7. Observation Reporting

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7.1 CHAPTER 7 CONTENTS

7.2 PURPOSE

This chapter describes the transaction set required for sending structured patient-oriented clinical data from one computer system to another. A common use of these transaction sets will be to transmit observations and results of diagnostic studies from the producing system (e.g., clinical laboratory system, EKG system) (the filler), to the ordering system (e.g., HIS order entry, physician's office system) (the placer). Observations can be sent from producing systems to clinical information systems (not necessarily the order placer) and from such systems to other systems that were not part of the ordering loop, e.g., an office practice system of the referring physician for inpatient test results ordered by an inpatient surgeon. This chapter also provides mechanisms for registering clinical trials and methods for linking orders and results to clinical trials and for reporting experiences with drugs and devices.

These transaction sets permit the transmission of clinical observations including (but not limited to) clinical laboratory results, measures of patient status and condition, vital signs, intake and output, severity and/or frequency of symptoms.

If the observation being reported meets one or more of the following criteria, then the content would qualify as a medical document management message (MDM) rather than an observation message (ORU). The reader is referred to the MDM message type in Chapter 9.

- Documents/reports that require succession management to reflect the evolution of both document addenda and replacement documents. Succession management is described in Chapter 9.

- Documents/reports where the Sender wants to indicate the availability of the report for use in patient care using the availability status present in the TXA segment, as described in Chapter 9.

Additional considerations that may affect the appropriateness of using an MDM message:

- Documents/reports where the whole requires a signature as part of the message. While the ORU message does not support the inclusion of signature or authentication, some document content forms support these requirements. Of particular note, CDA documents provide for the inclusion of originator/signature. Thus, if a CDA document requires a signature but does not require succession management or report availability (as described above), then an ORU message may be appropriate. However, if the CDA document requires succession management or report availability, then an MDM message is required.

- Documents/reports where the whole requires authentication as part of the message. As described for signatures, authentication may exist within the document content form. Again, CDA documents provide for the identification of an authenticator. Thus if a CDA document does not require succession management or report availability, then an ORU message may be appropriate. If succession management or report availability are necessary, then an MDM message is required.

- Documents/reports where the content as a whole requires special confidentiality protection using the confidentiality status present in the TXA segment, as described in Chapter 9.

- Documents/reports where document storage status is useful for archival and purging purposes using the storage status present in the TXA segment, as described in Chapter 9.

Using these criteria, the following examples of documents/reports would typically qualify as medical document management (MDM) messages. Note that as clinical content, the following documents/reports typically require succession management and/or report availability thus would require an MDM message even if the payload utilizes CSA.

- History and Physical

- Consultation reports

- Discharge summaries

- Surgical/anatomic pathology reports

- Diagnostic imaging reports

- Cardio-diagnostic reports

- Operative reports

- As an international example, microbiology reports may include clinical interpretation and require authentication. This may not be the case in all jurisdictions, but is an example that the use or requirement of MDM messages may be influenced by local considerations.

Usage Notes:

Transcription is not a defining quality for the selection of an MDM or ORU message. In an MDM message, the document/report is typically dictated or transcribed, but not always. Machine-generated or automated output is an example of a document/report that is appropriate to the MDM but is not transcribed.

Observations may be transmitted in a solicited (in response to a query) or unsolicited mode. In the solicited mode, a user requests a set of observations according to criteria transmitted by the user. The sending system responds with existing data to satisfy the query (subject to access controls). Queries do not elicit new observations by the target system, they simply retrieve old observations. (See Chapter 5 for full discussion of the query transmission.)

The unsolicited mode is used primarily to transmit the values of new observations. It is the mode used by producing services to return the values of observations requested by an ordering system. A laboratory system, for example, would usually send the results of an AM electrolytes to the ordering HIS via the unsolicited mode. An intensive care system would send the blood pressures to the same HIS by the same mode. Calling such transactions unsolicited may sound like a misnomer, but is not. The placing service solicits the producing service to make the observation. It could also (through a query) solicit the value of that observation after it has been made. However, such an approach would demand continuous polling of the producing system until the result was produced. Using the unsolicited mode, the producing service returns the value of an observation as soon as it is available. The unsolicited mode can also be used to transmit new results to a system (e.g., an archival medical record system) that did not order the observation. The transactions that define these modes are more fully described in Section7.2, "Trigger Events & Message Definitions."

Observations are usually ordered and reported as sets (batteries) of many separate observations. Physicians order electrolytes (consisting of sodium, potassium, chloride, bicarbonate) or vitals (consisting of diastolic blood pressure, systolic blood pressure, pulse, and temperature). Moreover, tests that we may think of as single entity, e.g., cardiac echo, usually yield multiple separate measurements, e.g., left ventricular diameter, left atrial diameter, etc. Moreover, observations that are usually reported as text (e.g., the review of systems from the history and physical) can also be considered a set of separately analyzable units (e.g., cardiac history, pulmonary history, genito-urinary history, etc.). We strongly suggest that all text clinical reports be broken down into such separate analyzable entities and that these individual entities be transmitted as separate OBX segments. Because many attributes of a set of observations taken at one time will be identical, one OBR segment serves as a header for the report and carries the information that applies to all of the individual observations in the set. In the case of ordered observations, the OBR segment is a "turn-around document" like the manual request forms it replaces. It carries information about the order to the producing service; a copy of the OBR with additional fields completed is returned with the observations to the requesting service. Alternately, text documents can be encoded as a CDA document and sent within a single OBX.

Not all observations are preceded by an order. However, all observations whether explicitly ordered or initiated without an order are reported with an OBR segment as the report header.

The major segments (OBR, OBX) defined in this chapter, their fields, and the code tables have been defined in collaboration with ASTM E31.11 with the goal of keeping HL7 observation transmission the same as ASTM E1238 in pursuit of the goals of ANSI HISPP and the Message Standards Developers Subcommittee. (Some sections of this chapter have been taken with permission directly from the E1238-91 document and vice versa in pursuit of those goals).

The OBR segment provides information that applies to all of the observations that follow. It includes a field that identifies a particular battery (or panel or set) of observations (e.g., electrolytes, vital signs or Admission H&P). For simplicity we will refer to the observation set as the battery. The battery usually corresponds to the entity that is ordered or performed as a unit. (In the case of a query, observation sets may be a more arbitrary collection of observations.) The OBX segment provides information about a single observation, and it includes a field that identifies that single observation (e.g., potassium, diastolic blood pressure or admission diagnosis). Both of these fields assume master tables that define coding systems (the universe of valid identifying codes) for batteries and observations, respectively. These tables will usually be part of the producing and sending services application and (usually) include many other useful pieces of information about the observation or battery. Segments for transmitting such master file information between systems that produce and systems that use clinical information are described in Chapter 8.

This Standard does not require the use of a particular coding system to identify either batteries or single observations In the past, local institutions tended to invent their own unique code systems for identifying test and other clinical observations because standard codes were not available. Such local code systems sufficed for transmitting information within the institutions but presented high barriers to pooling data from many sources for research or for building medical record systems. However, standard code systems such as LOINC® and SNOMED now exist for many of these purposes, and we strongly encourage their use in observation reporting. These codes can be sent either as the only code or they can be sent along with the local historic code as the second code system in a CE code.

In past versions of the HL7 standard, Appendix A to Chapter 7 presented suggestions for constructing clinical codes from existing procedure code systems such as CPT4. Appendix A is now part of the Implementation Guide and contains LOINC® codes for most laboratory tests and many common clinical variables and codes for reporting observations from the laboratory, 12-lead EKG, cardiac echoes, obstetrical ultrasounds, radiology reports, history and physical findings, tumor registries, vital signs, intake and outputs, and more. The most recent version of the LOINC® database, which includes records for more than 26,000 observations and includes codes, names, synonyms and other attributes (such as the molecular weights of chemical moieties) for each observation, is available from the Regenstrief Institute file server at **http://www.regenstrief.org/loinc/loinc.htm** . Codes for Neurophysiologic variables (EEG, EMG, Evoked potentials) are provided in Appendix X2 of ASTM E1467. Some parts of this document (the discussion and tables defining units, the discussion of the rules of mapping observations to OBX segments, and some of the examples at the end of the chapter have been copied (with permission) from ASTM E1238.

As is true throughout this Standard, the emphasis should be on the abstract messages, defined without regard to the encoding rules. The example messages, however, are based upon the HL7 encoding rules.

7.2.1 Preface (organization of this chapter)

Following this Purpose and general information section, the remainder of this chapter is organized into four main subject areas; General, Clinical Trials, Product Experience and Waveform. Sections 7.1 to 7.5 document the trigger events, message definitions, segment definitions and examples for general observation reporting. Sections 7.6 to 7.9 include all information related to Clinical Trials. Sections 7.10 to 7.13 include all information related to Product Experience messaging, and sections 7.14 to 7.17 include Waveform messaging information. Large tables can be found in section 7.18 and outstanding issues are listed in section 7.19.

7.2.2 Glossary

7.2.2.1 Placer:

Person or service that requests (places order for) an observation battery, e.g., the physician, the practice, clinic, or ward service, that orders a lab test, X-ray, vital signs, etc. The meaning is synonymous with, and used interchangeably with, requestor. See *ORC-2-placer order number*, Section 4.3.1.2, “Placer order number.”

7.2.2.2 Filler:

Person, or service, who produces the observations (fills the order) requested by the requestor. The word is synonymous with "producer" and includes diagnostic services and clinical services and care providers who report observations about their patients. The clinical laboratory is a producer of lab test results (filler of a lab order), the nursing service is the producer of vital signs observations (the filler of orders to measure vital signs), and so on. See *ORC-3-filler order number*, Section 4.3.1.3, “Filler order number.”

7.2.2.3 Battery:

A set of one or more observations identified as by a single name and code number, and treated as a shorthand unit for ordering or retrieving results of the constituent observations. In keeping with the mathematical conventions about set, a battery can be a single observation. Vital signs, electrolytes, routine

admission tests, and obstetrical ultrasound are all examples. Vital signs (conventionally) consist of diastolic and systolic blood pressure, pulse, and respiratory rate. Electrolytes usually consist of Na+, K+, Cl-, and HCO3-. Routine admission tests might contain CBC, Electrolytes, SMA12, and Urinalysis. (Note that the elements of a battery for our purposes may also be batteries). Obstetrical ultrasound is a battery made up of traditional component measurements and the impression, all of which would be returned as separate results when returned to the requestor. A test involving waveform recording (such as an EKG) can be represented as a battery comprised of results of many categories, including digital waveform data, labels and annotations to the data, measurements, and the impression

The word battery is used in this specification synonymously with the word profile or panel. The individual observation elements within a battery may be characteristic of a physiologic system (e.g., liver function tests), or many different physiologic systems.

