.5.2. In addition, some or all of the specimen(s), along with the results, are forwarded to another pathology laboratory with a consultation request, which asks the second laboratory to perform additional (or repeat) analyses of the specimen(s). The specimen(s) are accessioned again at the consulting laboratory, additional analysis is performed, and new/additional results are recorded. These new results are returned to the requesting laboratory, which may append them to the original report (or append or otherwise reference the new findings) and then sends the combined results back to the requesting facility. Any of these facilities may send the results to the cancer registry. Alternatively, the consulting laboratory may send only its own results directly to the cancer registry, and sufficient identifying information must be present in such a message to permit the registry to merge the reports from the separate sources. These alternate flows tend to be messaging facility and/or jurisdiction specific, and they may be driven by the messaging capabilities of the participants. See Appendix E for an example of this.

2.2.4.   Dynamic Interaction Model
This section describes in detail two different scenarios for specimen processing and reporting involving different numbers of facilities and different ways of assigning specimen identifiers and accession numbers to the specimens. Each scenario is documented with a process flow diagram, followed by an interaction diagram showing specific sequences of interactions making up the dynamic definition for the scenario. Each of the scenarios is described in a section below. In the interaction diagrams, the interactions that are implemented as HL7 messages are indicated with a dashed line; all other interactions are shown with solid lines.

2.2.5.   Single Hospital Specimen Processing and Reporting
The case of a flow of information from a single hospital involves the communication between a specimen collector (generally the surgical department of a hospital or ambulatory surgery center), the pathology laboratory, and the cancer registry. The source of the gross observations and findings about the specimen are generated by the pathologist and surgeon for the case and may include observations made by other participants in the process who work in the laboratory. Similarly, the source of the microscopic

observations and findings about the specimen are generated by the pathologist for the case and may include observations made by other participants in the process who work in the laboratory.

The process flow diagram in figure 5 illustrates this simple case, and the sequence of processes and functions that occur, from the collection of the specimen to the transmission of the cancer report, both to the cancer registry and back to the original collecting facility.

In this common case, one or more specimens are removed from a patient at a surgical center, marked "surgery" in the diagram. This is generally, but not always, in a hospital. The specimen(s) are placed in containers with the appropriate fixative and labeled. The appropriate documentation is completed, and the entire package is physically transported to a pathology laboratory, which may or may not be in the same facility. In the laboratory, the case is created in the laboratory's computer system, and an accession number identifying the received specimen(s) is created and entered. The specimen is processed through a sequence of operations, and slides are created. Observations may be recorded during these processes and saved with the case in the laboratory system.

The slides are then passed to a pathologist, who microscopically examines them and generates a collection of observations and findings. The results of the examination may be in different forms, depending on the technical capabilities and setup of the workflow in the laboratory, and also may involve other staff, such as a transcriptionist who enters dictated observations from the pathologist into the case record on the laboratory system. On completion of the gathering and entering of the observations and findings, this set of case results is sent to the system at the facility where the surgical center is located, employing the HL7 ORU_R01 message that is defined in this specification. By institutional policy, the message also may be sent to the cancer registry.

The system at the facility that houses the surgical center receives the results message, extracts the case results, and stores the information in its own patient record. In some cases, institutional or statutory requirements trigger an additional transmission of the case results to the cancer registry from the system at the surgical center; these policies generally are set so that if the laboratory system sends the results to the cancer registry, the system at the surgical center does not; whereas if the laboratory does not send the results to the cancer registry, they must be sent from the hospital system. This message may or may not have additional case information unavailable to the laboratory and relevant to the documented cancer, from the Patient Record system. On receipt of either one of these messages, the cancer registry maps and processes the information and stores it into the registry's system databases.

Appendix E provides an example of an HL7 message that is generated from this flow and is sent to the cancer registry.

Figure 5: Process Flow, Single Hospital Specimen Processing and Reporting
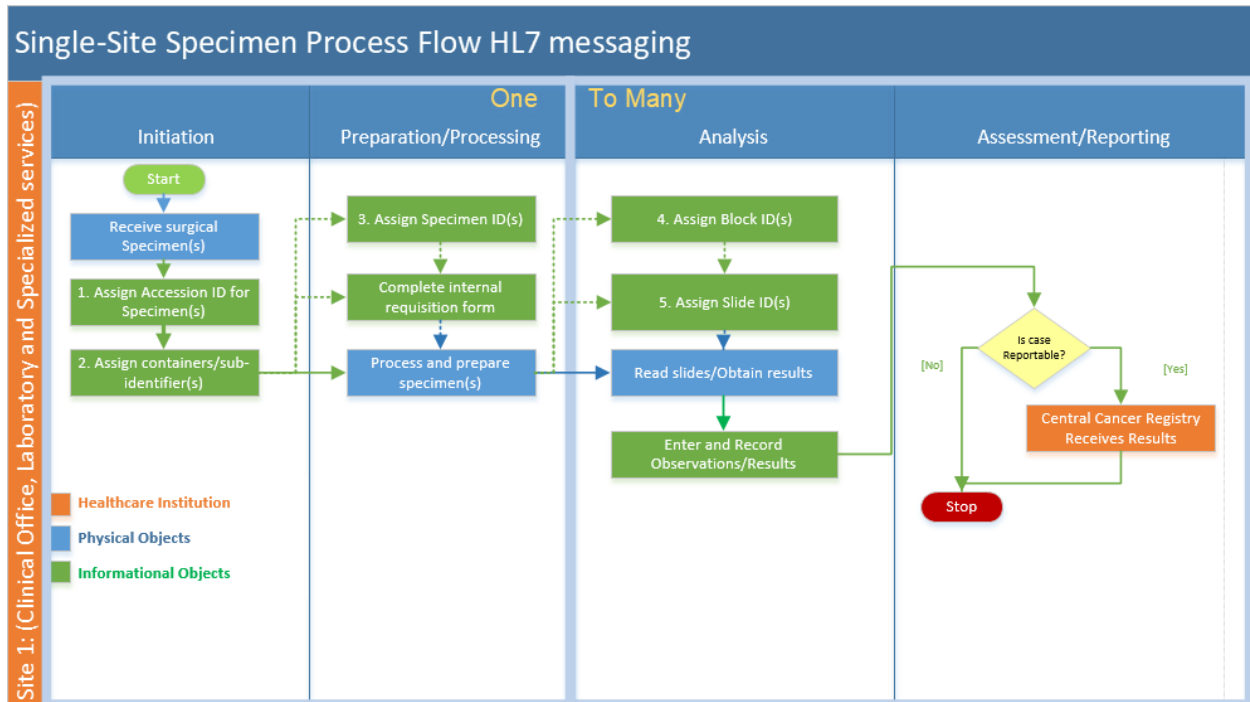
Figure 6: Interactions for Single Hospital Specimen Reporting
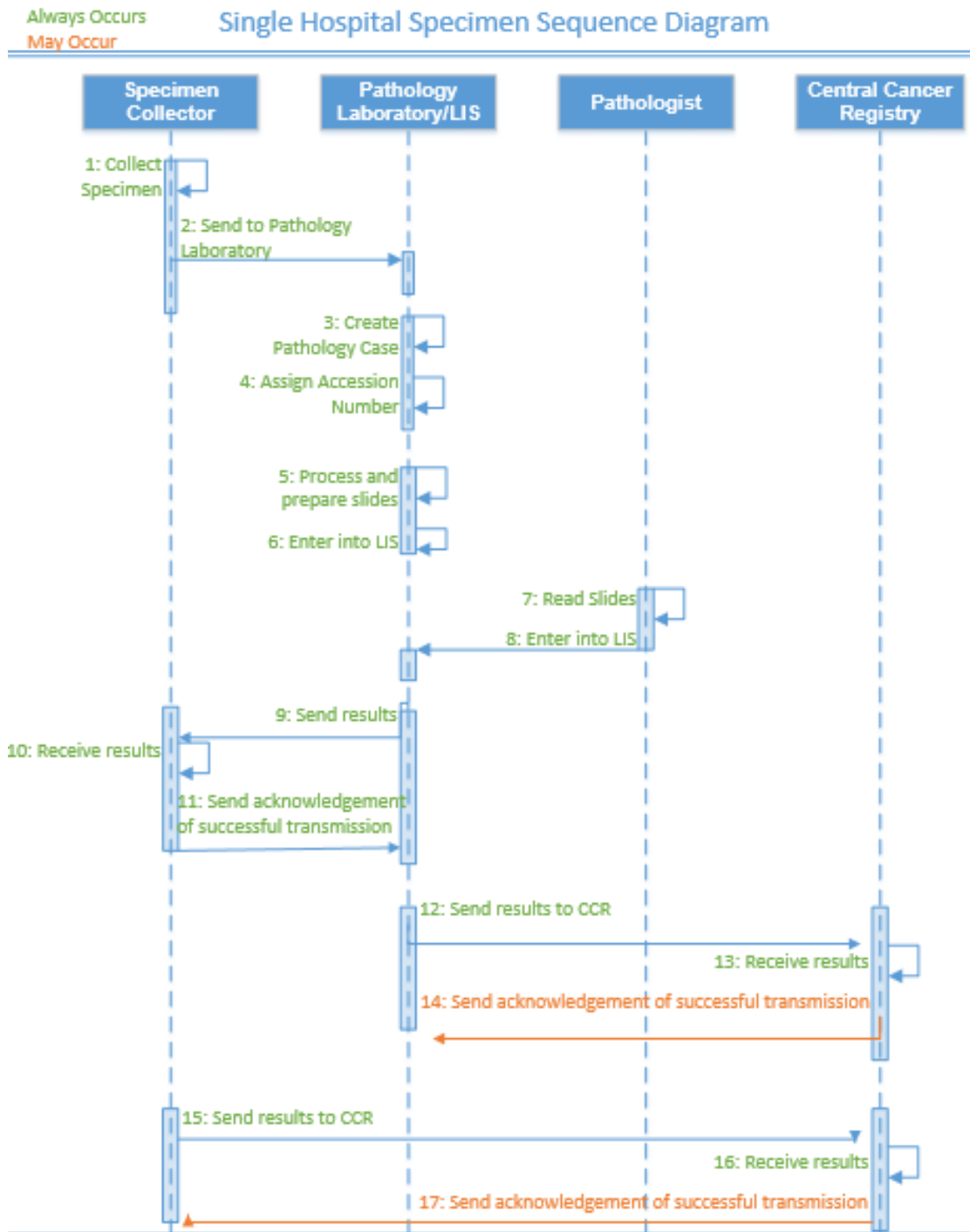
Interaction Descriptions

1. Collect specimen: A specimen is a piece of tissue or other material collected from a patient that is uniquely identified and delivered to a pathology department or facility for examination. If a specimen is separated into parts, each of those parts that is uniquely identified is also a specimen that has a relationship to the piece from which it was separated. The specimen also may be a collection of several specimens with a single identifier that is uniquely associated with the

collection. The material is considered to be "a specimen" if it is a single, discrete, uniquely identified unit that is the subject of one or more steps in the laboratory workflow. A specimen may be a tissue item, tissue section, tissue core, tissue spot, smear sample, touch preparation, dispersion, or similar subject of study. Each of the assigned identifiers is created and tracked by LIS systems and laboratory procedures. The tissue specimen is collected during the surgical procedure and placed into a specimen container with the appropriate fixative. The container is labeled with the patient identifier and a hospital requisition number. A second surgical pathology requisition containing additional details about the patient's specimen and clinical history also may be sent with the specimen and hospital requisition form. (See the examples in the E-Path Guidelines document). The information on both requisitions typically is filled out by the surgery department.

2. <u>Send to pathology laboratory</u>: The tissue samples, along with the patient identifier and the requisition information, are sent to the pathology laboratory. The information usually is sent non-electronically, but there may be an evolution in the future to integrate electronic ordering systems and synoptic surgical reporting solutions with Anatomic Pathology Laboratory Information Systems (APLIS).

3. <u>Create pathology case</u>: The patient identifier and requisition information are entered into the pathology LIS at the pathology laboratory, and the case record is created in the system.

4. <u>Assign accession number</u>: An accession ID is assigned to the specimen collection and associated with the case in the LIS. One or more specimen IDs also may be assigned at this point, depending on whether or not the case comprises multiple specimens.

5. <u>Process and prepare slides</u>: The staff at the pathology laboratory will process the specimen, create the blocks, and prepare and label the slides to be read by the pathologist. Typically, institutions have standard protocols for the stains and other processing based on the tissue types. In the most common case, a laboratory professional, either a pathology assistant or the pathologist, examines the specimen or the collection and dictates their gross observations. Further observations are dictated as the specimen is sliced or otherwise divided into portions to be processed for slide preparation. This usually is paraffin blocking, but also may involve cryogenic or other operations. These dictated observations usually are referred to as "gross findings" or "gross observations." After the "grossing" process is complete, the prepared portions of the specimen(s) are transferred to other laboratory personnel, who perform the slicing, mounting, and staining of the tissue and finalize the slides. The slides are almost always labeled with individual identifying information. Generally, no dictated observations are entered into the result record that documents the operation of staining and slide preparation. Occasionally, additional iterations of processing and preparing slides for additional studies may be triggered at this time.

6. <u>Enter into LIS</u>: The gross observations are entered into the case record in the pathology LIS. This may be done at the time of gross observation with the use of voice recognition software or may be dictated by either the pathologist or pathologist's assistant and later transcribed into the LIS by a transcriptionist. Either way, these observations are made available to the pathologist when the slides are read.

7. <u>Read slides</u>: The slides are made available to the pathologist, together with the identification information needed to access the gross observations and any patient or surgical information that was received from surgery with the specimen. The pathologist examines the slides and records observations and findings. Additional iterations of processing and preparing slides for additional studies may be triggered at this time.

8. <u>Enter into LIS</u>: The observations and findings are entered into the pathology LIS as results for the report, and the system groups and assembles the separate observations into the final report. This may be done by separate staff using dictation from the pathologist, or may be entered directly into

the system by the pathologist or other staff. Regardless of where the reading is done, the results are entered into the system at the pathology laboratory. The report then goes through various stages of error checking, validation, and final signing to advance to a complete status, and then it is made available for subsequent operations. The details and timing of these operations are not within the scope of the cancer registry reporting described in this document.

9. <u>Send results</u>: The case information that has been recorded in the laboratory system is converted into an HL7 ORU_R01 message, as specified in this Guide, and sent to the surgeon and other care providers, such as the primary care physician or members of a cancer care team.

10. <u>Receive results</u>: The results sent by the pathology laboratory are received in the system at surgery, unbundled, and processed into the system there.

11. <u>Send acknowledgment</u>: On successful receipt of the HL7 message, the system that receives the HL7 message at surgery sends an acknowledgment to the pathology laboratory messaging system. Note that in every case that HL7 messages are transmitted, a simple General Acknowledgment (ACK) message is used to acknowledge receipt of the message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this is always performed.

12. <u>Send results to central cancer registry</u>: The case information that has been recorded in the system at the laboratory is converted into an HL7 ORU_R01 message, as specified in this Guide, and sent to the central cancer registry. Although the clinical information contained in this report is the same as that sent to surgery, the layout or formatting may be different. Note that this is optional and is per local policy.

13. <u>Receive results</u>: The results are unbundled from the message and stored at the central cancer registry.

14. <u>Send acknowledgment</u>: The system that receives the HL7 message at the central cancer registry sends an ACK message back to the pathology laboratory messaging system on successful receipt of the HL7 message. Note that in every case that HL7 messages are transmitted, the ACK message is used to acknowledge receipt of the message; however, not all central cancer registries have implemented this at the current time. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this should always be performed. Note that this acknowledges the communication of the message; using standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

15. <u>Send results to central cancer registry</u>: The case results information that was received from the laboratory and saved in the local system at surgery is converted into an HL7 ORU_R01 message, as specified in this Guide. It may have additional information that was not available to the laboratory. This message is sent if the policy indicates that the system at the facility where the surgical center is located should send the results to the cancer registry rather than the laboratory.

16. <u>Receive results</u>: The central cancer registry receives the HL7 message containing the results via the HL7 interface, subjecting the message to any normal processing for that facility. The results are then stored in the central cancer registry database. Alternatively, the central cancer registry may have received results from the pathology laboratory (see interaction #11 above). Policy usually establishes that the results are received either from the laboratory or the hospital information system, but not both. The set of results from the hospital may or may not have additional information that the laboratory did not generate.

17. <u>Send acknowledgment</u>: On successful receipt of the HL7 message, the system that receives the HL7 message at the central cancer registry sends an ACK message to the messaging system at the facility where the surgical center is located.

2.2.5.1. Multiple Hospital Specimen Processing and Reporting with Consults

Specimen processing cases often are more complex than what was described in the section above and involve multiple facilities and institutions. In this scenario, multiple facilities are involved in the analysis of the specimens, and each generates a portion of the final report. More than one of these institutions might report to the central cancer registry. Generally, not all information is forwarded to the downstream systems. Thus, linking the portions of the report that are received at the central cancer registry may be challenging.

Figure 7 illustrates a typical scenario such as this, in which an additional pathologist analyzes the case and generates a second report on the same case, at a different time, and often from a different facility. This involves a set of issues around the identifiers of the specimen and the report, as each system involved accessions of the specimen prior to beginning work on the case. These identifiers must be appropriately handled so that confusion in complex cases with multiple different specimens from the same patient can be unambiguously interpreted.

The resulting information sent must incorporate the information for one patient and one specimen, and contain one patient identifier, one or two specimen identifiers, and different accession numbers, and two reports. Note that the second laboratory sends only its single report, but the first laboratory may or may not send the annotated report, the consult report, or the original report without the consult section.

Site 1 (Clinical Office) has a surgical center, where the specimen is collected in a surgical resection procedure, and a laboratory. The specimen is sent to the laboratory for an anatomical study, where it is accessioned and assigned one or more identifiers. Site 1 (Clinical Office) does not have molecular analysis capability, so the specimen is transported to Site 2 (Laboratory), which receives and accessions the specimen in its pathology laboratory. Site 2 (Laboratory) has inconclusive results and sends the specimen to Site 3 (Laboratory) for further testing. The specimen is again accessioned in the Site 3 (Laboratory) system, which then captures any additional results. The system at Site 3 (Laboratory) assembles the HL7 registry report message and sends it to both the registry and to the system at Site 2 (Laboratory). Site 2 (Laboratory) forwards the report back to Site 1 (Clinical Office), where the specimen was collected and where the patient records system links the reports to the original report and the remainder of the patient record. One key challenge for tracking and linking all the information in such a scenario is that the end result has one patient with one patient identifier and one specimen, but that specimen may have three or more specimen identifiers because its journey can continue indefinitely.

Interactions for Multiple Site Specimen Processing and Reporting

Some institutions participate in networks of facilities that collaborate to produce a final cancer report. These often have very complex flows of specimens and reports (both paper and electronic), collected and sent by independent laboratory systems. To illustrate a typical case, Figure 8 shows some of this complexity, and the flows that require the SPM-30 and SPM-31 so that reassigned accession numbers and specimen IDs can be linked properly when received by the central registry.

Figure 7: Process Flow, Multiple Hospital Specimen Processing and Reporting with Consults
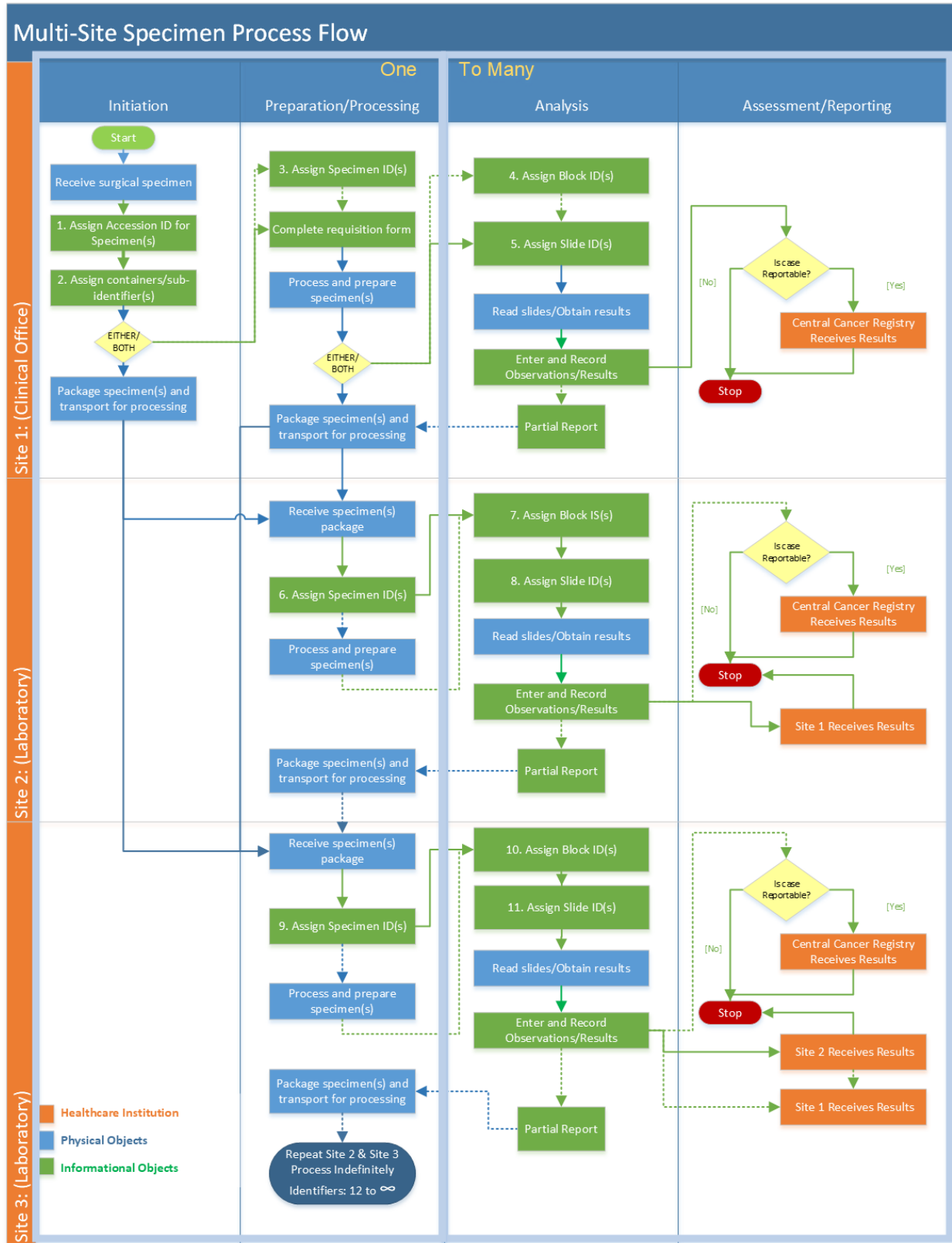
Figure 8: Interactions for Multiple Hospital Specimen Reporting

Multi-Hospital Specimen Sequence Diagram

Always Occurs
May Occur

Institution 1 (no Path Lab) | Institution 2 (Path Lab) | Institution 3 (Pathologists) | Institution 4 (Genetic Lab) | Central Cancer Registry

1: Collect Specimen
2: Assign identifier to specimen
3: Complete requisition form
4: Package specimen
5: Transport specimen package
6: Receive specimen package
7: Enter into Pathology LIS
8: Assign accession number
9: Process specimen and prepare slides
10: Access Pathologist Reporting Tool
11: Assign accession number
12: Enter observation into Pathologist Reporting Tool
13: Read slides and enter micro observations into Pathologist Reporting Tool
14: Send results
15: Send acknowledgement
16: Send results to CCR
17: Send acknowledgement
18: Send results
19: Send acknowledgement
20: Send results to CCR
21: Send acknowledgement
22: Send request for biomarker
23: Receive biomarker request
24: Enter case; assign accession number; run test; interpret; record result in LIS
25: Send results
26: Send acknowledgement
27: Send results
28: Send acknowledgement
29: Receive results
30: Send request for consult
31: Process the consult request
32: Enter case; assign accession number; interpret; record result in LIS
33: Send results
34: Send acknowledgement
35: Receive results
36: Send results
37: Send acknowledgement
38: Receive results
39: Enter results into Patient Record System
40: Send results to processing system of the CCR
41: Send acknowledgement
42: Receive results
43: Link reports for the same patient/tumor/encounter

Interaction Descriptions

1. Collect specimen: During a procedure, tissue is collected and labeled with both the patient identifier and a requisition number. The requisition information is typically filled out in surgery at Site 1 (no Path Lab).

2. Assign identifier to specimen: In some cases that have multiple specimens, an identifier with related clinical information about each individual specimen may be assigned as a specimen identifier by the collecting facility. This identifier is often used for laterality or location information relevant to the specimen collection.

3. Complete requisition form: This set of documentation that includes the patient identifier and any specimen identifiers also may include other relevant clinical information about the case (such as diagnosis or history); this is completed by the staff at the collecting facility.

4. Package specimen: The specimen container(s) is physically packaged with the requisition forms and documentation for transport to the pathology laboratory.

5. Transport specimen package: The specimen package is physically transported from Site 1 (no Path Lab) to Site 2 (Path Lab).

6. Receive specimen package: The specimen is examined for damage and completeness upon arrival at Site 2 (Path Lab), and necessary transport acknowledgment is performed.

7. Enter into Pathology LIS: The patient identifier, requisition number, associated received clinical information, and other tracking information is entered into the pathology LIS at Site 2 (Path Lab) to create the new case.

8. Assign accession number: A unique number associated with this specimen receipt and this case is created by Site 2 (Path Lab) and entered into the system with the other information.

9. Process specimen and prepare slides: The staff at Site 2 (Path Lab) processes the specimen, creates the blocks, and prepares and labels the slides to be read by the pathologist. Note that the "gross" observations may be recorded at this time as well by the staff performing the gross analysis. Typically, institutions have standard protocols for the stains and other processing based on the tissue types. In the most common case, a laboratory professional, perhaps a pathology assistant, examines the specimen or the collection and dictates observations about it. Further observations are dictated as the specimen is sliced or otherwise divided into portions to be processed for slide preparation. This usually is paraffin blocking but may also involve cryogenic or other operations. On completion of this preparation and examination step, there is a set of dictated observations that are referred to as "gross findings" or "gross observations"; in many cases, this information is entered into the LIS by a transcriptionist, and these observations are made available to the pathologist when the slides are read. After the "grossing" operation is complete, the prepared portions of the specimens are transferred to other laboratory personnel who perform the slicing, mounting, and staining of the tissue, and finalization of the slides. The slides are almost always labeled with individual identifying information. Generally, no dictated observations are entered into the result record during this operation. On completion, the slides are sent to the pathologist to be read, together with the necessary identification information for the pathologist to access the gross observations and any patient or surgical information that was received from surgery with the specimen.

10. Access Pathologist Reporting Tool: Site 2 (Path Lab) accesses the pathologist reporting tool. The pathology information capture and reporting mechanism at a different facility is accessed for use. This may be because the laboratory does not have its own pathology reporting system and is using a system shared among several laboratories, or it may be using one with capabilities that the local facility does not have. Several technical mechanisms—including remote login and web

access—may be used for this purpose. In this scenario, the computer system hosting the pathology documentation tooling is in a different facility managed by a different organizational entity than the pathology laboratory processing the specimen. Note that although Site 2 (Path Lab) has an LIS computer system, in this scenario Site 2 does not have the software to document pathology cases locally. This interaction creates the new case in the remote system.

11. Assign accession number: As the case is being entered into the system at Site 3 (Pathologists), a new accession number is assigned. Note that the physical specimens, and the staff generating the information, remain at Site 2 (Path Lab).

12. Enter observation(s) into Pathologist Reporting Tool: Making use of the pathology documenting and reporting tools at Site 3 (Pathologists), the staff at Site 2 (Path Lab) enters the gross observations for the case into the pathologist reporting tool running on the computer system at Site 3 (Pathologists). These observations will be available for the pathologist later, when the slides are read.

13. Read slides and enter micro observations into Pathologist Reporting Tool: The slides are made available to Site 3 (Pathologists), where staff examine them and create the observations and findings. Note that additional iterations of processing and preparing slides for additional studies may be triggered at this time. Using the reporting software at Site 3 (Pathologists) accessed over the network remotely, staff enter the observations and findings from reading the slides into the case record. At this time Site 3 (Pathologists) can also review the gross observations that were entered into the tool earlier on this case.

14. Send results: The case information that has been recorded at Site 3 (Pathologists) is bundled into an HL7 message and sent to Site 2 (Path Lab), where the information is stored in the LIS. Note that in this scenario, the LIS at Site 2 (Path Lab) is able to both send and receive HL7 result messages.

15. Send acknowledgment: The Site 2 (Path Lab) system that receives the HL7 message may or may not send an ACK message back to the pathology laboratory messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

16. Send results to Central Cancer Registry: Site 3 (Pathologists) sends results to the Central Cancer Registry. The case results information that was received from the laboratory and saved in the local system at surgery is converted into an HL7 ORU_R01 message, as specified in this Guide. It may have additional information that was not available to the laboratory. This message is sent if the policy indicates that the system at the facility where the surgical center is located should send the results to the cancer registry rather than the laboratory.

17. Send acknowledgment: The Central Cancer Registry sends an ACK message to Site 3 (Pathologists). The system that receives the HL7 message may or may not send an ACK message back to the pathology laboratory messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

18. Send results: The case information that has been recorded at Site 3 (Pathologists) is bundled into an HL7 message or forwarded and sent to the LIS at Site 1 (no Path Lab) from Site 2 (Path Lab),

where the information is stored in the LIS. Note that in this scenario, the LIS at Site 1 (no Path Lab) is able to both send and receive HL7 result messages.

19. Send acknowledgment: The Site 1 (no Path Lab) system that receives the HL7 message sends an ACK message back to the Site 2 (Path Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

20. Send results to central cancer registry: The case results information that was received from the Site 3 (Pathologists) and saved in the local system at Site 2 (Path Lab) is converted into an HL7 ORU_R01 message, as specified in this Guide, and sent to the Central Cancer Registry. It may have additional information that was not available to the laboratory.

21. Send acknowledgment: The Central Cancer Registry system that receives the HL7 message may or may not send an ACK message back to the Site 2 (Path Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

22. Send request for biomarker: The pathologist at Site 2 (Path Lab), upon review of the case, requests molecular analysis from a pathologist at Site 4 (Genetic Lab). The case information that was stored in the LIS in Site 2 (Path Lab) is bundled into an HL7 message and transmitted to Site 4 (Genetic Lab), where the information is stored for later access. Note that, in many circumstances, this information is transmitted to Site 4 (Genetic Lab) manually (non-electronically), rather than in an HL7 message. The slides for the case are packaged with the request and tracking paperwork and transported to Site 4 (Genetic Lab). At the current time, these requests are not handled by HL7 messaging, which is outside the scope of this specification. This scenario assumes that the request is sent by other mechanisms.

23. Receive biomarker request: The biomarker request and the blocks that have been transmitted from Site 2 (Path Lab) to Site 4 (Genetic Lab) for the case are received, and any necessary acknowledgments for both the paperwork and the set of slides are sent. This is not addressed by NAACCR Volume V, but needs to be addressed during implementation.

24. Enter case; assign accession number; run test; interpret; record result in LIS: The request is entered into the LIS at Site 4 (Genetic Lab), where a new case is created. The results previously received at Site 4 (Genetic Lab) from Site 2 (Path Lab) for this case are retrieved and linked to the new case. Generally, either the linking is performed manually or the linkage between the pathology report previously received, and the newly created case is verified as valid. As part of the institutional workflow at Site 4 (Genetic Lab), a new accession number is assigned to the case and specimen(s) for the newly created case. The pathologist interprets the results of the analysis, and the results for the case are entered into the LIS at Site 4 (Genetic Lab).

25. Send results: The combined report from Site 4 (Genetic Lab) includes the original results from Site 2 (Path Lab) processing and is entered on the documentation system at Site 3 (Pathologists), along with the molecular results from Site 4 (Genetic Lab) and is bundled into an HL7 message and sent back to Site 2 (Path Lab).

26. Send acknowledgment: The Site 2 (Path Lab) system that receives the HL7 message may or may not send an ACK message back to the Site 4 (Genetic Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is

not shown explicitly to simplify the diagrams, but this acknowledgment may be performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

27. Send results: The information for the case at Site 4 (Genetic Lab) is bundled into an HL7 message and transmitted to the Central Cancer Registry, along with the received patient identifier and any specimen IDs and accession numbers that were received. The new accession number from Site 4 (Genetic Lab) also is transmitted with this message. Note that this consultation report may consist of only the information generated at Site 4 (Genetic Lab), or it may be appended to the full report that was originally received from Site 2 (Path Lab) in step 17, above.

28. Send acknowledgment: The Central Cancer Registry system that receives the HL7 message may or may not send an ACK message back to the Site 4 (Genetic Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment may be performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

29. Receive results: The Central Cancer Registry receives the results of the molecular study from Site 4 (Genetic Lab) and links the report to any original case information.

30. Send request for consult: The pathologist at Site 2 (Path Lab), upon review of the case, requests a consult from Site 3 (Pathologist). The case information that was stored in the LIS in Site 2 (Path Lab) is bundled into an HL7 message and transmitted to Site 3 (Pathologist), where the information is stored for later access. Note that, in many circumstances, this information is transmitted to Site 3 (Pathologist) manually (non-electronically), rather than in an HL7 message. The slides for the case are packaged with the request and tracking paperwork and transported to Site 3 (Pathologist). At the current time, these requests are not handled by HL7 messaging, which is outside the scope of this specification. This scenario assumes that the request is sent by other mechanisms.

31. Process the consult request: If the ordering process is automated, some or all of the required information is added automatically in the consultant's system.

32. Enter case; assign accession number; interpret; record result in LIS: The request is entered into the LIS at Site 3 (Pathologist), where a new case is created. The results previously received by Site 3 (Pathologist) from Site 2 (Path Lab) for this case are retrieved and linked to the new case. Generally, either the linking is performed manually or the linkage between the pathology report previously received, and the newly created case is verified as valid. As part of the institutional workflow at Site 3 (Pathologist), a new accession number is assigned to the case and specimen(s) for the newly created case. The pathologist interprets the observations, and results for the case are entered into the LIS at Site 3 (Pathologist).

33. Send results: The combined report—including the original results from Site 2 (Path Lab), the molecular results from Site 4 (Genetic Lab), and the consult from Site 3 (Pathologist)—is bundled into an HL7 message and sent from Site 3 (Pathologist) to Site 2 (Path Lab).

34. Send acknowledgment: The Site 2 (Path Lab) system that receives the HL7 message may or may not send an ACK message back to the Site 3 (Path Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment may be performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

35. <u>Receive results</u>: Site 2 (Path Lab) receives the results of the consultation from Site 3 (Pathologist) and links the report to any original case information.

36. <u>Send results</u>: The combined report—including the original results from Site 2 (Path Lab), the molecular results from Site 4 (Genetic Lab), and the consult from Site 3 (Pathologist)—is bundled into an HL7 message and sent back to Site 1 (no Path Lab).

37. <u>Send acknowledgment</u>: The Site 1 (no Path Lab) system that receives the HL7 message sends an ACK message back to the pathology laboratory messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; using standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

38. <u>Receive results</u>: The patient medical record system at Site 1 (no Path Lab) receives the results of the combined consultation study from Site 3 (Pathologist), the molecular analysis from Site 4 (Genetic Lab), and the pathology study from Site 2 (Path Lab).

39. <u>Enter results into Patient Record System</u>: The results received from Site 2 (Path Lab) are entered into the patient medical record system at Site 1 (no Path Lab).

40. <u>Send results to the processing system of the Central Cancer Registry</u>: Site 2 (Path Lab) transmits the consultation report, along with any other information to be sent according to institutional policies, to the Central Cancer Registry. This report must contain all identifiers, such as the specimen IDs and accession numbers assigned by the various facilities that participated in generating portions of the result information.

41. <u>Send acknowledgment</u>: The processing system for the Central Cancer Registry system that receives the HL7 message sends an ACK message back to the Site 2 (Path Lab) messaging system on successful receipt of the HL7 message. In the other interaction diagrams in this chapter, this interaction is not shown explicitly to simplify the diagrams, but this acknowledgment is always performed. Note that this acknowledges the communication of the message; under standard HL7 acknowledgment protocol, the data received may not yet have been committed to the destination database.

42. <u>Receive results</u>: The Central Cancer Registry receives the results of the combined reports from Site 2 (Path Lab) and links the report to any original case information.

43. <u>Link reports for the same patient/tumor/encounter</u>: On receipt of the full report from Site 2 (Path Lab), the Central Cancer Registry must be able to link all the result reports on this case and specimen(s) that have been received from the various facilities.

2.2.6.   Registry Use Case

For the Central Cancer Registry and Site 1 to link all of these reports together, certain business rules for when and how patient identifiers and specimen identifiers must be populated, and by whom, must be followed.

The SPM-30 field SHOULD hold the original specimen identifier across every laboratory record transmitted downstream so that the registries can link independently received reports to the original surgical specimen. If the original specimen identifier is received with the specimen, then the receiving laboratory MUST save this original identifier and communicate it to any downstream laboratory. At a minimum, the reporting laboratory's assigned identifier and the original specimen identifier across ALL laboratories must be included in a report to a registry.

The diagrammed use case in Figure 9 shows the recommended use of order/case/specimen identifiers (OBR-2, OBR-3, SPM-2, SPM-3, SPM-4, SPM-5, SPM-30, and SPM-31), date/time stamps (OBR-7

OBR-14, OBR-22, OBX-14, and SPM-17, and SPM-18), institutional identifiers (MSH-4, MSH-6) and provider identifiers (OBR-16, OBR-32, ORC-21, PV1-7, and PV1-8) for each of the information flows between the facilities in this scenario. Note: SPM-2 has 2 components - the first one is for the placer (surgery center in the case of Blue, but could be any Specimen ID assigned by Blue for Grey or Purple; specimen ID assigned by Grey for Orange and Green - the second component is for the filler - so in the examples the filler assigned IDs need to be in the second component - and they SHOULD include the assigning authority.