7.2.2.4 Observation:

A measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result, a diastolic blood pressure, and a single chest X-ray impression are examples of observations. In certain circumstances, tracings and images may be treated by HL7 as individual observations and sent as a single OBX. These include waveform data described in Section 7.15, "Waveform – Trigger Events & Message Definitions," and encapsulated data aggregates using the ED data type described in Section 2.8.14, "ED-encapsulated data," (which can represent actual images, audio data, etc.).

7.2.2.5 Clinical Document Architecture (CDA):

The Health Level 7 Specification (ANSI/HL7 CDA R1.0-2000) for encoding and encapsulating clinical documents.

7.2.3 Narrative Reports as Batteries With Many OBX

Narrative reports from services such as Radiology usually consist of a number of subcomponents (e.g., a chest X-ray report may consist of a description, an impression, and a recommendation). Other studies, such as echocardiograms, contain analogous components, as well as numeric observations (e.g., left ventricular and diastolic diameter). Surgical pathology reports may contain information about multiple specimens and reports: the anatomic source, the gross description, the microscopic description, and a diagnostic impression for each specimen.

The current Standard treats each component of a narrative report as a separate "test" or observation. Just as a CHEM12 is transmitted as an order segment (OBR) plus 12 OBX segments, a chest X-ray would be transmitted as an order (OBR) segment plus three OBX segments, one for the description, one for the impression, and one for the recommendations. Similarly, an EKG report would be transmitted as an order segment (OBR), two OBX segments for the impression and recommendation, and additional OBX segments for each EKG measurement, e.g. the PR interval, QR interval, QRS axis, and so on.

We have defined code suffixes for constructing observation IDs for the common components of narrative reports (see Figure 7-1). The observation identifier for each such component is obtained by concatenating the observation battery ID (the ID in *OBR-4-universal service ID* of the preceding OBR from any coding system) with the appropriate suffix. The observation ID for a chest X-ray impression, for example, would be the chest X-ray observation ID (if CPT4, it would be 71020), a subcomponent delimiter, and the suffix, IMP, i.e., 71020&IMP.

This same combining rule applies to other coding systems including local and universal procedural codes (see Chapter 4). For example, if a local code for EKG was E793, and the locally agreed upon designation for that local code was EKG, the impression would be identified as E793&IMP^^99EKG.

Note: The "99EKG" in the 3rd component is included to indicate a local code. The EKG's description, in this case, would be E793&GDT^^99EKG.

Although it is strongly discouraged, the sender and receiver may agree to allow the omission of the observation ID component of a result segment when it is the same as the observation ID of the preceding OBR. In this case, only the ampersand and the suffix would have to be sent, e.g., &IMP or &REC, in *OBX-3-observation identifier* of a result segment. The full code would be assumed as the test identifier (recorded in the order segment) plus the category identifier recorded in the observation segment.

Figure 7-1. Observation ID suffixes

Coded Results	Suffix	Type
Diagnostic Impression	IMP	CE
Recommendation	REC	CE
Confirming procedures	CNP	CE
Procedure Medication	MED	CE
Anatomic Site	ANT	CE
Device/Instrument	DEV	CE
Serial # Device/Instrument	SER	ST
Bulk Text Reports		
Gross Or General Description Of The Study	GDT	TX or FT
Microscopic Or Secondary Description	MDT	TX or FT
Technician's Comment	TCM	TX or FT
Addendum Note	ADT	TX or FT
Other		
Diagnosis Onset Date/Time	ITM	TS
Diagnosis Resolution Date/Time	RTM	TS
Comparison Study	CMS	CE
Comparison Date/Time	CMT	TS
Comparison Results	CMR	CE
Comparison Change	CMC	CE
Predicted Value	PRD	ST
Percent Predicted	PPR	ST
After Drug Observed	AFD	ST
Predicted Value After Drug	ADP	ST
Percent Predicted After Drug	APP	ST
Timing Information	TIM	TS
Channel Definition Data	CHN	CD
Waveform Digital Data	WAS	NA or MA
Waveform Annotation	ANO	CE

7.2.4 Suffixes for Defining Observation IDs For Common Components of Narrative Reports

The following subsections define each of the suffices except for the specialized waveform suffices, which are defined in Section 7.14.1, Specific Observation Id Suffixes

7.2.4.1 Diagnostic impression (IMP)

When the suffix is IMP (*OBX-3-observation identifier*), the result is a diagnosis or finding, stored as a CE data type. Multiple result segments with an IMP suffix can be used if there are multiple parts to the study and each have an associated diagnosis (for example, the awake and sleep portion of an EEG). Each of these would have a different observation sub-ID. Multiple result segments with an IMP suffix can also be used if there are separate diagnoses corresponding to separate anatomic sites; in this case, the site for each diagnosis (each result segment with an IMP suffix) must be specified by an immediately preceding result segment with a suffix of ANT (see Section 7.2.4.5, "Anatomic site (ANT)"), which also has the same observation sub-ID. When multiple distinct diagnostic impressions are being reported, for example, mitral valve prolapse and aortic stenosis, each distinct impression should be sent in a separate OBX segment. More than one code may be included within one coded result segment, but only when such codes are modifiers of the principal impression, e.g., to report additional detail about the finding, not to report an entirely different finding. In this case, the *OBX-5-observation value* field may repeat, with each instance or repetition specifying one of the related coded impressions.

The coded data type for impressions does not mean that a reporting service must actually code all such impressions. The diagnostic impression can be sent as dictated text, but the text should be sent in the second component of the CE data type without a code to distinguish it from code, i.e. it should be preceded by a component delimiter, e.g., `^congestive heart failure`.

When multiple separate text impressions are being reported, they should be reported in separate OBX segments to indicate that they are distinct impressions.

7.2.4.2 Recommendation (REC)

When the suffix is REC (*OBX-3-observation identifier*), the value is a CE result, representing the reading physician's recommendations about repeat testing, follow up or therapy. For example, when an ambiguous lesion result is seen on a mammogram, the reading physician might recommend a repeat mammogram in six months, or a needle biopsy immediately. The recommended procedures are recorded as codes and/or text descriptions in the coded identifier structure.

If more than one follow up study is recommended, each such recommendation is sent in a separate REC.

7.2.4.3 Confirming procedures (CNP)

The confirming procedure OBX suffix identifies additional studies used to confirm the diagnosis reported in the IMP OBX. If, for example, electron microscopy was done to confirm a surgical pathology diagnosis, the identifier for electron microscopy *OBX-3-observation identifier* would be stored as the value field of an observation ID with a confirming procedure suffix. Confirming procedures are most important in surgical pathology reports. But they might also be used by services such as endoscopy, to record the fact that a biopsy, culture, etc., was taken during the procedure. If more than one confirming procedure was used, each is sent in a separate result segment with observation ID suffix CNP.

7.2.4.4 Procedure medication (MED)

A coded result segment with a suffix of MED (*OBX-3-observation identifier*) indicates that the segment contained information about medication given as part of the procedure -- contrast medication, medication intended to invoke a physiologic response (e.g., to be used in stress testing) or premedication. When patients receive more than one procedure medication, each medication should be reported in a separate

OBX medication segment. If the transmitting system has codes available for medications, they would be recorded as the first component of *OBX-3-observation identifier*. The name and/or the dosages could be included in the second component of *OBX-5-observation value*.

A coded result segment with a suffix of MED (procedure medication) may also be used to define a medication administered during recording of digital waveform data or other extended diagnostic procedure, e.g., exercise test. These may be displayed by the receiving system overlaid with the other events reported. The procedure medication is assumed to pertain to and be associated with the data recorded at the time specified in *OBX-14-date/time of the observation*, of the OBX segment labeled with MED, when present.

7.2.4.5 Anatomic site (ANT)

Some diagnostic studies include observations about more than one anatomic site within one report. If, for example, a patient had an appendectomy incidental to gallbladder surgery, the pathologist's assessment of both specimens would usually be included under a single specimen number in one report. Each distinct anatomic site would be reported as a separate OBX segment with a suffix of ANT (*OBX-3-observation identifier*). More than one coded anatomic location may be included within a single OBX segment only when such additional codes are used to construct an identity for a single site. In this case only, the *OBX-5-observation value* field may repeat, with each instance or repetition specifying one of the related locations. Each OBX segment with an ANT suffix could be followed by one or more OBX segments with an IMP or other suffix to transmit the diagnostic impression(s) associated with the anatomic site. These impressions or recommendations would be associated with a single anatomic site via a common observation ID.

7.2.4.6 Device/Instrument (DEV)

When required, the instrument or device which generated an observation can be transmitted as an additional result of the study. In this case, the suffix of *OBX-3-observation identifier* is DEV. Examples include: an automated instrument in the laboratory; an imaging device and model number in radiology; or an automatic blood pressure machine on the ward. The device is specified as a coded entry in anticipation that these identifiers could be specified as codes. Initially, we expect that most of the information about devices will be transmitted as text in the second component of the CE identifier.

7.2.4.7 Serial # device/instrument (SER)

Vendor's serial number of the device which generated the observation.

7.2.4.8 Gross or general description (GDT)

The general description suffix identifies the description component of a diagnostic study. In the case of anatomic pathology, it applies to the macroscopic (gross) description of the specimen. If the description consists of multiple paragraphs, the paragraphs should be separated by repeat delimiters so that the receiving computer can display them as paragraphs. It will not be necessary to include a description segment for a report when the impression segment says it all, e.g., for normal studies or studies such as EKG, whose reports are traditionally terse.

7.2.4.9 Microscopic or Secondary description (MDT)

For most studies, a secondary description will not be needed. In the case of surgical pathology, however, the microscopic description is a separate part of the report. It describes the histology as seen through the microscope. The microscopic description will be sent in a segment with the suffix MDT in *OBX-3-observation identifier*. If the microscopic description consists of multiple paragraphs, the paragraphs should be separated by repeat delimiters so that the receiving computer can display them as paragraphs.

7.2.4.10 Technician's comment (TCM)

This is free text stored in a result segment whose *OBX-3-observation identifier* has a suffix of TCM for technician comment. It is used to record information about technical performance of the procedure, usually recorded by the technician.

7.2.4.11 Addendum note (ADT)

Use to report information that is added as an addendum after the original dictation and sent as a separate labeled section of the report.

7.2.4.12 Diagnosis (problem) onset date/time (ITM)

Use to record the date-time that a problem was first perceived to exist.

7.2.4.13 Diagnosis (problem) resolution date/time (RTM)

Use to record the date-time that a problem became inactive, i.e., the problem was cured or remitted.

7.2.4.14 Comparison study (CMS)

When the reader of a diagnostic report compares the results for the current study with those of a previous study, this suffix allows them to report the nature of the comparison study as a separate result, i.e., an OBX segment with a segment whose observation ID has a suffix of CMS. Ordinarily, this would not be required because the observation ID in the other comparison OBXs would identify the test, if any of the other comparison values were transmitted.

7.2.4.15 Comparison date/time (CMT)

When the reader of a diagnostic procedure compares the current results with a previous study, this suffix allows them to report the date-time of the previous study (time optional) as a separate result within the current report.

7.2.4.16 Comparison results (CMR)

When the reader of a diagnostic procedure compares the current results with those of a previous study on the same patient, this suffix allows them to report the results (impression) of the previous study as a discrete result within the current report.

7.2.4.17 Comparison change (CMC)

When a diagnostic service reports a comparison between the current and a previous study, this suffix is used to report the degree of change (e.g., much worse, worse, minimal worsening, no change, slightly better, better, much better, returned to normal) as a separate result within the report.

In current dictation, information about comparison is usually contained in the descriptions of the study. The provision of the comparison suffixes listed above do not imply a *requirement* to send this information as separate components. The comparison variables are only meant to be enabling. When a system would like to transmit them as discrete report components, these suffixes give them the option.

7.2.4.18 Predicted value (PRD)

When an observation has a predicted value as is the case for many spirometry tests, this suffix identifies the predicted observation as distinguished from the actual observation. The AS4 code for forced vital capacity is 94010.1 (see the HL7 Implementation Guide). The predicted forced vital capacity would be 94010.1&PRD.

7.2.4.19 Percent predicted (PPR)

This is a computed observation = `(actual observation)/(predicted observation.` For forced vital capacity the percent predicted would be identified as 94010.1&PPR.

7.2.4.20 After drug observed (AFD)

An observation might be taken before and after a drug is given. This occurs especially in Spirometry. The predose observation is identified by the base ID. The post drug measure is identified by the AFD suffix. Using the AS4 base code for the forced vital capacity the post drug result would be identified by 94010.1&AFD.

7.2.4.21 Predicted value after drug (ADP)

The post drug predicted value is identified by the suffix, ADP. Following the pattern of the above example, it would be 94010.1&ADP.

7.2.4.22 Percent predicted after drug (APP)

The percent predicted after drug is identified by applying the suffix, APP to the base code – 94010.1&APP if using the AS4 code for forced vital capacity.

7.2.4.23 Timing information (TIM)

This suffix is used only for transmitting waveform data. It is fully described in Section 7.14.1.1.

7.2.4.24 Channel definition data (CHN)

This suffix is used only for transmitting waveform data. It is fully described in Section 7.14.1.2.

7.2.4.25 Waveform digital data (WAS)

This suffix is used only for transmitting waveform data. It is fully described in Section 7.14.1.3.

7.2.4.26 Waveform annotation (ANO)

This suffix is used only for transmitting waveform data. It is fully described in Section 7.14.1.4

7.2.4.27 Clinical observation codes

The recently introduced LOINC® codes (See Figure 7-2 for full information) may be more useful to many users. Code system information, including LOINC®, has been moved from Appendix 7A to the Implementation Guide.

7.3 GENERAL TRIGGER EVENTS & MESSAGE DEFINITIONS

The triggering events that follow are all served by the ORU (Observational report – Unsolicited) or the ORF (Observational Report Response) messages in combination with ACK and QRY. Each triggering event is listed below, along with the messages exchanged, and the segments that comprise the messages. The notation used to describe the sequence, optionality, and repeating of segments is described in Chapter 2, “Format for defining abstract messages.”

7.3.1 ORU – Unsolicited Observation Message (Event R01)

The ORU message is for transmitting laboratory results to other systems. The OUL message is designed to accommodate the laboratory processes of laboratory automation systems.

With the segment (OBX) defined in this chapter, and the OBR defined in Chapter 4, one can construct almost any clinical report as a multi-level hierarchy, with the PID segment defined in Chapter 3 at the upper level, an order record (OBR) at the next level with one or more observation records (OBX), followed by the specimen information (SPM) and one or more observations (OBX) directly associated with the specimen.

One result segment (OBX) is transmitted for each component of a diagnostic report, such as an EKG or obstetrical ultrasound or electrolyte battery.

The CTD segment in this trigger is used to transmit temporary patient contact details specific to this order.

ORU^R01^ORU_R01	Unsolicited Observation Message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
{	--- PATIENT_RESULT begin		
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and Comments		2
[{NK1}]	Next of Kin/Associated Parties		3
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
]	--- VISIT end		
]	--- PATIENT end		
{	--- ORDER_OBSERVATION begin		
[ORC]	Order common		4
OBR	Observations Request		7
{[NTE]}	Notes and comments		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
[{	--- OBSERVATION begin		
OBX	Observation related to OBR		7
{[NTE]}	Notes and comments		2

ORU^R01^ORU_R01	Unsolicited Observation Message	Status	Chapter
}]	--- OBSERVATION end		
[{FT1}]	Financial Transaction		6
{[CTI]}	Clinical Trial Identification		7
[{	--- SPECIMEN begin		
SPM	Specimen		
[{OBX}]	Observation related to Specimen		
}]	--- SPECIMEN end		
}	--- ORDER_OBSERVATION end		
}	--- PATIENT_RESULT end		
[DSC]	Continuation Pointer		2

ACK^R01^ACK	Acknowledgment	Status	Chapter
MSH	Message header		2
[{ SFT }]	Software segment		2
MSA	Message acknowledgment		2
[{ ERR }]	Error		2

Note: The ORC is permitted but not required in this message. Any information that could be included in either the ORC or the OBR must be included in the OBR on reporting. Notice also that the ORU (and the QRY) messages accommodate reports about many patients.

Many report headers (OBR) may be sent beneath each patient segment, with many separate observation segments (OBX) related to the order / observation request beneath each OBR. OBX segments that are related to specimens immediately follow the SPM segments. Note segments (NTE) may be inserted at different locations in the message. The note segment applies to the entity that immediately precedes it, i.e., the patient if it follows the PID segment, the observation request if it follows the OBR segment, and the individual result if it follows the OBX segment.

7.3.2 OUL – Unsolicited Laboratory Observation Message (Event R21)

This message was designed to accommodate laboratory automation systems. It permits the communication of the following kinds of information in addition to the results themselves:

- relation of the analysis results to a particular container with patient sample (SAC segment),
- relation of the analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-SID segments),
- basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

If the results are for QC specimen container, then the patient related segments (e.g., PID, PD1, PV1, PV2) are optional.

This message is kept here for backward compatibility reasons only. The new OUL messages with additional triggers should be used, when the Specimen information (segment SPM) with or without Container information (segment SAC) is required.

Refer to Chapter 13 Laboratory Automation for examples of usage.

OUL^R21^OUL_R21	Unsolicited Laboratory Observation Message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and Comments (for Patient ID)		2
]	--- PATIENT end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
]	--- VISIT end		
{	--- ORDER_OBSERVATION begin		
[	--- CONTAINER begin		
SAC	Specimen Container Details		13
[SID]	Substance Identifier		13
]	--- CONTAINER end		
[ORC]	Common Order		4
OBR	Observation		7
[{NTE}]	Notes and Comments (for Detail)		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- OBSERVATION begin		

OUL^R21^OUL_R21	Unsolicited Laboratory Observation Message	Status	Chapter
[OBX]	Observation Result		7
[TCD]	Test Code Detail		13
{[SID]}	Substance Identifier		13
[{NTE}]	Notes and Comments		2
}	--- OBSERVATION end		
[{CTI}]	Clinical Trial Identification		7
}	--- ORDER_OBSERVATION end		
[DSC]	Continuation Pointer		2

7.3.3 QRY/ORF - Query For Results Of Observation (Events R02, R04)

The query response format options are described in chapter 5, Section 5.2.4 “Response format”.

The QRD segment is defined in Chapter 5 Section 5.10.5.3, “QRD – original style query definition segment.” The Query Result Level field of the QRD determines the amount of data requested.

The QRF segment is defined in Chapter 5, Section 5.10.5.4, “QRF – original style query filter segment.”

The subject filters contained in the QRD and QRF segments are defined by local agreement between the inquiring system and the ancillary system.

The Set ID fields in the various segments (including PID) are used to count the number of segments of one kind transmitted at one level of the hierarchy.

The CTD segment in this trigger is used to transmit temporary patient contact details specific to this order.

QRY^R02^QRY_R02	Query	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
QRD	Query Definition		2
QRF	Query Filter		2

ORF^R04^ORF_R04	Observational Report	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
MSA	Message Acknowledgment		2
QRD	Query Definition		2
[QRF]	Query Filter		2
{	--- QUERY_RESPONSE begin		
[	--- PATIENT begin		

ORF^R04^ORF_R04	Observational Report	Status	Chapter
PID	Patient ID		3
[{NTE}]	Notes and Comments		3
]	--- PATIENT end		
{	--- ORDER begin		
[ORC]	Order common		
OBR	Observation request		7
{[NTE]}	Notes and comments		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
{	--- OBSERVATION begin		
[OBX]	Observation/Result		7
{[NTE]}	Notes and comments		2
}	--- OBSERVATION end		
{[CTI]}	Clinical Trial Identification		7
}	--- ORDER end		
}	--- QUERY_RESPNSE end		
[{ERR}]	Error		2
[QAK]	Query Acknowledgement		5
[DSC]	Continuation Pointer		2

7.3.4 ORU – Unsolicited Point-Of-Care Observation Message Without Existing Order – Place An Order (Event R30)

This event trigger instructs the receiving system to create a new order for the observation(s) contained in the message.