When a surgical facility removes tissue from a patient, the specimen is placed into one or more container(s). The specimen identifier is placed in SPM-2.2.1. When an order is placed for a test on that specimen, the unique identifier for that order should be placed in OBR-2). and is sent to facility **BLUE** for anatomical pathology analysis.

Facility **BLUE** sends a block to facility **GREY** for Estrogen Receptor (ER) Status/Progesterone Receptor (PgR) Status and any subsequent biomarker testing if applicable.

Facility **BLUE** also sends a slide to facility **PURPLE** for a consult on diagnosis.

Facility **GREY** then sends blocks to facility **ORANGE** for HER2 by immunohistochemistry (IHC) testing and to facility **GREEN** for HER2 (ERBB2) by in situ hybridization (ISH) testing

Facility **GREEN** has equivocal results for HER2 (ERBB2) by in situ hybridization (ISH), so they send the block to facility **PURPLE** for a secondary/confirmation HER2 (ERBB2) by in situ hybridization (ISH) test.

Figure 9: Registry Use Case Specimen Identifiers

Message 1a: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or GREY>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$|60568-3^Synoptic Report^LN||| Jan 1|||||||Jan 2||Dr.B|||||Jan 3||||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOME LABS&BLUE&CLIA||TS|K|||||||||||Jan 1| Jan 2|||||||||||BLUE_abcd|abcd
```

Message 1b: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$|60568-3^Synoptic Report^LN||| Jan 1|||||| Jan 2||Dr.B|||||Jan 3||||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOMELABS&BLUE&CLIA||TS|S|||||||||||Jan 1| Jan 2|||||||||||BLUE_abcd|cd
```

Message 2a: (Biomarker – ER/PR)

```
MSH|||BETTER THAN AWESOME LABS^GREY^CLIA||<null or ORANGE>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|GREY_%^&*|60569-1^Addendum Report.Synoptic^LN|||Jan 1|||||| Jan 4||Dr.B|||||Jan 5|||||||||Dr.GREY
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^ BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F|||Jan 3
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31160.1000043^Estrogen Receptor (ER) Status (Note A)^CAPECP||||||F|||Jan 5
SPM|1|^GREY_5678&BETTER THAN AWESOME LABS&GREY&CLIA||BLUE_1234|TS|K|||||||||||Jan 1| Jan 4|||||||||||BLUE_abcd, GREY_abcd|5678
```

Message 2b: (Consult on Anatomical Pathology Report)

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|PURPLE_)(*&|60571-7^Consultation Note Synoptic˜LN|||Jan 1|||||Jan 4||Dr.B|||||Jan 5|||||||||Dr.PURPLE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 5
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 5
SPM|1|^PURPLE_0987&ON PAR WITH BETTER THAN AWESOME LAB&PURPLE&CLIA|BLUE_1234|TS|S|||||||||||Jan 1| Jan 4|||||||||||BLUE_abcd, PURPLE_abcd|ab
```

Message 3a: (Biomarker ISH Testing – Indeterminate Results)

```
MSH|||OK LABS^GREEN^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|GREEN_#$%^|60569-1^Report Addendum.Synoptic˜LN|||Jan 1|||||||Jan 6||Dr.B,Dr.GREY||||||Jan
7||||||||||Dr.GREEN
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^ BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F|||Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization
(ISH)^CAPECP||||||F|||Jan 7
SPM|1|^GREEN_3456&OK LABS&GREEN&CLIA|GREY_5678|TS|K|||||||||||Jan 1| Jan 6|||||||||||||BLUE_abcd, GREY_abcd,
GREEN_abcd|3456
```

Message 3b: (Biomarker IHC Testing)

```
MSH|||JUST A LAB^ORANGE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|ORANGE_()!@|60569-1^Report Addendum.Synoptic˜LN|||Jan 1|||||||Jan 6||Dr.B,Dr.GREY||||||Jan
7||||||||||Dr.ORANGE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^ BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F|||Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP ||31163.1000043^HER2 by Immunohistochemistry
(IHC)^CAPECP||||||F|||Jan 7
SPM|1|^ORANGE_9012&JUST A LAB&ORANGE&CLIA|GREY_5678|TS|K|||||||||||Jan 1| Jan 6|||||||||||||BLUE_abcd,
GREY_abcd, ORANGE_abcd|9012
```

Message 4: (Biomarker ISH Testing – Positive Results)

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE ^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
  ORC||||||||||||||||||||BLUE, GREY, GREEN
OBR|1|GREEN_#$%^|PURPLE_&*()|60569-1^Report Addendum.Synoptic˜LN|||Jan 1||||||Jan
8||Dr.B,Dr.GREY,Dr.GREEN||||||Jan 9||||||||||Dr.TAUPE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^ BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F|||Jan 9
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization
(ISH)^CAPECP||||||F|||Jan 9
SPM|1|^PURPLE_7890&ON PAR WITH BETTER THAN AWESOME LABS&PURPLE&CLIA|GREEN_3456|TS|K|||||||||||Jan 1|
Jan 8|||||||||||||BLUE_abcd, GREY_abcd, GREEN_abcd, PURPLE_abcd|7890
```

Patient-derived specimens may be divided into multiple parts before or after arriving at the primary
receiving facility (Blue). The primary facility (Blue) may send one or more of these specimen parts to
downstream facilities (e.g., Grey). The left-to-right arrows in the figure indicate upstream facilities
sending specimen parts to downstream receiving facilities. Downstream facilities may send specimens to
even more downstream facilities (e.g., Orange, Green, and Purple).

Each receiving facility may assign its own values (date/times) to the received specimen and/or the parts
that it generates. As shown by the color-coded diagram in Figure 10, the HL7 fields containing those
identifiers are color-coded according to the facility that created those values. For example, facility Orange
assigned new values for SPM-18 OBR-14 and it preserved the values from facility Blue for OBR-7 and
SPM-17. Note that facility Orange did not preserve the values from facility Grey (OBX-14, SPM-18,
OBR-14 and OBR-22, which are relevant only to the local facility generating the report).

Figure 10: Registry Use Case Date/Timestamp

Date/Timestamp
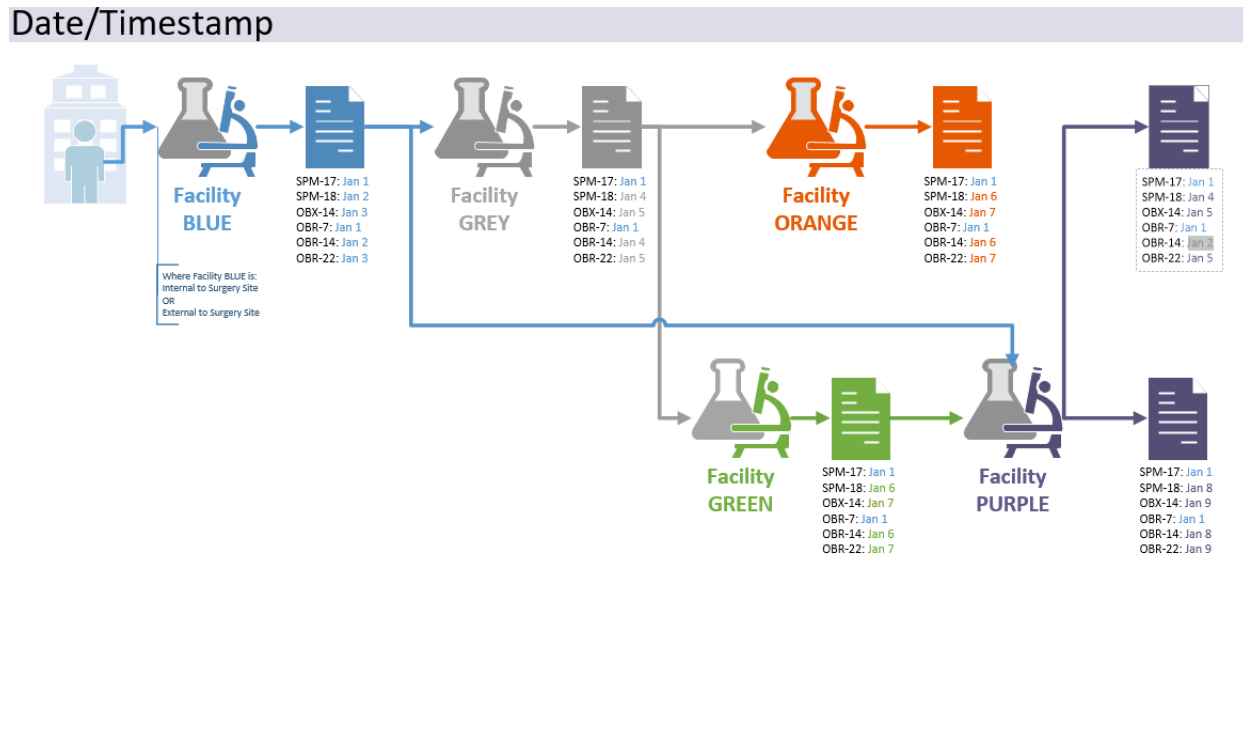
Date/Time fields are of vital importance to cancer registries, especially in deriving the diagnosis date. In the example above, facility Blue will populate SPM-17 (Specimen Collection Date/Time), and SPM-17 will remain unchanged throughout the chain of transmissions. Specimen collection time is the earliest time documented in the medical record that the specimen was removed. This value will be the same value populated in OBR-7. Facility Blue MAY also populate OBR-14 (Specimen Received Date/Time) and SPM-18 (Specimen Received Date/Time). Each downstream facility in the process will populate this field with the earliest Date/Time it received the specimen from the upstream facility. OBR-22 (Results rpt/status change date/time) is the date/time of the diagnostic pathology report sign off (final or corrected), as indicated in OBR-25 and OBX-11.

Each facility generally sends a report for the analysis that it conducted directly to the registry.

Message 1a: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or GREY>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$|60568-3^Synoptic Report^LN |||Jan 1|||||| Jan 2||Dr.B||||||Jan 3||||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-
sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOME LABS&BLUE&CLIA||TS|K|||||||||||Jan 1 Jan 2|||||||||||||BLUE_abcd|abcd
```

Message 1b: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$||60568-3^Synoptic Report^LN||Jan 1|||||| Jan 2||Dr.B||||||Jan 3||||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-
sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOME LABS&BLUE&CLIA||TS|K|||||||||||Jan 1 Jan 2|||||||||||||BLUE_abcd|cd
```

Message 2a: (Biomarker – ER/PR)

```
MSH|||BETTER THAN AWESOME LABS^GREY^CLIA||<null or ORANGE>
PID|
PV1||||||Dr.A|Dr.C
  ORC||||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|GREY_%^&*|60569-1^Addendum Report.Synoptic^LN|||Jan 1|||||| Jan 4||Dr.B||||||Jan 5|||||||||Dr.GREY
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 5
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31160.1000043^Estrogen Receptor (ER) Status (Note
A)^CAPECP||||||F|||Jan 5
SPM|1|^GREY_5678&BETTER THAN AWESOME LABS&GREY&CLIA|BLUE_1234|TS|K|||||||||||Jan 1 Jan
4|||||||||||||BLUE_abcd, GREY_abcd|5678
```

Message 2b: (Consult on Anatomical Pathology Report)

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|PURPLE_)(*&|60571-7^Consultation Note Synoptic^LN|||Jan 1|||||| Jan 4||Dr.B||||||Jan 5|||||||||Dr.PURPLE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F|||Jan 5
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-
sparing mastectomy)^CAPECP||||||F|||Jan 5
SPM|1|^PURPLE_0987&ON PAR WITH BETTER THAN AWESOME LABS&PURPLE&CLIA|BLUE_1234|TS|S|||||||||||Jan 1
Jan 4|||||||||||||BLUE_abcd, PURPLE_abcd|ab
```

Message 3a: (Biomarker ISH Testing – Indeterminate Results)

```
MSH|||OK LABS^GREEN^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|GREEN_#$%^|60569-1^Report Addendum.Synoptic^LN||| Jan 1 |||||| Jan 6 ||Dr.B,Dr.GREY|||||| Jan 7 |||||||||Dr.GREEN
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization (ISH)^CAPECP||||||F||| Jan 7
SPM|1|^GREEN_3456&OK LABS&GREEN&CLIA|GREY_5678|TS|K|||||||||||| Jan 1  Jan 6 |||||||||||||BLUE_abcd, GREY_abcd, GREEN_abcd|3456
```

Message 3b: (Biomarker IHC Testing)

```
MSH|||JUST A LAB^ORANGE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|ORANGE_()!@|60569-1^Report Addendum.Synoptic^LN||| Jan 1 |||||| Jan 6 ||Dr.B,Dr.GREY|||||| Jan 7 |||||||||Dr.ORANGE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP ||31163.1000043^HER2 by Immunohistochemistry (IHC)^CAPECP||||||F||| Jan 7
SPM|1|^ORANGE_9012&JUST A LAB&ORANGE&CLIA|GREY_5678|TS|K|||||||||||| Jan 1  Jan 6 |||||||||||||BLUE_abcd, GREY_abcd, ORANGE_abcd|9012
```

**Message 4: (Biomarker ISH Testing – Positive Results)**

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE ^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC||||||||||||||||||||BLUE, GREY, GREEN
OBR|1|GREEN_#$%^|PURPLE_&*()|60569-1^Report Addendum.Synoptic^LN ||| Jan 1 |||||| Jan 8 ||Dr.B,Dr.GREY,Dr.GREEN|||||| Jan 9 |||||||||Dr.TAUPE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 9
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization (ISH)^CAPECP||||||F||| Jan 9
SPM|1|^PURPLE_7890&ON PAR WITH BETTER THAN AWESOME LABS&PURPLE&CLIA|GREEN_3456|TS|K|||||||||||| Jan 1  Jan 8 |||||||||||||BLUE_abcd, GREY_abcd, GREEN_abcd, PURPLE_abcd|7890
```

Multiple providers and institutions are involved in the specimen journey. Capturing this information is needed for registry follow-up. Providers also can work at multiple institutions. In Figure 11, the Sending Facility (MSH-4) is the laboratory name and Clinical Laboratory Improvement Amendments (CLIA) number of the organization (e.g., Blue, Grey, Orange, Green, and Purple) transmitting the HL7 ORU report. The Receiving Facility (MSH-6) is the name of the organization (e.g., State Cancer Registry, Grey, Orange, Green, or Purple) receiving the HL7 ORU report. The report must provide the Ordering Provider (OBR-16) and the Ordering Facility Name (ORC-21) to allow the cancer registry to request additional demographic, diagnostic, and treatment data needed for public health surveillance and epidemiological research. The Ordering Provider (OBR-16) refers to the name and National Provider Identifier (NPI) number of the surgeon/physician (e.g., provider name) who submitted the order requisition and specimen to the laboratory for testing and interpretation. The Ordering Facility Name (ORC-21) includes the organization name (e.g., hospital, clinic, physician office/group, Blue, or Grey) and physician/organization identifier (e.g., NPI or CLIA) for the physician/entity that submitted the order

requisition and specimen for testing and interpretation. The Ordering Facility Name and identifier should correspond to the facility that the Ordering Provider is either employed by or practicing within. The Principal Result Interpreter (OBR-32) is the name of the physician (e.g., Blue pathologist name, Grey pathologist name, Orange pathologist name, Green pathologist name, Purple pathologist name, or external group pathologist name) and NPI number for the provider who made the final interpretation included on the specimen pathology report. The Attending Doctor (PV1-7) could include any other physician name and NPI number (e.g., surgeon, surgical oncologist, or oncologist) involved in the patient's cancer diagnosis and care. The Referring Doctor (PV1-8) is the physician's name and NPI number (e.g., primary care physician or specialty physician) for the provider who manages the overall care for the patient's health and will follow the diagnosis and treatment received.

Figure 11: Registry Use Case Ordering Provider Identifiers

Message 1a: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or GREY>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$|60568-3^Synoptic Report^LN||Jan 1|||||| Jan 2||Dr.B|||||Jan 3|||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F||| Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOME LABS&BLUE&CLIA||TS|K|||||||||||Jan 1| Jan 2|||||||||||BLUE_abcd|abcd
```

Message 1b: (Anatomical Pathology Report – Breast, NOS)

```
MSH|||AWESOME LABS^BLUE^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||||BLUE
OBR|1|<null or Reqid>|BLUE_!@#$|60568-3^Synoptic Report^LN|||Jan 1||||||Jan 2||Dr.B|||||Jan 3|||||||||Dr.BLUE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F||| Jan 3
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 3
SPM|1|^BLUE_1234&AWESOME LABS&BLUE&CLIA||TS|S|||||||||||Jan 1| Jan 2|||||||||||BLUE_abcd|cd
```

Message 2a: (Biomarker – ER/PR)

```
MSH|||BETTER THAN AWESOME LABS^GREY^CLIA||<null or ORANGE>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|GREY_%^&*|60569-1^Addendum Report.Synoptic^LN|||Jan 1||||||Jan 4||Dr.B|||||Jan 5|||||||||Dr.GREY
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 5
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31160.1000043^Estrogen Receptor (ER) Status (Note A)^CAPECP||||||F|||Jan 5
SPM|1|^GREY_5678&BETTER THAN AWESOME LABS&GREY&CLIA|BLUE_1234|TS|K|||||||||||Jan 1| Jan 4|||||||||||BLUE_abcd, GREY_abcd|5678
```

Message 2b: (Consult on Anatomical Pathology Report)

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||||BLUE
OBR|1|BLUE_!@#$|PURPLE_)(*&|60571-7^Consultation Note Synoptic^LN|||Jan 1||||||Jan 4||Dr.B|||||Jan 5|||||||||Dr.PURPLE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||189.1000043^INVASIVE CARCINOMA OF THE BREAST^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||3.000.001.REL||||||F||| Jan 5
OBX|4|CWE|58807.1000043^Procedure^CAPECP||39079.1000043^Total mastectomy (including nipple-sparing and skin-sparing mastectomy)^CAPECP||||||F|||Jan 5
SPM|1|^PURPLE_0987&ON PAR WITH BETTER THAN AWESOME LABS&PURPLE&CLIA|BLUE_1234|TS|S|||||||||||Jan 1| Jan 4|||||||||||BLUE_abcd, PURPLE_abcd|ab
```

Message 3a: (Biomarker ISH Testing – Indeterminate Results)

```
MSH|||OK LABS^GREEN^CLIA||<null or PURPLE>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|GREEN_#$%^|60569-1^Report Addendum.Synoptic^LN|||Jan 1||||||Jan 6||Dr.B, Dr.GREY||||||Jan
7||||||||Dr.GREEN
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization
(ISH)^CAPECP||||||F|||Jan 7
SPM|1|^GREEN_3456&OK LABS&GREEN&CLIA|GREY_5678|TS|K|||||||||||||Jan 1| Jan 6|||||||||||||BLUE_abcd, GREY_abcd,
GREEN_abcd|3456
```

Message 3b: (Biomarker IHC Testing)

```
MSH|||JUST A LAB^ORANGE^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||BLUE, GREY
OBR|1|GREY_%^&*|ORANGE_()!@|60569-1^Report Addendum.Synoptic^LN|||Jan 1||||||Jan 6||Dr.B, Dr.GREY||||||Jan
7||||||||Dr.ORANGE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 7
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP ||31163.1000043^HER2 by Immunohistochemistry
(IHC)^CAPECP||||||F|||Jan 7
SPM|1|^ORANGE_9012&JUST A LAB&ORANGE&CLIA|GREY_5678|TS|K|||||||||||||Jan 1| Jan 6|||||||||||||BLUE_abcd, GREY_abcd,
ORANGE_abcd|9012
```

Message 4: (Biomarker ISH Testing – Positive Results)

```
MSH|||ON PAR WITH BETTER THAN AWESOME LABS^PURPLE ^CLIA||<null>
PID|
PV1||||||Dr.A|Dr.C
ORC|||||||||||||||||BLUE, GREY, GREEN
OBR|1|GREEN_#$%^|PURPLE_&*()|60569-1^Report Addendum.Synoptic^LN|||Jan 1||||||Jan
8||Dr.B, Dr.GREY, Dr.GREEN||||||Jan 9||||||||Dr.TAUPE
OBX|1|ST|60573-3^Report template source^LN||CAP eCP||||||F
OBX|2|CWE|60572-5^Report template ID^LN||169.1000043^BREAST: Biomarker Reporting Template^CAPECP||||||F
OBX|3|ST|60574-1^Report template version ID^LN^VERSION^Template Version Identifier^L||1.000.001.REL||||||F||| Jan 9
OBX|4|CWE|31159.1000043^Test(s) Performed^CAPECP||31166.1000043^HER2 (ERBB2) by In Situ Hybridization
(ISH)^CAPECP
||||||F|||Jan 9
SPM|1|^PURPLE_7890&ON PAR WITH BETTER THAN AWESOME LABS&PURPLE&CLIA|GREEN_3456|TS|K|||||||||||||Jan 1|
Jan 8|||||||||||||BLUE_abcd, GREY_abcd, GREEN_abcd, PURPLE_abcd|7890
```
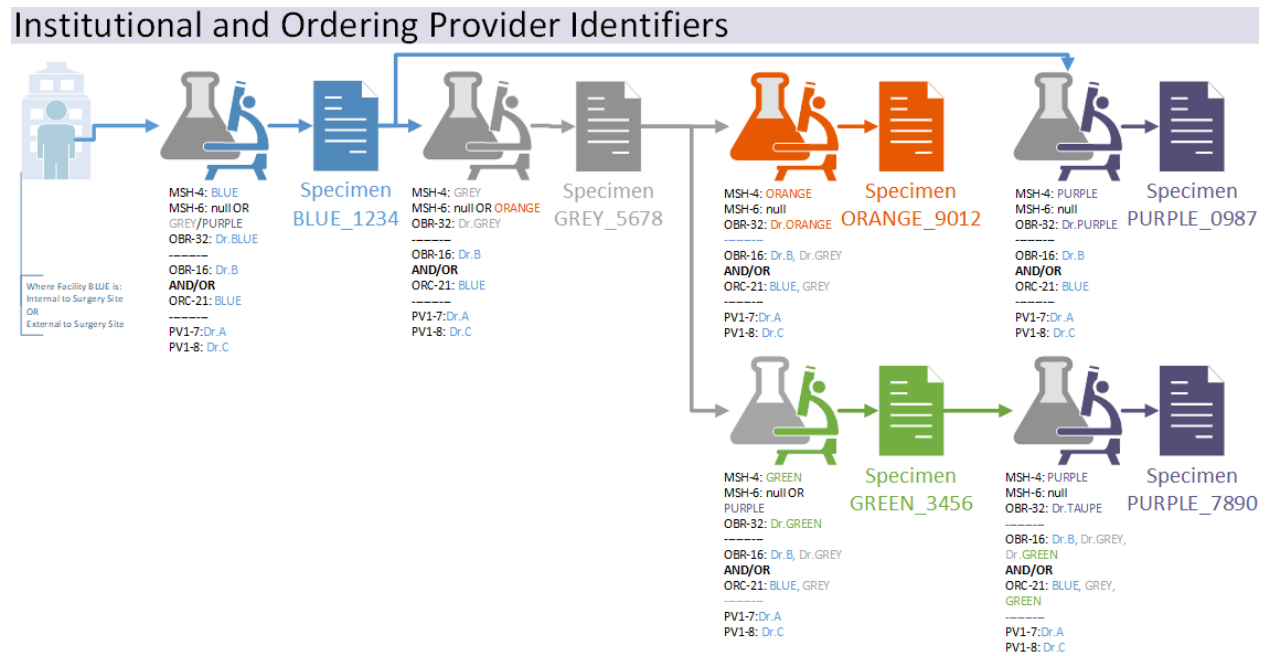
2.3. STATIC MODEL – MESSAGES

The static model of messaging describes the data layouts and formats used in the various interactions in the dynamic model. This section contains the two messages used in cancer registry messaging, the Unsolicited Observation message, which carries the pathology report; and the General Acknowledgment (ACK) message, used to confirm receipt of a message and/or report communications errors. All of the segments and data fields used in both of these messages are described below. A separate section discusses the HL7 batch protocol, which uses special message formats.

2.3.1. Unsolicited Observation Message (ORU)/Event R01

Laboratory result information is reported to cancer registries through the Unsolicited Observation ORU^R01 message. The supported segments in ORU message style are described in Table 7.

Table 7: ORU Unsolicited Observation Message (event R01)

ORU^R01	Observational Results (Unsolicited)	Cardinality	HL7 Standard Section
MSH	Message Header		2.15.9
[{SFT}]	Software	0..*	2.15.12
{	- PATIENT_RESULT begin	1..1	
[	-- PATIENT begin	1..1	
PID	Patient Identification	1..1	3.4.2
[PD1]	Additional Demographics	0..0	
[{NTE}]	Notes and Comments	0..0	
{[NK1]}	Next Of Kin/Associated Parties	0..*	3.4.5
[	VISIT begin	0..*	
PV1	Patient Visit	1..1	3.4.3
[PV2]	Patient Visit – Additional Info		
]	VISIT end		
]	-- PATIENT end		
{	-- ORDER RESULT begin	1..*	
[ORC]	Order Common	0..1	4.5.1
OBR	Observations Request	1..*	4.5.3 and 7.4.1
{[NTE]}	Notes and Comments segment	0..*	2.15.1
[{	Timing begin	0..0	
TQ1	Timing/Quantity		
[{TQ2}]	Timing/Quantity Order Sequence		
}]			
[CTD]	Contact Data	0..0	
{	--- RESULT begin	1..*	
OBX	Observation/Result segment	1..1	7.4.2
{[NTE]}	Notes and Comments segment	0..*	2.15.1
}	--- RESULT end		
[{FT1}]	Financial Transaction	0..0	
[{CTI}]	Clinical Trial Identification	0..0	
[{	--- SPECIMEN INFORMATION begin	1..*	
SPM	Specimen	1..*	7.4.3
{[OBX]}	Observation Related to Specimen	1..*	7.4.2
}]	--- SPECIMEN INFORMATION end		
}	-- ORDER RESULT end		
}	- PATIENT RESULT end		
[DSC]	Continuation Pointer	0..1	2.15.4

NOTE: The cardinality has been constrained to contain only 1 patient result group.

Using the basic "building blocks" of MSH, PID, OBR, and OBX segments (in Table 7), a clinical report can be constructed as a three-level hierarchy with the patient information (PID) segment at the upper level, an order record (OBR) at the next level, and one or more observation records (OBX) at the bottom. The Message Header (MSH) segment is required for all HL7 messages. Next-of-Kin (NK1) segments are optional and can provide information about parties associated with the patient.

The PV1 segment is used by registration/patient administration applications to communicate information on an account or visit-specific basis. For NAACCR usage, as specified in this Guide, the PV1 segment is considered "RE", i.e., required or empty, and not just optional. The PV1 segment carries information on the Attending Physician (PV1-7), the Referring Physician (PV1-8), and the Consulting Physician (PV1-9). Whenever possible, laboratories are strongly encouraged to populate those fields, in addition to OBR-16 (Ordering Provider ID and Name) and ORC-24 (Ordering Provider Address). Central cancer registries need provider information to contact providers and request additional information on the patient, patient's tumor, and/or treatment.

The common order (ORC) segment transmits fields common to all types of requested services; the Notes and Comments (NTE) segment is an optional segment that would follow its corresponding OBR or OBX, that provides a common note format.

The SPM segment contains detailed information about the samples that were examined. For NAACCR usage, as specified in this Volume V, Version 5.0, the SPM segment is required to correctly track identifiers in modern laboratory analyses.

Typically, an anatomical pathology report is associated with a surgical specimen and results in a single message or transmission. In a single transmission, one MSH segment, one ORC segment, and one OBR segment will be required. For cases in which multiple tests are performed on the same tumor, the message can include separate OBRs for each test. For cancer registry reporting, there could be multiple OBR segments for a single MSH segment if the text-based pathology report describes each of the multiple primaries in separate sections. In such a circumstance, it is recommended that there be a single OBR for each of the primary cancers being reported.

Another example of using a single MSH segment and multiple OBR segments would be transmitting an encoded checklist and raw text, plus a synoptic report with all data encoded.

Although certain elements of the message are required for laboratory-based reporting, data in non-required fields will not be rejected. The standard ORU message allows the optional use of several additional segments (e.g., PD1, PV2, CTI), but these segments are not defined or used in the laboratory-based cancer reporting message. For this reason, there is no discussion of these segments in this implementation guide. Messages containing these segments, however, will not be rejected. For electronic laboratory reporting purposes, acknowledgment messages are not yet implemented in most locations in North America. Therefore, although they are defined in this Guide, interfaces that have not implemented these messages will still be compliant.

2.3.1.1. How to Construct a Message Using the SPM Segment

Cancer report results to be encoded may be placed in OBX segments in either of the two locations in the message (one following the OBR and one following the SPM). The newer format for the message includes the required SPM segment and its associated OBX segments immediately following it to hold results associated with a particular specimen; this may be referred to as the SPM-style. Including all results in the first set of OBX segments in the message following the OBR may be referred to as the old style, because it is similar to earlier releases of the NAACCR Laboratory Electronic Pathology Reporting messaging. It is recommended that the following guidelines be followed:

- If all the specimen information is textual only, then all result information should be encoded in the first set of OBX segments in the message, immediately following the OBR. In this scenario, one SPM segment would follow the OBR and OBX segments that provide the specimen information for the overall case diagnosis.
- Results that are associated explicitly with the specimen should be encoded in the second set of OBX segments in the message—those that immediately follow the SPM segment (enclosed within the {[SPECIMEN INFORMATION begin]} and the {[SPECIMEN INFORMATION end]} markers in the message layout above). Typically, this would include at least the gross observations on the specimen. The overall findings for the case, along with observations not associated with a specimen (such as Clinical History), still should be encoded in the initial set of OBX segments as shown enclosed by the {RESULT begin} and {RESULT end} markers in the message layout above (SPM-style).
- If the case has multiple specimens, then a SPECIMEN INFORMATION set of segments (having an SPM plus one or more associated OBX segments) should be used to identify each of the specimens. Observations that are associated with a particular specimen should be encoded in OBX segments following the appropriate SPM segment in the repeating SPECIMEN

INFORMATION segments. Note that overall case findings still should be encoded in the set of OBX segments immediately following the OBR, identified in the message layout as the RESULT. NAACCR recommends that this SPM-style be used for messaging any case that has multiple specimens. If the laboratory is not able to report the specimen-specific observations separately, then the results for each specimen part should be placed in the OBX segments following the OBR segment. One or more SPM segments should follow the OBX segments with information on the specimens that were processed.

- If the result is a synoptic report, then the specimen-specific information may be encoded in the OBX segments in the SPECIMEN INFORMATION set if using the SPM-style of message construction, but alternatively may be sent wholly in the OBX segments in the RESULT set of segments (old style). Note that for fully encoded synoptic reports, all of the specimen information that may be carried in the SPM segment generally is carried in the OBX. The synoptic OBX SHALL BE followed by one (or more) SPM segments that describe the specimens covered by the synoptic OBX segments. The synoptic OBXs are not linked to their SPM segments in OBX-4. OBX-4 is used to create a hierarchy within the OBX segments. See Chapter 3 for more information on messaging and synoptic reporting.

Some fields that are required in segments are optional in the message, such as the PV1. The interpretation should be that the segment does not have to be in a message, but if it is present, then the fields that are required within it must be populated. In the same way, components of data types that are required should be interpreted to mean that if a field of that data type is populated, then any required data type components must be populated.

The file header segment (FHS), file trailer segment (FTS), batch header segment (BHS), and batch trailer segment (BTS) are required for batch submissions only (see Section 2.8, HL7 Batch Protocol).

What follows is an example of a message that uses one OBR and one SPM segment:

```
MSH|^~\&|SuperLink|SuperLab^01D1012357^CLIA|Cancer Registry|CR|
20190307121736||ORU^R01^ORU_R01|20190307121736_81778|D|2.5.1
|||||||||VOL_V_50_ORU_R01^NAACCR_CP| <CR>
PID|1||A001223/B2345676^^^St. Best Hospital^MR^St. Best Hospital
~999999999^^^USSSA^SS^USSSA~3344556^^^SuperLab SuperState ^PI^SuperLab
SuperState||Doe^Jane||19420222|F <CR>
PV1|1|N|||||^Welby^Marcus <CR>
ORC|RE||||||||||||||||||||||St. Best Hospital|11 Super
Street^^Supercity^NY^122286^United States
|^WPN^FX^^^123^4567891~^WPN^PH^^^123^3456788 <CR>
OBR|1||1112224|26435-8^Molecular Pathology Studies^LN^^EGFR Mutation
Analysis^L|||20190219000000|||||||20190226105600|^^Lung,
Left|^Howser^Doogie||||||20190306121401|||F||||||MALIGNANT NEOPLASM OF UNSPECIFIED
PART OF BRONCHUS OR LUNG, EGFR repeat|&Ben&Casey <CR>
OBX|1|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Mutation: Detected||||||F||||
01D1012357^SuperLab SuperState^CLIA <CR>
OBX|2|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Exon 18: Detected||||||F||||
01D1012357^SuperLab SuperState^CLIA <CR>
OBX|3|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Exon 19: Not
Detected||||||F||||01D1012357^SuperLab SuperState^CLIA <CR>
OBX|4|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Exon 20 T790M: Not
Detected||||||F||||01D1012357^SuperLab SuperState^CLIA <CR>
OBX|5|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Exon 20 Other Mutations: Not
Detected||||||F||||01D1012357^SuperLab SuperState^CLIA <CR>
OBX|6|TX|22637-3^Path Report Final Diagnosis^LN||EGFR Exon 21: Not
Detected||||||F||||01D1012357^SuperLab SuperState^CLIA <CR>
OBX|7|TX|22638-1^Path Report Comments^LN||Clinical Significance: Patients with non-
small cell lung cancer (NSCLC) and mutations in EGFR exons 18, 19, 20, or 21
usually respond to anti-EGFR tyrosine kinase inhibitors (TKIs) and have longer
survival when compared to EGFR mutation-negative patients. However, patients being
```

treated with TKIs may develop acquired resistance with secondary mutations in exon 20, such as T790M or, less commonly, L747S, D761Y and T854A.\x0A\\x0A\NSCLCs with exon 20 mutations, such as T790M mutation, are usually resistant to first-generation (erlotinib, gefitinib) and second-generation (afatinib, dacomitinib, neratinib) anti-EGFR TKIs, but may respond to third-generation TKIs, such as osimertinib. The less common resistance mutations (e.g. L747S, D761Y and T854A) may respond to second- or third-generation irreversible TKIs based on early studies. Most EGFR exon 20 insertions are resistant to EGFR TKIs with the exception of p.A763_Y764insFQEA, which is associated with increased sensitivity to EGFR TKIs. ||||||F||||05D1021650^NeoGenomics California^CLIA <CR>
OBX|8|TX|22638-1^Path Report Comments^LN||Methodology: DNA was isolated from cells or microdissection- enriched FFPE tissue. Formalin-fixed, paraffin-embedded tumor tissue sections were deparaffinized and DNA was isolated. EGFR tyrosine kinase domain mutations were evaluated in the entirety of exons 18 to 21. The patient's sequence is compared to the EGFR sequence database NM_005228. This assay is by Sanger sequencing method with Locked Nucleic Acid (LNA) for T790M. The sensitivity for detecting the T790M mutation in exon 20 is at least 3% with the remaining mutations having a sensitivity of 10 to 15% for detecting mutated EGFR DNA in a wild-type background. Various factors including quantity and quality of nucleic acid, sample preparation and sample age can affect assay performance.||||||F||||05D1021650^NeoGenomics California^CLIA <CR>
OBX|9|TX|22638-1^Path Report Comments^LN||
References: 1. Jänne PA, et al. Epidermal growth factor receptor mutations in non-small-cell lung cancer: implications for treatment and tumor biology. J Clin Oncol. 2005; 23:3227-34.\X0A\2. Lynch TJ, et al. Activating mutations in the epidermal growth factor receptor underlying responsiveness of non-small-cell lung cancer to gefitinib. N Engl J Med. 2004; 350:2129- 39.\X0A\3. Sequist LV, et al. Response to treatment and survival of patients with non-small cell lung cancer undergoing somatic EGFR mutation testing. Oncologist. 2007;12:90-8.\X0A\4. Paez JG, et al. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. Science. 2004; 304:1497-1500.\X0A\5. Costa DB, et al. Differential responses to erlotinib in epidermal growth factor receptor (EGFR)-mutated lung cancers with acquired resistance to gefitinib carrying the L747S and T790M secondary mutations. J Clin Oncol. 2008; 26:1182-4.\X0A\6. Felip E, Barlesi F, Besse B, et al. Phase 2 Study of the HSP-90 Inhibitor AUY922 in Previously Treated and Molecularly Defined Patients with Advanced Non-Small Cell Lung Cancer. J Thorac Oncol. 2018;13(4):576-584.||||||F||||05D1021650^NeoGenomics California^CLIA <CR>
SPM|1|^SN19-123-A|SN19-123-A|TISS^Tissue^HL70487^^Paraffin Tissue^L |||||||||||||20190219000000|20190226105600||||||||||||1112224|SN19-123-A <CR>

2.3.2. General Acknowledgment Message – ACK

If the registries are not supporting ACK messages, then all content in this section is Optional. Many registries may only be starting to implement this message; many are not sending acknowledgment messages back to the sending laboratories.

For background on Acknowledgments, see HL7 Messaging Standard Version 2.9 Chapter 2, Sections 2.3.3, 2.3.4 for the types of modes that can be used and Section 2.8 for processing rules (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=516) to understand the two types of supported levels and more specifically the Acknowledgement Choreography for the ORU^R01 message described in Chapter 7, section 7.3.1, which shows that for both commit level and application level the ACK message structure is used.