One example of this trigger's use case occurs when a Doctor verbally instructs a nurse to perform a test. Looking at this use case from an information management perspective, one might expect that, the nurse would enter an order into laboratory information or ordering system before performing the test. However, there usually isn't time for order entry in these use cases. In fact, it is highly desirable for the POC measurement process to become automated so that the only action a user needs to take is to make a measurement on the POC Device, with all other processes for generating an order and tying it in to the observation handled by the "machines."

In order to allow for the passing of specific information relating to the Patient, responsible Doctor, placing doctor, patient location etc, there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU

message type. One example of this trigger's use case occurs when a Doctor at a remote site without a shared Patient index instructs a nurse to perform a test. The testing is carried out without prior entry of a request into the LIS. Once performed, the results, along with the patient information are transmitted to the LIS. In some circumstances, the LIS may add clinical interpretation to this and report it back to the placing system and/or another system. In order to allow for this to take place, the requester, location etc information is required.

To allow the sending system to correlate every result with its associated order, the receiving system will return the placer number in the ORC segment of the OML^O21 message. If desired, this message may also contain information returned from the Observation Recipient, such as the name of the patient corresponding to the order and result placed.

ORU^R30^ORU_R30	**Unsolicited Point-Of-Care observation message without existing order**	**Status**	**Chapter**
MSH	Message Header		2
[{ SFT }]	Software Segment		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		3
]	--- VISIT end		
ORC	Common Order information		4
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		

ACK^R30^ACK	Acknowledgment	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

7.3.5 ORU – Unsolicited New Point-Of-Care Observation Message – Search For An Order (Event R31)

This event trigger instructs the receiving system to search for an existing order for the observation(s) contained in the message.

In this case, the sending system does not know if an order has been placed. This transaction instructs the receiving system to search for an existing order for the associated results. If the receiver finds an existing order, it should return the Placer ID to the sender in the ORC segment of an OML^O21 message. This information allows the Observation Reviewer to correlate every result with its associated order

The institution's business rules will determine what the receiving system does if it can't find a matching order. Possibilities include automatically placing an order (as in trigger event R30), or logging an exception rather than recording the result.

If it is necessary to pass specific information related to the Patient, responsible Doctor, placing doctor, patient location etc, there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU message type (see also ORU^R30 for description).

ORU^R31^ORU_R30	Unsolicited new Point-Of-Care observation message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		
]	--- VISIT end		
ORC	Common Order information		4
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		

ORU^R31^ORU_R30	Unsolicited new Point-Of-Care observation message	Status	Chapter
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		

ACK^R31^ACK	Acknowledgment	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

7.3.6 ORU – Unsolicited Pre-Ordered Point-Of-Care Observation (Event R32)

This event trigger instructs the receiver to place the result with the order information included in the message.

From a traditional clinical laboratory perspective, this event trigger's use case is probably the predominant (if not exclusive) one. However, in the POC environment, it is actually uncommon to have an order already generated when a test is performed. It does happen sometimes, though. If it is necessary to pass specific information related to the Patient, responsible Doctor, placing doctor, patient location etc, there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU message type (see also ORU^R30 for description).

ORU^R32^ORU_R30	Unsolicited Pre-ordered Point-Of-Care observation message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		
]	--- VISIT end		
ORC	Common Order information		4
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{	--- TIMING_QTY begin		

ORU^R32^ORU_R30	Unsolicited Pre-ordered Point-Of-Care observation message	Status	Chapter
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		

ACK^R32^ACK	Acknowledgment	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

7.3.7 OUL – Unsolicited Specimen Oriented Observation Message – (Event R22)

- This message was designed to accommodate specimen oriented testing. It should be applicable to container-less testing (e.g., elephant on a table) and laboratory automation systems requiring container.
- Generally this construct allows transfer of multiple results related to a specimen from a patient, where this specimen has been in none, one, or multiple containers.
- In addition to the patient results themselves it permits the communication of the following kinds of information:
- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments) – however for this purpose the “Unsolicited Specimen Container Oriented Observation Message” (OUL^R23) is recommended due to explicit relation between the observation and the container.
- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

OUL^R22^OUL_R22	Unsolicited Specimen Oriented Observation Message	Status	Chapter
MSH	Message Header		2
[{SFT}]	Software Segment		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and Comments (for Patient ID)		2
]	--- PATIENT end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
]	--- VISIT end		
{	--- SPECIMEN begin		
SPM	Specimen information		7
[{ OBX }]	Observation Result (for Specimen)		7
[{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)		13
}]	--- CONTAINER end		
{	--- ORDER begin		
OBR	Observation Order		7
[ORC]	Common Order		4
[{NTE}]	Notes and Comments (for Detail)		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		

OUL^R22^OUL_R22	Unsolicited Specimen Oriented Observation Message	Status	Chapter
[{	--- RESULT begin		
OBX	Observation Result		7
[TCD]	Test Code Detail		13
{[SID]}	Substance Identifier (e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2
}]	--- RESULT end		
[{CTI}]	Clinical Trial Identification		7
}	--- ORDER end		
}	--- SPECIMEN end		
[DSC]	Continuation Pointer		2

7.3.8 OUL – Unsolicited Specimen Container Oriented Observation Message – (Event R23)

- This message was designed to accommodate specimen oriented testing. It should be applicable to, e.g., laboratory automation systems requiring container.
- Generally this construct allows **transfer of multiple results related to one or more specific containers with one or more specimens from a patient.**
- In addition to the patient results themselves it permits the communication of the following kinds of information:
- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments).
- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

OUL^R23^OUL_R23	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		

OUL^R23^OUL_R23	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and Comments (for Patient ID)		2
]	--- PATIENT end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
]	--- VISIT end		
{	--- SPECIMEN begin		
SPM	Specimen information		7
[{ OBX }]			7
{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)		13
{	--- ORDER begin		
OBR	Observation Order		7
[ORC]	Common Order		4
[{NTE}]	Notes and Comments (for Detail)		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[{	--- RESULT begin		
OBX	Observation Result		7
[TCD]	Test Code Detail		13
{[SID]}	Substance Identifier (e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2

OUL^R23^OUL_R23	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
}]	--- RESULT end		
[{CTI}]	Clinical Trial Identification		7
}	--- ORDER end		
}	--- CONTAINER end		
}	--- SPECIMEN end		
[DSC]	Continuation Pointer		2

7.3.9 OUL – Unsolicited Order Oriented Observation Message – (Event R24)

- This message was designed to accommodate multi-specimen oriented testing. It should be applicable to, e.g., laboratory automation systems requiring container.
- Generally this construct allows **transfer of multiple results, each one related to none, one or more specific containers with one or more specimens from a patient.** (Example: Creatinine Clearance result with detailed information about the urine and serum specimens and their containers.)
- In addition to the patient results themselves it permits the communication of the following kinds of information:
- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments).
- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

OUL^R24^OUL_R24	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and Comments (for Patient ID)		2

OUL^R24^OUL_R24	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
]	--- PATIENT end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
]	--- VISIT end		
{	--- ORDER begin		
OBR	Observation Order		7
[ORC]	Common Order		4
[{NTE}]	Notes and Comments (for Detail)		2
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[{	--- SPECIMEN begin		
SPM	Specimen information		7
[{OBX}]			7
[{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)		13
}]	--- CONTAINER end		
}]	--- SPECIMEN end		
[{	--- RESULT begin		
OBX	Observation Result		7
[TCD]	Test Code Detail		13
{[SID]}	Substance Identifier (e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2
}]	--- RESULT end		
[{CTI}]	Clinical Trial		7

OUL^R24^OUL_R24	Unsolicited Specimen Container Oriented Observation Message	Status	Chapter
	Identification		
}	--- ORDER end		
[DSC]	Continuation Pointer		2

7.4 GENERAL SEGMENTS

The full definitions of many segments required for reporting clinical observations are included in other chapters. The patient identifying segment (PID) is provided in Chapter 3. The NTE segment is in Chapter 2.

7.4.1 OBR – Observation Request Segment

In the reporting of clinical data, the OBR serves as the report header. It identifies the observation set represented by the following atomic observations. It includes the relevant ordering information when that applies. It contains many of the attributes that usually apply to all of the included observations.

When a set of observations is ordered, the order message contains an OBR segment. However, observations can be collected and reported without an antecedent order. When observations are reported, the report message also includes one or more OBR segments. So, the OBR segment is like a turn-around document. Some fields in the OBR segment apply only to the ordering message and some to the reporting message. To those familiar with healthcare procedures, these should be obvious from their names (e.g., transcriptionist or principal result interpreter could only apply to the reporting phase). However, we have also flagged them in the OBR HL7 Attribute Table to indicate whether placer, filler, or both may send data in a given field.

HL7 Attribute Table – OBR – Observation Request

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	4	SI	O			00237	Set ID - OBR
2	22	EI	C			00216	Placer Order Number
3	22	EI	C			00217	Filler Order Number
4	250	CE	R			00238	Universal Service Identifier
5	2	ID	X			00239	Priority – OBR
6	26	TS	X			00240	Requested Date/Time
7	26	TS	C			00241	Observation Date/Time
8	26	TS	O			00242	Observation End Date/Time
9	20	CQ	O			00243	Collection Volume
10	250	XCN	O	Y		00244	Collector Identifier
11	1	ID	O		0065	00245	Specimen Action Code
12	250	CE	O			00246	Danger Code
13	300	ST	O			00247	Relevant Clinical Information
14	26	TS	B			00248	Specimen Received Date/Time
15	300	SPS	B			00249	Specimen Source
16	250	XCN	O	Y		00226	Ordering Provider
17	250	XTN	O	Y/2		00250	Order Callback Phone Number
18	60	ST	O			00251	Placer Field 1

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
19	60	ST	O			00252	Placer Field 2
20	60	ST	O			00253	Filler Field 1
21	60	ST	O			00254	Filler Field 2
22	26	TS	C			00255	Results Rpt/Status Chng - Date/Time
23	40	MOC	O			00256	Charge to Practice
24	10	ID	O		0074	00257	Diagnostic Serv Sect ID
25	1	ID	C		0123	00258	Result Status
26	400	PRL	O			00259	Parent Result
27	200	TQ	B	Y		00221	Quantity/Timing
28	250	XCN	O	Y		00260	Result Copies To
29	200	EIP	O			00261	Parent
30	20	ID	O		0124	00262	Transportation Mode
31	250	CE	O	Y		00263	Reason for Study
32	200	NDL	O			00264	Principal Result Interpreter
33	200	NDL	O	Y		00265	Assistant Result Interpreter
34	200	NDL	O	Y		00266	Technician
35	200	NDL	O	Y		00267	Transcriptionist
36	26	TS	O			00268	Scheduled Date/Time
37	4	NM	O			01028	Number of Sample Containers *
38	250	CE	O	Y		01029	Transport Logistics of Collected Sample
39	250	CE	O	Y		01030	Collector's Comment *
40	250	CE	O			01031	Transport Arrangement Responsibility
41	30	ID	O		0224	01032	Transport Arranged
42	1	ID	O		0225	01033	Escort Required
43	250	CE	O	Y		01034	Planned Patient Transport Comment
44	250	CE	O	N	0088	00393	Procedure Code
45	250	CE	O	Y	0340	01316	Procedure Code Modifier
46	250	CE	O	Y	0411	01474	Placer Supplemental Service Information
47	250	CE	O	Y	0411	01475	Filler Supplemental Service Information
48	250	CWE	C	N	0476	01646	Medically Necessary Duplicate Procedure Reason.
49	2	IS	O	N	0507	01647	Result Handling

Note: The OBR segment is documented in its entirety in Chapter 4. The segment definition table is included here for reader convenience and for clarity of items related to Observation Reporting messages.

7.4.1.0 OBR field definitions

The daggered (+) items in this segment are created by the filler, not the placer. They are valued by the filler as needed when the OBR segment is returned as part of a report.

The starred (*) fields are only relevant 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.

OBR-7-observation date/time and *OBR-8-observation end date/time* (flagged with #) 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., BP, Chest X-ray), they represent the start and end time of the observation.

7.4.1.1 OBR-1 Set ID - OBR (SI) 00237

Definition: For the first order transmitted, the sequence number shall be 1; for the second order, it shall be 2; and so on.

7.4.1.2 OBR-2 Placer Order Number (EI) 00216

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field is a case of the Entity Identifier data type (Section 2.16.28). The first component is a string that identifies an individual order (e.g., OBR). A limit of fifteen (15) characters is suggested but not required. It is assigned by the place (ordering application). It identifies an order uniquely among all orders from a particular ordering application. The second through fourth components contain the application ID of the placing application in the same form as the HD data type (Section 2.16.36, "HD - Hierarchic designator"). The second component, namespace ID, is a user-defined coded value that will be uniquely associated with an application. A limit of six (6) characters is suggested but not required. A given institution or group of intercommunicating institutions should establish a unique list of applications that may be potential placers and fillers and assign unique application IDs. The components are separated by component delimiters.

See *ORC-2-placer order number* (Section 4.5.1.2) for information on when this field must be valued.

A given institution or group of intercommunicating institutions should establish a list of applications that may be potential placers and fillers of orders and assign each a unique application ID. The application ID list becomes one of the institution's master dictionary lists that is documented in Chapter 8. Since third-party applications (those other than the placer and filler of an order) can send and receive ORM and ORR messages, the placer application ID in this field may not be the same as any sending and receiving application on the network (as identified in the MSH segment).

ORC-2-placer order number is the same as *OBR-2-placer order number*. If the placer order number is not present in the ORC, it must be present in the associated OBR and vice versa. If both fields, *ORC-2-placer order number* and *OBR-2-placer order number,* are valued, they must contain the same value. When results are transmitted in an ORU message, an ORC is not required, and the identifying placer order number must be present in the OBR segments.

These rules apply to the few other fields that are present in both ORC and OBR for upward compatibility (e.g., quantity/timing, parent numbers, ordering provider, and ordering call back numbers).

7.4.1.3 OBR-3 Filler Order Number (EI) 00217

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field is the order number associated with the filling application. This is a permanent identifier for an order and its associated observations. It is a special case of the Entity Identifier data type (Section 2.16.28, "EI - Entity Identifier").

The first component is a string that identifies an order detail segment (e.g., OBR). A limit of fifteen (15) characters is suggested but not required. It is assigned by the order filler (receiving) 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.

The second through fourth components contain the filler application ID, in the form of the HD data type (see Section 2.16.36, "HD - hierarchic designator"). The second component is a user-defined coded value that uniquely defines the application from other applications on the network. A limit of six (6) characters is suggested but not required. The second component of the filler order number always identifies the actual filler of an order.

A given institution or group of intercommunicating institutions should establish a list of applications that may be potential placers and fillers of orders and assign each a unique application ID. The application ID list becomes one of the institution's master dictionary lists that is documented in Chapter 8. Since third-party applications (those other than the placer and filler of an order) can send and receive ORM and ORR messages, the filler application ID in this field may not be the same as any sending and receiving application on the network (as identified in the MSH segment).

See *ORC-3-filler order number* for information on when this field must be valued.

ORC-3-filler order number is the same as *OBR-3-filler order number*. If the filler order number is not present in the ORC, it must be present in the associated OBR. (This rule is the same for other identical fields in the ORC and OBR and promotes upward and ASTM compatibility.) This is particularly important when results are transmitted in an ORU message. In this case, the ORC is not required and the identifying filler order number must be present in the OBR segments.

The *filler order number (OBR-3 or ORC-3)* also uniquely identifies an order and its associated observations. For example, suppose that an institution collects observations from several ancillary applications into a common database and this common database is queried by yet another application for observations. In this case, the filler order number and placer order number transmitted by the common database application would be that of the original filler and placer, respectively, rather than a new one assigned by the common database application.

Similarly, if a third-party application, not the filler or placer, of an order were authorized to modify the status of an order (say, cancel it), the third-party application would send the filler an ORM message containing an ORC segment with ORC-1-order control equal to "CA" and containing the original placer order number and filler order number, rather than assign either itself.

7.4.1.4 OBR-4 Universal Service Identifier (CE) 00238

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the identifier code for the requested observation/test/battery. This can be based on local and/or "universal" codes. We recommend the "universal" procedure identifier. The structure of this CE data type is described in the control section.

7.4.1.5 OBR-5 Priority (ID) 00239

Definition: ***This field has been retained for backward compatibility only.*** It is not used. Previously priority (e.g., STAT, ASAP), but that information is carried as the sixth component of *OBR-27-quantity/timing*.

7.4.1.6 OBR-6 Requested Date/Time (TS) 00240

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: ***This field has been retained for backward compatibility only***. This is not used. Previously requested date/time. That information is now carried in the fourth component of the *OBR-27-quantity/timing*.

7.4.1.7 OBR-7 Observation Date/Time (TS) 00241

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

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.

7.4.1.8 OBR-8 Observation End Date/Time (TS) 00242

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field is the end date and time of a study or timed specimen collection. If an observation takes place over a substantial period of time, it will indicate when the observation period ended. For observations made at a point in time, it will be null. This is a results field except when the placer or a party other than the filler has already drawn the specimen.

7.4.1.9 OBR-9 Collection Volume (CQ) 00243

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)>
```

Definition: For laboratory tests, the collection volume is the volume of a specimen. The default unit is ML. Specifically, units should be expressed in the ISO Standard unit abbreviations (ISO-2955, 1977). This is a results-only field except when the placer or a party has already drawn the specimen. (See Chapter 7 Section 7.4.2.6 for a full discussion regarding units.)

7.4.1.10 OBR-10 Collector Identifier (XCN) 00244

```
Components:  <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and
           Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III)
           (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^
           <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^
           <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier
           Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code
           (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^
           <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date
           (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
           <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
           Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From
           Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Name Context (CE):  <Identifier (ST)> & <Text (ST)> & <Name of
           Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
           & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR):  <Range Start Date/Time (TS)> &
           <Range End Date/Time (TS)>

           Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
           (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
           Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
           <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
           Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
```

```
            Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
            Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
            (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
            <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
            System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
            <Original Text (ST)>
```

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

7.4.1.11 OBR-11 Specimen Action Code (ID) 00245

Definition: This field is the action to be taken with respect to the specimens that accompany or precede this order. The purpose of this field is to further qualify (when appropriate) the general action indicated by the order control code contained in the accompanying ORC segment. For example, when a new order (ORC - "NW") is sent to the lab, this field would be used to tell the lab whether or not to collect the specimen ("L" or "O"). Refer to Chapter 4, Section 4.5.3.11, *HL7 Table 0065 - Specimen action code* for valid values.

7.4.1.12 OBR-12 Danger Code (CE) 00246

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)>
```

Definition: This field is the code and/or text indicating any known or suspected patient or specimen hazards, e.g., patient with active tuberculosis or blood from a hepatitis patient. Either code and/or text may be absent. However, the code is always placed in the first component position and any free text in the second component. Thus, free text without a code must be preceded by a component delimiter.

7.4.1.13 OBR-13 Relevant Clinical Information (ST) 00247

Definition: This field contains any additional clinical information about the patient or specimen. This field is used to report the suspected diagnosis and clinical findings on requests for interpreted diagnostic studies. Examples include reporting the amount of inspired carbon dioxide for blood gasses, the point in the menstrual cycle for cervical pap tests, and other conditions that influence test interpretations. For some orders this information may be sent on a more structured form as a series of OBX segments (see Chapter 7) that immediately follow the order segment.

7.4.1.14 OBR-14 Specimen Received Date/Time (TS) 00248

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: ***This field has been retained for backward compatibility only***. As of version 2.5, in messages where the SPM segment is present, the use of *SPM-18 Specimen Received Date/Time* is favored over this field

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.

7.4.1.15 OBR-15 Specimen Source (SPS) 00249

```
Components:  <Specimen Source Name or Code (CWE)> ^ <Additives (CWE)> ^ <Specimen
            Collection Method (TX)> ^ <Body Site (CWE)> ^ <Site Modifier (CWE)> ^
            <Collection Method Modifier Code (CWE)> ^ <Specimen Role (CWE)>

Subcomponents for Specimen Source Name or Code (CWE):  <Identifier (ST)> & <Text (ST)>
            & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
            Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
            Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
            Text (ST)>
```

```
Subcomponents for Additives (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
           <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Body Site (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
           <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Site Modifier (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
           Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
           & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
           & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Collection Method Modifier Code (CWE):  <Identifier (ST)> & <Text
           (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
           <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
           System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
           <Original Text (ST)>

Subcomponents for Specimen Role (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
           Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
           & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
           & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>
```

Definition: ***This field has been retained for backward compatibility only.*** As of version 2.5, in messages where 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.

Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

The first component contains the specimen source name or code (as a CWE data type component). (Even in the case of observations whose name implies the source, a source may be required, e.g., blood culture-heart blood.) Refer to *HL7 Table 0070 - Specimen Source Codes* for valid entries.

The second component should include free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.

The third is a free text component describing the method of collection when that information is a part of the order. When the method of collection is logically an observation result, it should be included as a result segment.

The fourth component specifies the body site from which the specimen was obtained, and the fifth is the site modifier. For example, the site could be antecubital fossa, and the site modifier "right." The components of the CWE fields become subcomponents. Refer to *User-Defined Table 0163 - Body Site* for valid entries.

The sixth component indicates whether the specimen is frozen as part of the collection method. Suggested values are F (Frozen); R (Refrigerated). If the component is blank, the specimen is assumed to be at room temperature.

Refer to *HL7 Table 0070 Specimen Source Codes* for valid values.

The 7th component indicates the role of the sample. Refer to *User-defined Table 0369 – Specimen Role* for suggested values. Each of these values is normally identifiable by the systems and its components and can influence processing and data management related to the specimen.

7.4.1.16 OBR-16 Ordering Provider (XCN) 00226

```
Components:  <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and
           Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III)
           (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^
           <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^
           <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier
           Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code
           (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^
           <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date
           (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
           <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
           Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From
           Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Name Context (CE):  <Identifier (ST)> & <Text (ST)> & <Name of
           Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
           & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR):  <Range Start Date/Time (TS)> &
           <Range End Date/Time (TS)>

           Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
           (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
           Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
           <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
           Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
           Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
           Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
           (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
           <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
           System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
           <Original Text (ST)>
```

Definition: This field identifies the provider who ordered the test. Either the ID code or the name, or both, may be present. This is the same as *ORC-12-Ordering provider*.

7.4.1.17 OBR-17 Order Callback Phone Number (XTN) 00250

```
Components:  <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^
           <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country
           Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension
           (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)>
           ^ <Unformatted Telephone number  (ST)>
```

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.

7.4.1.18 OBR-18 Placer Field 1 (ST) 00251

Definition: This field is user field #1. Text sent by the placer will be returned with the results.

7.4.1.19 OBR-19 Placer Field 2 (ST) 00252

Definition: This field is similar to placer field #1.

7.4.1.20 OBR-20 Filler Field 1 (ST) 00253

Definition: This field is definable for any use by the filler (diagnostic service).

7.4.1.21 OBR-21 Filler Field 2 (ST) 00254

Definition: This field is similar to filler field #1.

7.4.1.22 OBR-22 Results Rpt/Status Chng - Date/Time (TS) 00255

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field specifies the date/time results reported or status changed. This field is used to indicate the date and time that the results are composed into a report and released, or that a status, as defined in *ORC-5-order status*, is entered or changed. (This is a results field only.) When other applications (such as office or clinical database applications) query the laboratory application for untransmitted results, the information in this field may be used to control processing on the communications link. Usually, the ordering service would want only those results for which the reporting date/time is greater than the date/time the inquiring application last received results.

7.4.1.23 OBR-23 Charge to Practice (MOC) 00256

```
Components:  <Monetary Amount (MO)> ^ <Charge Code (CE)>

Subcomponents for Monetary Amount (MO):  <Quantity (NM)> & <Denomination (ID)>

Subcomponents for Charge Code (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)>
```

Definition: This field is the charge to the ordering entity for the studies performed when applicable. The first component is a dollar amount when known by the filler. The second is a charge code when known by the filler (results only).

7.4.1.24 OBR-24 Diagnostic Serv Sect ID (ID) 00257

Definition: This field is the section of the diagnostic service where the observation was performed. If the study was performed by an outside service, the identification of that service should be recorded here. Refer to Chapter 4, Section 4.5.3.24, *HL7 Table 0074 - Diagnostic service section ID* for valid entries.

7.4.1.25 OBR-25 Result Status (ID) 00258

Definition: This field is the status of results for this order. This conditional field is required whenever the OBR is contained in a report message. It is not required as part of an initial order.

There are two methods of sending status information. If the status is that of the entire order, use *ORC-15-order effective date/time* and *ORC-5-order status*. If the status pertains to the order detail segment, use *OBR-25-result status* and *OBR-22-results report/status change - date/time*. If both are present, the OBR values override the ORC values.

This field would typically be used in a response to an order status query where the level of detail requested does not include the OBX segments. When the individual status of each result is necessary, *OBX-11-observ result status* may be used. Refer to Chapter 4, Section 4.5.3.25, *HL7 Table 0123 - Result status* for valid entries.

7.4.1.26 OBR-26 Parent Result (PRL) 00259

```
Components:  <Parent Observation Identifier (CE)> ^ <Parent Observation Sub-identifier
           (ST)> ^ <Parent Observation Value Descriptor (TX)>
```

```
Subcomponents for Parent Observation Identifier (CE):  <Identifier (ST)> & <Text (ST)>
           & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
           Text (ST)> & <Name of Alternate Coding System (ID)>
```

Definition: This field is defined to make it available for other types of linkages (e.g., toxicology). This important information, together with the information in *OBR-29-parent,* uniquely identifies the parent result's OBX segment related to this order. The value of this OBX segment in the parent result is the organism or chemical species about which this battery reports. For example, if the current battery is an antimicrobial susceptibility, the parent result's identified OBX contains a result which identifies the organism on which the susceptibility were run. This indirect linkage is preferred because the name of the organism in the parent result may undergo several preliminary values prior to finalization.

The third component may be used to record the name of the microorganism identified by the parent result directly. The organism in this case should be identified exactly as it is in the parent culture.

We emphasize that this field does not take the entire result field from the parent. It is meant only for the text name of the organism or chemical subspecies identified. This field is included only to provide a method for linking back to the parent result for those systems which could not generate unambiguous Observation IDs and sub-IDs.

This field is present only when the parent result is identified by *OBR-29-parent* and the parent spawn child orders for each of many results. (See Chapter 7 for more details about this linkage.)

A second mode of conveying this information is to use a standard observation result segment (OBX). If more than one organism is present, *OBX-4-observation subID* is used to distinguish them. In this case, the first OBX with subID N will contain a value identifying the Nth microorganism, and each additional OBX with subID N will contain susceptibility values for a given antimicrobial test on this organism.

7.4.1.27 OBR-27 Quantity/Timing (TQ) 00221

```
Components:  <Quantity (CQ)> ^ <Interval (RI)> ^ <Duration (ST)> ^ <Start Date/Time
           (TS)> ^ <End Date/Time (TS)> ^ <Priority (ST)> ^ <Condition (ST)> ^ <Text
           (TX)> ^ <Conjunction (ID)> ^ <Order Sequencing (OSD)> ^ <Occurrence
           Duration (CE)> ^ <Total Occurrences (NM)>

Subcomponents for Quantity (CQ):  <Quantity (NM)> & <Units (CE)>

           Note subcomponent contains sub-subcomponents

Subcomponents for Interval (RI):  <Repeat Pattern (IS)> & <Explicit Time Interval
           (ST)>

Subcomponents for Start Date/Time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
           Precision (ID)>

Subcomponents for End Date/Time (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
           (ID)>

Subcomponents for Order Sequencing (OSD):  <Sequence/Results Flag (ID)> & <Placer
           Order Number: Entity Identifier (ST)> & <Placer Order Number: Namespace ID
           (IS)> & <Filler Order Number: Entity Identifier (ST)> & <Filler Order
           Number: Namespace ID (IS)> & <Sequence Condition Value (ST)> & <Maximum
           Number of Repeats (NM)> & <Placer Order Number: Universal ID (ST)> &
           <Placer Order Number: Universal ID Type (ID)> & <Filler Order Number:
           Universal ID (ST)> & <Filler Order Number: Universal ID Type (ID)>

Subcomponents for Occurrence Duration (CE):  <Identifier (ST)> & <Text (ST)> & <Name
           of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text
           (ST)> & <Name of Alternate Coding System (ID)>
```

Definition: ***This field is retained for backward compatibility only.*** The reader is referred to the TQ1 and TQ2 segments described in sections 4.5.4 and 4.5.5 respectively.

This field contains information about how many services to perform at one service time and how often the service times are repeated, and to fix duration of the request.

7.4.1.28 OBR-28 Result Copies To (XCN) 00260

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Definition: This field is the people who are to receive copies of the results. By local convention, either the ID number or the name may be absent.

7.4.1.29 OBR-29 Parent (EIP) 00261

Components: <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field is identical to *ORC-8-parent*. This field relates a child to its parent when a parent/child relationship exists. For example, observations that are spawned by previous observations, e.g., antimicrobial susceptibilities spawned by blood cultures, need to record the parent (blood culture) filler order number here. The parent/child mechanism is described under the order control field notes (see Segment ORC field notes in Section 4.3.1.1.1, “Table notes for order control codes of ORC.” It is required when the order is a child.

7.4.1.30 OBR-30 Transportation Mode (ID) 00262

Definition: This field identifies how (or whether) to transport a patient, when applicable. Refer to Section 4.5.3.30, *HL7 Table 0124 - Transportation mode* for valid codes.

7.4.1.31 OBR-31 Reason for Study (CE) 00263

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field is the code or text using the conventions for coded fields given in Chapter 2, Control. This is required for some studies to obtain proper reimbursement.

7.4.1.32 OBR-32 Principal Result Interpreter (NDL) 00264

```
Components:  <Name (CNN)> ^ <Start Date/time (TS)> ^ <End Date/time (TS)> ^ <Point of
             Care  (IS)> ^ <Room  (IS)> ^ <Bed (IS)> ^ <Facility (HD)> ^ <Location
             Status  (IS)> ^ <Patient Location Type (IS)> ^ <Building  (IS)> ^ <Floor
             (IS)>

Subcomponents for Name (CNN):  <ID Number (ST)> & <Family Name (ST)> & <Given Name
             (ST)> & <Second and Further Given Names or Initials Thereof (ST)> &
             <Suffix (e.g., JR or III) (ST)> & <Prefix (e.g., DR) (ST)> & <Degree
             (e.g., MD (IS)> & <Source Table (IS)> & <Assigning Authority   - Namespace
             ID (IS)> & <Assigning Authority  - Universal ID (ST)> & <Assigning
             Authority  - Universal ID Type (ID)>

Subcomponents for Start Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>

Subcomponents for End Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
             <Universal ID Type (ID)>
```

Definition: This field identifies the physician or other clinician who interpreted the observation and is responsible for the report content.