Table 8: General Acknowledgment Message – ACK

ORU^R01	Observational Results (Unsolicited)	Cardinality	HL7 Standard Section
MSH	Message Header	1..1	2.15.9
[{SFT}]	Software	0..*	2.15.12
MSA	Message Acknowledgment	1..1	2.15.8
[{ERR}]	Error	0..*	2.15.5

Note: Based on the values identified in MSH-15 and MSH-16 of the ORU message the receiver shall send either just an Accept Level Acknowledgement Message (MSH-15 = 'AL', 'SU' or 'ER' and MSH-16 = 'NE'), and Application Level Acknowledgement Message (MSH-15 = 'NE' or blank and MSH-16 = 'AL, 'SU' or 'ER' or blank) or both (MSH-15 and MSH-16 = 'AL, 'SU' or 'ER') or none (MSH-15 and MSH-16 = 'NE').

Note that due to the ACK^R01^ACK message being used for both the Accept Level and Application Level acknowledgements, the only way to distinguish whether this is an Accept Level message is the value of MSA-1.

For the ACK message, the value of MSH-9-2-Trigger event is equal to the value of MSH-9-2-Trigger event in the message being acknowledged. The value of MSH-9-3-Message style for the general acknowledgment message is always ACK.

2.3.2.1. Message Acknowledgment (MSA) Segment
The MSA segment contains information sent while acknowledging another message.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	2	ID	R		0008	00018	Acknowledgment code		R	[1..1]
2	20	ST	R			00010	Message control ID		R	[1..1]
3	80	ST	B			00020	Text message		C(RE/X)	[0..1]
4	15	NM	O			00021	Expected sequence number		RE	[0..1]
5			W			00022	Delayed acknowledgment type		X	[0..0]
6	250	CWE	B		0357	00023	Error condition		C(R/X)	[0..1]
18	16	ID	O	Y	0211	00692	Character set		X	[0..0]
19	250	CWE	O			00693	Principal language of message		RE	[0..1]
20	20	ID	O		0356	01317	Alternate character set handling scheme		X	[0..0]
21	427	EI	O	Y		01598	Message profile identifier		RE	[0..3]

MSA Field Definitions

MSA-1 Acknowledgment Code (ID-2, Required) 00018

Definition: This field contains an acknowledgment code; see message processing rules. Refer to *HL7-Defined Table 0008 – Acknowledgment Code* for valid values.

MSA-2 Message Control ID (ST-20, Required) 00010

Definition: This field contains the message control ID of the message sent by the sending system. It allows the sending system to associate this response with the message for which it is intended.

MSA-3 Text Message (ST-80, Conditional or Empty) 00020

Definition: This optional field further describes an error condition. This text may be printed in error logs or presented to an end user.

The MSA-3 was deprecated as of Version 2.4. The reader is referred to the ERR segment. The ERR segment allows for richer descriptions of the erroneous conditions. However, for systems unable to populate the ERR segment, this field may be used to pass the error text message. Conditionality predicate: The error text must be populated here if the ERR is not used and an error occurs.

MSA-4 Expected Sequence Number (NM-15, Required or Empty) 00021

Definition: This optional numeric field is used in the sequence number protocol.

MSA-6 Error Condition (CWE-250, Conditional or Empty) 00023

Definition: This field allows the acknowledging system to use a user-defined error code to further specify AR or AE type acknowledgments.

The MSA-6 was deprecated as of version 2.4. The reader is referred to the ERR segment. The ERR segment allows for richer descriptions of the erroneous conditions. This may be used if the sending system is unable to populate an ERR segment. Conditionality predicate: The error code must be populated here if the ERR is not used and an error occurs.

Refer to HL7-Defined Table 0357 – Message Error Condition Codes for valid values.

2.3.2.2. Error (ERR) Segment

The ERR segment is used to add error comments to acknowledgment (ACK) messages.

Use Cases:

Severity: A receiving application generates two messages, one an error and the other a warning, and sends each of them. The application displays them both, prefixing the messages appropriately with the severity.

Application Error Code: A receiving application generates an error that reports an application error code and returns this information in its response. This code in turn is used by helpdesk staff to pinpoint the exact cause of the error, or by the application to prompt an appropriate response from the user. (Example: Deceased date must be greater than or equal to birth date.)

Application Error Parameter: A receiving application encounters an error while processing a transaction. In addition to an error code, the application provides an error parameter that gives greater detail about the exact nature of the error. The receiving application looks up the message corresponding to the error code, substitutes in the parameter, and displays the resulting message to the user.

Diagnostic Information: While processing a transaction, a receiving application encounters an exception. When the exception is thrown, it provides a volume of detailed information relating to the error encountered. The receiving application captures the information and sends it in its response. The user reports the error to the help desk and, on request, faxes a copy of the diagnostic information to assist in analyzing the problem.

User Message: A user executes an application function that generates a transaction that is sent to another application for further processing. During this processing, the receiving application encounters an error and, as part of the error-handling routine, retrieves a User Message that it returns in its response. The originating application receives the error and displays it to the end user with the intent that the error condition can be resolved and the user can re-execute the function without error.

Support for Multiple Error Locations: Two fields are marked as conditional, with the condition that one of the two must be specified. The sending application leaves both blank. The receiving application detects the problem and sends back a single error indicating that one of the fields must be filled in. The ERR segment identifies both positions within the message that relate to the error.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	493	ELD	B	Y		00024	Error code and location		X	[0..0]
2	18	ERL	O	Y		01812	Error location		RE	[0..*]
3	705	CWE	R		0357	01813	HL7 error code		R	[1..1]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
4	2	ID	R		0516	01814	Severity		R	[1..1]
5	705	CWE	O		0533	01815	Application error code		X	[0..0]
6	80	ST	O	Y/10		01816	Application error parameter		X	[0..0]
7	2048	TX	O			01817	Diagnostic information		RE	[0..1]
8	250	TX	O			01818	User message		RE	[0..1]
9	20	IS	O	Y	0517	01819	Inform person indicator		X	[0..0]
10	705	CWE	O		0518	01820	Override type		X	[0..0]
11	705	CWE	O	Y	0519	01821	Override reason code		X	[0..0]
12	652	XTN	O	Y		01822	Help desk contact point		RE	[0..3]

ERR-2 Error Location (ERL-18, Required or Empty, Repeating maximum 5) 01812

Definition: Identifies the location in a message related to the identified error, warning, or message. If multiple repetitions are present, the error results from the values in a combination of places.

ERR-3 HL7 Error Code (CWE-705, Required) 01813

Definition: Identifies the HL7 (communications) error code. Refer to *HL7-Defined Table 0357 – Message Error Condition Codes* for valid values.

ERR-4 Severity (ID-2, Required) 01814

Definition: Identifies the severity of an application error. Knowing if something is an error, a warning, or information is intrinsic to how an application handles the content. Refer to *HL7-Defined Table 0516 – Error Severity* for valid values. If ERR-3 has a value of "0", ERR-4 will have a value of "I".

Example: A warning could be used to indicate that notes were present but ignored because they could not be automatically processed, and therefore information could have been missed.

Example of information: When submitting a claim, a payer might indicate remaining coverage under limit.

ERR-7 Diagnostic Information (TX-2048, Required or Empty) 01817

Definition: Non-coded information that may be used by help desk or other support personnel to diagnose a problem.

ERR-8 User Message (TX-250, Required or Empty) 01818

Definition: The text message to be displayed to the application user. This differs from the actual error code and may provide more diagnostic information.

Example: |This program is having trouble communicating with another system. Please contact the help desk.|

ERR-12 Help Desk Contact Point (XTN-652, Required or Empty, Repeating maximum 3) 01822

Definition: Lists telephone, email, fax, and other relevant numbers for helpdesk support related to the specified error.

2.4.   STATIC MODEL – SEGMENT OVERVIEW

2.4.1.   HL7 Standard Segments

Each message is composed of a series of segments. Each segment is identified by its unique three-letter code. The segments used in this HL7 implementation guide are defined in Section 2.5. The segment definitions are given in the most logical order for cancer pathology report messages and do not strictly adhere to the order in which they are presented in the HL7 Standard. The header rows for the segment attribute tables look like this:

Seq	Len	DT	Opt	RP#	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardnlty

Following the table, each field is listed and defined. For each field, the HL7 segment code and reference number are listed, followed by the field name. Items in parentheses after the field name show, respectively, data type and length of field, whether the field is required or optional, and list "repeating" if the field is allowed to repeat. Note that these conformance criteria are the constrainable conformance set defined by NAACCR for cancer pathology report messaging. The HL7 item number follows the parenthesis and is given for reference convenience. As part of the definitions, usage notes for NAACCR reporting are provided, a description of the data type is given in small font, and a statement about how the fields are valued in the example is given.

Fields that NAACCR does not anticipate cancer registries using have a NAACCR Usage of "X" for Not Supported. These fields are listed in the Segment Tables. Users interested in learning more about the fields not discussed here should refer to the full text of HL7 Standard, Version 2.5.1.

The terms used in the header rows of the segment attribute tables and their definitions are as follows:

ABBREVIATION	DEFINITION
Seq	The sequence of the elements as they are numbered in the segment.
Len	The standard HL7 length of the element.
DT	The standard HL7 data type of the element. See Appendix C.
Opt	Whether the field is required, optional, or conditional in a segment. Required fields are defined by HL7 2.5.1 and do not refer to requirements for reporting laboratory findings to cancer registries. The designations are: (R) Required. (RE) Required or empty. The element may be missing from the message, but it must be sent by the sending application if there is relevant data. A conforming sending application must be capable of providing all "RE" elements. If the conforming sending application knows the required values for the element, then it must send that element. If the conforming sending application does not know the required values, then that element will be omitted. Receiving applications will be expected to process (save/print/archive/etc.) or ignore data contained in the element, but must be able to successfully process the message if the element is omitted (no error message should be generated because the element is missing). (O) Optional. (C) Conditional on the trigger event or on some other field(s). The field definitions following the segment attribute table should specify the algorithm that defines the conditionality for the field. (X) Not supported. (B) Left in for backward compatibility with previous versions of HL7. The field definitions following the segment attribute table should denote the optionality of the field for prior versions.

ABBREVIATION	DEFINITION
RP #	Indicates if element may repeat per HL7 Standard. If the number of repetitions is limited, the number of allowed repetitions is given.
Tbl #	HL7 specific table reference. Tables used in public health messages are listed in Appendix B.
Item #	HL7 unique item number for each element.
Element Name	HL7 descriptive name of element in the segment.
NAACCR Item #	NAACCR data item number for each element that corresponds to a NAACCR data item.
NAACCR Usage	Indicates the conformance usage of specific elements, which determines whether or not the element is required per NAACCR implementation, according to HL7 Conformance Rules for implementable specifications and profiles. Uses the same codes as the HL7 optionality codes described above, with the exception of "O – Optional" and "B – Backward Compatibility," which are not used in implementation conformance.
NAACCR Cardnlty	Indicates the conformance cardinality for NAACCR messaging. This is used to determine if element may repeat per NAACCR implementation and, if the number of repetitions is limited, the number of allowed repetitions.

2.4.2.   Code Tables Identified in Segment Fields

The columns labeled "Tbl#" in the Segment Tables contain the numeric identifier of the code tables associated with that field (see Appendix B). Fields that do not contain coded data from the tables do not have any value in this field. Fields that are of data types that refer to more than one table may have more than one table number listed in this column.

The tables for all fields and field components that are supported for cancer registry messaging are listed in Appendix B, Code Tables. Code tables that are associated with fields and components that are not supported in this specification are not listed; for the full definition and listing of their suggested content, refer to the HL7 Standard Version 2.5.1.

Code tables that are referred to in the descriptions of the segment fields are hyperlinked to their content definition in Appendix B for convenience.

2.5.   MESSAGE CONTROL SEGMENT DEFINITIONS

These segments are necessary to support the functionality described in the Control/Query chapter of the HL7 Standard.

2.5.1.   Message Header (MSH) Segment

The Message Header (MSH) Segment is used to define the intent, source, destination, and some specifics of the syntax of a message.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	1	ST	R			00001	Field separator		R	[1..1]
2	4	ST	R			00002	Encoding characters		R	[1..1]
3	227	HD	O			00003	Sending application		RE	[0..1]
4	227	HD	O			00004	Sending facility	7010, 7020	R	[1..1]
5	227	HD	O			00005	Receiving application		RE	[0..1]
6	227	HD	O			00006	Receiving facility		RE	[0..1]
7	24	DTM	O			00007	Date/time of message	7490	R	[1..1]
8	40	ST	O			00008	Security		X	[0..0]
9	15	MSG	R		0003, 0076, 0354	00009	Message type		R	[1..1]
10	20	ST	R			00010	Message control ID	7500	R	[1..1]
11	3	PT	R			00011	Processing ID	7510	R	[1..1]
12	60	VID	R		0104	00012	Version ID		R	[1..1]
13	15	NM	O			00013	Sequence number		RE	[0..1]
14	180	ST	O			00014	Continuation pointer		RE	[0..1]
15	2	ID	O		0155	00015	Accept acknowledgment		X	[0..0]
16	2	ID	O		0155	00016	Application acknowledgment type		X	[0..0]
17	3	ID	O		0399	00017	Country code		RE	[0..1]
18	16	ID	O	Y	0211	00692	Character set		X	[0..0]
19	250	CWE	O			00693	Principal language of message		RE	[0..1]
20	20	ID	O		0356	01317	Alternate character set handling scheme		X	[0..0]
21	427	EI	O	Y		01598	Message profile identifier		RE	[0..3]

Example:

```
MSH|^~\&|HLS|HITECK PATH LAB-
  ATL^3D9328409^CLIA||GCCR|20081124122230||ORU^R01^ORU_R01|200811241222300023|P|2.5
  .1|||||||||||VOL_V_50_ORU_R01^NAACCR_CP
```

This example segment shows a Version 2.5.1 ORU (result) message being sent from a pathology laboratory in Atlanta to the Georgia Comprehensive Cancer Registry on November 24, 2008, at 12:22 p.m. The message control ID indicates that this is the 23rd message of the day from this laboratory.

MSH Field Definitions

Usage Notes: It is not anticipated that several MSH fields (MSH-17 through MSH-20) will be used for electronic laboratory reporting purposes.

MSH-1 Field separator (ST-1, Required) 00001

Definition: The character to be used as the field separator for the rest of the message. The field separator always appears in the fourth character position of the MSH segment and is used to separate adjacent data fields within a segment. The recommended value is |, ASCII (124), as shown in the examples.

MSH-2 Encoding characters (ST-4, Required) 00002

Definition: Four characters in the following order:

Component separator	"^"	ASCII (94)
Repetition separator	"~"	ASCII (126)
Escape character	"\"	ASCII (92)
Subcomponent separator	"&"	ASCII (38)

Note that the characters in MSH-2 appear as:

```
MSH|^~\&|
```

The component separator (^) separates adjacent components of a data field, and the subcomponent separator (&) separates the adjacent subcomponents of a data field. An example of a compound element using components and subcomponents from PID-2, described in Section 2.6.1, would appear as:

```
MSH|10543^^^^^Columbia Valley Memorial Hospital&01D0355944&CLIA|
```

and <u>not</u> as:

```
MSH|10543^^^^^Columbia Valley Memorial Hospital~01D0355944~CLIA|
```

The tilde (~) should not be used as a separator, but rather should be used to identify when a repeating field or component occurs.

MSH-3 Sending application (HD-180, Required or Empty) 00003

Definition: This field uniquely identifies the sending application among all other applications within the network enterprise. The network enterprise consists of all those applications that participate in the exchange of HL7 messages within the enterprise. The field is entirely site-defined. For Cancer Registry messaging, this table cannot realistically be pre-populated or effectively maintained, so it is not required for conformance of this field. By site agreement however, implementers may use *User-Defined Table 0361 – Sending/Receiving Application* for the first component.

MSH-4 Sending facility (HD-180, Required) 00004

Definition: This is the facility that is transmitting the HL7 message. The originator of the HL7 message will place the text name of the sending laboratory or reporting site, followed by the unique Clinical Laboratory Improvement Amendments (CLIA) identifier of the originating institution (in the United States; in Canada, please see the jurisdictional authority for regulations on which identifier to be used). Information about CLIA can be found at https://www.cms.gov/clia.

Example:

```
MSH||||HITECK PATH LAB-ATL^3D9328409^CLIA|
```

HD data type components: <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

namespace ID	Text name of the sending laboratory
universal ID	Universal identifier for the sending facility, such as a CLIA number for a commercial laboratory or other identifier
universal ID type	Name of the type of universal identifier, such as "CLIA","" indicating that the universal ID is a nationally assigned unique identifier and of which type

Note for cancer registries: If the facility sending the message is the same facility that generated the Pathology Report, then this will correspond to the NAACCR data items Reporting Facility ID No [7010] and Path Lab Name [7020]. See OBX-23 for other sources for these NAACCR data items.

Although the HL7 Standard identifies *User-Defined Table 0361 – Sending/Receiving Application* for the first component, this table will not be used for conformance for Cancer Registry Messaging.

MSH-5 Receiving application (HD-180, Required) 00005

Definition: Uniquely identifies the receiving application among all other applications within the network enterprise. The network enterprise consists of all the applications that participate in the exchange of HL7 messages within the enterprise. The field is entirely site-defined. For Cancer Registry messaging, this table cannot realistically be pre-populated or effectively maintained, so it is not required for conformance of this field. By site agreement, however, implementers may use *User-Defined Table 0361 – Sending/Receiving Application* for the first component.

If this field is known to the sending system, it should be valued.

MSH-6 Receiving facility (HD-180, Required) 00006

Definition: This field identifies the receiving application among multiple identical applications running on behalf of different organizations. This may be used to identify the receiving state health department or cancer registry systems. Certain state health departments may request that a unique identifier for the cancer registry or other specific program appear here.

Note: This field may be blank, but for the example it is valued as |STJ|, indicating that the receiver of the result message is Saint Joseph's Hospital.

Although the HL7 Standard identifies *User-Defined Table 0361 – Sending/Receiving Application* for the first component, this table will not be used for conformance for Cancer Registry Messaging. But if the value is known to the sending system, it should be valued.

MSH-7 Date/time of message (DTM-24, Required) 00007

Definition: Date/time the sending system created the message. It is expected that the granularity of this field is year, month, day, hour, and minutes.

Example: 6:30 p.m., February 17, 2001, would appear as—

```
MSH|||||||200102171830|
```

Note for cancer registries: Corresponds to NAACCR data item E-Path Date/Time Stamp [7490].

MSH-9 Message type (MSG-15, Required) 00009

Definition: The receiving system uses this field to identify the data segments to recognize and, possibly, the application to which to route this message.

The unsolicited transmission of an observation message would appear as—

```
MSH|||||||||ORU^R01^ORU_R01|
```

MSH-10 Message control ID (ST-199, Required) 00010

Definition: Number or other identifier that uniquely identifies the message. The receiving system echoes this ID back to the sending system in the message acknowledgment. For electronic laboratory reporting, NAACCR recommends using the date/time stamp followed by the sequence number as—

YYYYMMDDHHMMSS#### (# = counter number).

The example below shows that the date of this message is February 17, 2001, and the sequence number is 0042.

```
MSH||||||||||200102170042|
```

Note: This field must be unique within all transmissions from the same sender.

Note for cancer registries: Corresponds to NAACCR data item Message Control ID [7500].

MSH-11 Processing ID (PT-3, Required) 00011

Definition: Used to decide how to process the message as defined in HL7 processing rules. The field appears as P for production, T for training, or D for debugging.

For example—

```
MSH|||||||||||P|
```

In the example, the use is production. The second component is not specified, indicating current processing as the default.

Note for cancer registries: Corresponds to NAACCR data item Processing ID [7510].

MSH-12 Version ID (VID-60, Required) 00012

Definition: Matched by the receiving system to its own HL7 version to be sure the message will be interpreted correctly. Default Value = 2.5.1

MSH-13 Sequence number (NM-15, Required or Empty) 00013

Definition: A non-null value in this field implies that the sequence number protocol is in use. This numeric field is incremented by one for each subsequent value.

In the example, the field is not valued or expected to be used.

MSH-14 Continuation pointer (ST-180, RE) 00014

Definition: Used to define continuations in application-specific ways. For cancer messaging, if a message exceeds the maximum length supported by the interface and must be broken up, this field is used to indicate a message containing the continuation from the previous message.

In the example, the field is not valued or expected to be used.

MSH-17 Country code (ID-3, Required or Empty) 00017

Definition: This field contains the country of origin for the message. It will be used primarily to specify default elements, such as currency denominations. The values to be used are those of International Standards Organization (ISO) 3166-1.[8] The ISO 3166 table has three separate forms of the country code: HL7 specifies that the 3-character (alphabetic) form be used for the country code.

Note: In earlier versions of the NAACCR Laboratory Electronic Pathology Reporting Guidelines specifications, the 2-character (alphabetic) form of the country codes was specified, but the 3-character ISO 3166-1 set is to be used for Cancer Pathology Report Messaging using HL7 Version 2.5.1, as described in this implementation guide. If this value is present in a system that may use more than one language, then it must be sent.

Refer to *HL7-Defined Table 0399 – Country Code* for the 3-character codes as defined by ISO 3166-1.

In the example, this field is not valued.

---

[8] Available from ISO 1 Rue de Varembe, Case Postale 56, CH 1211, Geneve, Switzerland.

MSH-19 Principal language of message (CWE-60, Required or Empty) 00693

Definition: This field contains the principal language of the message. Codes come from ISO 639. Note that in Canada, both English and French are supported for HL7 messaging.

In the example, this field is not valued.

MSH-21 Message Profile Identifier (EI-427, Required) 01598

> **This value must be** |VOL_V_51_ORU_R01^NAACCR_CP|

Definition: Sites may use this field to assert adherence to, or reference, a message profile. Message profiles contain detailed explanations of grammar, syntax, and usage for a particular message or set of messages.

2.5.2. Software (SFT) Segment

This segment is optional and provides additional information about the software product(s) used as a Sending Application.

Implementers are encouraged to use message profile identifiers to control the behavior of the receiving application rather than relying on application or version information in the SFT segment.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	567	XON	R			01834	Software vendor organization		R	[1..1]
2	15	ST	R			01835	Software certified version or release number		R	[1..1]
3	20	ST	R			01836	Software product name		R	[1..1]
4	20	ST	R			01837	Software binary ID		RE	[0..1]
5	1024	TX	O			01838	Software product information		RE	[0..1]
6	8	DT	O			01839	Software install date		RE	[0..1]

Use Case: An external application has been customized to communicate with a centralized patient drug history system. However, due to certain known characteristics of the external software package, the centralized system must modify its behavior to process transactions correctly. In one example, the external application may have multiple versions in production. As such, the centralized application will need to know the name of the **Software Vendor Organization**, the **Software Release Number**, the **Software Product Name**, and the **Software Binary ID** so that it can correctly identify the software submitting the transaction and modify its behavior appropriately.

While preparing a transaction for submission to a centralized system, the sending application specifies its **Software Install Date** and its configuration settings (**Software Product Information**). While processing the transaction, the centralized system encounters an error. Upon examining the error, install date, and configuration of the software that sent the message, helpdesk staff are able to determine that the sending application has not been updated to reflect recent application changes.

Use Case: In circumstances in which a message is manipulated or modified by multiple systems, a repetition of this segment may be appended by each system.

Example:
```
MSH
[{SFT|Abbott
  Informatics^^^^^Abbott&2.16.840.1.114222.4.1.217446&ISO^XX^^^123445678|9.416|STAR
  LiMS|Binary ID unknown|Configuration B|20100101}]
```

SFT Field Definitions

SFT-1 Software Vendor Organization (XON-567, Required) 01834

Definition: Organization identification information for the software vendor that created this transaction. The purpose of this field, along with the remaining fields in this segment, is to provide a more complete picture of applications that are sending HL7 messages. The Software Vendor Organization field would allow the identification of the vendor who is responsible for maintaining the application.

SFT-2 Software Certified Version or Release Number (ST-15, Required) 01835

Definition: The latest software version number of the sending system that has been compliance tested and accepted. The Software Certified Version or Release Number helps to provide a complete picture of the application that is sending/receiving HL7 messages. Versions are important in identifying a specific release of an application. In some situations, the receiving application validates the Software Certified Version or Release Number against a list of certified versions/releases of the particular software to determine if the sending application adheres to specific business rules required by the receiving application.

Alternatively, the software may perform different processing depending on the version of the sending software.

SFT-3 Software Product Name (ST-20, Required) 01836

Definition: The name of the software product that submitted the transaction. A key component in the identification of an application is its Software Product Name.

SFT-4 Software Binary ID (ST-20, Required or Empty) 01837

Definition: Issued by a vendor for each unique software version instance to distinguish between like versions of the same software, e.g., a checksum.

Software Binary IDs are issued for each unique software version instance. As such, this information helps to differentiate between differing versions of the same software. Identical Primary IDs indicate that the software is identical at the binary level (configuration settings may differ).

SFT-5 Software Product Information (TX-1024, Required or Empty) 01838

Definition: Software identification information that can be supplied by a software vendor with their transaction; might include configuration settings, etc. This field would contain any additional information an application provides with the transaction it has submitted. This information could be used for diagnostic purposes and provides greater flexibility in identifying a piece of software. Possibilities include setup or configuration parameter information.

This field should not be sent unless performing diagnostics.

SFT-6 Software Install Date (DT-8, Required or Empty) 01839

Definition: Date the submitting software was installed at the sending site.

   Must be year, month and day format.

A Software Install Date on its own often can provide key information about the behavior of the application and is necessary to provide a complete picture of the sending application.

   TS data type components: <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>

2.5.3.   Continuation Pointer (DSC) Segment
The DSC segment is used in the continuation protocol.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	180	ST	O			00014	Continuation pointer		RE	[0..1]
2	1	ID	O		0398	01354	Continuation style		RE	[0..1]

DSC Field Definitions

DSC-1 Continuation Pointer (ST-180, Required or Empty) 00014

Definition: This field contains the continuation pointer. In an initial query, this field is not present. If the responder returns a value of null or not present, then there is no more data to fulfill any future continuation requests. For use with continuations of unsolicited messages, see the published HL7 Standard Version 2.5.1 Chapter 5 and Section 2.10.2, "Continuation messages and segments." Note that continuation protocols work with both display- and record-oriented messages.

DSC-2 Continuation Style (ID-1, Required or Empty) 01354

Definition: Indicates whether this is a fragmented message (see Section 2.10.2, "Continuation messages and segments" in the published HL7 Standard Version 2.5.1), or if it is part of an interactive continuation message (see Section 5.6.3, "Interactive continuation of response messages" in the published HL7 standard).

2.6.   PATIENT ADMINISTRATION MESSAGE SEGMENTS

2.6.1.   Patient Identification (PID) Segment
Used by all applications as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			00104	Set ID – PID		R	[1..1]
2	20	CX	B			00105	Patient ID (External)		X	[0..0]
3	250	CX	R	Y		00106	Patient identifier list	2300, 2320	R	[1..8]
4	20	CX	B	Y		00107	Alternate patient ID – PID		X	[0..0]
5	250	XPN	R	Y		00108	Patient name	2230, 2240, 2250	R	[1..8]
6	250	XPN	O			00109	Mother's maiden name		X	[0..0]
7	24	DTM	O			00110	Date/time of birth	240	RE	[0..1]
8	1	IS	O		0001	00111	Sex	220	RE	[0..1]
9	250	XPN	B	Y		00112	Patient alias	2280	O	[0..8]
10	250	CWE	O	Y	0005	00113	Race	160	RE	[0..6]
11	250	XAD	O	Y		00114	Patient address	70, 80, 100, 2330, 7520	RE	[0..4]
12	4	IS	B		0289	00115	County code		X	[0..0]
13	250	XTN	O	Y		00116	Phone number – home	2360	RE	[0..8]
14	250	XTN	O	Y		00117	Phone number – business		RE	[0..4]
15	250	CWE	O		0296	00118	Primary language		RE	[0..1]
16	250	CWE	O		0002	00119	Marital status	150	RE	[0..1]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
17	250	CWE	O		0006	00120	Religion	260	RE	[0..1]
18	250	CX	O			00121	Patient account number		RE	[0..1]
19	16	ST	B			00122	SSN number – patient		X	[0..0]
20	25	DLN	B			00123	Driver's license number - patient		X	[0..0]
21	250	CX	O	Y		00124	Mother's identifier		X	[0..0]
22	250	CWE	O	Y	0189	00125	Ethnic group	190	RE	[0..4]
23	250	ST	O			00126	Birthplace		X	[0..1]
24	1	ID	O		0136	00127	Multiple birth indicator		X	[0..0]
25	2	NM	O			00128	Birth order		X	[0..0]
26	250	CWE	O	Y	0171	00129	Citizenship		X	[0..0]
27	250	CWE	O		0172	00130	Veterans military status		X	[0..0]
28	250	CWE	B		0212	00739	Nationality		X	[0..0]
29	24	DTM	O			00740	Patient death date and time		RE	[0..1]
30	1	ID	O		0136	00741	Patient death indicator	1760	RE	[0..1]
31	1	ID	O		0136	01535	Identity unknown indicator		RE	[0..1]
32	20	IS	O	Y	0445	01536	Identity reliability code		RE	[0..3]
33	24	DTM	O			01537	Last update date/time		X	[0..0]
34	241	HD	O			01538	Last update facility		X	[0..0]
35	250	CWE	C		0446	01539	Species code		X	[0..0]
36	250	CWE	C		0447	01540	Breed code		X	[0..0]
37	80	ST	O			01541	Strain		X	[0..0]
38	250	CWE	O	Y/2	0429	01542	Production class code		X	[0..0]
39	250	CWE	O	Y	0171	01840	Tribal citizenship		RE	[0..5]

Example:

```
PID|1||00466144^^^UNIVERSITY HOSPITAL&470381&AHA^MR^ UNIVERSITY HOSPITAL
 ~999999999^^^USSSA^SS^USSSA~97 810430^^^HITECK PATH LAB-ATL&3D9328409&CLIA^PI~
 ~3270686987^^^USHC^PN^USHC||SAMPLE30^ALLAN||19530621|M|||112 BROAD STREET^APT
 10^ATLANTA^GA^30301^^H
```

This example segment shows that the patient named Allan Sample30 is a male born on June 21, 1953. A laboratory and a hospital patient identifier are included, along with the patient's address.

PID Field Definitions

Usage Notes: It is not anticipated that several PID fields (PID-23 through PID-28) will be used for electronic laboratory reporting purposes.

PID-1 Set ID – PID (SI-4, Required) 00104

Definition: The Set ID field numbers the repetitions of the PID segment (i.e., multiple patient reports). For the first occurrence of the segment, the sequence number shall be 1.

```
PID|1|
```

Note: NAACCR standard reports have only one Patient per report, so this field should never contain anything other than "1."

PID-3 Patient Identifier List (CX-250, Required, Repeating maximum 8) 00106

Definition: This field contains the list of identifiers (one or more) used by the facility to uniquely identify a patient (e.g., medical record number, billing number, birth registry). For cancer reporting, the patient identifiers must be in the specified order (Medical Record Number [MR]; Social Security Number [SS]; then any other patient identification number); and at least one of the patient identifiers must contain information other than "unknown." The collection of SS information is critical to the success of cancer registry reporting requirements for linking multiple patient reports when received from different reporting sources.

Note for cancer registries: Corresponds to NAACCR items Medical Record Number [2300] and Social Security Number [2320].

HL7 Version 2.3 provided a field to record the patient's Social Security number in PID-19 SSN – Patient. Since Version 2.3.1, HL7 has recommended using PID-3 Patient Identifier List for all patient identifiers along with the appropriate identifier type code (*HL7-Defined Table 0203 – Identifier Type*).

Cancer reporting will use PID-3 for multiple patient identifiers. For example, the first instance below is the Medical Record Number (MR) from St. Joseph's Hospital (STJ) as assigning authority, with the NPI number for St. Joseph's; the second is the patient's Social Security number (SS); and the third is the Laboratory's unique Patient Internal Identifier (PI), with the laboratory's CLIA number.

```
PID|||010203040^^^ST. Joseph's Hospital (STJ)&1679664395&NPI^MR^ ST. Joseph's
   Hospital (STJ) ~111223333^^^USSSA^SS^USSSA~97 810430^^^HITECK PATH LAB-
   ATL&3D9328409&CLIA^PI^HITECK PATH LAB-ATL |
```

If the SS is not available, then place blank or 9's in the 2nd iteration of patient identifier. This will accommodate any systems that are expecting the SS to be in the 2nd iteration.

```
PID|||010203040^^^ST. Joseph's Hospital (STJ)&1679664395&NPI^MR^ST. Joseph's
   Hospital (STJ)~999999999^^^USSSA^SS^USSSA~97 810430^^^HITECK PATH LAB-
   ATL&3D9328409&CLIA^PI^HITECK PATH LAB-ATL |
```

Sometimes, however, laboratories use other labs as reference labs. For example, an anatomic pathology specimen from the Columbia Valley Memorial Hospital laboratory is sent to a reference laboratory named MediLab Co., and the result is reported to a cancer registry by MediLab Co. In the scenario described, the unique patient identifier from MediLab Co. would always appear first with the type code as PI, along with the name and CLIA number for MediLab Co. as the assigning authority. Repetitions of the field also allow a reporting laboratory (MediLab Co.) to provide the medical record number and/or other patient identifiers assigned at the original institution that submitted a specimen for testing (i.e., Columbia Valley Memorial Hospital). The type code for the Columbia Valley Hospital identifier will be PT for Patient external identifier

Example:

```
PID|||010678509^^^Columbia Valley Memorial Hospital&01D0355944&CLIA^MR^Columbia
   Valley Memorial Hospital~111223333^^^USSSA^SS^USSSA~95101100001^^^MediLabCo-
   Seattle&45D0470381&CLIA^PI^MediLabCo- Seattle ~10543^^^Columbia Valley Memorial
   Hospital&01D0355944&CLIA^PT^Columbia Valley Memorial Hospital |
```

Because HL7 allows users to define the values for the subcomponents of the HD data type, the <assigning facility> has the following definition for the laboratory-based reporting message:

namespace ID	Name of originating laboratory
universal ID	Unique CLIA number of originating laboratory
universal ID type	"CLIA"

If a hospital laboratory will be reporting the result (and thus there will be only one hospital involved in collecting and processing the specimen), then the hospital laboratory's patient identifier and the hospital CLIA ID will appear with typecode PI; no information will appear as an external ID. Likewise, if a reference laboratory receives a specimen from a doctor's office and no preceding originating laboratory is used, then the reference laboratory's patient identifier and reference laboratory CLIA ID will appear with the typecode PI; no information will appear as an external ID.

```
PID|||010678509^^^Columbia Valley Memorial Hospital&01D0355944&CLIA^MR^Columbia
  Valley Memorial Hospital~999999999^^^USSSA^SS^USSSA~10543^^^Columbia Valley
  Memorial Hospital&01D0355944&CLIA^PI^Columbia Valley Memorial Hospital |
```

Please note that in Canada, identifier types may be determined by the local jurisdictional authority. Many of the common types have been added to User Defined Table 0203 (see Appendix B). An example of a Quebec health card number:

```
PID|||AETU 7452 0315^^^Quebec Ministry of Health^JHN^^^^ Quebec&QC&ISO3166_2|
```

Also illustrated in this example is the Assigning Jurisdiction component, which in this case is Provence de Québec (Canada), identified with the code from the ISO 3166-2 coding system (QC).

PID-5 Patient Name (XPN-250, Required, Repeating maximum 8) 00108

Definition: This field contains the names of the patient; the primary or legal name of the patient is reported first. Therefore, the name type code in this field should be "L – Legal." Refer to *HL7-Defined Table 0200 – Name Type* for valid values. Repetition of this field is allowed for representing the same name in different character sets. Note that "last name prefix" is synonymous with "own family name prefix" in previous versions of HL7, as is "second and further given names or initials thereof" to "middle initial or name." Multiple given names and/or initials are separated by spaces.

Example:

```
PID|||||SAMPLE30^ALLAN^^^^^L|
```

Note for cancer registries: The first repeat of this field, with name type "L--Legal," corresponds to NAACCR items Name--Last [2230], Name--First [2240], and Name--Middle [2250]. If the name type is "A--Alias" for an additional repeat, then this corresponds to NAACCR item Name--Alias [2280].

PID-7 Date/Time of Birth (DTM-24, Required or empty) 00110

Definition: This field contains the patient's date and time of birth.

Example: June 21, 1953, 5:03pm, would appear as:

```
PID|||||||195306211703|
```

Note for cancer registries: Corresponds to NAACCR item Birth Date [240].

PID-8 Sex (IS-1, Required or empty) 00111

Definition: This field contains the patient's sex. Refer to *User-Defined Table 0001 – Sex* for valid values.

Example: Female would appear as:

```
PID||||||||F|
```

Map defined value from Table 0001 "Other" to NAACCR value "Other (hermaphrodite)."

Note for cancer registries: Corresponds to NAACCR item Sex [220]. Requires conversion to NAACCR codes (see NAACCR Standards Volume II).

PID-9 Patient Alias (XPN-250, Required or Empty, Repeating maximum 8) 00112

Definition: This field contains names by which the patient has been known at some time.

From version 2.4, this field has been retained for backward compatibility only. It is recommended to use PID-5 – Patient Name for all patient names. This field contained the name(s) by which the patient has been known at some time. Refer to *HL7-Defined Table 0200 – Name Type* for valid values; to indicate alias use 'A'.

In the example, this field is not valued.

Note for cancer registries: Corresponds to NAACCR item Name--Alias [2280]. If an alias is collected for the patient and it cannot be populated as a repeat of PID-5, then this field should be populated.

PID-10 Race (CWE-250, Required or empty, Repeating maximum 6) 00113

Definition: This field identifies the patient's race and coding system used to code race. Refer to *User-Defined Table 0005 – Race* for required values. For a more detailed table of race values, see CDC's Race/Ethnicity Code Set at:
https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.6.238.

Example:

```
PID||||||||||2054-5^Black or African American^HL70005^B^Black^L|
```

Note for cancer registries: Corresponds to NAACCR item Race 1 [160], Race 2 [161], Race 3 [162], Race 4 [163], and Race 5 [164]. Requires conversion to NAACCR codes (see NAACCR Standards Volume II).
PID-11 Patient Address (XAD-250, Required or empty, Repeating maximum 4) 00114

Definition: This field lists the mailing address of the patient (residence at diagnosis). Multiple addresses for the same person may be sent in the following sequence: The primary mailing address must be sent first in the sequence; if the mailing address is not sent, then a repeat delimiter must be sent in the first sequence.

Example:

```
PID|||||||||||2166 Wells Dr^Apt B^Seattle^WA^98109^USA^M^^King^^A|
```

Note for cancer registries: Corresponds to NAACCR items Addr at DX--City [70], Addr at DX--State [80], Addr at DX--Postal Code [100], Addr at DX--No & Street [2330] and Address Type Code [7520].

PID-13 Phone Number – Home (XTN-250, Required or Empty, Repeating maximum 8) 00116

Definition: The patient's personal telephone numbers. All personal telephone numbers for the patient are sent in this sequence. The first sequence is considered the primary number. If the primary number is not sent, then a repeat delimiter is sent in the first sequence

Refer to *HL7-Defined Table 0201 – Telecommunication Use Code* and *HL7-Defined Table 0202 – Telecommunication Equipment Type* for valid values.

Example:

```
PID|||||||||||||^PRN^PH^^^206^6793240^^after 5:00 pm~^VHN^PH^^^206^6795772|
```

or

```
PID|||||||||||||^^^^^206^6793240|
```

Note for cancer registries: Corresponds to NAACCR item Telephone [2360]. This field should be sent if the value is known.

Note: The legacy method of sending a formatted telephone number in the first component of the telephone number is discouraged. It is preferable to send the area code as component 6 and the telephone number as component 7 to prevent problems with parsing and displaying of telephone numbers received.

In the example, this field is not valued.

PID-14 Phone Number – Business (XTN-250, Required or Empty, Repeating maximum 4) 00117

Definition: Patient's business telephone number. Repetitions are permitted, with the first one being the primary number. If the primary number is not sent, then a repeat delimiter is sent in the first sequence.

Refer to *HL7-Defined Table 0201 – Telecommunication Use Code* and *HL7-Defined Table 0202 – Telecommunication Equipment Type* for valid values.

Note for cancer registries: Corresponds to NAACCR item Telephone [2360]. This telephone number may be used if the Home Phone number is not known.

This field should be sent if the value is known.

PID-15 Primary Language (CWE-250, Required or Empty) 00118

Definition: Patient's primary language. Refer to *User-Defined Table 0296 – Primary Language* (ISO 639) for suggested values.

This field should be sent if the value is known. The default value if this is not populated may vary from jurisdiction to jurisdiction

PID-16 Marital Status (CWE-250, Required or empty) 00119

Definition: This field contains the patient's marital status. Refer to *User-Defined Table 0002 – Marital Status* for suggested values.

Example:

```
PID||||||||||||||||S^single^HL70002|
```

Note for cancer registries: Corresponds to NAACCR item Marital Status at DX [150]. Requires conversion to NAACCR codes (see NAACCR Standards Volume II).

PID-17 Religion (CWE-250, Required or Empty) 00120

Definition: This field contains the patient's religion, for example, Christian, Buddhist, Muslim, etc. *User-Defined Table 0006 – Religion* from HL7 Standard Version 2.5 is used as the HL7 identifier for the user-defined table of values for this field.

PID-18 Patient Account Number (CX-250, RE) 00121

Definition: This field contains the patient account number assigned by accounting to which all charges, payments, etc., are recorded. It is used to identify the patient's account. Refer to *HL7-Defined Table 0061 – Check Digit Scheme* in Appendix B.

In the example, this field is not valued.

Patient Account number should be populated in the PID-3 Patient Identifier List and identifier type code will be 'AN'. If the value is known and the system is unable to populate the PID-3, then the value should be populated here.

PID-22 Ethnic Group (CWE-250, Required or Empty, Repeating maximum 4) 00125

Definition: This field further defines patient ancestry. Suggested values are listed in *User-Defined Table 0189 – Ethnic Group.* State or locally defined codes may be listed in the first triplet. For a more detailed

table, see CDC's Race/Ethnicity Code Set at:
https://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=2133-7.

According to HL7, the second triplet of the CE data type for Ethnic Group (alternate identifier, alternate text, and name of alternate coding system) is reserved for codes consistent with the categories established by the U.S. Office of Management and Budget (OMB). When both triplets are used, the second triplet codes must map to the OMB- compliant codes.

Note for cancer registries: Corresponds to NAACCR data item Spanish/Hispanic Origin [190].

PID-29 Patient Death Date and Time (DTM-24, Required or empty) 00740

Definition: This field contains the date and time at which the patient's death occurred. This field should be valued only if PID-30 is valued "yes."

In the example, this field is not valued.

Note for cancer registries: Corresponds to NAACCR data item Path-Date of Death [7550].

PID-30 Patient Death Indicator (ID-1, Required or empty) 00741

Definition: This field indicates whether or not the patient is deceased. Refer to *HL7-Defined Table 0136 – Yes/No Indicator* for valid values.

The value of an ID data type follows the formatting rules for an ST data type, except it is drawn from a table of HL7 legal values.

In the example, this field is not valued.

Note for cancer registries: Corresponds to NAACCR data item Vital Status [1760]. Requires conversion to NAACCR codes (see NAACCR Standards Volume II).

PID-31 Identity Unknown Indicator (ID-1, Required or Empty) 01535

Definition: This field indicates whether or not the patient's/person's identity is unknown. Refer to *HL7-Defined Table 0136 – Yes/No Indicator* for valid values.

>   Y – the patient's/person's identity is unknown
>   N – the patient's/person's identity is known

PID-32 Identity Reliability Code (IS-20, Required or Empty, Repeating maximum 3) 01536

Definition: This field contains a coded value used to communicate information regarding the reliability of patient/person identifying data transmitted via a transaction. Values could indicate that certain fields on a PID segment for a given patient/person are known to be false (e.g., use of default or system-generated values for Date of Birth or Social Security Number. Refer to *User-Defined Table 0445 – Identity Reliability Code* for suggested values.

PID-39 Tribal Citizenship (CWE-250, Required or Empty, Repeating maximum 5) 01840

Definition: This field contains the information related to a person's tribal citizenship. For tribal citizenship, in the United States, HL7 recommends using the Bureau of Indian Affairs (BIA) Tribal Identity List. For a local definition, *User-Defined Table 0171 – Citizenship* should be used.

This field repeats because persons can have tribal membership(s) and can be members of more than one tribe. The Name of Coding System component(s) of the CWE data type should be used to identify the table from which tribal membership is drawn.

2.6.2. Next of Kin/Associated Parties (NK1) Segment
Contains information about the patient's next of kin and other associated or related parties. This is a repeating segment, allowing multiple related parties. This segment is optional for cancer reporting.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	R			00190	Set ID – NK1		R	[1..1]
2	250	XPN	O	Y		191	Name		RE	[0..4]
3	250	CWE	O		0063	00192	Relationship		RE	[0..1]
4	250	XAD	O	Y		00193	Address		RE	[0..4]
5	250	XTN	O	Y		194	Phone number		RE	[0..4]
6	250	XTN	O	Y		00195	Business phone number		X	[0..0]
7	250	CWE	O		0131	00196	Contact role		X	[0..0]
8	8	DT	O			00197	Start date		X	[0..0]
9	8	DT	O			00198	End date		X	[0..0]
10	60	ST	O			199	Next of kin/AP job title		X	[0..0]
11	20	JCC	O		0327/	00200	Next of kin/AP job code/class		X	[0..0]
12	250	CX	O			00201	Next of kin/AP employee number		X	[0..0]
13	250	XON	O	Y		00202	Organization name – NK1		X	[0..0]
14	250	CWE	O		0002	00119	Marital status		X	[0..0]
15	1	IS	O		0001	00111	Sex		X	[0..0]
16	26	DTM	O			00110	Date/time of birth		X	[0..0]
17	2	IS	O	Y	0223	00755	Living dependency		X	[0..0]
18	2	IS	O	Y	0009	00145	Ambulatory status		X	[0..0]
19	250	CWE	O	Y	0171	00129	Citizenship		X	[0..0]
20	250	CWE	O		0296	00118	Primary language		X	[0..0]
21	2	IS	O		0220	00742	Living arrangement		X	[0..0]
22	250	CE	O		0215	00743	Publicity code		X	[0..0]
23	1	ID	O		0136	00744	Protection indicator		X	[0..0]
24	2	IS	O		0231	00745	Student indicator		X	[0..0]
25	250	CE	O		0006	00120	Religion		X	[0..0]
26	250	XPN	O	Y		00746	Mother's maiden name		X	[0..0]
27	250	CE	O		0212	00739	Nationality		X	[0..0]
28	250	CE	O	Y	0189	00125	Ethnic group		X	[0..0]
29	250	CE	O	Y	0222	00747	Contact reason		X	[0..0]
30	250	XPN	O	Y		00748	Contact person's name		X	[0..0]
31	250	XTN	O	Y		00749	Contact person's telephone number		X	[0..0]
32	250	XAD	O	Y		00750	Contact person's address		X	[0..0]
33	250	CX	O	Y		751	Next of kin/AP's identifiers		X	[0..0]
34	2	IS	O		311	752	Job status		X	[0..0]
35	250	CE	O	Y	5	113	Race		X	[0..0]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
36	2	IS	O		295	753	Handicap		X	[0..0]
37	16	ST	O			754	Contact person social security #		X	[0..0]
38	250	ST	O			1905	Next of kin birthplace		X	[0..0]
39	2	IS	O		99	146	VIP indicator		X	[0..0]

Example:

The sample report does not contain next of kin or emergency contact information, so an example is added here.

```
NK1|1|SAMPLE30^JANET^ALICE^^^L|MTH^MOTHER^HL70063|2166 Wells Dr^Apt
  B^Seattle^WA^98109|^^^^^679^3211320
```

This example segment shows information data for the patient's mother, Janet Alice Sample30, as the next of kin. The mother's contact information, such as home address and telephone number, is shown here.

NK1 Field Definitions

NK1-1 Set ID – NK1 (SI-4, Required) 00190

Definition: The Set ID field numbers the repetitions of the segment within its association with the PID. For the first occurrence of the segment, the sequence number shall be 1, for the second occurrence, the sequence number shall be 2, etc.

A Set ID of 1 indicates that this segment is the first set of next-of-kin data and a Set ID of 2 indicates that this segment is the second set of next-of-kin data.

NK1-2 Name (XPN-250, Required or Empty, Repeating maximum 4) 00191

Definition: This field gives the name of the next of kin or associated party. Multiple names for the same person are allowed, but the legal name must be sent in the first sequence. If the legal name is not sent, then the repeat delimiter must be sent in the first sequence.

Example:

```
NK1||Sample30^Janet^Alice^^^^L|
```

where L indicates that the name type is a legal name.

If the value is known, it should be populated in this field.

NK1-3 Relationship (CE-250, Required or Empty) 00192

Definition: This field defines the personal relationship of the next of kin. *User-Defined Table 0063 – Relationship* gives suggested values from HL7 Standard, Version 2.5.1.

Example:

```
NK1|||MTH^mother^HL70063|
```

If the value is known, it should be populated in this field.

NK1-4 Address (XAD-250, Required or Empty, Repeating maximum 4) 00193

Definition: This field lists the mailing address of the next of kin/associated party identified above. Multiple addresses for the same person may be sent in the following sequence: the primary mailing address must be sent first in the sequence; if the mailing address is not sent, then a repeat delimiter must

be sent in the first sequence. If there is only one repetition of this field and an address type is not given, it is assumed to be the primary mailing address.

Example:

```
NK1||||2166 Wells Dr^Apt B^Seattle^WA^98109^USA^M^^King^^A|
```

When sending multiple addresses, the appropriate type code must be indicated. If the value is known, it should be populated in this field.

NK1-5 Phone Number (XTN-250, Required or Empty, Repeating maximum 4) 00194

Definition: The next of kin/associated party's personal telephone numbers. All personal telephone numbers for the next of kin/associated party are sent in this sequence. The first sequence is considered the primary number. If the primary number is not sent, then a repeat delimiter is sent in the first sequence.

Refer to *HL7-Defined Table 0201 – Telecommunication Use Code* and *HL7-Defined Table 0202 – Telecommunication Equipment Type* for valid values.

Example:

```
NK1|||||^^^^^206^6793240|
```

If the value is known, it should be populated in this field.

2.6.3.   Patient Visit (PV1) Segment

The PV1 segment is used by cancer reporting applications to communicate associated provider information. Not all vendor software may be able to support this segment; if not supported, this segment is not required. Note change in PV1-3 from not supported (X) to optional (O).

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			00131	Set ID – PV1		RE	[0..1]
2	1	IS	R		4	132	Patient class		R	[1..1]
3	80	PL	O			00133	Assigned patient location		O	[0..0]
4	2	IS	O		7	134	Admission type		X	[0..0]
5	250	CX	O			135	Preadmit number		X	[0..0]
6	80	PL	O			136	Prior patient location		X	[0..0]
7	250	XCN	O	Y		137	Attending doctor	2460, 2465	RE	[0..2]
8	250	XCN	O	Y		138	Referring doctor	2470, 2475	RE	[0..2]
9	250	XCN	B	Y		00139	Consulting doctor		RE	[0..2]
10	3	IS	O		0069	00140	Hospital service		X	[0..0]
11	80	PL	O			00141	Temporary location		X	[0..0]
12	2	IS	O		0087	00142	Preadmit test indicator		X	[0..0]
13	2	IS	O		0092	00143	Re-admission indicator		X	[0..0]
14	6	IS	O		0023	00144	Admit source		X	[0..0]
15	2	IS	O	Y	0009	00145	Ambulatory status		X	[0..0]
16	2	IS	O		0099	00146	VIP indicator		X	[0..0]
17	250	XCN	O	Y		00147	Admitting doctor		RE	[0..2]
18	2	IS	O		0018	00148	Patient type		X	[0..0]
19	250	CX	O			00149	Visit number		X	[0..0]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
20	50	FC	O	Y	0064	00150	Financial class		X	[0..0]
21	2	IS	O		0032	00151	Charge price indicator		X	[0..0]
22	2	IS	O		0045	00152	Courtesy code		X	[0..0]
23	2	IS	O		0046	00153	Credit rating		X	[0..0]
24	2	IS	O	Y	0044	00154	Contract code		X	[0..0]
25	8	DT	O	Y		00155	Contract effective date		X	[0..0]
26	12	NM	O	Y		00156	Contract amount		X	[0..0]
27	3	NM	O	Y		00157	Contract period		X	[0..0]
28	2	IS	O		0073	00158	Interest code		X	[0..0]
29	4	IS	O		0110	00159	Transfer to bad debt code		X	[0..0]
30	8	DT	O			00160	Transfer to bad debt date		X	[0..0]
31	10	IS	O		111	161	Bad debt agency code		X	[0..0]
32	12	NM	O			162	Bad debt transfer amount		X	[0..0]
33	12	NM	O			163	Bad debt recovery amount		X	[0..0]
34	1	IS	O		111	164	Delete account indicator		X	[0..0]
35	8	DT	O			165	Delete account date		X	[0..0]
36	3	IS	O		112	166	Discharge disposition		X	[0..0]
37	47	DLD	O		113	167	Discharged to location		X	[0..0]
38	250	CE	O		114	168	Diet type		X	[0..0]
39	2	IS	O		115	169	Servicing facility		X	[0..0]
40	1	IS	B		116	170	Bed status		X	[0..0]
41	2	IS	O		117	171	Account status		X	[0..0]
42	80	PL	O			172	Pending location		X	[0..0]
43	80	PL	O			173	Prior temporary location		X	[0..0]
44	26	DTM	O			174	Admit date/time		X	[0..0]
45	26	DTM	O	Y		175	Discharge date/time		X	[0..0]
46	12	NM	O			176	Current patient balance		X	[0..0]
47	12	NM	O			177	Total charges		X	[0..0]
48	12	NM	O			178	Total adjustments		X	[0..0]
49	12	NM	O			179	Total payments		X	[0..0]
50	250	CX	O		203	180	Alternate visit ID		X	[0..0]
51	1	IS	O		326	1226	Visit indicator		X	[0..0]
52	250	XCN	B	Y	10	1274	Other health care provider		X	[0..0]

Example:

```
PV1|1|N||||||ATTENDINGID^ATTENDINGDR^MANAGING|REFERRINGID^REFERRER^FOLLOWUP^^^DR
```

This example segment portrays the sending of a managing and a referring provider for the example report.

PV1 Field Definitions

PV1-1 Set ID – PV1 (SI-4, Required or Empty) 00131

Definition: This field contains the number that identifies this transaction. For the first occurrence of the segment, the sequence number shall be 1; for the second occurrence, the sequence number shall be 2; etc.

Note: Set ID should be |1| because the PV1 is not expected to repeat.

PV1-2 Patient Class (IS-1, Required) 00132

Definition: This field is used by systems to categorize patients by site. It does not have a consistent industry- wide definition. It is subject to site-specific variations. Refer to *User-Defined Table 0004 – Patient Class* for suggested values.

Note: PV1-2 is an HL7 required field—because there is no practical usage for this field in the cancer reporting message, the value "N" for Not Applicable will be sent.

PV1-7 Attending Doctor (XCN-250, Required or empty, Repeating maximum 2) 00137

Definition: This field contains the attending physician information. Multiple names and identifiers for the same physician may be sent. The field sequences are not used to indicate multiple attending doctors. The legal name must be sent in the first sequence. If the legal name is not sent, then a repeat delimiter must be sent in the first sequence. Depending on local agreements, either the ID or the name may be absent in this field. For cancer reporting, the preferred ordering provider identifiers are listed in order from most to least preferred: National Provider Identifier (NPI); State Medical License Number (MD).

For the purpose of cancer registries: Corresponds to NAACCR item Physician Managing [2460], defined as "the physician responsible for the overall management of the patient during diagnosis and/or treatment for this cancer," for state medical license number or NPI Physician Managing [2465] for National Provider Identifier (NPI) or Physician Managing Other [7580] other local number. It is recommended at least one identifier is included in PV1-7.

Depending on local agreements, either the ID or the name may be absent from this field. Refer to *User-Defined Table 0010 – Physician ID* for suggested values.

PV1-8 Referring Doctor (XCN-250, Required or empty, Repeating maximum 2) 00138

Definition: This field contains the referring physician information. Multiple names and identifiers for the same physician may be sent. The field sequences are not used to indicate multiple referring doctors. The legal name must be sent in the first sequence. If the legal name is not sent, then a repeat delimiter must be sent in the first sequence. Depending on local agreements, either the ID or the name may be absent from this field. Refer to *User-Defined Table 0010 – Physician ID* for suggested values. For cancer reporting, the preferred ordering provider identifiers are listed in order from most to least preferred: National Provider Identifier (NPI); State Medical License Number (MD). It is recommended at least one identifier is included in PV1-8.

Note for cancer registries: Corresponds to NAACCR item Physician Follow-up [2470] for state medical license number or NPI Physician Follow-up [2475] for National Provider Identifier (NPI) or Physician Follow-up Other [7590] for other local number.

PV1-9 Consulting Doctor (XCN-250, Required or empty, Repeating maximum 2) 00139

Definition: Although HL7 has recommended that this field be used for backward compatibility only, because it has been replaced with the ROL segment as of version 2.5, this replacement was done only for Patient Administration messages. Results messages have incorporated the ROL segment only in later versions of the HL7 standard; therefore, NAACCR recommends that this field be used to transmit the

consulting physician information in this version of cancer reporting messaging. The field sequences are used to indicate multiple consulting doctors. Depending on local agreements, either the ID or the name may be absent from this field.

Refer to *User-Defined Table 0010 – Physician ID* for suggested values. For cancer reporting, the preferred ordering provider identifiers are listed in order from most to least preferred: National Provider Identifier (NPI); State Medical License Number (MD); It is recommended at least one identifier is included in PV1-9.

Note for cancer registries: Corresponds to NAACCR item Physician 3 [2490] for state medical license number or NPI Physician 3 [2495] for National Provider Identifier (NPI) or Path Physician 3 [7600] for other local number.

PV1-17 Admitting Doctor (XCN-250, Required or empty, Repeating maximum 2) 00147

Definition: This field contains the admitting physician information. Multiple names and identifiers for the same physician may be sent. The field sequences are not used to indicate multiple admitting doctors. The legal name must be sent in the first sequence. If the legal name is not sent, then a repeat delimiter must be sent in the first sequence. By local agreement, the name or ID may be absent in this field. Refer to *User-Defined Table 0010 – Physician ID* for suggested values. It is recommended at least one identifier is included in PV1-17.

2.7. SEGMENTS COMMON TO ORDERS AND OBSERVATIONS

2.7.1. Common Order (ORC) Segment

Used to transmit fields that are common to all orders (all types of services that are requested).

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	2	ID	R		0119	00215	Order control		R	[1..1]
2	22	EI	C			216	Placer order number		X	[0..0]
3	22	EI	C			217	Filler order number		X	[0..0]
4	22	EI	O			218	Placer group number		X	[0..0]
5	2	ID	O		38	219	Order status		X	[0..0]
6	1	ID	O		0121	00220	Response flag		X	[0..0]
7	200	TQ	O			00221	Quantity/timing		X	[0..0]
8	200	EIP	O			00222	Parent		X	[0..0]
9	26	DTM	O			00223	Date/time of transaction		X	[0..0]
10	250	XCN	O	Y		00224	Entered by		X	[0..0]
11	250	XCN	O	Y		00225	Verified by		X	[0..0]
12	250	XCN	O	Y		00226	Ordering provider		X	[0..0]
13	80	PL	O			00227	Enterer's location		X	[0..0]
14	250	XTN	O	Y		00228	Call back phone number		X	[0..0]
15	26	DTM	O			00229	Order effective date/time		X	[0..0]
16	250	CE	O			00230	Order control code reason		X	[0..0]
17	250	CE	O			00231	Entering organization		X	[0..0]
18	250	CE	O			00232	Entering device		X	[0..0]
19	250	XCN	O	Y		00233	Action by Advanced beneficiary		X	[0..0]
20	250	CE	O		0339	01310	Notice code		X	[0..0]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
21	250	XON	O	Y		01311	Ordering facility name	7190, 7200	R	[0..1]
22	250	XAD	O	Y		01312	Ordering facility address	7210, 7220, 7230, 7235 7240	RE	[0..4]
23	250	XTN	O	Y		01313	Ordering facility phone number	7250	RE	[0..4]
24	250	XAD	O	Y		01314	Ordering provider address	7140, 7150, 7160, 7165, 7170	RE	[0..4]
25	250	CWE	O			01473	Order status modifier		X	[0..0]
26	60	CWE	C		0552	01641	Advanced beneficiary notice override reason		X	[0..0]
27	26	DTM	O			01642	Filler's expected availability date/time		X	[0..0]
28	250	CWE	O		0177	00615	Confidentiality code		RE	[0..1]
29	250	CWE	O		0482	01643	Order type		X	[0..0]
30	250	CNE	O		0483	01644	Enterer authorization mode		X	[0..0]
31	250	CWE	O			2286	Parent universal service identifier		X	[0..1]

Example:

```
ORC|RE|||||||||||||||||||||||ATLANTA CANCER SPECIALISTS|STREET ADDRESS 1^SUITE
   #^ATLANTA^GA ^30303|^^^^^404^3213000
```

This example segment shows the name, address, and phone number for Atlanta Cancer Specialists, the ordering facility.

ORC Field Definitions

ORC-1 Order Control (ID-2, Required) 00215

Definition: Determines the function of the order segment.

Note: Because ORC-1 is an HL7 required field, the value "RE" (Observations to Follow) will be used for this interface.

ORC-21 Ordering Facility Name (XON-250, Required) 01311

Definition: This field indicates the medical facility where the specimen was obtained. Examples include inpatient facilities, outpatient surgical facilities, and medical clinics. Knowledge of the ordering facility allows public health officials to follow up on positive tests to obtain further clinical and epidemiologic information. Information on the ordering facility is most relevant to cancer registries. Both the Ordering Facility Name (ORC-21) and the Ordering Provider (OBR-16) must be provided; both fields cannot be blank. Note that both may be valued if both the Ordering Facility and the Ordering Provider are being transmitted.

The facility's identifier (ORC-21.10) shall be placed in the tenth component <Organization Identifier (ST)>.

Example:

```
ORC|||||||||||||||||||||||University Hospital^^^^^CMS^NPI^^^1234567890|
```

Note for cancer registries: Corresponds to NAACCR items Path Ordering Facility Number NPI [7195] (for National Provider Identifier) or Path Ordering Facility Number [7190] (for other facility identification number) and Path Ordering Facility Name [7200] or use field Text Remarks [2680] if your facility does not support pathology data items in the 7000 range.

ORC-22 Ordering Facility Address (XAD-250, Required or empty, Repeating maximum 4) 01312

Definition: This field contains the address of the facility placing the order.

For valid values in these components, refer to *User-Defined Table 0212 – Nationality* for country codes, *HL7-Defined Table 0190 – Address Type* for address type codes, *User-Defined Table 0289 – County/Parish* for county/parish codes, *User-Defined Table 0288 – Census Tract* for census tract codes, and HL7 Table 0465 – Name/Address Representation for address representation codes.

Example:

```
ORC||||||||||||||||||||||2217 Rainier Way^^Renton^WA^98002^USA^M^^Black Hawk^^A|
```

Note for cancer registries: Corresponds to NAACCR items Path Ordering Fac Addr--No & St [7210], Path Ordering Fac Addr--City [7220], Path Ordering Fac Addr--State [7230], Path Ordering Fac--Postal Code [7240], and Path Ordering Fac-Country [7235].

ORC-23 Ordering Facility Phone Number (XTN-250, Required or empty, Repeating maximum 4) 01313

Definition: This field contains the telephone number of the facility placing the order. This field further identifies the laboratory identified in ORC-21.

Refer to *HL7-Defined Table 0201 – Telecommunication Use Code* and *HL7-Defined Table 0202 – Telecommunication Equipment Type* for valid values.

Example:

```
ORC||||||||||||||||||||||^ASN^PH^helpline@medilab.com^^206^5549097|
```

Note for cancer registries: Corresponds to NAACCR item Path Ordering Fac--Telephone [7250].

ORC-24 Ordering Provider Address (XAD-250, Required or empty, Repeating maximum 4) 01314

Definition: This field contains the address of the care provider requesting the order. This field contains relevant address information for the ordering provider described in OBR-16.

For valid values in these components, refer to *User-Defined Table 0212 – Nationality* for country codes, *HL7-Defined Table 0190 – Address Type* for address type codes, *User-Defined Table 0289 – County/Parish* for county/parish codes.

Example:

```
ORC||||||||||||||||||||||||115 Pike Plaza^Suite 2100^Seattle^WA^98122^USA^^^^^A|
```

Note for cancer registries: Corresponds to NAACCR items Path Ordering Client/Phys Addr--Street [7140], Path Ordering Client/Phys Addr--City [7150], Path Ordering Client/Phys Addr--State [7160], Path Ordering Client/Phys Addr--Postal Code [7170], and Path Order Client/Phys Addr—Country [7165].

ORC–28 Confidentiality Code (CWE-250, Required or Empty) 00615

Definition: This field contains information about the level of security and/or sensitivity surrounding the order (e.g., highly sensitive, not sensitive, sensitive). Refer to *HL7-Defined Table 0177 – Confidentiality Code* for allowed values. The specific treatment of data with a particular confidentiality level is subject to site-specific negotiation.

2.7.2. Observation Request Segment (OBR)

The Observation Request (OBR) segment is used to transmit information specific to an order for a diagnostic study or observation, physical exam, or assessment. The OBR defines the attributes of a particular request for diagnostic services or clinical observations. For laboratory-based reporting, the OBR defines the attributes of the original request for laboratory testing. Essentially, the OBR describes a battery or panel of tests that is being requested or reported. The OBR is somewhat analogous to a generic laboratory slip that is filled out when a physician requests a laboratory test. The individual test names and results for the panel of tests performed are reported in OBX segments, which are described below. As defined by the ORU syntax, there can be many OBXs per OBR, and there can be many OBRs per PID.

For cancer reporting, each OBR holds a single report. These reports may be of various types and styles. The identifying LOINC code reported in OBR-4 specifies the type of report, and the LOINC code reported in OBX-3 describes the type of information reported in OBX-5.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			00237	Set ID – OBR		R	[1..1]
2	22	EI	C			00216	Placer order number		RE	[0..1]
3	22	EI	C			00217	Filler order number	7090	R	[1..1]
4	250	CWE	R			00238	Universal service ID	7480	R	[1..1]
5	2	ID	B			00239	Priority		X	[0..0]
6	24	DTM	B			00240	Requested date/time		X	[0..0]
7	24	DTM	C			00241	Observation date/time	732	R	[1..1]
8	24	DTM	O			00242	Observation end date/time		X	[0..0]
9	20	CQ	O			00243	Collection volume		X	[0..0]
10	250	XCN	O	Y		00244	Collector identifier	2480	RE	[0..4]
11	1	ID	O		0065	00245	Specimen action code		X	[0..0]
12	250	CE	O			00246	Danger code		X	[0..0]
13	300	ST	O			00247	Relevant clinical information		X	[0..0]
14	24	DTM	B			00248	Specimen received date/time		RE	[0..1]
15	300	SPS	B		0070	00249	Specimen source	7100	RE	[0..1]
16	250	XCN	O	Y		00226	Ordering provider	7110, 7120, 7130	R	[0..4]
17	250	XTN	O	Y		00250	Order callback phone number	7180	RE	[0..4]
18	60	ST	O			00251	Placer field 1		X	[0..0]
19	60	ST	O			00252	Placer field 2		X	[0..0]
20	60	ST	O			00253	Filler field 1		X	[0..0]
21	60	ST	O			00254	Filler field 2	7070	RE	[0..1]
22	24	DTM	C			00255	Results rpt/status change - date/time	7530	R	[0..1]
23	40	MOC	O			00256	Charge to practice		X	[0..0]
24	10	ID	O		0074	00257	Diagnostic serv sect ID		X	[0..0]
25	1	ID	C		0123	00258	Result status	7330	R	[1..1]
26	400	PRL	O			00259	Parent result		RE	[0..1]
27	200	TQ	B	Y		00221	Quantity/timing		X	[0..0]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
28	250	XCN	O	Y		00260	Result copies to		X	[0..0]
29	200	EIP	O			00261	Parent		RE	[0..1]
30	20	ID	O		0124	00262	Transportation mode		X	[0..0]
31	250	CE	O	Y		00263	Reason for study		RE	[0..20]
32	200	NDL	O			00264	Principal result interpreter	7260, 7270, 7280, 7290, 7300, 7310	R	[1..1]
33	200	NDL	O	Y		00265	Assistant result interpreter		X	[0..0]
34	200	NDL	O	Y		00266	Technician		X	[0..0]
35	200	NDL	O	Y		00267	Transcriptionist		X	[0..0]
36	24	DTM	O			00268	Scheduled date/ time		X	[0..0]
37	4	NM	O			01028	Number of sample containers		X	[0..0]
38	250	CE	O	Y		01029	Transport logistics of collected sample		X	[0..0]
39	250	CE	O	Y		01030	Collector's comment		X	[0..0]
40	250	CE	O			01031	Transport arrangement responsibility		X	[0..0]
41	30	ID	O		0224	01032	Transport arranged		X	[0..0]
42	1	ID	O		0225	01033	Escort required		X	[0..0]
43	250	CE	O	Y		01034	Planned patient transport comment		X	[0..0]
44	250	CWE	O		0088	00393	Procedure code		RE	[0..1]
45	250	CE	O	Y	0340	01316	Procedure code modifier		X	[0..0]
46	250	CE	O	Y	0411	01474	Placer supplemental service information		X	[0..0]
47	250	CE	O	Y	0411	01475	Filler supplemental service information		X	[0..0]
48	250	CWE	C		0476	01646	Medically necessary duplicate procedure reason		X	[0..0]
49	2	IS	O		0507	01647	Result handling		RE	[0..1]
50	250	CWE	O			02286	Parent universal service identifier		RE	[0..1]

[a] These items are known to the filler, not the placer. They are valued by the filler as needed when the OBR segment is returned as part of a report.

[b] *OBR-7-observation date/time* and *OBR-8-observation end date/time* are the physiologically relevant times. In the case of an observation on a specimen, they represent the start and end of the specimen collection. In the case of an observation obtained directly from a subject (e.g., blood pressure, chest X-ray), they represent the start and end time of the observation.

[c] These fields are relevant only when an observation is associated with a specimen. These are completed by the placer when the placer obtains the specimen. They are completed by the filler when the filler obtains the specimen.

Example:

```
OBR|1||97810430^SOMELABNAME^11D2234578^CLIA|11529-5^SURGICAL PATHOLOGY
  STUDY^LN^^PATHOLOGY REPORT^L|||20030922|||||||||
  1643417389^ONCOLOGIST^HANNAH^^^DR^^^CMS^^^^NPI||||||20030922021500|||C|||||||1097
  72&PATHOLOGIST&QUINCY
```

This segment shows that a Surgical Pathology report identified by 97810430 was conducted on September 22, 2003. Dr. Hannah Oncologist ordered the report, and the pathologist who read the report was Quincy Pathologist. The "C" in OBR-25 indicates that this is a correction.

OBR Field Definitions

For electronic laboratory purposes, the placer and filler are defined as follows:

The <u>placer</u> is the person or service that requests (places order for) an observation battery (e.g., the physician, practice, clinic, or ward service that orders a laboratory test—X-ray, vital signs, etc.). The meaning is synonymous with, and used interchangeably with, "requestor." See OBR-2 "Placer order number."

The <u>filler</u> is the person or service that produces the observations (fills the order) requested by the requestor. The word is synonymous with "producer" and includes diagnostic and clinical services and care providers who report observations about their patients. The clinical laboratory is a producer of laboratory test results (filler of a laboratory order), the nursing service is the producer of vital signs observations (the filler of orders to measure vital signs), and so on. See OBR-3 "Filler order number."

OBR-1   Set ID – OBR (SI-4, Required) 00237

Definition: This field identifies the sequence number of one of multiple OBRs under one PID. For the first order transmitted, the sequence number shall be 1; for the second order, it shall be 2; and so on. For example, the second OBR under a single PID would appear as:

```
OBR|2|
```

OBR-2 Placer Order Number (EI-22, Required or Empty) 00216

Definition: This field identifies an order number uniquely among all orders from a particular ordering application. The identifier contained on the pathology study requisition form, commonly referred to as the requisition number, should be reported in this field. This field should not contain the accession number for a specimen. The first component is a string that identifies an individual order. A limit of 15 characters is suggested but not required. It is assigned by the placer (ordering application). The second through fourth components contain the application ID of the placing application in the same form as the HD data type.

If the Placer Order Number is known to the laboratory (Filler), then this field should be included in the results message.

OBR-3 Filler Order Number (EI-22, Required) 00217

Definition: This field is the order number associated with the filling application. It is assigned by the order filler application. This string MUST uniquely identify the order (as specified in the order detail segment) from other orders in a particular filling application (e.g., clinical laboratory). This uniqueness must persist over time. For laboratory-based reporting, this field will be used to report the pathology report number, sometimes referred to as the laboratory specimen "accession number." This is the identifier that the laboratory uses to track the specimen and the report record of the examination of the specimen and is assigned by the laboratory on receipt of the specimen(s).

The registry consolidates multiple reports for a case, such as when a reference laboratory or consult report is sent, which may carry a different Accession Number and/or Laboratory ID. When multiple reports from multiple facilities are included in a single HL7 message as components of the Pathology Report Collection, the Filler Order Number (with its assigning Laboratory ID) that is identified in the OBR containing the LOINC code in OBR-4 for the collection (60567-5 Comprehensive pathology report panel) should be used to identify the overall case.

NOTE: If Cancer Registry operations do not have a date of diagnosis provided from any other reporting source (e.g., hospital, ambulatory provider, etc.), then the specimen collection date is often used as a date of diagnosis.

Example:

```
OBR|||97 810430^SOMELABNAME^12D4567890^CLIA|
```

In the above example, 97810430 is the number assigned by the pathology laboratory for the surgical specimen. In multi-specimen cases, this number refers to the entire Pathology Study case, with all of its specimens.

The second through fourth components are required or empty. These components should contain the name and ID of the laboratory that performed the test. The testing facility may be different than the Sending Facility reported in MSH-4. If the testing facility is different, then NAACCR recommends reporting the name of the testing laboratory in OBX-23 Performing Organization Name and OBX-24 Performing Organization Address.

Note for cancer registries: Corresponds to NAACCR item Path Report Number [7090]. The combination of laboratory ID and filler order number MUST uniquely identify a case. Note that, generally, each laboratory creates its own Accession Number, so for parts of the report that contain results from other laboratories (reference send-outs), the Accession Numbers will be different. When a report from a reference laboratory is included as a supplemental report in the Pathology Report Collection, the Pathology Report Number is the Accession Number of the laboratory sending the collection. If the reference laboratory sends its report directly to the Registry, the burden is on the Registry to link the reference report to the rest of the reports on the case; at this time there is no standardized solution to this issue.