7.4.1.33 OBR-33 Assistant Result Interpreter (NDL) 00265

```
Components:  <Name (CNN)> ^ <Start Date/time (TS)> ^ <End Date/time (TS)> ^ <Point of
             Care  (IS)> ^ <Room  (IS)> ^ <Bed (IS)> ^ <Facility (HD)> ^ <Location
             Status  (IS)> ^ <Patient Location Type (IS)> ^ <Building  (IS)> ^ <Floor
             (IS)>

Subcomponents for Name (CNN):  <ID Number (ST)> & <Family Name (ST)> & <Given Name
             (ST)> & <Second and Further Given Names or Initials Thereof (ST)> &
             <Suffix (e.g., JR or III) (ST)> & <Prefix (e.g., DR) (ST)> & <Degree
             (e.g., MD (IS)> & <Source Table (IS)> & <Assigning Authority   - Namespace
             ID (IS)> & <Assigning Authority  - Universal ID (ST)> & <Assigning
             Authority  - Universal ID Type (ID)>

Subcomponents for Start Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>

Subcomponents for End Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
             <Universal ID Type (ID)>
```

Definition: This field identifies the clinical observer who assisted with the interpretation of this study.

7.4.1.34 OBR-34 Technician (NDL) 00266

```
Components:  <Name (CNN)> ^ <Start Date/time (TS)> ^ <End Date/time (TS)> ^ <Point of
             Care  (IS)> ^ <Room  (IS)> ^ <Bed (IS)> ^ <Facility (HD)> ^ <Location
```

```
            Status  (IS)> ^ <Patient Location Type (IS)> ^ <Building  (IS)> ^ <Floor
            (IS)>

      Subcomponents for Name (CNN):  <ID Number (ST)> & <Family Name (ST)> & <Given Name
            (ST)> & <Second and Further Given Names or Initials Thereof (ST)> &
            <Suffix (e.g., JR or III) (ST)> & <Prefix (e.g., DR) (ST)> & <Degree
            (e.g., MD (IS)> & <Source Table (IS)> & <Assigning Authority   - Namespace
            ID (IS)> & <Assigning Authority  - Universal ID (ST)> & <Assigning
            Authority  - Universal ID Type (ID)>

      Subcomponents for Start Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
            Precision (ID)>

      Subcomponents for End Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
            (ID)>

      Subcomponents for Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
            <Universal ID Type (ID)>
```

Definition: This field identifies the performing technician.

7.4.1.35 OBR-35 Transcriptionist (NDL) 00267

```
      Components:  <Name (CNN)> ^ <Start Date/time (TS)> ^ <End Date/time (TS)> ^ <Point of
            Care  (IS)> ^ <Room  (IS)> ^ <Bed (IS)> ^ <Facility (HD)> ^ <Location
            Status  (IS)> ^ <Patient Location Type (IS)> ^ <Building  (IS)> ^ <Floor
            (IS)>

      Subcomponents for Name (CNN):  <ID Number (ST)> & <Family Name (ST)> & <Given Name
            (ST)> & <Second and Further Given Names or Initials Thereof (ST)> &
            <Suffix (e.g., JR or III) (ST)> & <Prefix (e.g., DR) (ST)> & <Degree
            (e.g., MD (IS)> & <Source Table (IS)> & <Assigning Authority   - Namespace
            ID (IS)> & <Assigning Authority  - Universal ID (ST)> & <Assigning
            Authority  - Universal ID Type (ID)>

      Subcomponents for Start Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
            Precision (ID)>

      Subcomponents for End Date/time (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
            (ID)>

      Subcomponents for Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
            <Universal ID Type (ID)>
```

Definition: This field identifies the report transcriber.

7.4.1.36 OBR-36 Scheduled - Date/Time (TS) 00268

```
      Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field is the date/time the filler scheduled an observation, when applicable (e.g., action code in *OBR-11-specimen action code* = "S"). This is a result of a request to schedule a particular test and provides a way to inform the Placer of the date/time a study is scheduled (result only).

7.4.1.37 OBR-37 Number of Sample Containers (NM) 01028

Definition: This field identifies the number of containers for a given sample. For sample receipt verification purposes; may be different from the total number of samples which accompany the order.

7.4.1.38 OBR-38 Transport Logistics of Collected Sample (CE) 01029