OBR-4 Universal Service ID (CWE-250, Required) 00238

Definition: This field is the identifier code for the ordered observation/test/battery (not the test performed). An example valuing all of the CE data type components for a surgical pathology report would appear as:

```
OBR|||||11529-5^SURGICAL PATHOLOGY STUDY^LN^1000^PATHOLOGY REPORT^L|
```

An example valuing all of the CE data type components for a cytology report would appear as:

```
OBR||||33716-2^Study Report: Cytology.non-gyn^LN^1100^CYTOLOGY REPORT^L|
  |60568-3^Synoptic Report^LN^1100^CYTOLOGY REPORT^L|
```

An example valuing all of the CE data type components for an immunophenotype report would appear as:

```
OBR||||55230-7^Study Report: Immunophenotyping^LN^1200^IMMUNOPHENOTYPE REPORT^L|
```

No coding recommendation for laboratory-based reporting has been made for OBR-4 because the field describes the originally requested order (e.g., a hepatitis panel or antimicrobial susceptibility testing battery). The value of OBR-4 will be continued from the original order because this is a required field, but the information in OBR-4 will not be used routinely. The "informative field" for laboratory-based reporting is OBX-3, which should be used to provide an unambiguous, specific test name, and OBX-5 should provide the result of the test.

An example of the universal service identifier for a report of a hematology panel would appear as:

```
OBR||||^^^10002^Complete Blood Count^L|
```

Here, the code is a user-defined "local" code, as indicated by the <L> in the sixth subcomponent. Note that the Universal Service ID is a code that often represents the battery or collection of tests that make up

a routine laboratory panel. The individual results of the different components of the CBC are reported in the OBX segments described below. For most laboratory tests that are reportable to public health officials, the description of the test and result is sufficiently given in OBX and does not need repetition here.

Note for cancer registries: Allowable OBR-4 values correspond roughly to the values allowed for NAACCR data item "Path Report Type 1" [#7480], but OBR-4 uses more-specific LOINC codes rather than NAACCR " Path Report Type 1" codes. See Section 1.5.3 for a description of the various report types and styles.

When multiple reports from multiple facilities are included in a single HL7 message as components of the Pathology Report Collection, the Filler Order Number (and Laboratory ID) that is identified in the OBR containing the LOINC code in OBR-4 for the collection (60567-5 Comprehensive pathology report panel) should be used to identify the overall case. When applicable the earliest specimen collection date should be used when reporting a comprehensive pathology report panel for the overall case. NOTE: If Cancer Registry operations do not have a date of diagnosis provided from any other reporting source (e.g., hospital, ambulatory provider, etc.), then the specimen collection date is often used as a date of diagnosis.

The following table shows typical OBR-4 values used in cancer reporting, with their corresponding NAACCR "Path Report Type 1" [#7480] codes:

Examples of OBR-4 for Cancer Reporting
NAACCR Codes	**Description**	**Kind of Report**	**Style of Reporting**	**LOINC code**	**LOINC Component**
01	Pathology	Pathology Report Collection	any	*60567-5	Comprehensive pathology report panel
01	Pathology	**Primary Report**	Narrative Text Synoptic Summary Synoptic Structured	11529-5	Surgical pathology study
01	Pathology	Supplemental Report	Narrative Text Synoptic Summary Synoptic Structured	**22639-9	Path report.supplemental reports
01	Pathology	Consult Report	Narrative Text Synoptic Summary Synoptic Structured	60570-9 24611-6 (legacy systems)	Consultation note
01	Pathology	Autopsy Report	Narrative Text Synoptic Summary Synoptic Structured	18743-5	Autopsy note
01	Pathology	Addendum	Narrative Text Synoptic Summary Synoptic Structured	35265-8	Path report.addendum
01	Pathology	**Primary Report**	CAP Synoptic Summary any Synoptic Segmented CAP eCP	60568-3	Synoptic report
01	Pathology	Consult Report	CAP Synoptic Summary any Synoptic Segmented CAP eCP	60571-7	Consultation note.synoptic
01	Pathology	Addendum	CAP Synoptic Summary any Synoptic Segmented CAP eCP	60569-1	Report addendum.synoptic
02	Cytology			33716-2	Study Report: Cytology.non-gyn
03	Gyn Cytology			33717-0	Study Report: Cytology.Cvx/Vag

Examples of OBR-4 for Cancer Reporting					
NAACCR Codes	Description	Kind of Report	Style of Reporting	LOINC code	LOINC Component
04	Bone Marrow (biopsy/aspirate)			48807-2	Bone marrow aspiration report
05	Autopsy			18743-5	Autopsy note
06	Clinical Laboratory Blood Work, NOS			Various	
07	Tumor Marker (p53, CD's Ki, CEA, Her2/Neu, etc.)			Various	
08	Cytogenetics			55228-1	Study Report; Cytogenetics
09	Immuno-histochemical Stains			55229-9	Study Report; Immune Stains
10	Molecular Studies			26435-8	Molecular pathology studies
11	Flow Cytometry, Immuno-phenotype			33719-6 55230-7	Study Report FC Immunophenotype
98	Other			NA	NA
99	Unknown			NA	NA

* When code 60567-5 (Comprehensive Pathology Report Panel) is used in OBR-4, the specimen collection date (OBR-7) must be populated with the earliest specimen collection date of all tests performed.

* This code (#22639-9) was used for supplemental reports, but because there are explicit LOINC codes for consult reports and addenda, the use of this code is deprecated and it should not be used in any new or updated interfaces. LOINC code 35265-8 should be used for narrative supplemental reports, and LOINC code 60569-1 should be used in OBR-4.1 for CAP synoptic checklists that are specific to tumor marker/biomarker tests.

OBR-7 Observation Date/Time (DTM-24, Required) 00241

Definition: This field is the clinically relevant date/time of the observation. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field shall represent the date and time the specimen was collected or obtained. (This is a results-only field, except when the placer or a third party has already drawn the specimen.) This field is conditionally required. When the OBR is transmitted as part of a report message, the field must be filled in. If it is transmitted as part of a request and a sample has been sent along as part of the request, this field must be filled in because this specimen time is the physiologically relevant date-time of the observation.

When applicable, the earliest specimen collection date should be used when reporting a comprehensive pathology report panel for the overall case.

Date structure would be reported as YYYYMMDDHHMMSS(+/-)ZZZZ

> **Example:** OBR|||||11529-5^SURGICAL PATHOLOGY STUDY^LN^1000^PATHOLOGY
> REPORT^L|||**19760704010159-0500**|

Note: The above date in OBR-7 represents July 4, 1976, at 1:01:59 in Eastern Standard Time Zone (US). The DTM data type allows precision to be truncated based on the data available for reporting. If time is unknown, then the month, day and year would be reported as |19760704|. Midnight is represented as 0000. If a time is provided but seconds are unknown, then seconds must be provided as 00.

If the laboratory does not have the date when the case of observations taken from the subject, then this field should be populated with a value of January 1, 1800 00:00 that will be represented in the HL7 message as: |180001010000|.

In addition to populating OBR-7 (because it is required by the HL7 message definition of a result message) this value should also be reported in the Specimen Collection Date/Time field (SPM-17) when implementing version 5.0 or more recent releases of the NAACCR Laboratory Electronic Pathology Reporting Guidelines specification.

Note for cancer registries: Corresponds to NAACCR item Path--Date Spec Collection [7320].

OBR-10 Collector Identifier (XCN-250, Required or empty, Repeating maximum 4) 00244

Definition: When a specimen is required for the study, this field will identify the person who collected the specimen. Either name or ID, or both, may be present.

Example:

```
OBR|||||||||||EMLOYEEID^PHLEBOTOMIST^PAMELA|
```

(Pamela Phlebotomist is included as having drawn a blood sample.)

Note for cancer registries: When the specimen is collected by the surgeon, this field corresponds to NAACCR item Physician—Primary Surgeon [2480].

OBR-14 Specimen Received Date/Time (DTM-24, Required or empty) 00248

Definition: For observations requiring a specimen, the "specimen received date/time" is the actual login time at the diagnostic service. This field must contain a value when the order is accompanied by a specimen, or when the observation required a specimen and the message is a report. For cancer reporting, generally surgery will collect the specimen; the date and time on the Pathology Study requisition form that accompanies the specimen is the timestamp filled in here.

Example:

```
OBR|||||||||||||||200011270930|
```

NOTE: This field duplicates SPM-18. Refer to SPM-18 for further instruction.

OBR-15 Specimen Source (SPS-300, RE) 00249

Definition: *This field has been retained for backward compatibility only.* As of version 2.5, messages in which the SPM segment is present, the use of SPM Specimen segment is favored over this field. This field identifies the site where the specimen should be obtained or where the service should be performed.

The first component contains the specimen code, specimen source name, and code system (as a CWE data type component). Refer to *HL7-Defined Table 0487 – Specimen Type* (replaces HL7 Table 0070 – Specimen Source Codes) for valid entries.

Note: The value reported in this component should also be reported in the required SPM segment in SPM-4.

An example using SNOMED CT:

```
OBR|||||||||||||||||119359002&Bone Marrow specimen (specimen)&SCT|
```

Where <119359002> is the code, <Bone marrow specimen (specimen)> (is the text of the code, and <SCT> is the SNOMED CT coding system from which the code and text were drawn. Refer to

the SNOMED CT (SNOMED International January 2019) web browser tool to identify valid SNOMED CT codes at: https://www.snomed.org/software-tools.

An example using HL7 Table 0487:

```
OBR||||||||||||||BNMRW&Bone Marrow&HL70487|
```

When the coding system used is drawn from an HL7 table, the third subcomponent—name of coding system—is valued as HL70487.

An example of a prostate specimen (right lobe) in which the specimen source code is from ICD-O-3 (name of coding system):

```
OBR||||||||||||||C619&Prostate, NOS (C619) Right&ICDO3|
```

An example for lymph nodes using the same coding system:

```
OBR||||||||||||||C773&Lymphoma, axilla or arm-(C773) Right&ICDO3|
```

It is strongly recommended that actual specimen sources be provided in OBR-15 and not surrogate descriptions such as "lavender-top" or "serum-separator tube."

Non-Coded Specimen Sources: If coded text is not available, then the information is provided as either:

- The uncoded value in the second subcomponent of the first component of the SPS, as: |&free text uncoded data|
- Use the original text in the CWE, which is the ninth subcomponent, as |&&&&&&&&free text uncoded data|
- Use the HL7 Table 0487 code "TISS" to indicate the specimen type is tissue, and encode OBR-15 as:
  |TISS&TISSUE&HL70487|

Note OBR-15 should only be used in place for backwards compatibility:

Elements previously reported in

- OBR-15.1 are now reported in SPM-4
- OBR-15.2 are now reported in SPM-6
- OBR-15.3 are now reported in SPM-7
- OBR-15.4 are now reported in SPM-8
- OBR-15.5 are now reported in SPM-9
- OBR-15.6 do not have a specific field for collection method, however there is SPM-24 (Specimen Condition i.e. Frozen…)
- OBR-15.7 are now reported in SPM-11

OBR-16 Ordering Provider (XCN-250, Required, Repeating maximum 4) 00226

Note: This field has now been made Required since NAACCR Standards Volume V version 4.0

Definition: This field identifies the provider who ordered the pathology report (e.g., surgeon/physician who ordered the pathology report). The ID code and the name must be present. The Ordering facility name (ORC-21) and the Ordering provider (OBR-16) must be provided. For cancer reporting, the preferred ordering provider identifiers are listed in order from most to least preferred: National Provider Identifier (NPI); State Medical License Number (MD); or any other local provider identifier, such as Doctor Number (DN). OBR-16 must have at least one provider identifier included.

For example, the NPI number for Dr. Marcus Welby:

```
OBR||||||||||||||||1234567^Welby^M^J^Jr^Dr^^^&2.16.840.1.113883.4.6&ISO^L^^^NPI|
```

Note on assigning authority: The Namespace ID of the HD datatype for all Assigning Authority fields in XCN and CX data types is drawn from a local table (0300). Generally, this is an obstacle to interoperability, so NAACCR recommends the use of the Universal ID component instead, which is an OID registered with HL7.

The OID for the Medicare/CMS NPI namespace is 2.16.840.1.113883.4.6.

Note for cancer registries: Corresponds to NAACCR data items Path Ordering Client/Phys--Lic No [7100] or Path Ordering Client/Phys--Lic No NPI [7105], Path Ordering Client/Phys--LName [7110], Path Ordering Client/Phys--FName [7120], and Path Ordering Client/Phys--MName [7130].

OBR-17 Order Callback Phone Number (XTN-250, Required or Empty, Repeating maximum 4) 00250

Definition: This field is the telephone number for reporting a status or a result using the standard format with extension and/or beeper number when applicable.

Example:

```
OBR|||||||||||||||||^WPN^PH^^^206^2770908^^before 5:00 pm~^ASN^PH^^^206^5620767|
```

or

```
OBR|||||||||||||||||^^^^^^^^^(206) 277-0908|
```

Note for cancer registries: Corresponds to NAACCR data item Path Ordering Client/Phys--Phone [7180]. If the value is known, it should be populated in this field.

OBR-21 Filler Field 2 (ST-60, Required or empty) 00254

Definition: This field is used by NAACCR for collection of the reporting facility telephone number (i.e., the laboratory telephone number).

Note for cancer registries: Corresponds to NAACCR data item Path Lab Phone Number [7070].

OBR-22 Results Rpt/Status Change – Date/Time (DTM-26, Required) 00255

Definition: This field specifies the date/time results are reported or status changed. The field is used to indicate the date and time that the results are composed into a report and released, or that a status is entered or changed.

The user values the field only as far as needed. The time zone is assumed to be that of the sender.

Note for cancer registries: Corresponds to NAACCR data item Date/Time Results Written as a Report or Report Changed [7530].

OBR-25 Result Status (ID-1, Required) 00258

Definition: This field is the status of results for this order. Refer to *HL7-Defined Table 0123 – Result Status* for valid entries.

Codes C (corrected) and F (final) are used for reporting to cancer registries. Note that code P (preliminary) is generally not sent to cancer registries.

Note for cancer registries: Corresponds to NAACCR item Path--Result Status [7330].

OBR-26 Parent Result (PRL-400, Conditional or Empty) 00259

Definition: This field provides linkages to messages describing previously performed tests. This important information, together with the information in *OBR-29-parent* (the identifiers associated with the parent placer and filler), uniquely identifies the OBX segment from the previously performed test that is related to this order (description of OBX segment provided below). The value reported in this OBX segment in the parent result is the organism or chemical species about which this battery reports. For example, if the current battery (as designated in OBR-4) is an antimicrobial susceptibility test, the parent result in OBR-26 contains a result from a previously performed antimicrobial susceptibility test, which identified the organism on which the current susceptibility was run. HL7 specifies here that the OBX-5 data will show only the text, or the second component of the CE data type used in the previous message. However, for electronic laboratory reporting, all the CE data type components of field OBX-5 from the previous parent message appear in this field of the present OBR, using subcomponent delimiters. This indirect linkage is preferred because the name of the organism in the parent result may undergo several preliminary values prior to finalization. **This is an exception to the HL7 description for this component**.

This field may be valued for cases in which there are multiple primary cancers, or inclusion of multiple reports on the same cancer of different types (such as Coded Synoptic and Text).

OBR-29 Parent (EIP-200, Conditional or Empty) 00261

Definition: This field relates a child to its parent when a parent/child relationship exists. It is recommended that the field be sent if available for laboratory-based reporting when a parent result is provided. Reporting of antimicrobial susceptibility data requires that the parent result be populated with the name of the organism for which testing was performed (OBR-26). When the report message contains multiple OBR segments for multiple cancers, this field should be populated to link the different reports to the correct cancer. See Appendix E for more details.

An example showing a message fragment with an OBR for the overall case report on two cancers; two OBRs with text reports, each one of which is specific to one of the cancers; and two additional OBRs, each one containing a synoptic report for the different cancers. In this example there is a report on bladder and colorectal cancers, with both textual reports and synoptic reports on each, all linked, and in the same message. Note that the numerous OBX segments containing the actual report contents are not shown in this example.

```
OBR|1||58839674&^SomeLab^11D1234567^CLIA|11529-5^SURGICAL PATHOLOGY STUDY^LN|...
   ||...

OBR|2||58839697|11529-5^SURGICAL PATHOLOGY STUDY^LN|...
   ||^58839674&^SomeLab^11D1234567^CLIA|...

OBR|3||58839703|11529-5^SURGICAL PATHOLOGY STUDY^LN|...
   ||^58839674|...

OBR|4||58839775|^^^2567^BLADDER BIOPSY SYNOPTIC PATH REPORT^L|...
   |^58839697|...

OBR|5||58839775|^^^2567^COLON/RECTUM RESECTION SYNOPTIC PATHREPORT^L|...
   |^58839703|...
```

For more detailed examples, see Appendix E.

OBR-31 Reason for Study (CWE-250, Required or Empty, Repeating maximum 20) 00263

Definition: For public health reporting, ICD-10-CM codes used to support testing and reimbursement should be used here. This field can repeat to accommodate multiple diagnoses. Refer to the website https://www.cdc.gov/nchs/icd/icd-10-cm.htm for information on ICD-10-CM codes.

The field would appear as:

```
OBR|||||||||||||||||||||||||||||||C34.90^Malignant neoplasm of unspecified part of
  unspecified bronchus or lung^I10C|...
```

If there is a known value for this field, it should be populated.

OBR-32 Principal Result Interpreter (NDL-200, Required) 00264

Definition: This field identifies the physician who interpreted the observation and is responsible for the report content. Note: This would be the physician that can respond to any inquiries about the report. If no physician is available, then the best contact person should be provided, such as a clinical geneticist.

Comment: Use the first and last name of the physician who interpreted the observation/result, and include a provider identifier, such as NPI.

For cancer reporting, OBR-32 should have at least one provider identifier included. The ordering provider identifiers are listed in order from most to least preferred: National Provider Identifier (NPI); State Medical License Number (MD); or any other local provider identifier, such as Doctor Number (DN).
If NPI and State Medical License Number (MD) are not available, then implementers may use the locally *User-Defined Table 0363 – Namespace ID* for the first component. This table cannot be realistically pre-populated or effectively maintained, so it is not required for conformance of this field.

In the event the state license number is used record the state (two letters) or province code (up to four letters) before the state license number (MD), if the national provider identifier (NPI) is used, prepend NPI; if the local physician number is used, prepend DN.

```
OBR|||||||||||||||||||||||||||||||109772&PATHOLOGIST&QUINCY&&&DR&&&NY
  _PHYSICIANLICENSE^201009301000^201009301040|...
```

Note for cancer registries: Corresponds to NAACCR items: Pathologist Last Name [7260], Pathologist First Name [7270], Pathologist Middle Name [7280], Pathologist Name Suffix [7290], Pathologist Lic Number [7300], Pathologist Lic--State [7310]. Also note that the NAACCR data items numbered 7000 and higher are specifically for use in Pathology Reporting as described in this Guide. Note that the Principal Result Interpreter is required for reporting to cancer registries. This OBR-32 field has been relaxed to "Required or Empty" because some laboratories include this information in the prose of a text report and do not populate it separately in this field. This practice is discouraged; reasonable effort should be made to populate the Principal Result Interpreter in this OBR-32 field to reduce the burden on receiving registries.

An example showing this field with Dr. Quincy Pathologist, M.D., as the Principal Result Interpreter with an NPI of 109772 and recording the times that he actually read the slides would appear as:

```
OBR|||||||||||||||||||||||||||||||109772&PATHOLOGIST&QUINCY&&&DR&&&NPI^20100930100
  0^201009301040|...
```

Alternatively, if the registered OID for the namespace National Provider Identifier is to be used rather than using the local Namespace ID table 0363, the message would appear as:

```
OBR|||||||||||||||||||||||||||||||109772&PATHOLOGIST&QUINCY&&&DR&&NPI&&2.16.840.1.
  113883.4.6&ISO^201009301000^201 009301040|...
```

Note: The examples are showing only the population of the OBR-32 field; other fields in the segment are represented by ellipses (. . .).

OBR-44 Procedure Code (CWE-250, Conditional or Empty) 00393

Definition: This field contains a unique identifier assigned to the procedure, if any performed, associated with the Universal Service ID reported in OBR-4. This generally is the procedure that was used to obtain the specimen. For cancer reporting, this field is being used to differentiate a surgical resection from a biopsy procedure. ***This field has been changed to a CWE data type (from a CE in the HL7 standard) for compatibility with clinical and ancillary systems that need to report the procedure in this field (rather than in an OBX) but need to send it as the Original Text component of the datatype.***

It is recommended that ICD-10-PCS codes be used to identify the procedure performed to obtain the specimen. Refer to: 2020 ICD-10-PCS | CMS for a list of procedure codes.

Example of reporting ICD-10-PCS code for Prostate Needle Biopsy:

```
OBR|||||||||||||||||||||||||||||||||||||||||||||0VB03ZZ^Excision of Prostate,
  Percutaneous Approach^I10P|
```

Example of reporting ICD-10-PCS code for Excision of Left Breast:

```
OBR|||||||||||||||||||||||||||||||||||||||||||||0HBU0ZZ^ Excision of Left Breast,
  Open Approach^I10P|
```

OBR-50 Parent Universal Service Identifier (CWE-250, Conditional or Empty) 02286

Definition: This field contains the universal service identifier code for the parent order, as identified in OBR-29 Parent (if present), which caused this observation/test/battery to be performed. This can be based on local and/or "universal" codes. HL7 recommends the "universal" service identifier.

Notes:

- OBR-29 Parent does not have to be present for OBR-50 to be used. However, the absence of OBR-29 Parent introduces potential ambiguity of the actual order being referenced.
- OBR-29 Parent identify an individual parent order (e.g., OBR) for the ORC-31 Parent Universal Service Identifier and OBR-50 Parent Universal Service Identifier.
- ORC-31 Parent Universal Service Identifier is the same as OBR-50, Parent Universal Service Identifier. If both fields are valued, they must contain the same value.
- OBR-50 will be deprecated in version 2.7 to enable message developers to start to adjust and be prepared for supporting the intended 1:1 relationship between Placer/Filler Order Number and Universal Service Identifier.

2.7.3. Observation/Result (OBX) Segment
The OBX segment is used to transmit a single observation or observation fragment. It represents the smallest indivisible unit of a report. Its principal mission is to carry information about observations in report messages. Although OBR gives general information about the order for the test and ORC gives information on all services that are requested, the OBX segment gives the specific, individual tests performed (OBX-3) and the specific results for each test (OBX-5). Laboratory-based reporting to cancer registries focuses on OBX-3 and OBX-5 as the most informative elements of the message; thus, every effort should be made to make OBX-3 and OBX-5 as complete and unambiguous as possible.

The OBX segment is used in two different locations in the ORU_R01 message defined in this Guide: immediately following the OBR segment, and immediately following the SPM segment. The first location, where a repeating set of OBX segments follows the OBR, is intended to carry information about the overall case being reported. The second location in the message, where a repeating set of OBX

segments is associated with an SPM segment, is intended to carry information that is specific to a particular specimen

For the structure of the message and OBX usage for particularly complex reports, such as those involving multiple cancers and multiple specimens, please refer to Appendix E.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			00569	Set ID – OBX		R	[1..1]
2	3	ID	C		0125	00570	Value type		R	[1..1]
3	250	CWE	R			00571	Observation identifier		R	[1..1]
4	20	ST	C			00572	Observation sub-ID		RE	[0..1]
5	65536b	Varies	C	Yd		00573	Observation value	7400, 7410, 7420, 7430, 7440, 7450, 7460, 7470, 2600, 7080, 7340, 7350, 7360, 7370, 7380, 7390	R	[1..12]
6	250	CE	O			00574	Units	7540	RE	[0..1]
7	60	ST	O			00575	Reference range		RE	[0..1]
8	5	IS	O	Y	0078	00576	Abnormal flags		RE	[0..5]
9	5	NM	O			00577	Probability		X	[0..1]
10	2	ID	O	Y	0080	00578	Nature of abnormal test		RE	[0..5]
11	1	ID	R		0085	00579	Observation result status	7330	R	[1..1]
12	26	DTM	O			00580	Effective date of reference range values		X	[0..0]
13	20	ST	O			00581	User-defined access checks		X	[0..0]
14	26	DTM	O			00582	Date/time of the observation		RE	[0..1]
15	250	CE	O			00583	Producer's reference		C	[0..0]
16	250	XCN	O	Y		00584	Responsible observer		RE	[0..5]
17	250	CE	O	Y		00936	Observation method		RE	[0..6]
18	22	EI	O			01479	Equipment instance identifier		X	[0..1]
19	26	DTM	O			01480	Date/time of the analysis		RE	[0..1]
20							Reserved for harmonization with v2.6		X	[0..0]
21							Reserved for harmonization with v2.6		X	[0..0]
22							Reserved for harmonization with v2.6		X	[0..0]
23	567	XON	O	N		02283	Performing organization name		RE	[0..1]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
24	631	XAD	O	N		02284	Performing organization address		RE	[0..1]
25	3002	XCN	O	N		02285	Performing organization medical director		X	[0..0]
33		EIP	O	Y		02454	Observation Related Specimen Identifier		RE	[0..*]

[a] For laboratory-based reporting, LOINC is strongly recommended for OBX-3, and SNOMED CT is strongly recommended for OBX-5 when results are coded and CE data types are used.

[b] The length of the observation value field is variable, depending upon value type. See *OBX-2-value type*.

[c] The data type for OBX-5 can vary and is determined by OBX-2.

[d] May repeat for multipart, single answer results with appropriate data types (e.g., CE, TX, and FT data types).

Examples:

For cancer reporting using text value type results:

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN^^DIAGNOSIS^L|1|LEFT
    INGUINAL LYMPH NODE – GRANULOMATOUS LYMPHADENITIS|||||||F
```

For patient age and employment:

```
OBX|1|NM|21612-7^Age - Reported^LN||47|yr^year^ANSI+|... OBX|2|TX|11294-6^Current
    employment^LN||laboratory technician|...
```

OBX Field Definitions

OBX-1 Set ID – Observation Simple (SI-4, Required) 00569

Definition: This field contains the sequence number. There can be many OBXs per OBR. The set ID allows the receiver to maintain the relational aspects of the message.

Example:

```
OBX|1|
```

This field can be used to track a number of results within one test panel.

OBX-2 Value Type (ID-3, Required) 00570

Definition: This field contains the data type that defines the format of the observation value in OBX-5. An explanation of possible data types is given in Appendix C.

This field contains the data type of the observation value reported in OBX-5. For instance, if the value in OBX-2 is "CWE," then the result reported in OBX-5 must be a coded element. When the value type is TX or FT, then the results in OBX-5 are bulk text. The choices allowed for the value type of an observation are listed in *HL7-Defined Table 0125 – Value Type*. All HL7 data types are valid in this field except CM, CQ, SI, and ID. TX should not be used except to send large amounts of text. ST should be used to send short, and possibly encodable, text strings. For laboratory-based reporting, the CWE, NM, and SN data types should be used whenever possible so that results can be interpreted easily.

When no standard format for the reported result is available, it is recommended to use (see OBX-5 for additional explanation):

1. CWE with subsequent NTE for non-standard coded results when the result is a predefined text block.

2. TX for results that are truly free text.

Observations that usually are reported as numbers will sometimes have the string (ST) data type because non- numeric characters are often reported as part of the result (e.g., "<0.06") to indicate the result was lower than detected by the present mechanism. In the example "<0.06," "<" is a text symbol and the digit, "0.06" is considered a numeric value. However, this usage of the ST type should be discouraged because the SN (structured numeric) data type accommodates such reporting. The SN data type is described under OBX-5 below.

Example:

```
OBX|17|SN|31150-6^HER2/neu FISH^LN^^^||>^6.0|||P|||F<CR>
```

OBX-3 Observation Identifier (CWE-250, Required) 00571

Definition: This field contains a unique identifier for the observation and often is referred to as the question code. It identifies what is being reported in OBX-5, which often is referred to as the answer code. Examples of OBX-3 include the name of the specific test or observation method, and the name of the component part of the pathology report. For pathology reporting, OBX-3 uses a CE data type construct.

As noted in the table below, anatomical pathology reports, cytology reports, and hematology reports typically are in a narrative style format, and the information is contained within different sections or headings. This field contains the LOINC codes, which must be used when transmitting text-based information, for the text-based NAACCR data items. In addition to the below text-based LOINC codes, a pathology report may contain additional coded data elements and text-based information. Possible coded data elements include ICD-10-CM, CPT, ICD-O-3, and SNOMED CT information (see OBX-5). In the United States and Canada, the typical convention is to use LOINC codes as the question code (OBX-3). The codes in this table are components of the NAACCR Data Standards and Data Dictionary reporting panel and are used primarily for labeling the sections of narrative reports; although some may be used in synoptic reports under certain circumstances (see Section 1.5.2, above). These are only used when a section is separate from the set of OBX segments holding the synoptic report structured data.

NAACCR Item Name	NAACCR Item#	LOINC Code	LOINC Component Name
Path--Final Diagnosis	7450	22637-3	Path report.final diagnosis
Path--Text Diagnosis	7400	33746-9	Pathologic findings
Path--Clinical History	7410	22636-5	Pathology report.relevant Hx
Path--Nature of Specimen	7420	22633-2	Pathology report.site of origin
Path--Gross Pathology	7430	22634-0	Pathology report.gross observation
Path--Micro Pathology	7440	22635-7	Path report.microscopic observation
Path--Comment Section	7460	22638-1	Pathology report.comments
Path--Suppl Reports	7470	*22639-9	Pathology report.supplemental reports
Path—Addendum	N/A	35265-8	Path report.addendum
—	—N/A	60568-3	Path report.synoptic summary
Path--Addendum (Synoptic Report)	—N/A	60569-1	Report addendum.synoptic
		**76540-4	Pathology diagnosis ICD Code

* This code (#22639-9) was used for supplemental reports, but because there are explicit LOINC codes for consult reports and addendum, the use of this code is deprecated and should not be used in any new or updated interfaces. LOINC code 35265-8 should be used for narrative supplemental reports, and LOINC code 60569-1should be used in OBX-3.1 for CAP synoptic checklists that are specific to tumor marker/biomarker tests.

** This code (76540-4) should be used to report the pathologist assigned ICD-10-CM Code diagnosis in a separate OBX segment placed within the OBR-OBX-SPM combination that contains the associated text diagnosis.

If there were multiple specimens that have individual specimen diagnosis, but there is an overall case interpretation then the case level Path Diagnosis ICD-10-CM code should be placed in an OBX segment under the first OBR. An example of how to use this LOINC code can be found in Appendix E under E.1.4, Example 2.

In addition to the above elements, pathology, hematology, and cytology reports may contain additional test or report results such as Complete Blood Count, Flow Cytometry, Estrogen Receptor Assay (ERA), Progesterone Receptor Assay (PRA), and Fluorescence *in situ* Hybridization (FISH). If these additional test results are available as discrete data elements, they should be included in the message as separate OBXs with the appropriate LOINC test code and name in OBX-3. The associated value (or text-finding) and test reference ranges, if appropriate, should be included in OBX-5. The LOINC codes for additional related laboratory tests can be found at no cost at the LOINC website: http://www.loinc.org. The entire terminology may be downloaded for local use, or it may be searched at that location. For example, a report that is encoded might use LOINC codes such as 59847-4 Histology and Behavior ICD-O-3 or 59848-2 Morphology.ICD-O-3 to indicate such an ICD-O-3 code in the report.

The first component of OBX-3 is the LOINC code for a data element (text-based or coded) that will be transmitted. The second component is the name of the data element (text-based or coded) as it appears in the LOINC coding system. The third component is a code representing the name of the coding system that has the table in which the codes and names of the data elements (text-based or coded) can be found (e.g., LN is the code for LOINC). Coding systems other than LOINC, such as SNOMED CT or CPT, can be used. The codes for identifying coding systems are found in the HL7 standard documentation (http://www.hl7.org). Codes anticipated for use in public health and cancer registration reporting are shown in https://terminology.hl7.org/5.1.0/CodeSystem-v2-0396.html.

Below are examples of LOINC codes used to identify sections of a pathology report, such as nature of specimen/site of origin and final diagnosis.

```
OBX|2|ST|22633-2^Pathology report site of origin Narrative^LN|1|left breast
  biopsy…
```

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN|1|Malignant
  lymphoma, small B-cell type with plasmacytic differentiation and crystal-storing
  histiocytosis|…
```

Where <22633-2> is the identifier from the LOINC table for nature of specimen, <Pathology report site of origin Narrative> is the Long text name in LOINC, <LN> is the name of the coding system, <1> specifies that it is the first specimen, and <left breast biopsy> identifies the site the specimen was removed from, including the method used.

```
OBX|9|TX|22637-3^Pathology report final diagnosis Narrative^LN||1. Infiltrating
  duct carcinoma, left breast…
```

Where <22637-3> is the identifier from the LOINC table for the final diagnosis, < Pathology report final diagnosis Narrative> is the Long text name in LOINC, <LN> is the name of the coding system, and <1> specifies that it is the first specimen, and <1. Infiltrating duct carcinoma, left breast> is the final diagnosis for this first specimen.

For cancer reporting, patient age is sometimes needed when the birth date may not be available. The PID segment in HL7 Version 2.5.1 has only a field for date of birth, not for patient age. Many applications compute patient age based on birth date. In the absence of birth date, patient age may be recorded within an ORU message in an additional OBR/OBX combination of segments. The suggested data type for patient age is NM, which is recorded in OBX-2. The LOINC code for age is represented in OBX-3, and actual age is represented in OBX-5. Patient age can be "reported age" at specimen collection (LOINC code 35659-2) or "estimated age" (LOINC code 21611-9). When birth date is unknown, age may be estimated by a third party on the basis of physical evidence.

OBX-4 Observation sub-ID (ST-20, Required or Empty) 00572

Definition: This field is used to distinguish between multiple OBX segments with the same observation ID organized under one OBR. For example, a blood culture may have three different organisms growing, or a chest X-ray report might include three separate diagnostic impressions. The standard requires three OBX segments, one for each impression. By recording 1 in the sub-ID of the first of these OBX segments, 2 in the second, and 3 in the third, each OBX segment can be uniquely identified for editing or replacement. The sub-identifier can be further extended by adding decimals (e.g., 2.1, 2.2). It is strongly recommended that numeric values be used for laboratory-based reporting so that receiving applications can easily maintain the relational quality of the data.

The sub-identifier also is used to group related components in reports such as surgical pathology. It is traditional for surgical pathology reports to include all the tissues taken from one surgical procedure in one report. The example below has two segments of the report, one for each of the two tissues, the right colon, and the Rectosigmoid colon. Thus, there are two site-of-origin segments, there are two gross description segments, and there are two microscopic segments. Segments that apply to the right colon all have the sub-identifier 1.

Segments that apply to the Rectosigmoid colon all have sub-identifier 2. The use of the sub-ID to distinguish repeating OBXs for the same observation ID is really a special case of using the sub-ID to group related subdivisions of information within the overall observation category. In such multi-specimen cases, this value must be populated. This field must be used carefully to avoid introducing ambiguities.

Example of sub-identifier usage for narrative reports:

```
OBR|1||97 810430^SOMELABNAME^12D4567890^CLIA |11529-5^Surgical pathology
    study^LN|... |||||||||202011091000|202011100900|||||||||||||1A-97
    810430^^^PATHCONSULTANTS

OBX|1|ST|22633-2^Pathology report site of origin NarrativeNarrative^LN|1|right
    colon…

OBX|2|TX|22634-0^Pathology report gross observation Narrative^LN|1|A: Specimen #1
    is labeled "colon" and consists of a segment of bowel measuring 13cm in length
    after fixation…

OBX|3|TX|22635-7^Pathology report microscopic observation Narrative Other
    stain^LN|1|A:  Sections show two biopsies of colon in which there is mild chronic
    inflammation in the lamina propria.      The colonic glands are regular and the
    goblet cell population is preserved.      There is no evidence of dysplasia or
    malignancy in the plane of sections examined…

OBX|4|TX|22637-3^Pathology report final diagnosis Narrative^LN|1|A:   BIOPSIES OF
    RIGHT COLON – NO EVIDENCE OF DYSPLASIA OR MALIGNANCY…

SPM|1|^97 810430||TISS^Tissue^HL70487||||C189^Colon NOS^ICDO3
    |||||||||202011091000|202011100900|||||||||||||1A-97 810430^^^PATHCONSULTANTS

OBR|2||97 810430^SOMELABNAME^12D4567890^CLIA|11529-5^Surgical pathology
    study^LN|...

OBX|1|ST|22633-2^Pathology report site of origin Narrative^LN|2|Rectosigmoid colon,
    biopsy…

OBX|2|TX|22634-0^Pathology report gross observation Narrative^LN|2|B: The specimen
    consists of a single dark tan, multi-lobulated sessile polyp that measures 2.1…

OBX|3|TX|22635-7^Pathology report microscopic observation Narrative Other
    stain^LN|2|B: Sections show invasive, moderately differentiated adenocarcinoma…

OBX|4|TX|22637-3^Pathology report final diagnosis Narrative^LN|2|B: ADENOCARCINOMA
    IN A BACKGROUND OF A TUBULAR ADENOMA…
```

```
SPM|2|^97 810430||TISS^Tissue^HL70487|||||C199^Rectosigmoid
  junction^ICDO3|||||||||||202011091000|202011100900||||||||||||||||1B-97
  810430^^^PATHCONSULTANTS
```

Use of OBX-4 in structured reports:

The Observation sub-ID is used to link certain types of multi-part answers. Multiple question-answer pairs that are grouped together under a particular heading should be linked together with the OBX-4 sub-ID field to preserve their association. However, this is not an absolute requirement, as some systems may be unable to construct this linkage. See Section 3.4.2.2 Synoptic Segmented in Chapter 3 for additional guidance.

OBX-5 Observation Value (Data type varies, User-assigned, Required, Repeating maximum 12) 00573

Definition: The results of the test appear here. For cancer registry reporting, the text of the pathology report (e.g., nature of specimen, gross pathology, final diagnosis) will be recorded in this segment. OBX-3 is typically referred to as the question code, and OBX-5 is referred to as the answer code. If multiple results or different sections of the pathology report are being reported for a case, it is recommended that they be entered in separate OBX segments. (See Chapter 3 for an example of a pathology report with multiple OBX segments.)

Below are some examples of segments for the transmission of text pathology report data.

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN||Malignant lymphoma,
  small B-cell type with plasmacytic differentiation and crystal-storing
  histiocytosis|...
```

```
OBX|1|TX|22636-5^Pathology report relevant history Narrative^LN|| The patient was a
  58 year-old woman who had inflammatory ductal carcinoma of the left breast
  diagnosed on a core biopsy in January 2005. An axillary lymph node was positive
  for metastatic disease on a concurrent FNA. The tumor was found to be ER-
  positive, PR-negative, and Her2-Neu weakly positive. Workup for further
  metastatic disease found multiple lesions in the liver and spine as well as a 5
  cm mass in the upper pole of the left kidney. She received neoadjuvant
  chemotherapy and then underwent a modified radical mastectomy in September 2005
  that found extensive primary tumor as well as metastases in 14 of 14 axillary
  lymph nodes.|...
```

For laboratory-based reporting, SNOMED CT is strongly recommended for OBX-5 whenever the CWE (coded element) data type is indicated in OBX-2. If CWE appears in OBX-2, it is assumed that OBX-3 uses a LOINC code and the result in OBX-5 is coded using SNOMED CT, ICD-10-CM, or CPT. OBX-5.3 indicates the coding system used based on a code from the table of the coding systems (Table 0396).

When numeric results are sent in OBX-5, the SN or NM data type is preferred for OBX-2 and, thus, SNOMED CT is not required. OBX-5 may have either the SNOMED CT code for "positive" or the SNOMED CT-specific names of organisms identified in the tests described in OBX-3. It is strongly recommended that the SNOMED CT code be used for the modifiers "positive" and "negative." Other modifiers should be avoided, such as "limited findings," "insufficient specimen," "patient not at bedside," or "see technician." Further information on SNOMED CT can be found at the SNOMED CT website at http://www.snomed.org.

Examples:

An example for a SNOMED CT-coded final diagnosis:

```
OBX|1|CWE|22637-3^path report.final diagnosis^LN||82711006^Infiltrating duct
  carcinoma^SCT|...
```

An example for malignant melanoma as final diagnosis; has an ICD-10-CM Disease Code in OBX-5:

```
OBX|1|CWE|22637-3^Path report.final diagnosis^LN||C43.30^Malignant melanoma of
  other and unspecified parts of face^I10C|...
```

An example for the transmission of CPT-coded elements:

```
OBX|1|CWE|33721-2^Bone marrow pathology biopsy report^LN||38221^Diagnostic bone
  marrow biopsy^C4|...
```

An example with the transmission of an ICD-10-PCS Procedure Code:

```
OBX|1|CWE|21938-6^Surgical approach^LN||OBTJ0ZZ^Resection of left lower lung lobe,
  open approach^I10P|...
```

An example for the transmission of an ICD-O-3-coded element for histology:

```
OBX|2|CWE|31205-8^Histology ICD-O-3^LN||98613^Acute myeloid leukemia NOS

      ^ICDO3|...
```

An example for the transmission of an ICD-O-3-coded element for a tumor site:

```
OBX|11|CWE|22035-0^Primary site Cancer^LN||C11.3^Anterior wall of nasopharynx

      ^ICDO3|...
```

An example of a CWE data type for primary site with the version of the SNOMED CT code system noted in the OBX-5:

```
OBX|1|CWE|21855-2^Primary site Cancer^LN||93796006^Primary malignant neoplasm of
  female breast^SCT^^^^20230131|...

OBX|14|CWE|405979002^ Pathologic TNM Stage^SCT

||373204007^pT1b: Tumor more than 0.5 cm but not more than 1.0 cm in greatest
  dimension (breast)^SCT^^^^20070731||||||F
```

An example of a complete OBX segment coded for reported age of the patient at time of specimen collection:

```
OBX|1|NM|21612-7^Age Patient Qn Reported^LN||47|yr^year^ANSI+|...
```

Similarly, a complete OBX segment for patient employment would appear as:

```
OBX|2|TX|11294-6^Current employment Narrative - Reported^LN||coal miner||||||F
```

An example for malignant melanoma as final diagnosis; has an ICD9-CM in OBX-5:

```
OBX|1|CWE|22637-3^Path report.final diagnosis^LN||C43.3^Malignant melanoma Other
  and unspecified parts of face^I10C|...
```

An example with two separate OBX rows. The first row pertains to nature of specimen and has a CPT-4 code in the OBX-5 field. The second row has final diagnosis (morphology as both histology and behavior) sent using ICD-O-3:

```
OBX|1|CWE|22633-2^Path report.nature of specimen^LN||85097^Bone marrow biopsy^C4|...
   OBX|2|CWE|59847-4^Histology and Behavior ICD-O-3^LN||98613^Acute myeloid leukemia

NOS^ICDO3|...
```

When numeric results are sent in OBX-5, the SN or NM data type is preferred for OBX-2.

Here is an example for NM, which includes the units:

```
OBX|1|NM|^^^LN||2.8|cm^CentiMeter^UCUM|...
```

Here is an example for SN, which includes the units:

```
OBX|1|SN|74860-8^ERBB2 gene copy number/nucleus in Tissue by
  FISH^LN||>^6.0|{#}/{nucleus}^number per nucleus^L|...
```

Where the "UCUM" style SN (structured numeric) means "greater than 6.0" gene copies per nucleus. Note this is NOT in the UCUM standard codes; the 'L' stands for Local.

```
OBX|1|SN|30457-6^Nonhematic cells/100 leukocytes^LN||^20^-^30|number of cells/100
  leukocytes^number^L|...
```

This illustrates another use of SN, in this case a range.

An example of reporting OBX-5 with a large block of text as formatted text (OBX-2 = 'FT') for easier processing by the receiving system. Format character used in cancer reporting is \X0D\\X0A\, which is a computer-readable instruction indicating the start of a new line.

> Synoptic Summary for Thyroid OBX-5; with formatting characters
>
> Synoptic Summary\X0D\\X0A\Thyroid\X0D\\X0A\Procedure: Total thyroidectomy; right paratracheal lymph node\X0D\\X0A\biopsy\X0D\\X0A\Tumor Focality: Multifocal\X0D\\X0A\Tumor Site: Right\X0D\\X0A\Tumor Size: 1.0 cm and 0.5 cm\X0D\\X0A\Histologic Type: Papillary, well differentiated\X0D\\X0A\Margins: Free; the closest inked resection margin < 0.1 cm\X0D\\X0A\Angioinvasion (Vascular Invasion): Not identified\X0D\\X0A\Lymphatic Invasion: Not identified\X0D\\X0A\Perineural Invasion: Not identified\X0D\\X0A\Extrathyroidal Extension: Not identified\X0D\\X0A\Regional Lymph Nodes\X0D\\X0A\Number of Lymph Nodes Involved: 1, level VI\X0D\\X0A\Number of Lymph Nodes Examined: 1\X0D\\X0A\Size of Largest Metastatic Deposit (centimeters): 0.2 cm\X0D\\X0A\Extranodal Extension (ENE): Present\X0D\\X0A\Pathologic Staging (pTNM):\X0D\\X0A\TNM Descriptors: m\X0D\\X0A\Primary Tumor (pT) mpT1a\X0D\\X0A\Regional Lymph Nodes(pN): mpN1a\X0D\\X0A\Distant Metastasis
>
> (pM): mpMx\X0D\\X0A\Additional Pathologic Findings: None

The above special characters would result in the printed output below.

```
Synoptic Summary:

Thyroid
Procedure: Total thyroidectomy; right paratracheal lymph node biopsy
Tumor Focality: Multifocal
Tumor Site: Right
Tumor Size:      1.0 cm and 0.5 cm
Histologic Type: Papillary, well differentiated
Margins: Free; the closest inked resection margin < 0.1 cm Angioinvasion
(Vascular Invasion): Not identified
Lymphatic Invasion: Not identified
Perineural Invasion: Not identified
Extrathyroidal Extension: Not identified
Regional Lymph Nodes
Number of Lymph Nodes Involved: 1, level VI
Number of Lymph Nodes Examined: 1
Size of Largest Metastatic Deposit (centimeters): 0.2 cm
Extranodal Extension (ENE): Present
Pathologic Staging (pTNM):
TNM Descriptors: m
Primary Tumor (pT) mpT1a
Regional Lymph Nodes( pN):    mpN1a
Distant Metastasis (pM):      mpMx
Additional Pathologic Findings:     None
```

If your message contains special characters, they must be encoded with the character encodings below. Note that every new line must be replaced with \X0D\\X0A\. See previous synoptic summary example.

Character	Conversion Description
\Cxxyy\	Single-byte character set escape sequence with two hexadecimal values not converted
\E\	Escape character converted to escape character (e.g., '\')
\F\	Field separator converted to field separator character (e.g., '|')
\H\	Start highlighting not converted
\Mxxyyzz\	Multi-byte character set escape sequence with two or three hexadecimal values (zz is optional) not converted
\N\	Normal text (end highlighting) not converted
\R\	Repetition separator converted to repetition separator character (e.g., '~')
\S\	Component separator converted to component separator character (e.g., '^')
\T\	Subcomponent separator converted to subcomponent separator character (e.g., '&')
\Xdd…\	Hexadecimal data (dd must be hexadecimal characters) converted to the characters identified by each pair of digits
\X0A\	ASCII character 10; line feed
\X0D\	ASCII character 13; carriage return
\Zdd…\	Locally defined escape sequence not converted

Examples:

Original final diagnosis data exported from the laboratory information system into an HL7 message – this message will create a parsing error:

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN||Malignant lymphoma,
  small B-cell type with plasmacytic differentiation & histiocytosis|...
```

Use of \T\ encoded character reported like this will make this message properly parsable:

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN||Malignant lymphoma,
  small B-cell type with plasmacytic differentiation \T\ histiocytosis|...
```

Parser would give the following as text for the result field:

```
Malignant lymphoma, small B-cell type with plasmacytic differentiation &
  histiocytosis|...
```

OBX-6 Units (CE-250, Required or empty) 00574

Definition: This field contains the units for the observation value in OBX-5 (ISO, ANSI, or UCUM). The default value is the ISO+ abbreviation. The ISO+ and ANSI+ customary units are shown in Section 7.3.2.6.2 of the HL7 Version 2.5.1 Standard. Commonly used ISO units include grams (gm or g), kilograms (kg), millimeter (mm), centimeter (cm), milligram per milliliter (mg/mL), gram per liter (gm/L), and moles per milligram (moles/mg).

Example for ISO+:

```
OBX|||||||Ug/mL^microgram/milliliter^ISO+|
```

The units for age would be yr, wk, mo, d (in ANSI+ standards representation) in OBX-6.

Example for ANSI+:

```
OBX|||||||mo^month^ANS+|
```

Example for UCUM:

```
OBX|||||||ng/mL^Nanograms per milliliter^UCUM|
```

This field is left empty if the OBX-5 Observation value holds data that is not a measurement, such as a coded value. Note that not all numeric values are measurements; some are counts. For example, an integer indicating the number of metastases observed would not require any units in OBX-6, whereas an integer indicating the size of a lesion would require units.

Note for cancer registries: Corresponds to the NAACCR data item **Units** for Age at Specimen [7540].

In the United States, UCUM is the preferred system for reporting units. Existing laboratory systems may populate this units field using ANSI units of measure, in which case the code system should be reported using the code for the ANSI+ code system, which is "ANS+." Some laboratory systems may report using ISO units following the ISO 2955.83 standard with HL7 extensions; in this case, the code system in the third component of this field should be "ISO+."

OBX-7 References Range (ST-60, Required or Empty) 00575

Definition: When the observation quantifies the amount of a toxic substance, then the upper limit of the range identifies the toxic limit. If the observation quantifies a drug, the lower limits identify the lower therapeutic bounds and the upper limits represent the upper therapeutic bounds, above which toxic side effects are common.

If numeric, the values of this field may report several values in one of the following three formats:

lower limit-upper limit	e.g., "3.5 – 4.5"
greater than…	e.g., "greater than 10"
less than…	e.g., "less than 15"

If alphabetical, the normal value may be reported in OBX-7. For instance, the normal result on an assay may be "pink."

For those test results that have reference ranges that are known in the sending system, this field should be populated.

OBX-8 Abnormal Flags (IS-5, Required or Empty, Repeating maximum 5) 00576

Definition: This field contains the microbiology sensitivity interpretations. Refer to *HL7-Defined Table 0078 – Observation Interpretation* for valid entries.

Abnormal flags should be used for reporting microbiology sensitivity data. Abnormal flags for antimicrobial sensitivity reporting should conform to the recommendations of the National Committee for Clinical Laboratory Standards (NCCLS). For most reported findings, the allowable values are S, I, or R, and may be provided in addition to the numeric value in OBX-5. For results when a laboratory typically identifies the test as normal or abnormal, this field may be valued.

Microbiology results rarely are transmitted as part of cancer reporting, so this field is rarely valued in such reports. Other specific laboratory tests occasionally are included with cancer pathology reports, such as tumor marker tests; if the laboratory collects these abnormal flags with the results, they should be sent. For example, in HER2/neu testing, a FISH result of greater than 6.0 copies may be reported in OBX-5, and the laboratory may have a policy of reporting a positive using the abnormal flag, which is then reported using this field.

Example:

```
OBX|17|SN|31150-6^ERBB2 gene dup FISH Ql (Tiss^LN^^^||>^6.0|||POS|||F
```

Note: Only certain abnormal flags are appropriate for specific laboratory tests.

OBX-10 Nature of abnormal test (ID-2, Required or Empty, Repeating maximum 5) 00578

Definition: This field contains the nature of the abnormal test. Valid values are drawn from *HL7-Defined Table 0080 – Nature of Abnormal Testing*.

OBX-11 Observation Result Status (ID-1, Required) 00579

Definition: This field describes the status of this individual result.   Refer to *HL7-Defined Table 0085 – Observation Result Status Codes Interpretation* for valid values. This field reflects the current completion status of the results for data contained in the *OBX-5 – Observation Value* field. It is a required field. Previous versions of HL7 stated this implicitly by defining a default value of "F," indicating that the result has been verified to be correct and final.

Note for cancer registries: Corresponds to NAACCR item Path--Result Status [7330].

OBX-14 Date/Time of The Observation (DTM-26, Required or Empty) 00582

Definition: Records the time of the observation. It is the physiologically relevant date-time or the closest approximation to that date-time of the observation. This field is required in two circumstances. The first is when the observations (OBXs) reported beneath one report header (OBR) have different dates, for instance when one measurement within a battery may have a different time/date than another measurement.

Example:

```
OBX|||||||||||||200012161330|
```

Date-time of the observation also is needed in the case of OBX segments that are being sent by the placer to the filler, in which case the date of the observation being transmitted is likely to have no relation to the date of the requested observation. In France, requesting services routinely send a set of the last observations along with the request for a new set of observations. The date of these observations is important to the filler laboratories.

In all cases, the observation date-time is the physiologically relevant date-time or the closest approximation to that date-time. In the case of tests performed on specimens, the relevant date-time is the specimen's collection date-time. In the case of observations taken directly on the patient (e.g., X-ray images, history, and physical), the observation date-time is the date-time that the observation was performed.

OBX-15 Producer's Reference (CWE-250, C) 00583

Note: If you use OBX-15, also populate OBX-23, noting the difference in data type (XON)

Definition: Contains a unique identifier of the responsible entity producing service. The identifier for the producing service must be included for all cancer pathology report messages that are reported to cancer registries, and most often this is the sender of the message (laboratory) as identified in the *MSH-4 – Sending Facility.* However, when an observation in an OBX has been made by a facility other than that defined in the MSH, it must be identified here. When this field is null, the receiving system assumes that the observations were produced by the sending organization. In the United States, this is generally the CLIA identifier. In Canada, the local jurisdictional authority may mandate the use of certain identifiers for pathology laboratories; please contact the local authority for guidance. When the test results are produced at outside laboratories, the CLIA identifier for the laboratory that performed the test must appear here and will be different from the identifier listed as the sending facility in the MSH-4. Note that because the data type of this field is a CE-coded element rather than an EI (entity identifier), when populating this field the first component, "identifier," should contain the identifier of the organization; the

second component, "text," should contain the name of the organization; and the third component, Name of coding system," should contain the type of identifier, e.g., "CLIA." Conditionality predicate: Populate the identifier of the facility or organization producing this observation if different from the identifier in *MSH-4 Sending Facility* in this message.

Examples:

```
OBX||||||||||||||01D0301145^HITECK PATH LAB^CLIA|
```

or

```
OBX||||||||||||||UNIVERSITY HEALTH NETWORK^3910^MOH|
```

(where MOH [Ministry of Health] is the assigning authority for Hospital Master numbers in Ontario, Canada)

OBX-16 Responsible Observer (XCN-250, Required or Empty, Repeating maximum 5) 00584

Definition: This field contains the identifier of the individual directly responsible for the observation (the person who either performed or verified it). In a laboratory, the observer is the technician who performed or verified the analysis.

If a responsible observer is not the Principal Result Interpreter in OBR-32, then person should be recorded here.

```
OBX|31|CWE|21855-2^Primary site
  Cancer^LN||4121600^Prostate^SCT||||||F|||||57684^McCoy^Bones^M^Jr^Mr^^^01D0301145
  &HITECK PATH LAB&CLIA^L^^^EI|
```

OBX-17 Observation Method (CWE-250, Required or Empty, Repeating maximum 6) 00936

Definition: This field is used to transmit the method or procedure by which an observation was obtained when the sending system wants to distinguish among one measurement obtained by different methods and the distinction is not implicit in the test code.

The vast majority of information in a Pathology Report is textual information (contained in the OBX segment) and produced directly by the pathologist or other clinicians in the Pathology Laboratory. If this field is not populated, then the Observation Method is considered to be the usual method for that type of result (physical examination for the Gross Pathology Study, microscopic examination by the pathologist for the Microscopic Study, etc.). However, in some circumstances, the result carried in the OBX segment is generated by other means. Such means may include but are not limited to specific probes for molecular studies, codes assigned by the tumor registrar, and coded results generated by an autocoder system or Natural Language Processing (NLP) system. When this occurs, it is recommended that this field, OBX-17, be used to indicate the method of obtaining those results. The recommended codes to indicate this circumstance are:

Code	Description
CTR	Generated by Certified Tumor Registrar
AUT	Generated by Autocoder or other automated system
OTH	Other staff (other than Tumor Registrar or Pathologist)

The code system to be populated in the third component of the CWE triplet when using these codes should be "99NAACCROMC" (NAACCR Observation Method Code).

Example of a Histology code assigned by the registrar:

```
OBX|46|CWE|59847-4^Histology and Behavior ICD-O-3 Cancer^LN||81403^Adenocarcinoma,
  NOS, Malignant^ICDO3||||||F|||||||CTR^Generated by Certified Tumor
  Registrar^99NAACCROMC|...
```

Example of an anatomical location assigned by an NLP autocoder program:

```
OBX|23|CWE|21934-5^Surgery site.primary
   Cancer^LN||41216001^Prostate^SCT||||||F||||||AUT^Generated by Autocoder or other
   automated system^99NAACCROMC|...
```

For many newly emerging molecular studies, no standard or commonly used codes exist for the test method used. The following example, specifying a particular probe used in the HER2 FISH test, shows how this may be populated with a local name for the method (no local or standard code):

```
OBX|58|SN|49683-6^HER2/CEP17 Tiss FISH-Rto^LN||5.0||||||F||||||^PathVysion HER-2
   DNA FISH|...
```

OBX-19 Date/Time of the Analysis (DTM-26, RE) 01480

Definition: This field is used to transfer the time stamp associated with generation of the analytical result by the instrument specified in Equipment Instance Identifier (see above).

OBX-23 Performing Organization Name (XON-567, Required or Empty, Must Not Repeat) 02283

Definition: This field contains the name of the organization/service responsible for performing the service. When this field is null, the receiving system assumes that the observations were produced by the sending organization. The information for the performing organization is recorded as an XON data type. In the United States, the Medicare number of the performing organization is suggested as the identifier (component 10).

For laboratory, this field specifies the laboratory that produced the test result described in this OBX segment. It should be reported explicitly when the test results are produced at outside laboratories, for example. This information supports CLIA regulations in the United States. For the U.S.-producing laboratories, which are CLIA certified, the CLIA identifier should be used for the organization identifier (component 10). In Canada, use the identifier mandated by the local jurisdictional authority.

Note: If you are reporting a laboratory, due to the data type, this field cannot accept CLIA and is recommended to use FI as Facility ID (numeric).

Examples:

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN||Malignant lymphoma,
   small B-cell type with plasmacytic differentiation &
   histiocytosis||||||||||||||||||||HITECK PATH LAB-ATL ^L^^^^^FI^^^ 3D9328409|
```

OBX-24 Performing Organization Address (XAD-631, Required or Empty, Must Not Repeat) 02284

Definition: This field contains the address of the organization/service responsible for performing the service.

For laboratories, this field specifies the address of the laboratory that produced the test result described in this OBX segment. It should be reported explicitly when the test results are produced at outside laboratories, for example. This information supports CLIA regulations in the United States.

Example:

```
OBX|1|TX|22637-3^Pathology report final diagnosis Narrative^LN||Malignant lymphoma,
   small B-cell type with plasmacytic differentiation &
   histiocytosis||||||||||||||||||||HITECK PATH LAB-ATL ^L^^^^^FI^^^ 3D9328409|101 Fun
   Street^^Fun City^FL^30001^USA^B|
```

2.7.4.   Notes and Comments (NTE) Segment

The NTE segment is a common format for sending notes and comments. This optional, repeating segment may be inserted after any of the OBX segments, or the OBR segment, in the ORU message. The NTE segment applies to the information in the segment that immediately precedes it (i.e., the observation reported in the preceding OBX segment, or the type of observation identified in the OBR segment). The NTE segment is not further defined by HL7.

Note: This segment is not routinely completed and is discouraged for use when reporting to central cancer registries. However, if this section is used, it should only include general comments.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			00096	Set ID – NTE		RE	[0..1]
2	8	ID	O		0105	00097	Source of comment		RE	[0..1]
3	64k	FT	O	Y		00098	Comment		RE	[0..4]
4	250	CE	O		0364	01318	Comment type		RE	[0..1]

Example:

```
NTE|1|L|THIS WOULD BE A COMMENT THAT COMES FROM THE LABORATORY.
```

NTE Field Definitions

NTE-1 Set ID (SI-4, Required or Empty) 00096

Definition: This field may be used where multiple NTE segments are included in a message. Their numbering must be described in the application message definition.

NTE-2 Source of Comment (ID-8, Required or Empty) 00097

Definition: This field is used when the source of comment must be identified. *HL7-Defined Table 0105 – Source of Comment* may be extended locally during implementation.

NTE-3 Comment (FT-64k, Required or Empty, Repeating maximum 4) 00098

Definition: This field contains the comment contained in the segment.

NTE-4 Comment Type (CE-250, Required or Empty) 01318

Definition: This field contains a value to identify the type of comment text being sent in the specific comment record. Allowable values are given in *User-Defined Table 0364 – Comment Type.*

Note: NTE-2 already identifies one source of comment (e.g., ancillary, placer, other). However, some applications need to support other types of comment text (e.g., instructions, reason, remarks, etc.). A separate NTE segment can be used for each type of comment (e.g., instructions are on one NTE and remarks on another NTE).

2.7.5.   Specimen (SPM) Segment

The intent of this segment is to describe the characteristics of a specimen. It differs from the intent of the OBR in that the OBR addresses order-specific information. It differs from the SAC segment in that the SAC addresses specimen container attributes. An advantage afforded by a separate specimen segment is that it generalizes the multiple relationships among order(s), results, specimen(s) and specimen container(s).

A specimen is defined as "A physical entity that is an individual, a group, an item, or a part representative of a larger group, class, or whole that is the target of an observation or analysis for the purpose of drawing

conclusions about the group, class, or whole." Note that any physical entity in the universe has the potential to become a specimen.

A specimen is collected or obtained from a source and may be representative of the source or may represent a deviation within the source. A specimen may be wholly or partially consumed during an observation and any remaining portion of the specimen is persistent and can be stored.

This segment also may be used in limited cases to describe a "virtual" specimen. A "virtual" specimen can be a digital image, or some other computer representation, such as genomics data files. In particular, to identify the characteristics required for a specimen in the context of a specific observation or test.

In summary, SPM represents the attributes specific and unique to a specimen.

For cancer reporting, there are many different paths that the specimens and reports may follow, depending upon the complexity of the environment. Several diagrams in Chapter 2 illustrate the simplest flow, when all participants and HL7 users are within the same institution. This can be referred to as a "One Hospital Flow," when there is one institution, one specimen, one Patient ID, and one Specimen ID for the entire report, which is sent (when complete) to the Cancer Registry.

Alternatively, sometimes there may be very complex paths that specimens take among multiple laboratories and systems, with one or more of these laboratories reporting to the registry in addition to the facility collecting the specimen and originating the order. Please see the illustration of an example of such a complex case after the SPM attributes table, below.

As illustrated in the section on Multiple Hospital Flows in the Interaction discussion in Section 2.2.3, complex flows of information tracking among multiple institutions, several of which may assign their own Specimen ID and/or Accession Number to the case or portion thereof, must be handled. To properly address these requirements, the two fields SPM-30 and SPM-31 are being pre-adopted from the HL7 Standard version 2.7; these fields were added to HL7 at that time specifically to address these types of scenarios involving multiple identifiers for specimens in a report sent to a central monitoring or surveillance agency. These scenarios are currently active in North America and must be addressed for reporting to registries.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	4	SI	O			01754	Set ID – SPM		RE	[0..1]
2	80	EIP	O			01755	Specimen ID		R	[1..1]
3	80	EIP	O	Y		01756	Specimen parent IDs		RE	[0..1]
4	250	CWE	R		487	1900	Specimen type		R	[1..1]
5	250	CWE	O	Y	541	1757	Specimen type modifier		X	[0..0]
6	250	CWE	O	Y	371	1758	Specimen additives		X	[0..0]
7	250	CWE	O		488	1759	Specimen collection method		X	[0..0]
8	250	CWE	O		9100	1901	Specimen source site		RE	[0..1]
9	250	CWE	O	Y	542	1760	Specimen source site modifier		C	[0..1]
10	250	CWE	O		543	1761	Specimen collection site		X	[0..0]
11	250	CWE	O	Y	369	1762	Specimen role		RE	[0..1]
12	20	CQ	O			1902	Specimen collection amount		X	[0..0]
13	6	NM	C			1763	Grouped specimen count		C	[0..0]
14	250	ST	O	Y		1764	Specimen description		X	[0..0]

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
15	250	CWE	O	Y	376	1908	Specimen handling code		X	[0..0]
16	250	CWE	O	Y	489	1903	Specimen risk code		X	[0..0]
17	49	DTM	O			1765	Specimen collection date/time		R	[1..1]
18	26	DTM	O			248	Specimen received date/time		RE	[0..1]
19	26	DTM	O			1904	Specimen expiration date/time		X	[0..0]
20	1	ID	O		136	1766	Specimen availability		X	[0..0]
21	250	CWE	O	Y	490	1767	Specimen reject reason		RE	[0..2]
22	250	CWE	O		491	1768	Specimen quality		X	[0..0]
23	250	CWE	O		492	1769	Specimen appropriateness		X	[0..0]
24	250	CWE	O	Y	493	1770	Specimen condition		X	[0..0]
25	20	CQ	O			1771	Specimen current quantity		X	[0..0]
26	4	NM	O			1772	Number of specimen containers		X	[0..0]
27	250	CWE	O			1773	Container type		X	[0..0]
28	250	CWE	O		544	1774	Container condition		X	[0..0]
29	250	CWE	O		494	1775	Specimen child role		RE	[0..1]
30	20	CX	O	Y		2314	Accession ID		RE	[0..25]
31	20	CX	O	Y		2315	Other specimen ID		RE	[0..300]

Example:

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||TISS^Tissue^HL70487||||C619^Prostate^
   ICDO3|||G||3|||||200711091000|200711100900|||RN^Contamination^HL70490|||||||||A^
   Aliquot^HL70494|57482739^^^Hospital 2 Lab~987204926^^^Hospital 3
   Lab|H2_3444444^^^HOSPITAL 2 Lab~H4_3333333^^^HOSPITAL 4 Lab|
```

SPM Field Definitions

SPM-1 Set ID – SPM (SI-4, Required or Empty) 01754

Definition: This field contains the sequence number. This field is used to identify SPM segment instances in message styles where the SPM segment repeats. In messages in which the SPM segment does not repeat, this field may be empty.

SPM-2 Specimen ID (EIP-80, Required) 01755

Definition: This field contains a unique identifier for the specimen as referenced by the Placer application, the Filler application, or both.

This field may be empty, as there are HL7 use cases in which a unique specimen identifier may not exist. For Cancer reporting, this field is always populated by the Filler application, as there are always actual specimens. Filler applications would be expected to assign a Specimen ID and populate this field accordingly.

For any ORU message being sent to either a system from which a specimen was received or to the central registry, the Placer Assigned Identifier is the specimen ID that was received with the specimen from the external "upstream" system. If the message is being sent by the originating HIS, then this is the original ID assigned during the specimen collection procedure prior to sending to any pathology laboratory for the results. The Filler Assigned Identifier is the number assigned by the laboratory sending the results

(usually during the accessioning process, but for child/parts of specimens, it can be during the division of the specimen).

When a laboratory is returning a results message (ORU) to its upstream system with the information received from another laboratory it sent the specimen to, this filler number is its own number; the filler number assigned by the laboratory the reference results are received from should be populated in the SPM-31 Other Specimen ID.

Note that for complex flows among multiple institutions, each of which may assign their own Specimen ID and/or Accession Number, this field may not hold all the information from the multiple institutions. In these cases, the SPM-31 Other Specimen ID should be used to carry this additional information.

Note: When multiple physical specimens are assigned with the same ID, only a single SPM labeled with that ID in this field must describe the collection of specimens. Additional SPMs must be used if the descriptions are different.

SPM-3 Specimen Parent IDs (EIP-80, Required or Empty, Does not Repeat) 01756

Definition: This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

If this field repeats, then SPM-11-Specimen Role should be valued with "L" (pooled). The repetitions of this field then carry the specimen IDs of the parent specimens contributing to the pool.

SPM-4 Specimen Type (CWE-250, Required) 01900

Definition: This field describes the precise nature of the entity that will be the source material for the observation.

Any physical entity that may have observations made about it may qualify as a specimen. The entry in this attribute describes the specific entity as precisely as possible, whether that is a complex organism (e.g., an ostrich) or a specific cellular mass (e.g., a specific muscle biopsy).

This attribute corresponds to the first component of OBR.15 – Specimen Source and SAC.6 – Specimen Source component 1 – *Specimen source name or code.* These components, and the SPS data type, were deprecated upon the development of this segment.

A nationally recognized coding system is to be used for this field. Valid coding sources for this field include:

- *HL7-Defined Table 0487 – Specimen Type* (replaces HL7 table 0070 – Specimen Source Codes)

NAACCR supported. Note that for cancer reporting, the recommended HL7 values *HL7-Defined Table 0487 – Specimen Type* have been abbreviated in this document to those recommended for Cancer Reporting.

Example:

```
SPM||||TISS^Tissue^HL70487|
```

SPM-8 Specimen Source Site (CWE-250, Required or Empty) 01901

Definition: This field contains the source from which the specimen was obtained. For biological samples, it represents the anatomical site from which the specimen was collected.

For NAACCR values refer to *User-Defined Table 9100*.

SPM-9 Specimen Source Site Modifier (CWE-250, Conditional With Exception) 01762

Definition: This field contains modifying or qualifying description(s) about the specimen source site, such as "left" or "right". This field must be populated if 8.1 or 8.9 are populated.

Refer to User-Defined Table 9101 for a list of NAACCR values.

SPM-11 Specimen Role (CWE, Required or Empty) 01762

Definition: This field indicates the role of the sample. Refer to User-Defined Table 0369 – Specimen Role for suggested values. Each of these values normally is identifiable by the systems and its components and can influence processing and data management related to the specimen.

If this field is not populated, then the specimen described has no special or specific role other than serving as the focus of the observation. Such specimens include patient, environmental, and other specimens that are intended for analysis.

A grouped specimen consists of identical specimen types from multiple individuals who do not have individual identifiers and on which the same services will be performed. If the specimen role value is "G," then the Grouped Specimen Count (SPM-13) must be valued with the total number of specimens contained in the group.

If the specimen role is "L" for pooled specimen, then all repetitions of Parent Specimen ID (SPM-3) represent the individual parent specimens that contribute to the pooled specimen. A pooled specimen example would be urine samples that were collected over a range of time, then combined to a single sample. Typically, the single sample date/time of collection would be the first collection date/time.

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||UR^Urine^HL70487|||C619^Prostate^ICD
   O3|||G^Grouped^HL70369|||...
```

SPM-13 Grouped Specimen Count (NM, Conditional) 01763

Definition: This field provides the number of specimens that are part of the group analyzed.

Condition Predicate: Required, when SPM-11 is valued 'G'.

For example, a grouped specimen would be multiple prostate core biopsies.

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||TISS^Tissue^HL70487|||C619^Prostate^
   ICDO3|||G^Grouped^HL70369||3|...
```

SPM-17 Specimen Collection Date/Time (DR Required) 01765

Definition: The date and time when the specimen was acquired from the source. The use of the Date Range data type allows for description of specimens collected over a period of time, for example, a 24-hour urine collection. For specimens collected at a point in time, only the first component (start date/time) will be populated.

For cancer reporting, SPM-17.1 is collected using DTM and SPM-17.2 is not supported.

Note for cancer registries: This field may be used as a possible source for the following NAACCR Data items Path--Date Spec Collection [7320-7324]; Date of Diagnosis [390]; Date of 1st Contact [580]; and Date of Last Contact [1750]. During the consolidation process, the data for these NAACCR Data Items may change based on other data sources received.

NOTE: This field (SPM-17) should be used when implementing version 5.0 or more recent releases of the NAACCR Laboratory Electronic Pathology Reporting Guidelines. OBR-7 should be used for all previous versions of NAACCR Volume V.

SPM-18 Specimen Received Date/Time (DTM-24, Required) 00248

Definition: The specimen received date/time is the time that the specimen is received at the diagnostic service. The actual time that is recorded is based on how specimen receipt is managed and may correspond to the time the sample is logged in. This is fundamentally different from SPM-17 Specimen Collection date/time.

NOTE: This field (SPM-18) should be used when implementing version 5.0 or more recent releases of the NAACCR Laboratory Electronic Pathology Reporting Guidelines. OBR-14 should be used for all previous versions of NAACCR Standards Volume V.

SPM-21 Specimen Reject Reason (CWE-250, Required or Empty, Repeating maximum 2) 01767

Definition: This describes one or more reasons the specimen is rejected for the specified observation/result/analysis. Refer to *HL7-Defined Table 0490 – Specimen Reject Reason* for valid values.

Example:

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||TISS^Tissue^HL70487|||||C619^Prostate^
    ICDO3|||G||3|||||2007110 91000|200711100900||| RN^Contamination^HL70490|...
```

SPM-29 Specimen Child Role (CWE-250, Required or Empty) 01775

Definition: For child specimens, this field identifies the relationship between this specimen and the parent specimen. If this field is populated, then SPM-3-Specimen Parent ID must be populated. This field differs from SPM-15-Specimen Role in that this field refers to the role of this specimen relative to a parent role rather than the role of this specimen to the ordered service.

Refer to *HL7-Defined Table 0494 – Specimen Child Role* for valid values.

When a child specimen is the subject of additional studies and its role must be documented, this field should be populated.

SPM-30 Accession ID (CX-20, Required or Empty, Repeating maximum 25) 02314

Definition: This field contains accession identifier(s) associated with the specimen. In many cases, applications involved in the collection, transport, or testing of the specimen will assign their own accession identifiers. This field allows communication of these accession identifiers.

An accession ID may or may not, depending on laboratory practice, identify a single specimen. In addition, accession IDs are commonly re-used over time, so the accession ID may not uniquely identify a specimen. On the other hand, there is a great demand for unambiguously communicating the accession identifier(s). If the sending system has additional accession identifiers for this specimen, they must be populated in this field.

Note: The SPM-30 field SHOULD hold the original specimen identifier across every laboratory send-out downstream so that the registries can link independently received reports to the original surgical specimen. If the original specimen identifier is received with the specimen, then the receiving laboratory MUST save this original identifier and communicate it to any downstream laboratory. At a minimum, the reporting laboratory's assigned identifier and the original specimen identifier across ALL laboratories must be included in a report to a registry.

Example showing the SPM-30 field illustrating multiple accession numbers reported to the cancer registry.

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||TISS^Tissue^HL70487|||||C619^Prostate^
    ICDO3|||G||3|||||2007110 91000|200711100900||| RN^Contamination^HL70490|||||||||A^
    Aliquot^HL70494|57482739^^^Hospital 2 Lab~987204926^^^Hospital 3 Lab|...
```

SPM-31 Other Specimen ID (CX-20, Required or Empty, Repeating maximum 300) 02315

Definition: This field contains other identifier(s) for the specimen as referenced in an application. Normally this field is used to carry additional identifiers for the specimen in addition to those identified in SPM-2 Specimen ID. In many cases other applications involved in the collection, transport, or testing of the specimen will assign additional specimen identifiers. This field allows communication of those other specimen identifiers. If the sending system has additional specimen identifiers for this specimen, they must be populated in this field.

Example showing the SPM-31 field for the message in Section 2.2.4.2 *Interactions for Multiple Hospital Specimen Processing and Reporting with Consults*, illustrating how the multiple Specimen IDs that were assigned by the Hospital 2 laboratory and the Hospital 4 laboratory are reported to the cancer registry.

```
SPM|1|3444444&&123456&AHA^92756H&HITECKSPCID||TISS^Tissue^HL70487||||C619^Prostate^
    ICDO3|||G||3||||200711091000|200711100900||| RN^Contamination^HL70490||||||||A^
    Aliquot^HL70494|57482739^^^Hospital 2 Lab~987204926^^^Hospital 3
    Lab|H2_3444444^^^HOSPITAL 2 Lab~H4_3333333^^^HOSPITAL 4 Lab|
```

2.8.   HL7 BATCH PROTOCOL
There are instances when it is convenient to transfer a batch of HL7 messages for reporting to cancer registries. Such a batch could be sent online using SFTP or HTTPS.

2.8.1.   HL7 Batch File Structure
A batch of HL7 messages may be sent online using a common file transfer protocol or offline via tape or diskette. If needed, a group of batches may be sent using the file header and trailer segments. The FHS and FTS are optional and need not be sent if the transaction is one batch of records. The file/batch syntax follows:

[FHS]	(file header segment)
{ [BHS]	(batch header segment)
{ [MSH	(zero or more HL7 messages)
PID	
OBR	
....	
] }	
[BTS]	(batch trailer segment)
}	
[FTS]	(file trailer segment)

The sequence numbering protocol has a natural application in batch transfers. See the discussion of batch acknowledgments that follows. A batch for reporting to cancer registries will consist of a single type of message (i.e., ORU). Batches usually should contain at least one HL7 message. There are only two cases in which an HL7 batch file may contain zero HL7 messages: (1) a batch containing zero HL7 messages may be sent to meet a requirement for periodic submission of batches when there are no messages to send; and (2) a batch containing zero negative acknowledgment messages may be sent to indicate that all of the HL7 messages contained in the batch being acknowledged are implicitly acknowledged. The attribute tables and field definitions for batch- related segments are given below.

Related Segments and Data Usage: The following segments relate to the HL7 Batch Protocol: (1) BHS – Batch Header, (2) BTS – Batch Trailer, (3) FHS – File Header, and (4) FTS – File Trailer. The BTS segment contains a field, *BTS-3-batch totals*, which may have one or more totals drawn from fields within the individual messages. The method for computing such totals resides with the sending facility.

2.8.2.   Acknowledging Batches

In general, the utility of sending batches of data is that the data are accepted all at once, with errors processed on an exception basis. However, it is a permissible application of HL7 to acknowledge all messages. Several options for acknowledgment are given in the HL7 Version 2.5.1 Standard and are not addressed further here.

2.8.3.   Batch Segments

2.8.3.1. File Header (FHS) Segment

The FHS segment is used to head a file (group of batches). Ideally, a single sending facility, for instance a regional laboratory for a hospital consortium, could send a group of batches of reportable findings from separate laboratories within the consortium. In this setting, each separate BHS would have a different CLIA identifier.

The FHS would have a different CLIA number as well or would have the same CLIA number as the one batch that was performed at the sending facility. This complexity of message processing is not common yet, either at laboratories or cancer registries. The description of batch reporting in this guide demonstrates reporting from a single facility and thus the CLIA number is the same for MSH, BHS, and FHS. This segment is required for batch submissions only.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinalty
1	1	ST	R			00067	File field separator		R	[1..1]
2	4	ST	R			00068	File encoding characters		R	[1..1]
3	227	HD	O			00069	File sending application		RE	[0..1]
4	227	HD	O			00070	File sending facility		R	[1..1]
5	227	HD	O			00071	File receiving application		RE	[0..1]
6	227	HD	O			00072	File receiving facility		RE	[0..1]
7	26	DTM	O			00073	File creation date/time		R	[1..1]
8	40	ST	O			00074	File security		RE	[0..1]
9	20	ST	O			00075	File name/ID/type		RE	[0..1]
10	80	ST	O			00076	File comment		RE	[0..1]
11	20	ST	O			00077	File control ID		RE	[0..1]
12	20	ST	O			00078	Reference file control ID		RE	[0..1]

FHS Field Definitions

Usage Notes: FHS fields 1–8 have the same definitions as the corresponding fields in the MSH segment. FHS segment was not shown in the examples, but the field definitions are provided below for reference.

FHS-1 File Field Separator (ST-1, Required) 00067

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-2 File Encoding Characters (ST-4, Required) 00068

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-3 File Sending Application (HD-227, Required or Empty) 00069

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-4 File Sending Facility (HD-227, Required) 00070

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-5 File Receiving Application (HD-227, Required or Empty) 00071

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-6 File Receiving Facility (HD-227, Required or Empty) 00072

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-7 File Creation Date/Time (DTM-26, Required) 00073

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-8 File Security (ST-40, Required or Empty) 00074

Definition: This field has the same definition as the corresponding field in the MSH segment.

FHS-9 File Name/ID (ST-20, Required or empty) 00075

Definition: This field can be used by the application processing file. Its use is not further specified.

FHS-10 File Header Comment (ST-80, Required or Empty) 00076

Definition: This field contains the free text field, the use of which is not further specified.

FHS-11 File Control ID (ST-20, Required or Empty) 00077

Definition: This field is used to identify a particular file uniquely. Use Timestamp plus a counter similar to MSH-10 to uniquely identify the file here. It can be echoed back in *FHS-12-reference file control ID*.

FHS-12 Reference File Control ID (ST-20, Required or Empty) 00078

Definition: This field contains the value of the *FHS-11-file control ID* when this file was originally transmitted. Not present if this file is being transmitted for the first time.

2.8.3.2. File Trailer (FTS) Segment
Used to define the end of a file. This segment is required for batch submissions only.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	10	NM	O			00079	File batch count		R	[1..1]
2	80	ST	O			00080	File trailer comment		RE	[0..1]

FTS Field Definitions

Usage Notes: FTS segment was not used in the given examples, but the field definitions are provided below for reference.

FTS-1 File Batch Count (NM-10, Required) 00079

Definition: This field contains the number of batches contained in the file.

FTS-2 File Trailer Comment (ST-80, Required or Empty) 00080

Definition: The use of this free text field is not further defined in the HL7 protocol.

2.8.3.3. Batch Header (BHS) Segment
Used to define the start of a batch. This segment is required for batch submissions only.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	1	ST	R			00081	Batch field separator		R	[1..1]
2	3	ST	R			00082	Batch encoding characters		R	[1..1]
3	227	HD	O			00083	Batch sending application		RE	[0..1]
4	227	HD	O			00084	Batch sending facility		R	[1..1]
5	227	HD	O			00085	Batch receiving application		RE	[0..1]
6	227	HD	O			00086	Batch receiving facility		RE	[0..1]
7	26	DTM	O			00087	Batch creation date/time		R	[1..1]
8	40	ST	O			00088	Batch security		RE	[0..1]
9	20	ST	O			00089	Batch name/ID/type		RE	[0..1]
10	80	ST	O			00090	Batch comment		RE	[0..1]
11	20	ST	O			00091	Batch control ID		RE	[0..1]
12	20	ST	O			00092	Reference batch control ID		RE	[0..1]

BHS Field Definitions

Usage Notes: BHS fields 1–8 have the same definitions as the corresponding fields in the MSH segment. BHS segment was not shown in the examples, but the field definitions are provided below for reference.

BHS-1 Batch Field Separator (ST-1, Required) 00081

Definition: This field contains the separator between the segment ID and the first real field, BHS-2-batch encoding characters. As such, it serves as the separator and defines the character to be used as a separator for the rest of the message. Recommended value is | (ASCII 124).

BHS-2 Batch Encoding Characters (ST-3, Required) 00082

Definition: This field contains the four characters in the following order: component separator, repetition separator, escape characters, and subcomponent separator. Recommended values are ^~\& (ASCII 94, 126, 92, and 38, respectively).

BHS-3 Batch Sending Application (HD-227, Required or Empty) 00083

Definition: This field uniquely identifies the sending application among all other applications within the network enterprise. The network enterprise consists of all those applications that participate in the exchange of HL7 messages within the enterprise. Entirely site-defined.

BHS-4 Batch Sending Facility (HD-227, Required) 00084

Definition: This field contains the address of one of several occurrences of the same application within the sending system. Absent other considerations, the Medicare Provider ID might be used with an appropriate sub- identifier in the second component. Entirely site-defined.

BHS-5 Batch Receiving Application (HD-227, Required or Empty) 00085

Definition: This field uniquely identifies the receiving applications among all other applications within the network enterprise. The network enterprise consists of all those applications that participate in the exchange of HL7 messages within the enterprise. Entirely site-defined.

BHS-6 Batch Receiving Facility (HD-227, Required or Empty) 00086

Definition: This field identifies the receiving application among multiple identical instances of the application running on behalf of different organizations. See comments for BHS-4-batch sending facility. Entirely site- defined.

BHS-7 Batch Creation Date/Time (DTM-26, Required) 00087

Definition: This field contains the date/time that the sending system created the message. If the time zone is specified, it will be used throughout the message as the default time zone.

BHS-8 Batch Security (ST-40, Required or Empty) 00088

Definition: In some applications of HL7, this field is used to implement security features. Its use is not yet further specified.

BHS-9 Batch Name/ID/Type (ST-20, Required or Empty) 00089

Definition: This field can be used by the application processing the batch. It can have extra components if needed.

BHS-10 Batch Comment (ST-80, Required or Empty) 00090

Definition: This field is a comment field that is not further defined in the HL7 protocol.

BHS-11 Batch Control ID (ST-20, Required or Empty) 00091

Definition: This field is used to uniquely identify a particular batch. Use Timestamp and a counter similar to MSH-10 to uniquely identify the batch. It can be echoed back in the BHS-12-reference batch control ID if an answering batch is needed.

BHS-12 Batch Reference Batch Control ID (ST-20, Required or Empty) 00092

Definition: This field contains the value of the BHS-11-batch control ID when this batch was originally transmitted. This field is not valued if this batch is being sent for the first time.

2.8.3.4. Batch Trailer (BTS) Segment
Used to define the end of a batch. This segment is required for batch submissions only.

Seq	Len	DT	Opt	RP #	Tbl#	Item#	Element Name	NAACCR Item #	NAACCR Usage	NAACCR Cardinality
1	10	ST	O			00093	Batch message count		R	[1..1]
2	80	ST	O			00094	Batch comment		RE	[0..1]
3	100	NM	O	Y		00095	Batch totals		RE	[0..4]

<u>BTS Field Definitions</u>

Usage Notes: BTS segment was not shown in the examples, but the field definitions are provided below for reference.

BTS-1 Batch Message Count (ST-10, Required) 00093

Definition: This field contains the count of the individual messages contained within the batch.

BTS-2 Batch Comment (ST-80, Required or Empty) 00094

Definition: This field is a comment field that is not further defined in the HL7 protocol.

BTS-3 Batch Totals (NM-100, Required or Empty, Repeating maximum 4) 00095

Definition: This field contains the batch total. The numbers of messages should be counted and represented here to allow recipients to have simple batch-level auditing.

3. Creating OBR/OBX Segments for Anatomic Pathology and Biomarker Reports

3.1. NARRATIVE AND SYNOPTIC REPORTS

This chapter primarily addresses reports from anatomic (surgical) pathology laboratories. These reports may include anatomic pathology data as well as ancillary pathology studies (e.g., molecular biomarkers, gene mutations, etc.) contained in a single report. While the instructions in this chapter primarily focus on initial resection and biopsy procedures, they also may be used for other report types (e.g., consult, autopsy, cytogenetics, cytology) that fit one of the synoptic report formatting categories outlined below.

As described in section 4 the traditional **narrative** pathology report may be **unstructured**, i.e., produced as a single block of text, or it may be **structured** into sections (e.g., specimens, gross, microscopic, final diagnosis, etc.). **Unstructured** narrative reports are generally included within a single OBX row. **Structured** narrative sections use multiple OBX rows, and begin their separate OBX rows with a LOINC descriptor in OBX-3 (section1.5.2.2, Table 1) to identify which section of the pathology report is being reported in OBX-5 (see section 1.5.2.2 and Appendix E). In unstructured and structured **narrative** reports, multiple pathological findings are often generally found in a single OBX-3 text block in a single OBX row. The text blocks may have substantial variations in clinical content, terminology, and structure, and thus require manual parsing and mapping to individual NAACCR data items.

A better level of report formatting uses the **synoptic** style, promoted by the College of American Pathologists (CAP), and described in Appendix A. Synoptic reports divide individual pathological findings into separate question/answer (data element, DE) areas, but this DE layout may take a variety of textual formats that are difficult to process automatically. In many cases, synoptic reports are formatted so poorly that they must be handled as one or more blocks of unstructured text, with each text block and all its pathological findings (i.e., all DEs) placed within a single OBX row. This style of reporting is called a **synoptic summary**; for HL7 messaging, the pathological findings are sometimes handled as a single text block in a single OBX row, in a similar manner to the **unstructured narrative** format described above. This synoptic format is not recommended since it requires labor-intensive manual data extraction.

CAP Cancer Protocol (CCP)-based **synoptic summaries** should be formatted according to section 3.4.1 for the first 3 OBX metadata rows, which describe the CAP Cancer Protocol (CCP) in use for the report. If the CCP report data is **unstructured**, it is placed in a single OBX (the 4th OBX) following the first 3 metadata OBX rows; see section 1.5.2.1 (Unstructured Narrative) for encoding the report content. If the CCP report is a **structured narrative**, see section 1.5.2.2 (Structured Narrative) for encoding the report content, starting with the 4th OBX.

Non-CAP synoptic summaries do not need to use the first 3 OBXs to hold report metadata (section 3.4.1). However, if a synoptic template was used and information is available, it should be encoded as described in section 3.4.1. Non-CAP **synoptic summaries** in **unstructured narrative** format are processed according to section 1.5.2.1. Non-CAP **synoptic summaries** in **structured narrative** format are processed according to section 1.5.2.1.

Within the broad definition of synoptic report layouts, the preferred synoptic print report layouts utilize a single line of information for each discrete pathological finding (DE), with a separate question part and a separate answer part for each DE. In the context of an HL7 message, synoptic HL7 reporting uses one OBX row for each DE, where the question part is placed in OBX-3, and the answer part is placed in OBX-5. This style of reporting is termed a **synoptic segmented** report, in which each DE is placed into its own OBX segment row. See section 3.4.2 and Appendix E for more information.

Narrative, **synoptic summary** and **synoptic segmented** HL7 formatting all result in messages that require a degree of manual processing. CAP's fully computer-readable electronic Cancer Protocol (**CAP eCP**) technology[9] was designed to address this problem. Because the eCP format is standardized and encoded with stable identifiers (**ID**s) for each DE question and answer choice, it provides a direct path to fully automated HL7 message handling. Since the CAP eCP model can be used to fully automate the creation, parsing, mapping and registry-incorporation of standardized cancer reports, the bulk of this chapter describes the creation of synoptic eCP messages that use the standard eCP **ID**s.

Currently, many eCP-based software systems are not creating HL7 messages using the eCP instructions present in this manual. Instead, they incorrectly create HL7 messages designed for non-eCP **narrative**, **synoptic summary**, and **synoptic segmented** pathology reports. These non-eCP HL7 formats should not be used with eCP software implementations. eCP software using the non-eCP formats require updating to produce the proper eCP HL7 message format, which is described in this chapter.

Although the CAP is the predominant source of anatomic cancer pathology report guidelines in North America, many centers use custom report content and formats that do not adhere strictly to the CAP pathology content or synoptic formatting guidelines. In addition, pathology reports that do not involve primary tumor resections often use ad-hoc formatting that can be challenging to convert into optimal HL7 representations. Internationally, pathology agencies may develop their own local standards for cancer pathology reporting. Some of these non-CAP-adherent approaches adopt a variant of synoptic layouts for human-readable reporting and also for HL7 message creation, and they may fall into the **synoptic summary** or **synoptic segmented** classification, thereby enabling message processing according to the rules for these report styles that are described in this chapter. At this time, standard **ID**s and terminologies for non-CAP content are not available, so the eCP style of HL7 message processing will not be possible in these cases.

Reports that exist as one or more non-synoptic or mixed synoptic/non-synoptic text blocks or sub-reports are handled with OBR segmentation as described in Section **Error! Reference source not found.**. Each p athology sub-report in a multipart (multi-report) HL7 transmission will use a separate OBR segment. Each OBR segment should use the NAACCR Laboratory Electronic Pathology Reporting Guidelines instructions appropriate for that OBR's content (narrative unstructured, narrative structured, synoptic summary, synoptic segmented and eCP).

3.2.   OBR SEGMENT VARIANTS IN PATHOLOGY REPORTS

Section 2.7.2 describes the details of OBR segment construction. Here, we focus on special considerations for transmitting variations of anatomic pathology and biomarker reports. These reports may include several sub-reports or components, adding complexity to message creation and processing.

A single NAACCR Laboratory Electronic Pathology Reporting Guidelines transmission ideally should provide a pathology report derived from a single burst of laboratory activity based on a specimen or specimens derived from that one episode of care, such as a biopsy or resection procedure. Separate messages may be generated for each type of laboratory activity (e.g., cytology, anatomic pathology, flow cytometry, biomarkers, etc., or any combination of these).

Multiple tumors: In the case of multiple tumors diagnosed at the same time, ideally, separate Laboratory Electronic Pathology Reporting Guidelines messages should be generated for each tumor type. However, this may not be possible when multiple tumors are described in a single report generated by a pathology laboratory (see Appendix E for examples).

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[9] These were previously called CAP electronic Cancer *Checklists* (eCCs).

Multiple OBRs: In many cases, a Laboratory Electronic Pathology Reporting Guidelines message will consist of several OBR segments, each of which will contain multiple OBX rows that represent the pathology report. For messages with both narrative and eCP-formatted OBRs, the contents of each OBR report may differ somewhat, and this is the common practice for narrative reports accompanied by eCP-based message data. For example, a mixed narrative/synoptic report from a single resection may contain gross, narrative report and/or final diagnosis sections combined in one OBR/OBX segment group that is separate from the eCP OBR/OBX segment group.

Separate OBR for each modality: Reports of different testing modalities, such as anatomic pathology, cytology, molecular pathology and/or flow cytometry, should be included in separate OBR-OBX sets (one OBR per testing modality), unless they have been merged into a single report at the sending site.

Single OBR for merged modalities: Reports of multiple testing modalities may be included in a single OBR message. Results derived from a small group of tightly related specimen collection events and procedures on the specimen may be formed as a merged or unified report. For example, flow cytometry data often are merged with hematopathology reports into a single unified or composite report.

In summary, each Laboratory Electronic Pathology Reporting Guidelines message will contain at least one OBR segment. When more than one report format (e.g., narrative plus eCP) or separate report components (e.g., separate cytology and anatomic pathology reports) are transmitted in a single message, each report format and report type will be found in its own OBR segment in the message.

OBR-4: This field is the Universal Service ID, which indicates the type of report that is being transmitted in the OBX rows that follow it. For populating OBR-4, refer to the table in Section 2.7.2 for the correct report type value.

Report Type Descriptors in the OBR and OBX Segments for CCP-based Reports: Three basic synoptic report types are considered in this chapter. The OBR group for each synoptic report type requires special handling, as introduced in the next section.

3.2.1.   OBR/OBX Patterns in Pathology Reports

The division of pathology report styles into 2 non-synoptic and 3 synoptic report types allows us to optimize the HL7 OBR/OBX content handling approach for each reporting style. The major HL7 patterns are summarized in the following table. More detailed information will be presented later.

For any **synoptic** report derived from a CAP Cancer Protocol (CCP), the first 3 OBX rows under the report OBR contain metadata about the CCP and eCP template (if used).   If a non-CCP/eCP **synoptic** report is used, the same three metadata OBX rows are still used, albeit without CAP-specific values; information about the non-CAP report is included instead.

The content of a synoptic pathology report follows these 3 metadata OBX rows. The report content may be found in one or more OBX rows, depending on the Report/OBR style. The **synoptic summary** report contains a single OBX row containing the entire synoptic report in one narrative text block. The **synoptic segmented** report contains one OBX row per DE in the report. The CAP eCP report additionally includes the eCP `ID`s that uniquely identify the questions and selected answers from the original eCP XML template. Additional metadata OBX rows are not required for CCP/eCP-based synoptic reporting and should be avoided; there is no standard way to process unexpected/undefined metadata. Some synoptic and eCP OBX rows may contain optional OBX data such as mapped LOINC, SNOMED CT and ICD-O-3.2 codes.

For **narrative** reports, there are no defined rules for including OBX rows with report metadata, so ad-hoc metadata rows may be found using different patterns and in different locations under the report's OBR segment. However, there are 2 main patterns for including the pathological findings. The **unstructured**

narrative pattern uses a single OBX row to contain the entire report, whereas the **structured narrative** pattern uses a separate OBX segment (row) for each section structure (e.g., specimens, gross, microscopic, final diagnosis, etc.) in the report (see section 1.5.2.2).

Report/OBR Style	Metadata OBX Rows per OBR	Content OBX Rows
Synoptic Report Styles		
Synoptic summary	3 metadata OBX rows (section 3.4.1)	1 OBX with the synoptic text summary (section 1.5.2.1)
Synoptic segmented	3 metadata OBX rows (section 3.4.2)	1 text-based OBX per synoptic DE (section 1.5.2.2)
CAP eCP	3 metadata OBX rows (section 3.4.3)	1 `ID`-based OBX per synoptic DE (section 3.5)
Narrative Report Styles		
Unstructured narrative	None	1 OBX per report (section 1.5.2.1)
Structured narrative	ad hoc, if used	1 OBX per report section (section 1.5.2.2)

3.3.   THE CAP CANCER PROTOCOLS (CCPS)

The CCPs are detailed guidelines for creating complete standardized pathology reports for new cancer cases. Each CCP contains one or more case summaries (i.e., checklists or templates) and extensive background notes with instructions for completing the case summaries. The widespread use of the CCPs for cancer resections is driven by a requirement to use them for laboratory and/or cancer center accreditation by CAP and the American College of Surgeons Commission on Cancer (CoC). In many cases, CCPs for biopsies and biomarkers are also used, but this is less widespread because few biopsy and biomarker CCPs are required for laboratory or cancer center accreditation. As a national entity that sets standards and accredits cancer programs, CoC-accredited cancer programs treat [more than 70 percent of all cancer patients nationwide](#).

3.3.1.   CCP-Derived Reports

CCPs are used in three main workflows, including dictation from the case summary template, the use of Word macros, and increasingly, the use of the computer-readable eCP XML format.

The eCPs allow developers to automate the creation of data entry forms in software systems, which include Laboratory Information Systems (LIMS), Anatomic Pathology (AP) software, electronic health record (EHR) systems, and middleware software that connects to EHR and pathology systems. CCPs are freely available to all on the CAP website, and the eCPs are available for registry and nonprofit research work with a free license from CAP (email: capecc@cap.org). Regardless of the CCP workflow employed, CAP and CoC urge pathologists to produce reports in a streamlined question-answer layout known as the "synoptic report," as described earlier, and in Appendix A.

3.3.2.   CAP eCP Report Messages

eCP-based pathology reports are formatted in synoptic style.   They also have the capacity to be transmitted automatically to registries and clinical nodes in a well-defined structure and computer-readable format. This format does not require manual parsing or the use of Natural Language Processing (NLP) approaches to be incorporated automatically into registry or clinical software. Each section, question, and answer in an eCP template (the XML version of a CCP case summary) has a unique identifier (`ID`). eCP `ID`s appear as a decimal number according to CAP's "Ckey" or "Composite Key" `ID` format.

eCP XML is the computer-readable blueprint that laboratory software uses to create data entry forms for eCP pathology reporting. It contains all of the information needed to construct an eCP-based OBR segment group.[10] Prior versions of eCP XML formats were called "legacy eCC" and later, "enhanced eCC" (enh eCCs). The production of these XML formats ceased in 2018. These older eCP formats were replaced by a new XML format called Structured Data Capture (SDC). For more information, refer to https://github.com/IHE-SDC-WG.

Vendors extract the information from the eCP XML and render data-entry forms for pathologists to complete. Vendor systems must retain the eCP XML metadata so that it can be used to transmit all pathology report data in an unambiguous, complete, and interoperable manner.

In recent years, much effort has been devoted to maintaining close levels of conformance between the site- specific data item (SSDI) data elements, the CAP eCP structures, and the American Joint Committee on Cancer (AJCC) requirements for data collection. To build on this conformance process, the eCP **ID**s are being mapped to appropriate ICD-O-3 codes when applicable (for histologies and primary tumor site).

The **ID**s are also being mapped to NAACCR data item fields and codes (as found in the NAACCR Data Dictionary and the SSDI, STORE, and Grade manuals) and to SNOMED codes. This mapping work eventually will enable much more robust interoperability between registries and clinical research efforts. However, this interoperability will only be available for eCP data sets, because text-based reports cannot be readily transformed into registry-conformant codes.

New and improved versions of the CCPs and eCPs are released up to four times a year by the CAP, and this can introduce some version-management issues. To this end, CAP maintains an online eCP XML comparison tool that allows eCP users to compare any two versions of an eCP template released since 2009 and produce a detailed difference report in a variety of formats. The eCP XML comparison report allows registry users to study how eCP data element changes could affect registry data collection in the past, present, and future.

3.4.   OBX MANAGEMENT FOR THE THREE TYPES OF SYNOPTIC REPORTS

A CAP CCP or eCP-derived synoptic report message may be either in a **synoptic summary** message style, a **synoptic segmented** message style (without special eCP **ID**s for the questions and answers), or a **synoptic eCP** message that is additionally encoded with **ID**s. These types of reports are distinguished by the *first OBX row* in the report (see table below), which indicates which message type is being reported.

OBX-3.1 Value (LOINC code)	OBX-5 Value (Document Source Style)	Explanation
60573-3	CAP Synoptic Summary	**Synoptic Summary message**
60573-3	CAP Synoptic Segmented	**Synoptic Segmented message**
60573-3	CAP eCP	**CAP Synoptic electronic Cancer Protocol (eCP) message**

If a non-CAP-based **synoptic summary** or **synoptic segmented** report is used, then the word "CAP" must not be used in the OBX-5 value. At this time, the **CAP eCP** report and message structure is limited to the reporting of CAP eCPs, and must not be used for other types of reports.

Later sections describe in detail how to report each of the first three OBX segments.

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[10]The segment group was introduced in HL7 Version 2.5.1 and completed in HL7 Version 2.6.

3.4.1. Synoptic Summary

Synoptic Summary reports are pathology reports that are in synoptic format for human reading but are *not* processed as one OBX per question-answer pair in the HL7 message and are *not* considered to be proper synoptic NAACCR Laboratory Electronic Pathology Reporting Guidelines messages. These types of report messages are processed similarly to narrative-style messages (one OBX contains the entire report or sub-report), regardless of their synoptic report origin. This style of reporting should be avoided. In particular, eCP data must not be transmitted in this format.

To create a synoptic summary message format, the first three OBX rows should identify the CAP or non-CAP template in use. If the synoptic summary is not based upon a CCP or other standard template, then the first three OBXs described in this section should be omitted entirely.

The **first OBX row** in the OBR group will indicate the type of template that was used to construct the report:

- OBX-1 will be **1**

- OBX-2 will be **TX**

- OBX-3.1 will contain LOINC code **60573-3**

- OBX-3.2 will contain the text: **Report template Source**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**

- OBX-5 will contain the text: **CAP Synoptic Summary**

  - For templates that are not derived from a CCP, this OBX value must *not* be **CAP Synoptic Summary**. Instead, this OBX-5 value must identify the template system in use (e.g., "State U. Medical Center", and end with the words " **Synoptic Summary** ", yielding, e.g., "State U. Medical Center **Synoptic Summary**".

The **second OBX row** in the OBR group will contain the identifier of the specific template used to construct the report:

- OBX-1 will be 2

- OBX-2 will be **TX**

- OBX-3.1 will use the LOINC code **60572-5**

- OBX-3.2 will contain the text: **Report template ID**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**

- OBX-5 will contain the CAP title of the CCP case summary (or non-CCP template name/ID) used for the report. The CCP case summary title is found at the top of the first page of each case summary.

The **third OBX row** in the OBR group will contain the version of the CCP or other template used to construct the report:

- OBX-1 will be 3

- OBX-2 will be **TX**

- OBX-3.1 will contain LOINC code **60574-1**

- OBX-3.2 will contain the text: **Report template version ID**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**

- OBX-5 will contain the version of the CCP or other synoptic template.

   - The version is found in the CCP document (or the non-CCP template document) . The CCP version ID format is similar to the following: '4.0.1.1' and is found in the upper righthand corner of each CCP case summary. It is also found in the filename of the PDF and Word version of the case summaries.

One additional OBX segment will contain question/answer content in the OBX-5 component. See section 1.5.2.1 for more information.

3.4.2.   Synoptic Segmented

A **synoptic segmented** message must not have any OBX that contains more than one question-answer pair. If the synoptic report is derived from a **CAP eCP** message template, then skip this section and follow the instructions in the section titled "CAP eCP".

To create a non-eCP (non-encoded) synoptic segmented message format from a CCP-based report, the first three OBX rows should identify the CAP template in use.

The **first OBX row** in the OBR group will indicate the type of template that was used to construct the report:

- OBX-1 will be 1

- OBX-2 will be **TX**

- OBX-3.1 will contain LOINC code **60573-3**

- OBX-3.2 will contain the text: **Report template Source**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**.

- OBX-5 will contain the text: **CAP Synoptic Segmented**

   - For templates that are not derived from a CCP, this OBX value must *not* be **CAP Synoptic Segmented**. Instead, this OBX-5 value must identify the template system in use (e.g., "Colon Cancer Resection Template", and end with the words "**Synoptic Segmented**".

The **second OBX row** in the OBR group will contain the identifier of the specific template used to construct the report:

- OBX-1 will be 2

- OBX-2 will be **TX**

- OBX-3.1 will use the LOINC code **60572-5**

- OBX-3.2 will contain the text: **Report template ID**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**.

- OBX-5 will contain the name of the CCP (or other non-CCP) template used for the report.

   - If the transmission of a *local* name for a CCP or non-CCP template is desired, then the name should be populated in the ninth component ("original text") of the CWE in the OBX-5.

The **third OBX row** in the OBR group will contain the version of the template used to construct the report:

- OBX-1 will be 3

- OBX-2 will be **TX**

- OBX-3.1 will contain LOINC code **60574-1**

- OBX-3.2 will contain the text: **Report template version ID**

- OBX-3.3 will contain the LOINC code system abbreviation: **LN**.

- OBX-5 will contain the *version* of the template:

  o The version is the CCP version found in the CCP document (or a non-CCP template version ID). The CCP version ID format is similar to the following: "4.0.1.1"

All remaining OBX question/answer rows under the parent OBR will contain the actual content of the pathology report in synoptic format, using one question-answer pair per OBX row. OBX rows for section headers and sub-headers may be interspersed as needed. The OBX rows for question/answer pairs will place the text of each question into OBX-3.2 and the answer text into OBX-5.

Because the synoptic segmented message may be derived from a formatted text report with little or no computer-readable metadata, no standard codes, terminologies, or data types (other than TX [text]) will be available in many cases.

See Appendix E.2.3 for examples of CCP-based synoptic segmented messages.

3.4.2.1. Headers and Nesting in Synoptic Segmented Messages
For line items in a report that are headers or sections containing groups of related items, such as the collection of entered data for margins, the header section is encoded in the following way: OBX-3 contains the fixed text value "Header," and OBX-5 contains the text of the header/section. This technique is not used for eCP message format reports that have eCP **ID**s (see below).

To ease the task of registries that must process the received message, it is recommended that the OBX-4 Observation Sub-ID be used to group all of the items that the header refers to with the same numeric value. The items that are "nested" within that header should all share the same OBX-4 Observation Sub-ID value that is defined in the OBX containing the header, making it easier for registries to understand the grouping of the entered information.

For example:

```
OBX|10|TX|^Header|2|Histologic grade||||||F
OBX|11|TX|^Header|2.1|Gleason Pattern||||||F
OBX|12|TX|^Primary Pattern|2.1|3|||||||F
OBX|13|TX|^Secondary Pattern|2.1|4||||||F
```

In this example, note the decimal segmentation for the "2.1" sub-header, nested under the "**2**" section header. This decimal pattern is recommended to keep the section headers in correct hierarchical (nested) alignment. The items that are "nested" within the sub-header all share the same OBX-4 Observation Sub-ID value (2.1) that is defined in the OBX containing the 2.1 header, making it easier for registries to understand the grouping of the entered information.

Some laboratories may be unable to format the message in this way, but if used, registries will have an easier time determining the grouping of the reported synoptic data.

3.4.3.   CAP eCP
The CAP eCP message style fully encodes each Question-and-Answer pair in one OBX segment row. Each OBX segment contains one or more identifiers derived from the XML template. Sending facilities

must ensure that receiving facilities are able to accept and process messages in this way. However, the eCP message format is very similar to non-eCP synoptic segmented messages, differing primarily by the inclusion of eCP **ID**s in OBX-3.1 and OBX-5, in addition to other metadata.

For eCP message format reporting, pathology system software generates data entry forms by reading the form definition metadata inside a CAP eCP XML file, which is based on the SDC XML format. Thus, for a given eCP- based report, the most generic approach to locate the requisite eCP metadata (e.g., eCP **ID**s, units, data types, title text) is to examine the SDC XML file used to create the eCP data entry form used to create the synoptic pathology report. Although it is possible to extract this eCP metadata from vendor software systems as well, each vendor maintains its metadata in a proprietary format, making those vendor formats inappropriate to use for the examples in this chapter. Because the SDC XML template is the common denominator for all eCP-based vendor systems, this document shows metadata location examples derived from the source SDC XML documents rather than from a proprietary eCP-based software system. Understanding the SDC source XML is critical to the proper validation of eCP messages. However, each creator of HL7 messages should be able to extract the same metadata directly from the vendor software system, based on the imported SDC metadata.

3.4.3.1. The OBX Report Metadata Rows for eCP-Based Reports

To recap the earlier discussion for non-eCP synoptic segmented messages, CAP eCP message format templates are identified with (a) the source/publisher of the template, (b) the ID and name of the template, and (c) the version of the template. Specific LOINC codes identify each of these:

LOINC	Definition
60573-3	Report template source
60572-5	Report template ID
60574-1	Report template version ID

These LOINC codes are used to define the content of the first three OBX-3 rows, which are found immediately following the OBR segment identifying the report as a synoptic report message. At this time, there is no special OBR code to indicate that the OBR represents an eCP-encoded synoptic report. This information must be obtained from the first OBX row.

The **first OBX row** contains this invariant string for the **Report template source**

```
OBX|1|ST|60573-3^Report template source^LN||CAP eCC||||||F
```

The following example shows how metadata for the next two OBX rows is extracted from a source SDC XML document. Below is a partial SDC XML sample from the Radical Prostatectomy eCP template. The color-shaded areas are described in the rules below.

```
<FormDesign ID="Prostate.Res.128_3.003.001.REL_sdcFDF"
baseURI="www.cap.org/eCC"
fullURI="_baseURI=www.cap.org/eCC&amp;lineage=Prostate.Res.128&amp;_
        version=3.003.001.REL&amp; docType=sdcFDF"
formTitle="PROSTATE GLAND: Radical Prostatectomy"
lineage="Prostate.Res.128"
filename="Prostate.Res.128_3.003.001.REL_sdcFDF.xml"
version="3.003.001.REL"
xmlns="urn:ihe:qrph:sdc:2016">
…
<Property name="TemplateID" type="CAPeCC_meta" order="8"
propName="TemplateID" val="128.100004300" />
…
```

In the **second OBX row:**

- OBX-2 will be "CWE."

- OBX-5.1 will contain the **eCP template ID**. This value may be found by applying the following XPath to the source SDC XML template:
  /**FormDesign**/**Property**[*@name*="TemplateID"]/*@val*

- OBX-5.2 will contain the **eCP template's (form) title**, derived from the **formTitle** attribute of the **FormDesign** element (XPath:/**FormDesign**/*@formTitle*) of the eCP SDC XML file.

Here is the second OBX row derived from the XML snippet above:

```
OBX|2|CWE|60572-5^Report template ID^LN||128.100004300
     ^PROSTATE GLAND: Radical Prostatectomy^CAPECP|||||||F
```

In the **third OBX row:**

For SDC eCP message format templates, the value for the **eCP template's version ID** is found in the **version** attribute of the **FormDesign** element of the eCP SDC XML file. The **version** may be found by applying the following XPath to the eCP's source SDC XML: /**FormDesign**/*@version*. The format of **version** is similar to the following: **3.003.001.REL**

Here is the third OBX row derived from the XML snippet above:

```
OBX|3|ST|60574-1^Report template version ID^LN||3.003.001.REL|||||||F
```

The 3 metadata OBX segments are shown below:

```
OBR|1||123456789|60568-3^Synoptic report^LN|
OBX|1|ST|60573-3^Report template source^LN||CAP eCP|||||||F
OBX|2|CWE|60572-5^Report template ID^LN||128.100004300
     ^PROSTATE GLAND: Radical Prostatectomy^CAPECP|||||||F
OBX|3|ST|60574-1^Report template version ID^LN||3.003.001.REL|||||||F
```

3.5. ECP XML COMPONENTS FOR HL7 TRANSMISSION

In eCP message format SDC XML templates, the primary data element building blocks are **Question** (Q), **ListItem** (LI; i.e., answer choice), and **Section** (S). For user-entered text and numeric responses, eCP message format SDC XML includes the **Response** and **ListItemResponse** (LIR) structures. Note that each of these SDC XML-derived components is indicated with an initial capital letter to indicate that it is a fundamental kind of SDC XML object, and is represented with an XML element, rather than an XML attribute. Each of these components and their relevant substructures will be described below.

3.5.1. Essential SDC Data Element Concepts

A data element (DE) in a CAP eCP template consists of a Question (Q) and a set of XML computer instructions that guide the user's response to that Question. In many cases, the Q is associated with a set of ListItem (LI) answer choices, and these LIs may be single-select (QS) or multi-select (QM). In other cases, a Question is set up to receive a user-entered text or numeric response (QR), and in this case, the Q contains no LI options. Sometimes, a LI can also accept a user-entered response value after that LI is selected by the user. This special type of LI is called a ListItemResponse (LIR).

3.5.2. Formatting of the Chapter Examples

Several text formatting conventions will help the reader connect regions of SDC XML, Data Entry Form (DEF) images, and HL7 message segments and fields that appear in the remainder of this chapter. These

formatting conventions are shown in the following table. XML attributes and their content may be bolded as needed for emphasis. Font and font size may change as needed.

Visual Cue	Description
`Section` (S)	SDC Section element
`Question` (Q/QR)	SDC Question element, when the Question contains a selected ListItem or a user response.
`Question title text`	The content of a Question's `title` attribute, when the Question contains a selected ListItem or a user response.
`ListItem` (LI/LIR)	SDC ListItem element and the LI `title` text, if the LI is selected by the user (when `selected="true"` in XML)
~~`Unselected ListItem`~~	LI that was not selected by the user
`Response` (R)	User-entered response to a Question
`Response` (R)	User-entered response to a *repeated* QR or LIR
__1	Repeat suffix, appended to the SDC `ID` of a repeated S, Q, LI, or LIR
`attributeName`	Most SDC XML attribute names
`"attribute value"`	Most SDC XML attribute values
`1234.100004300`	OBX-3 `ID` value; the text "OBX-3" is also colored.
`1234.100004300`	OBX-4 `ID` in an LIR response OBX, containing the parent LIR's OBX-5.1 value; The text "OBX-4" is also colored.
+`1234.100004300`	OBX-4 `ID` pointing to hierarchical parent (i.e., when + prefix is present) in the SDC XML
`1234.100004300`	OBX-5 `ID` from LI/LIR
`1234.100004300`	Original ID value in OBX-3.7 or OBX 5.7; used when the OBX represents a repeated data element. The text "OBX-3.7" and "OBX 5.7" are also colored.
`Emphasized text`	Emphasized XML and/or HL7 text, not defined above

3.5.3. The OBX 3/5 Question/Answer Pattern

In general, for each eCP data element (question/answer pair), one new OBX row is added. The OBX-3.1 and 3.2 fields contain the Question's eCP `ID` and the question text (e.g., `1234.100004300^Histologic Type`), and the OBX-5 field contains the answer data. The OBX-5 field records answer data using several related formats, as described below in detail. If more than one answer is provided for a question, then one additional OBX row is used for each additional answer. The number of OBX rows to add for various eCP question/answer patterns will be described later as well. **The OBX-5 data type** is populated in OBX-5.2. The default data type for all selected **LI** and **LIR** items will be **CWE** (coded with exceptions), to permit the eCP `ID` value to be sent as a coded answer. When OBX-5 contains a user-entered text or numeric value, then OBX-2 will reflect the data type of that value. Several examples will be provided later.

3.5.4. eCP IDs

eCP IDs use the "composite key" (Ckey) format, which is a decimal format having up to nine digits before the decimal point (the integer part), with nine digits permitted after the decimal point (the decimal part). The integer part is a curated identifier that uniquely labels an eCP Section, Question, or ListItem in a particular eCP template. The decimal part is a number (called a "namespace") assigned by CAP staff to identify the organization that is authorized to edit the eCP templates. CAP's internal namespace is "`100004300`". The trailing zeros are significant in some systems and thus should not be omitted.

eCP data elements must be transmitted using the eCP ID values for each Question and ListItem found in the eCP XML template that was used to generate the pathology report. When eCP **ID**s are used in the HL7 message, the **ID** value will be the full decimal value of the **ID**, including any trailing zeros (e.g., `1234.100004300`). The Coding System value in OBX-3.3 and OBX-5 for eCP **ID**s is "CAPECP."

Below are three examples of elements with eCP IDs from SDC XML.

```
<Section ID="17097.100004300" title="SPECIMEN (Note A)">
...
<Question ID="18225.100004300" title="Procedure">
...
<ListItem ID="18226.100004300" title="Radical prostatectomy">
```

As with all SDC metadata, these should be obtainable from within the eCP-based vendor software.

3.5.5. Question (Q)

All eCP Question data are placed in OBX-3. The eCP **ID** for the Question is placed in OBX-3.1. The **title** text for the Question is placed OBX-3.2. There are three main types of questions: **Single-Select** (QS), **Multi-Select** (QM), and **Response** (QR). The QR was previously called Question-Fillin (QF). Each of these will be explored in detail later.

3.5.6. ListItem (LI)

A ListItem is an answer choice presented to a user in a DEF, usually with a list of other LI answer choices that may be selected. The eCP **ID** for the selected answer choice is placed in OBX-5.1. The **title** content (**Radical prostatectomy** in the SDC XML example below) for the selected LI is placed in OBX-5.2. The LI was previously known as Answer (A).

Example:

```
<ListItem ID="18226.100004300" title="Radical prostatectomy" selected="true">
```
```
OBX|9|CWE|18225.100004300^Procedure^CAPECP||
OBX-5 →  18226.100004300^Radical prostatectomy^CAPECP|||||||||
```

More LI examples will be shown in the sections below.

- **Note:** In some cases, selecting an LI presents the user with a **ListItemResponseField** (LIRF), in which the user can select the ListItem and then enter a value, generally with a string or numeric data type. An LI paired with an LIRF is called the "ListItem Response" (LIR) pattern. The LIR previously was known as the Answer-Fillin (AF). (This is covered later.)

3.5.7. Single-Select Questions (QS)

Questions supplied with a list of LIs, where the user may select only one of the provided Lis in the list. Each QS with its selected LI will be transmitted using a single OBX segment row. The eCP **ID** for the selected answer choice is placed in OBX-3.1. Selection is indicated with **selected="true"** in the **ListItem** SDC XML The **title** content for the question is placed in OBX-3.2.
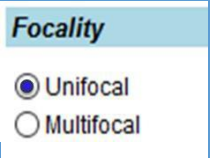
- **Exception:** If the selected LIs is an LIR, then two OBX rows will be needed for the selected LIR. (This is covered later in more detail.)

Here is an example of SDC XML for a QS that represents part of a data entry form. The inset is showing a QS (titled "*Focality*") with LIs represented by radio buttons. One LI, titled "**Unifocal**", has been selected as the answer to the QS:

```
<Question ID="39102.100004300" title="Focality" >
   <ListField>
      <List name>
         <ListItem ID="3845.100004300" title="Unifocal" selected="true" />
         <ListItem ID="3849.100004300" title="Multifocal" />
      </List>
   </ListField>
      >
</Question>
```

Focality

◉ Unifocal
○ Multifocal

The OBX row for this simple QS is shown below. (OBX-4 and the fields after OBX-5 are omitted for simplicity.)

```
OBX|5|CWE|39102.100004300^Focality^CAPECP||
OBX-5 →   3845.100004300^Unifocal^CAPECP|||||||||
```

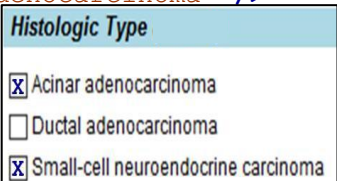### 3.5.8.   Multi-Select Questions (QM)

A QM is a Question supplied with a list of LIs, where the user may select one or more of the provided LIs. Multi-select questions with several (x) selected LIs will usually contain *x* OBX segments, where the eCP question **ID** is repeated in each of the *x* OBX-3 fields, but the OBX-5 answer field will contain the eCP **ID** for a single selected LI. The OBX segment rows repeat such that each selected LI has a single OBX row to represent it.

Exception: If a selected LI is an LIR (i.e., has an area for entering additional response data), then one extra OBX row will be needed for the selected LIR. (This is covered later in more detail.). Here is an example of SDC XML for a QM with part of a data entry form (inset):

```
<Question ID="53672.100004300" title="Histologic Type">
   <ListField maxSelections="0">
      <List>
         <ListItem ID="56746.100004300" title="Acinar adenocarcinoma"
            selected="true" />
         <ListItem ID="55730.100004300" title="Ductal adenocarcinoma" />
         <ListItem ID="50277.100004300"
            title="Small-cell neuroendocrine carcinoma"
            selected="true"/>
      </List>
   </ListField>
</Question>
```

Histologic Type

[X] Acinar adenocarcinoma
[ ] Ductal adenocarcinoma
[X] Small-cell neuroendocrine carcinoma

The **ListField** element above shows the metadata item **maxSelections="0",** which indicates that this is a QM, not a QS. The XML and the inset image show that two LIs have been selected by the user. In **ListItem**, this is represented with **selected="true"**. The OBX for the two selected LIs would look like the following example. Note that both LIs share the same OBX-5 Question metadata. (OBX-4 and fields after OBX-5 are omitted for simplicity.)

```
OBX|9|CWE|53672.100004300^Histologic Type^CAPECP||
OBX-5
→      56746.100004300^Acinar adenocarcinoma^CAPECP|||||||||
```
```
OBX|10|CWE|53672.100004300^Histologic Type^CAPECP||
OBX-5
→      50277.100004300^Small-cell neuroendocrine carcinoma^CAPECP|||||||||
```

3.5.9. The Question Response (QR) Pattern

Some questions have fill-in **Response Fields** (RFs) instead of LIs; this is the "Question-Response" (QR) pattern. In the QR pattern, the user's response (e.g., the text or number entered in the data entry form) is placed in OBX-5. Here is a QR example:

```
<Question ID="40273.100004300" title="Comment(s)">
    <ResponseField>
        <Response>
            <string maxLength="4000" minLength="0" val="My Comment!"/>
        </Response>
    </ResponseField>
</Question>
```
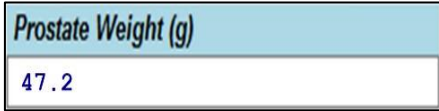
Comment(s)
My Comment!

An OBX sample follows. Note the use of "TX" (not "ST") to indicate user-entered alphanumeric content in OBX-3.1. (OBX-4 and fields after OBX-5 are omitted for simplicity.)

```
OBX|20|TX|40273.100004300^Histologic Type^CAPECP||My Comment!^CAPECP|||||||||
```

Another QR example demonstrates how a numeric data type (**decimal**) and units (grams) are encoded in the SDC XML and the OBX:

```
<Question ID="18230.100004300" title="Prostate Weight (g)" >
  <ResponseField>
    <Response>
      <decimal val="47.2"/>
    </Response>
    <ResponseUnits val="g" unitSystem="UCUM" />
  </ResponseField>
</Question>
```

Prostate Weight (g)
47.2

The OBX is shown below. "NM" (numeric) is used in OBX-2 and units metadata are in OBX-6. Note that OBX-6.2 is empty, and the **title** text "**(g)**" (which indicates units of grams) is *not* used here in OBX-6, even though to the human reader, it is related to the units metadata in the XML. See the section on units below for more information on filling OBX-6 from eCP-derived metadata.

```
OBX|6|NM|18230.100004300^Prostate Weight (g)^CAPECP||47.2|g^grams^UCUM||||||||
```

3.5.10. Title Text and Report Text

3.5.10.1. Normal title Text

The **title** attributes in the previous SDC XML examples contain the text that should appear in the pathology software data entry form. In most cases, the **title** content should appear in OBX-3.2 and OBX-5 in the HL7 message, as described later.

3.5.10.2. Handling reportText

In some cases, the **title** text should not appear in a printed pathology report. If the reported text should be different from the data entry form **title** content, it is stored in an SDC **reportText Property** that is a child element of the modified Question, ListItem, or Section element, e.g.,

```
<Question ID="17043.100004300" title="?TNM Descriptors">
    <Property propName="reportText" val="TNM Descriptors" />
...
```

In the above example, a leading "**?**" symbol in the **title** has been removed for generation of the pathology **reportText**'s **val** content (*TNM Descriptors*). Whenever possible, the text included in HL7 messages should have the **reportText** 's **val** content (*TNM Descriptors* in this case) override the **title** attribute in the parent element. This will make the HL7 message better match the printed report and prevent misinterpretation of the transmitted results.

3.5.10.3.   Reports that Omit title Text

In some cases, the **title** text used in the data entry form is completely omitted from the report. This is indicated by the use of "**{no text}**" in the **val** attribute of the **reportText** type of **Property**. In this special case, the original **title** text (e.g., **"Other histologic type not listed (specify)"** in the following example) should be used in OBX 3.2. This will provide better context to the recipient of the message.

```
<ListItem ID="16809.100004300" title="Other histologic type not listed (specify)">
    <Property propName="reportText" val="{no text}" />
...
```

3.5.10.4.   Missing title Text in Questions

In some cases, the **title** text used in a **Question** is intentionally empty (e.g., **title** = **""**), contains whitespace (e.g., **title** = **"   "**) or the **title** attribute is missing entirely from the **Question** element. This situation arises when the **Question** meaning is obvious from its surrounding context in the data entry form. This "untitled **Question**" pattern most commonly occurs when a question-answer-set data element is nested under an LI. In this case, the untitled **Question** acts as a sub-question that does not require a new **title** to infer its meaning. In these cases, the **altText Property** is used to provide reasonable alternative text for the untitled **Question** element. The **val** content from the **altText Property,** if present, should be used to populate OBX-3.2. If an untitled **Question** does not have an **altText Property** with usable (non-null, non-whitespace) **val** content, then OBX-3.2 should be populated with "**{no text}**".

In the example below, note that the **title** attribute is entirely missing in the **Question** element, so it has no usable value for OBX-3.2. Also note that there is an **altText Property** with usable **val** content. Therefore, the **val** content from the **altText Property** (**"Ductal Carcinoma in Situ (DCIS) (Note G)"**) should be transmitted in OBX-3.2.

```
<Question ID="16308.100004300" >
    <Property propName="altText" val="Ductal Carcinoma in Situ (DCIS) (Note G)" />
...
```

3.5.11.   The ListItem Response Pattern (LIR)

In some cases, a selected LI provides the user a place to enter a fill-in response after the answer is selected. This response is "attached" to the selected LI, and the pattern is called a **List Item Response** (LIR). For example, an LIR may appear in a list of LIs with special text such as "Other (specify)." If the user selects this LIR (indicated here with **selected="true"**), the user will type in the form's response field to provide a string or numeric value (**string** in this example). In this case, one *additional* OBX row is used to carry the user's response for the LIR. This extra OBX shares (repeats) the question's eCP **ID** and **title** content in OBX-3, but the selected LIR's eCP **ID** ("**10799.**100004300" in the image below) is placed in OBX-4 (*not* in OBX-5), and the user's response value ("**5**" in this example) is placed in OBX-5.

Below is an example with three **ListItemResponseField** (LIRF) element blocks. Only the first LIRF is shown; the others were omitted to save space (at the ellipsis [**...**] symbols).

Note the use of **reportText** with a value of **{no text}** in the first LIRF. This indicates that we should *not* show the LI **title** text (**Specify number**) in the report. Instead, we would substitute the user's response value, which in this case is the integer **5**. Nevertheless, for HL7 messages, the OBX message should preserve the original **title** text in OBX-5.2 when **reportText** has a value of "**{no text}**".The use of **reportText** is very common in the LIRF pattern.

```
<Question ID="4907.100004300" title="Number of Lymph Nodes Examined">
  <ListField>
    <List>
      <ListItem ID="10799.100004300" title="Specify number" selected="true" >
        <Property propName="reportText" val="{no text}" />
        <ListItemResponseField responseRequired="true">
          <Response>
            <integer val="5"/>
          </Response>
        </ListItemResponseField>
      </ListItem>
      <ListItem ID="33429.100004300" title="At least">
...
      </ListItem>
      <ListItem ID="14505.100004300" title="Number cannot be determined
      (explain)">
...
      </ListItem>
    </List>
  </ListField>
</Question>
```

Number of Lymph Nodes Examined
◉ Specify number 5
◯ At least
◯ Number cannot be determined (explain)

```
OBX|36|CWE|4907.100004300^Number of Lymph Nodes Examined^CAPECP||
OBX-5→   10799.100004300^Specify number^CAPECP|||||||||

OBX|37|NM| 4907.100004300^Number of Lymph Nodes
Examined^CAPECP|10799.100004300|
OBX-5→   5|||||||||
```

In a printed synoptic report, the **title** text is removed according to the **reportText** instructions, and this data element would thus appear as follows:
"Number of Lymph Nodes Examined: **5**.

Note that we used an extra OBX to carry the user's response (**5**) in OBX-5. Also note that the LI **ID** of the first OBX-3.1 (**10799.100004300**) was placed into OBX-4.

Note that OBX-2 contains "CWE" for the first OBX (which contains an LI **ID** in OBX-5) and "NM" for the second OBX (which contains a numeric value (**5**) in OBX-5).

3.5.12. Units of Measure

For NM types on QR and LIR OBX rows, the OBX-6 field should include the units information, whenever units metadata is available in the SDC XML template. The units can be found in the `ResponseUnits` element inside the QR's `ResponseField` or the LIR's `ListItemResponseField`, when applicable. The content of `val` and `unitSystem` in `ResponseUnits` should be used to populate OBX-6.1 and OBX-6.3. The `val` content of `TextAfterResponse` should be used to populate OBX-6.2, because this is the text that appears in the synoptic report.

When this `Response` data type element name is `string,` the OBX-2 value should be "ST." When this element name is `integer`, `decimal`, or any other numeric type, the OBX-2 value type should be "NM."

Here is an example of a `ResponseField` from a QR:

```
<ResponseField>
    <Response>
        <decimal val="10"/>
    </Response>
    <TextAfterResponse val="Millimeters (mm)"/>
    <ResponseUnits val="mm" unitSystem="UCUM"/>
</ResponseField>
```

For the above QR `ResponseField` example, OBX-6 would appear like the example below. (The value **10** was entered by the user in the data entry form, and belongs in OBX-5 [not shown]):

```
|mm^Millimeters (mm)^UCUM|
```

3.5.13. eCP Sections

Each `Section` is placed in a new OBX row. The eCP `ID` and title text are placed in OBX-3.1 and 3.2. No mapped codes are used. OBX-5 contains the word "SECTION." OBX-2 contains "ST." The inclusion of an OBX row for each `Section` is a change from the previous NAACCR Laboratory Electronic Pathology Reporting Guidelines. When used with XML and/or HL7 OBX examples, `SECTION` references receive special formatting, as shown below.

```
OBX|36|ST| 17097.100004300^SPECIMEN (Note A)^CAPECP||SECTION|||||||||
```

3.5.14. eCP Contextual Nesting and the HL7 Message Style

The SDC-based eCP templates are based on a context-preserving hierarchy that links Sections, Questions and ListItems with child → parent pointers. Maintaining these child → parent eCP linkages in the HL7 message for each Section, Question and ListItem is strongly recommended. The mechanism to represent these linkages in message transmissions is unique to the SDC model. To preserve the linkages, the parent eCP `ID` should be populated in OBX-4; the content of OBX-4 should be prefixed with a "+" to indicate that this is a parent eCP `ID`. The parent eCP `ID` is the `ID` on the first XML ancestor element that contains an `ID` attribute. Sections and Questions may have parents of Section, Question, or ListItem (or its LIR variant). Nesting to any depth is supported with this approach. Examples of nesting using OBX-4 are shown in the next section and in Appendix E.

For sending sites (e.g., Labs) unable to generate child → parent eCP linkages using OBX-4, the native nested eCP data element structure in HL7 will be effectively flattened because the internal contextual linkages between OBX rows will be missing. The flattened transmission format can result in misinterpretation of the transmitted data if the data are printed out in a flattened format and then used for

clinical purposes. Although the original layout usually can be reconstructed by repopulating the original eCP XML template with the transmitted data, this takes extra work and errors may be introduced.

3.5.15. Repeating Sections and Questions

3.5.15.1. Handling Unique IDs

Some Sections and Questions are allowed to repeat inside the data entry form, along with all of their child content. To prevent ambiguity in the HL7 message due to duplicate `ID`s, `ID`s are incremented with new unique values for each Section, Question, and ListItem in the repeated area. New repeating `ID`s are created by the data entry form software and are converted to new OBX rows. New OBX rows, with their new repeat `ID`s, are added in the same manner as in the original SDC XML.

`ID`s used in repeated SDC areas have a special format. The repeating `ID`s begin with the original unrepeated `ID` from the SDC XML, followed by two underscores (__) and a monotonically increasing integer value that is incremented by 1 for each new repeated area in the data entry form. For example, 1234.100004300 in the SDC XML would become 1234.100004300__1 for the first repeat. All descendant Sections, Questions, and ListItems in the repeated area (i.e., those Sections, Questions, and ListItems contained in the repeated Section, or subsumed by a repeated Question in the SDC XML) would have the same suffix (__1) appended to their `ID`s. This new `ID` suffix would replace the existing repeat suffix on those `ID`s, if present from a previous repeat cycle. Assignment of new `ID`s to repeated Sections, Questions, and ListItems is covered in the [SDC Technical Reference Guide](#).

3.5.15.2. Repeating Blocks in CAP eCP Data Sets

The following image displays a small section of the data-entry form rendered from the SDC XML of the Colon and Rectum Biomarker eCP template. The image shows a single SDC XML Section titled Other Markers Tested (repeat as needed). This section is designed to allow a variety of user-entered microsatellite instability molecular markers and their test results in tumor tissue. Note that each Q and LI is preceded by an SDC `ID`, which is a red numeric value, e.g., 21557. For readability, the `ID` values are shortened from their real values in SDC XML templates (e.g., 21557.1000043).

The DEF section provides a ⊞ button (➔) to repeat the QR *Specify Marker* DE together with its descendant QS (*Marker Stability*) DE. The user has entered the free text *Marker1* in the *Specify Marker* QR, and selected the **Stable** LI in the *Marker Stability* QS. The DEF user now wants to add a second marker (and its result), and is preparing to click the ⊞ button, which will replicate these nested DEs.

Figure: This image is part of an eCP form showing the *Specify Marker* data element (DE) and its descendant *Marker Stability* DE. The form user is about to press the ⊞ button (➔) to repeat the *Specify Marker* DE together with its descendant DE (*Marker Stability*).

Figure: This image shows the eCP DEF after the repeat button (+) is clicked, and new *response* data entered in the repeated part of the DEF.

In the above figure, the original DE text response (*Marker1*) and LI selection (Stable) are shown as before. The two repeated DEs are marked with green arrows (→). In the repeated DEF area, the user has entered the free text *Marker2* in the *Specify Marker* QR, and selected the Cannot be determined (explain) LI in the *Marker Stability* QS. The user also entered the text *Equivocal* in the Response part of the Cannot be determined (explain) LIR. Note that every **ID** in the repeated block begins with the original **ID**, and also shares the same **ID** suffix, **__1**. Also note that the Response value, *Equivocal*, implicitly shares an SDC Question **ID** (29570__1) with the selected LIR, Cannot be determined (explain). As described earlier, an LIR requires an extra OBX segment to handle the user-entered Response value (*Equivocal*).

Every time an SDC block is repeated, all of its major SDC components (e.g., Sections, Questions and ListItems) receive a special suffix (**__1**) on their **ID** attributes. This ensures that all SDC **ID**s remain unique throughout the SDC dataset. The suffix consists of 2 consecutive underscores followed by an integer starting with the number 1. Each time an SDC block is repeated, its original contents are copied (i.e., without user responses), and the repeat integer is incremented by 1. In the example SDC-based DEF, the next repeat suffix would be **__2**, regardless of where in the DEF it occurs.

Below is a snippet of the SDC XML that defines the above DEF, beginning with a Section (`ID="`**`21556.100004300"`**). The original instance of the repeating area starts the first with Question (`ID="`**`21557. 100004300" title="`***`Specify Marker`***`"`**), and its subsumed XML nodes. The first repeat instance of the repeated XML block starts with the repeated **Question** (`ID="`**`21557.100004300__1" title="`***`Specify Marker`***`"`**) and continues with the copied XML nodes subsumed under it. ***User-entered responses*** are highlighted in yellow. Unselected

LIs are shown with ~~gray highlight and strikeout~~. Selected LI elements contain the XML attribute `selected="true"`.

First (original) XML instance:

```xml
<!--Earlier parts of the SDC template are omitted -->
    <Section ID="2156.100004300" title="Other Markers Tested (repeat as needed)">
      <ChildItems
        <Question ID="2157.100004300" title="Specify Marker" minCard="0" maxCard="20">
          <ResponseField>
            <Response>
              <string val="Marker1"/>
            </Response>
          </ResponseField>
          <ChildItems >
            <Question ID="2925.100004300" minCard="0" title="Marker Stability">
              <ListField>
                <List>
                  <ListItem ID="2968.100004300" title="Stable" selected="true"/>
                  <ListItem ID="29569.100004300" title="Unstable"/>
                  <ListItem ID="29570.100004300" title="Cannot be determined (explain)">
                    <ListItemResponseField responseRequired="true">
                      <Response>
                        <string />
                      </Response>
                    </ListItemResponseField>
                  </ListItem>
                </List>
              </ListField>
            </Question>
          </ChildItems>
        </Question>
<!-- The following xml block shows a repeated instance that was copied from the
original (above) as a block.  Note that all of the subsumed Question and ListItem
nodes have the "__1" suffix appended to their ID attributes. Unselected ListItems are
shown with strikeout and a gray background
-->
        <Question  ID="2157.100004300__1" title="Specify Marker" minCard="0" maxCard="20">
          <ResponseField>
            <Response>
              <string val="Marker2"/>
            </Response>
          </ResponseField>
          <ChildItems>
            <Question ID="2925.100004300__1" minCard="0" title="Marker Stability">
              <ListField>
                <List>
                  <ListItem ID="29568.100004300__1" title="Stable"/>
                  <ListItem ID="29569.100004300__1" title="Unstable"/>
                  <ListItem ID="2970.100004300__1" title="Cannot be determined (explain)"
                        selected="true">
                    <ListItemResponseField responseRequired="true">
                      <Response>
                        <string val="Equivocal"/>
                      </Response>
```

```
                    </ListItemResponseField>
                  </ListItem>
               </List>
            </ListField>
         </Question>
      <!--  End of the repeated xml block. -->
       </ChildItems>
     </Question>
   </ChildItems>
  </Section>
<!--The remainder of the SDC result template is omitted -->
```

(Note: The SDC **name** and **order** attributes, as well as other non-essential attributes, have been removed from the above XML to enhance readability. If the **order** attribute is used in the result-carrying SDC XML, the XML document should receive new sequential **order** values; If **name** attributes are used, they must receive the same repeat suffix as the ancestor **ID**, throughout the entire repeated block of elements. Neither **name** nor **order** attributes are required in the SDC XML. However, they may facilitate processing of the SDC XML by the receiver. SDC XML is not used currently in NAACCR Vol V data transmissions. See the SDC Technical Reference Guide for more information and examples.)

When creating an HL7 message for the above data, the following essential data are used to construct 5 OBX segments. Relevant SDC XML content is also shown in the last column for context and for comparison with the sample XML above, but it is not used directly for our HL7 message construction. Repeating rows are shown below the thick horizontal line.

Repeat Suffix	Question	Response Type	User Response	eCP IDs	Relevant XML Content
(none)	Specify Marker	QR Text	Marker1	Q: 21557.100004300	val="*Marker1*"
(none)	Marker Stability	LI Selection	Stable	Q: 29525.100004300 LI: 29568.100004300	selected="true"
__1	Specify Marker	QR Text	Marker2	Q: 21557.100004300__1	val="*Marker2*"
__1	Marker Stability	LIR Selection	Cannot be determined (explain)	Q: 29525.100004300__1 LI: 29570.100004300__1	selected="true"
__1		LIR Text	*Equivocal*	Q: 29525.100004300__1	val="*Equivocal*"

The HL7 V2.5.1 OBX segments for this above data would appear as follows. OBX numbering starts arbitrarily from the 20th OBX segment, OBX|**20**|.

Note that the OBX segment for the parent `Section`, shown in the earlier XML, is omitted below. However, this section **ID** is referenced as a parent node in OBX-4 (**+**21556.100004300), when appropriate.

```
OBX|20|ST|21557.100004300^Specify Marker^CAPECP|+21556.100004300|Marker1||||||F|||2
  02112301500

OBX|21|CWE|29525.100004300^Marker Stability^CAPECP|+21557.100004300|29568.100004300^
  Stable^CAPECP||||||F|||202112301500

OBX|22|ST|21557.100004300__1^Specify Marker^CAPECP.RPT^^^^21557.100004300^^CAPECP|
  +21556.100004300|Marker2||||||F|||202112301500

OBX|23|CWE|29525.100004300__1^Marker Stability^CAPECP.RPT^^^^29525.100004300^^CAPEC
  P|
  +21557.100004300__1|29570.100004300__1^Cannot be determined (explain)^CAPECP.RPT^^^
  ^29570.100004300^^CAPECP||||||F|||202112301500

OBX|24|ST|29525.100004300__1^Marker Stability^CAPECP.RPT^^^^29525.100004300^^CAPECP|
```

```
29570.100004300__1|Equivocal||||||F|||202112301500
```

A diagrammatic view of the same OBX segments is shown in the following table.

OBX Field	Comment	HL7
		Original Data Elements
OBX|**20**|		
OBX-1 & 2		OBX|**20**|ST|
OBX-3	Question	21557.100004300^**Specify Marker**^CAPECP|
OBX-4	+Parent Section	**+**21556.100004300|
OBX-5	Response value	**Marker1**|
OBX-6+		||||F|||202112301500
OBX|**21**|		
OBX-1 & 2		OBX|**21**|CWE|
OBX-3	Question	29525.100004300^**Marker Stability**^CAPECP|
OBX-4	+Parent Question	**+**21557.100004300|
OBX-5	ListItem	29568.100004300^**Stable**^CAPECP|
OBX-6+		||||F|||202112301500
		Repeated Data Elements (using __1 suffix)
OBX|**22**|		
OBX-1 & 2		OBX|**22**|ST|
OBX-3	Question	21557.100004300__1^**Specify Marker**^CAPECP.**RPT**^^^21557.100004300^^CAPECP|
OBX-4	+Parent Section	**+**21556.100004300|
OBX-5	Response value	**Marker2**|
OBX-6+		||||F|||202112301500
OBX|**23**|		
OBX-1 & 2		OBX|**23**|CWE|
OBX-3	Question	29525.100004300__1^**Marker Stability**^CAPECP.**RPT**^^^29525.100004300^^CAPECP|
OBX-4	+Parent Question	**+**21557.100004300__1|
OBX-5	**ListItem** (OBX-3.1) see the associated ListItemResponse (LIR) free text in OBX|**24**|	29570.100004300__1^"**Cannot be determined (explain)**"^CAPECP.**RPT**^^^^29570.100004300^^CAPECP|
OBX-6+		||||F|||202112301500
OBX|**24**|		
OBX-1 & 2		OBX|**24**|ST|
OBX-3	ListItemResponse	29525.100004300__1^**Marker Stability**^CAPECP.**RPT**^^^^29525.100004300^^CAPECP|
OBX-4	Link to OBX|**23**| in OBX-5.1	29570.100004300__1|
OBX-5	Response value	*Equivocal*|
OBX-6+		||||F|||202112301500

In the table, **solid green** arrows point from the repeated OBXs (comprising OBX|**22**|, OBX|**23**| and OBX|**24**|) to the original source OBXs. The **blue** arrow points from the OBX-3.1 **ID** value in the LIR's response-holding OBX|**24**| to its source in OBX-3.1 from OBX|**23**|. (Remember that the selection of an LIR results in *two* OBX rows (OBX|**23**| and OBX|**24**|) – one OBX row to hold the **ID** of the selected LIR (29570.100004300) in OBX-5 and another OBX row to hold the user's typed response (*Equivocal*) in OBX-5.

The **purple** arrows point from each OBX-4 value to its source OBX. For OBX|**24**|, the OBX-4 value represents the selected LI's **ID** (29570.100004300__1). This **ID** value documents the LIR's selected

ListItem from OBX-5.1 in OBX|**23**|. The other OBX-4 values in the above table are prefixed with "+", indicating that the following **ID** value points to the hierarchical parent (an S, Q, or LI node) in the SDC XML.

The OBX segments containing the data for the repeat block use the **__1** suffix in OBX-3.1 (OBX field 3, component 1), and also have a Coding System of "CAPECP.**RPT**" in OBX-3.3. The special "CAPECP.**RPT**" value for Coding System indicates that OBX-3.1 uses a repeated CAPECP **ID** that contains a repeat suffix. For example, see OBX-3.1 to OBX-3.3 in OBX|**23**| in the above table.

Note that the original eCP **ID** value, without the repeat suffix **__1**, is used in OBX-3.7, and the original non-repeat "CAPECP" Code System value (without the .**RPT** suffix) is used in OBX-3.9 (see …295**25.**100004300^^CAPECP in the above table, for OBX|**23**|).

When an LI or LIR is selected as the answer response (e.g., OBX|**23**| - **Cannot be determined (explain)**), OBX-5.1 uses the **__1** suffix with the LI's eCP **ID** (295**70.**100004300**__1**), and OBX-5.3 uses the Code System value, "CAPECP.**RPT**". The original eCP **ID** value (without the repeat suffix **__1**) is used in OBX-5.7, and the original non-repeat "CAPECP" Code System value is used in OBX-5.9 (e.g., see …295**70.**100004300^^CAPECP in the above table, for OBX|**23**|).

When handling an LIR's *response value* (see *Equivocal* in OBX|**24**|), the OBX-3 field is handled exactly like OBX|**23**|. However, OBX-4.1 receives the eCP **ID** (295**70.**100004300**__1**) of the selected LIR, and OBX-5.1 receives the user-entered response value (*Equivocal*). The **ID** of the selected LIR is found in the OBX-5.1 field of OBX|**23**|. The *LIR Response* to selected LIR's link in OBX|**24**|, in the OBX-4 field, is *not* prefixed with "+". This distinguishes this *LIR Response* → selected LIR OBX-4 link as different from standard hierarchical OBX-4 child to parent links, which are prefixed with "+".

3.6. SECONDARY CODE SYSTEMS

The OBX-3 and OBX-5 fields support the inclusion of a secondary code value (e.g., ICD-O-3 or NAACCR codes). The secondary codes for registry reporting include:

- **ICD-O-3 Codes** for histologic site and primary tumor site ListItems (answers) (OBX-5)

- **SNOMED-CT Codes**. Some SNOMED CT codes are distributed in the CAP eCP releases in an eCP **ID**-to-SNOMED mapping file. These generally cover histologic type and primary tumor site; These SNOMED codes thus are similar to the ICD-O-3 code coverage. Work is in progress to map all eCP Question (OBX-3) and ListItem **ID**s (OBX-5) to SNOMED CT codes.

To supply inline secondary codes in OBX rows, the formats are as follows:

- **SNOMED CT:** When SNOMED-CT codes are transmitted in the HL7 message, the Coding System value will be "SCT". For Questions, **OBX-3.4** - **OBX 3.6** would contain this pattern:

```
...^conceptID^FullySpecifiedName^SCT...
```

and the same pattern would be used for OBX-5. For example, see the highlighted OBX-5 subfields inside the **OBX-5.4** - **OBX-5.6** fields:

```
OBX|9|CWE|16800.100004300^Histologic Type (Note A)^CAPECC||
16802.100004300^Adenocarcinoma (acinar, not otherwise specified^CAPECC^
35917007^Adenocarcinoma, no subtype (morphologic abnormality)^SCT
||||||F|||200407261530
```

The same patterns are used for other code systems as well.

Note: Legacy SNOMED alphanumeric codes should NEVER be transmitted, because they are extremely outdated.

- **ICD-O-3 Codes:** ICD-O-3 codes are used only for histologic type answers and are not required in eCP messages. In most cases, it is preferable to apply the ICD-O-3 codes by matching the eCP **ID**s with the latest CAP ICD-O-3 map, and this is done at the cancer registry.

  o If ICD-O-3 codes are transmitted with the message, the complete ICD-O-3 code, including the behavior code, is placed in OBX-5.4. The behavior code should not be preceded by a forward slash. OBX-5.5 should contain the official WHO text for the ICD-O-3 code. OBX 5.6 contains the current version text, including the version, but without dashes, e.g., "ICDO32".

- **LOINC:** LOINC codes are not currently used for eCP data element values. However, when LOINC codes are transmitted in OBX-3, OBX 3.1 will contain the numeric LOINC code, OBX-3.2 will contain the LOINC text value, and OBX-3.3 will contain the code system, "LN."

Code Maps: eCP **ID**s are designed to be mapped to other terminologies, as needed for specific use cases. Maps are released and updated by CAP as needed for registry purposes. Maps are released in a simple XML format and are designed to be applied to transmitted eCP **ID**s after the HL7 messages have been received at an endpoint node. Efforts are underway to make maps between **ID**s, SNOMED CT, and registry codes broadly available to the registry community.

Code maps provide the ability to assign codes (e.g., from ICD-O-3, NAACCR, or SNOMED CT) to eCP data *after the eCP transmission has occurred*. Importantly, maps also provide the ability to fix incorrect codes and supply missing codes even years after the eCP messages were transmitted. For these reasons, maps are the preferred way to supply codes in conjunction with eCP transmissions.

Although code maps are designed for post-transmission application to eCP **ID**s, individual codes that originate in CAP eCP maps may be sent in individual OBX rows as well, if there is a use case to support this extra effort for message creators. If eCP **ID**s are not available in the sending system, it will not be possible to use the eCP maps to assign codes, and inline incorporation of static codes in OBX rows is the only available mechanism available in this manual to attach codes to the OBX rows. However, in the absence of approved eCP-linked maps and **ID**s to attach the codes, it is unlikely for correct registry-usable codes to be consistently available for inline use in OBX rows.

4. Revision Control

Laboratory Electronic Pathology Reporting Guidelines Revision Control		
Revision Date	**Section**	**Revision Note**
March 2024	2.5	MSH-14 usage changed to RE SFT-4 cardinality changed to 0…1
March 2024	2.6	PID-18 usage changed to RE PID-23 usage changed to X
March 2024	2.7	ORC-4 usage changed to X ORC-21 cardinality changed to 0…1 OBR-4 data type changed to CWE OBX-3 data type changed to CWE OBX-15 usage changed to C OBX-19 usage changed to RE SPM-9 usage changed to C SPM-17 data type changed to DTM