```
      Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)>
```

Definition: This field is the means by which a sample reaches the diagnostic service provider. This information is to aid the lab in scheduling or interpretation of results. Possible answers: routine transport van, public postal service, etc. If coded, requires a user-defined table.

7.4.1.39 OBR-39 Collector's Comment (CE) 01030

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field is for reporting additional comments related to the sample. If coded, requires a user-defined table. If only free text is reported, it is placed in the second component with a null in the first component, e.g., `^difficult clotting after venipuncture and ecchymosis`.

7.4.1.40 OBR-40 Transport Arrangement Responsibility (CE) 01031

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field is an indicator of who is responsible for arranging transport to the planned diagnostic service. Examples: Requester, Provider, Patient. If coded, requires a user-defined table.

7.4.1.41 OBR-41 Transport Arranged (ID) 01032

Definition: This field is an indicator of whether transport arrangements are known to have been made. Refer to Section 4.5.3.41 *HL7 Table 0224 - Transport arranged* for valid codes.

7.4.1.42 OBR-42 Escort Required (ID) 01033

Definition: This field is an indicator that the patient needs to be escorted to the diagnostic service department. Note: The nature of the escort requirements should be stated in the *OBR-43-planned patient transport comment* field. See Section 4.5.3.42, *HL7 Table 0225 - Escort required* for valid values.

7.4.1.43 OBR-43 Planned Patient Transport Comment (CE) 01034

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field is the code or free text comments on special requirements for the transport of the patient to the diagnostic service department. If coded, requires a user-defined table.

7.4.1.44 OBR-44 Procedure Code (CE) 00393

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains a unique identifier assigned to the procedure, if any, associated with the charge. Refer to *User-defined Table 0088 - Procedure code* for suggested values. This field is a CE data type for compatibility with clinical and ancillary systems.

7.4.1.45 OBR-45 Procedure Code Modifier (CE) 01316

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the procedure code modifier to the procedure code reported in *OBR-44-procedure code*, when applicable. Procedure code modifiers are defined by regulatory agencies such as CMS and the AMA. Multiple modifiers may be reported. *The modifiers are sequenced in priority according to user entry. This is a requirement of the UB and the 1500 claim forms. Multiple modifiers are allowed and the order placed on the form affects reimbursement*. Refer to *User-defined Table 0340 - Procedure code modifier* in Chapter 4, Section 4.5.3.46 for suggested values.

Usage Rule: This field can only be used if OBR-44-procedure code contains certain procedure codes that require a modifier in order to be billed or performed. For example HCPCS codes that require a modifier to be precise.

7.4.1.46 OBR-46 Placer Supplemental Service Information (CE) 01474

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains supplemental service information sent from the placer system to the filler system for the universal procedure code reported in *OBR-4 Universal Service ID*. This field will be used to provide ordering information detail that is not available in other, specific fields in the OBR segment. Multiple supplemental service information elements may be reported. Refer to *User-defined table 0411 - Supplemental service information values* in Chapter 4, Section 4.5.3.47 for suggested values.

This field can be used to describe details such as whether study is to be done on the right or left, for example where the study is of the arm and the order master file does not distinguish right from left or whether the study is to be done with or without contrast (when the order master file does not make such distinctions).

7.4.1.47 OBR-47 Filler Supplemental Service Information (CE) 01475

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains supplemental service information sent from the filler system to the placer system for the procedure code reported in *OBR-4 Universal Service ID.* This field will be used to report ordering information details that is not available in other, specific fields in the OBR segment. Typically it will reflect the same information as was sent to the filler system in *OBR-46-Placer supplemental* information unless the order was modified in which case the filler system will report what was actually performed using this field. Multiple supplemental service information elements may be reported. Refer to *User-Defined Table 0411 - Supplemental Service Information Values* in section 4.5.3.47 for suggested values.

This field can be used to describe details such as whether study is to be done on the right or left, for example where the study is of the arm and the order master file does not distinguish right from left or whether the study is to be done with or without contrast (when the order master file does not make such distinctions).

7.4.1.48 OBR-48 Medically Necessary Duplicate Procedure Reason (CWE) 01646

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field is used to document why the procedure found in OBR-44 (Procedure Code) is a duplicate of one ordered/charged previously for the same patient within the same date of service and has been determined to be medically necessary. The reason may be coded or it may be a free text entry.

This field is intended to provide financial systems information on who to bill for duplicate procedures.

Refer to *User-defined table 0476* in Chapter 4, Section 4.5.3.48 for suggested values.

7.4.1.49 OBR-49 Result Handling (IS) 01647

Definition: Transmits information regarding the handling of the result. For example, an order may specify that the result (e.g., an x-ray film) should be given to the patient for return to the requestor. Refer *to User-*

defined table 0507 Observation Result Handling in Chapter 4, Section 4.5.3.49 for suggested values. If this field is not populated then routine handling is implied.

7.4.2 OBX - Observation/Result Segment

The OBX segment is used to transmit a single observation or observation fragment. It represents the smallest indivisible unit of a report. The OBX segment can also contain encapsulated data, e.g., a CDA document or a DICOM image.

Its principal mission is to carry information about observations in report messages. But the OBX can also be part of an observation order (see Section 4.4, "Order Message Definitions"). In this case, the OBX carries clinical information needed by the filler to interpret the observation the filler makes. For example, an OBX is needed to report the inspired oxygen on an order for a blood oxygen to a blood gas lab, or to report the menstrual phase information which should be included on an order for a pap smear to a cytology lab. Appendix 7A includes codes for identifying many of pieces of information needed by observation producing services to properly interpret a test result. OBX is also found in other HL7 messages that need to include patient clinical information.

HL7 Attribute Table – OBX – Observation/Result

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID – OBX
2	2	ID	C		0125	00570	Value Type
3	250	CE	R			00571	Observation Identifier
4	20	ST	C			00572	Observation Sub-ID
5	99999[1]	varies	C	Y[2]		00573	Observation Value
6	250	CE	O			00574	Units
7	60	ST	O			00575	References Range
8	5	IS	O	Y	0078	00576	Abnormal Flags
9	5	NM	O			00577	Probability
10	2	ID	O	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observation Result Status
12	26	TS	O			00580	Effective Date of Reference Range
13	20	ST	O			00581	User Defined Access Checks
14	26	TS	O			00582	Date/Time of the Observation
15	250	CE	O			00583	Producer's ID
16	250	XCN	O	Y		00584	Responsible Observer
17	250	CE	O	Y		00936	Observation Method
18	22	EI	O	Y		01479	Equipment Instance Identifier
19	26	TS	O			01480	Date/Time of the Analysis

7.4.2.0 OBX field definitions

7.4.2.1 OBX-1 Set ID - OBX (SI) 00569

Definition: This field contains the sequence number. For compatibility with ASTM.

[1] The length of the observation field is variable, depending upon value type. See *OBX-2 value type*.

[2] May repeat for multipart, single answer results with appropriate data types, e.g., CE, TX, and FT data types.

7.4.2.2 OBX-2 Value Type (ID) 00570

Definition: This field contains the format of the observation value in OBX. It must be valued if *OBX-11-Observ result status* is not valued with an 'X". If the value is CE then the result must be a coded entry. When the value type is TX or FT then the results are bulk text. The valid values for the value type of an observation are listed in *HL7 Table 0125 - Value Type*.

The observation value must be represented according to the format for the data type defined in Chapter 2, Section 2.9, "Data Types." For example, a PN consists of 6 components, separated by component delimiters.

Although NM is a valid type, observations which are usually 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., >300 to indicate the result was off-scale for the instrument. In the example, ">300", ">" is a symbol and the digits are considered a numeric value. However, this usage of the ST type should be discouraged since the SN (structured numeric) data type now accommodates such reporting and, in addition, permits the receiving system to interpret the magnitude.

All HL7 data types are valid, and are included in Table 0125 except CM, CQ, SI, and ID. For a CM definition to have meaning, the specifics about the CM must be included in the field definition. *OBX-5-observation value* is a general field definition that is influenced by the data type *OBX-3*, so CMs are undefined in this context. CQ is invalid because units for *OBX-5-observation value* are always specified explicitly in an OBX segment with *OBX-6 units*. SI is invalid because it only applied to HL7 message segments, and ID because it requires a constant field definition.

The RP value (reference pointer) must be used if the actual observation value is not sent in OBX but exists somewhere else. For example, if the observation consists of an image (document or medical), the image itself cannot be sent in OBX. The sending system may in that case opt to send a reference pointer. The receiving system can use this reference pointer whenever it needs access to the actual image through other interface standards, e.g., DICOM, or through appropriate data base servers.

HL7 Table 0125 - Value type

Value	Description	Comment
AD	Address	
CE	Coded Entry	
CF	Coded Element With Formatted Values	
CK	Composite ID With Check Digit	
CN	Composite ID And Name	
CP	Composite Price	
CX	Extended Composite ID With Check Digit	
DT	Date	
ED	Encapsulated Data	
FT	Formatted Text (Display)	
MO	Money	
NM	Numeric	
PN	Person Name	
RP	Reference Pointer	
SN	Structured Numeric	
ST	String Data.	
TM	Time	
TN	Telephone Number	
TS	Time Stamp (Date & Time)	
TX	Text Data (Display)	
XAD	Extended Address	
XCN	Extended Composite Name And Number For Persons	

Value	Description	Comment
XON	Extended Composite Name And Number For Organizations	
XPN	Extended Person Name	
XTN	Extended Telecommunications Number	

The full definition of these data types is given in Chapter 2, Section 2.9, "Data Types." The structured numeric (SN) data type, new to version 2.3, provides for reporting ranges (e.g., 3-5 or 10-20), titres (e.g., 1:10), and out-of-range indicators (e.g., >50) in a structured and computer interpretable way.

We allow the FT data type in the OBX segment but its use is discouraged. Formatted text usually implies a meaningful structure e.g., a list of three independent diagnoses reported on different lines. But ideally, the structure in three independent diagnostic statements would be reported as three separate OBX segments.

TX should **not** be used except to send large amounts of text. In the TX data type, the repeat delimiter can only be used to identify paragraph breaks. Use ST to send short, and possibly encodable, text strings.

CDA documents are to be exchanged in the OBX segment in any message that can exchange documents (such as MDM or ORU). Within the OBX segment, the MIME package is encoded as an encapsulated (ED) data type.

7.4.2.3 OBX-3 Observation Identifier (CE) 00571

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains a unique identifier for the observation. The format is that of the Coded Element (CE). Example: 8625-6^P-R interval^LN.

In most systems the identifier will **point** to a master observation table that will provide other attributes of the observation that may be used by the receiving system to process the observations it receives. A set of message segments for transmitting such master observation tables is described in Chapter 8. The relation of an observation ID to a master observation table is analogous to the relationship between a charge code (in a billing record) and the charge master.

When local codes are used as the first identifier in this field we strongly encourage sending a universal identifier as well to permit receivers to equivalence results from different providers of the same service (e.g., a hospital lab and commercial lab that provides serum potassium to a nursing home). LOINC® is an HL7 approved code system for the Observation identifier. It covers observations and measurements, such as laboratory tests, physical findings, radiology studies, and claims attachments and can be obtained from www.regenstrief.org/loinc/loinc.htm. One possible **universal** identifier is LOINC® codes for laboratory and clinical measurements (see *HL7 defined Table 0396* and the HL7 www list server) and Appendix X2 of ASTM E1467 for neurophysiology tests.

For a discussion of the use of suffixes as related to narrative reports see Section 7.2.3 and Section 7.2.4.

7.4.2.4 OBX-4 Observation Sub-ID (ST) 00572

Definition: This field is used to distinguish between multiple OBX segments with the same observation ID organized under one OBR. For example, a chest X-ray report might include three separate diagnostic impressions. The standard requires three OBX segments, one for each impression. By putting a 1 in the Sub-ID of the first of these OBX segments, 2 in the second, and 3 in the third, we can uniquely identify each OBX segment for editing or replacement.

The sub-identifier is also 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. Consider, for example, a single surgical pathology report that describes the examination of gallbladder and appendix tissue. This report would be transmitted roughly as shown in Figure 7-2.

Figure 7-2. Example of sub-identifier usage

```
OBR|1||1234^LAB|88304&SURG PATH REPORT|...<cr>
OBX|1|CE|88304&ANT|1|T57000^GALLBLADDER^SNM|...<cr>
OBX|2|TX|88304&GDT|1|THIS IS A NORMAL GALLBLADDER|...<cr>
OBX|3|TX|88304&MDT|1|MICROSCOPIC EXAM SHOWS HISTOLOGICALLY
    NORMAL GALLBLADDER TISSUE|...<cr>
OBX|4|CE|88304&IMP|1|M-00100^NML^SNM|...<cr>
OBX|5|CE|88304&ANT|2|T66000^APPENDIX^SNM|...<cr>
OBX|6|TX|88304&GDT|2|THIS IS A RED, INFLAMED, SWOLLEN, BOGGY APPENDIX|...<cr>
OBX|7|TX|88304&MDT|2|INFILTRATION WITH MANY PMN's - INDICATING INFLAMATORY
    CHANGE|...<cr>
OBX|8|CE|88304&IMP|2|M-40000^INFLAMMATION NOS^SNM|...<cr>
```

The example in Figure 7-2 has two segments for each component of the report, one for each of the two tissues. Thus, there are two 88304&ANT segments; there are two 88304&GDT segments, and there are two 88304&MDT segments. Segments that apply to the gallbladder all have the sub-identifier 1. Segments that apply to the appendix all have sub-identifier 2.

The observation sub ID has other grouping uses. It can be used to organize the reporting of some kinds of fluid intakes and outputs. For example, when intake occurs through multiple intravenous lines, a number of separate observations (OBX segments), the intake volume, the type of intake (Blood, D5W, Plasma, etc.), the site of the IV line, etc. may be needed for each intravenous line, each requiring a separate OBX segment. If more than one IV line is running, we can logically link all of the OBX segments that pertain to the first IV line by assigning them an observation sub ID of 1. We can do the same with the second IV line by assigning them a sub ID 2 and so on. The same would apply to the outputs of surgical drains when there are multiple such drains.

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, as can be seen if we picture the OBX segments in Figure 7-2 as part of a table where the rows correspond to a particular species of observation and the cells correspond to the sub ID numbers that would be associated with each corresponding OBX.

Distinct Observations	88304&ANT	88304&GDT	80304&MDT	80304&IMP
Sub ID 1st Group	1	1	1	1
Sub ID 2nd Group	2	2	2	2

The use of Sub IDs to group results is equivalent to defining a table, and the use of sub IDs to distinguish repeats is just a special case, represented by one column in this table.

However, this approach introduces ambiguities if we have a set of repeating observations within a group, e.g., if the appendix observations include two impressions as in the 8th and 9th OBXs shown in Figure 7-3. This really represents the existence of a row nested within a single cell of the table given above.

Figure 7-3. Example of sub-identifier usage

```
OBX|1|CE|880304&ANT|1|T57000^GALLBLADDER^SNM|...<cr>
OBX|2|TX|880304&GDT|1|THIS IS A NORMAL GALL BLADDER|...<cr>
OBX|3|TX|880304&MDT|1|MICROSCOPIC EXAMINATION SHOWS HISTOLOGICALLY
    NORMAL GALLBLADDER TISSUE|...<cr>
```

```
OBX|4|CE|880304&IMP|1|M-00100^NML^SNM|...<cr>
OBX|5|CE|880304&ANT|2|T57000^APPENDIX^SNM|...<cr>
OBX|6|TX|880304&GDT|2|THIS IS A RED, INFLAMED APPENDIX|...<cr>
OBX|7|TX|880304&MDT|2|INFLAMMATION WITH MANY PUS CELLS-ACUTE INFLAMMATION|...<cr>
OBX|8|CE|880304&IMP|2|M-40000^INFLAMMATION NOS^SNM|...<cr>
OBX|9|CE|880304&IMP|2|M-30280^FECALITH^SNM|...<cr>
```

The text under *OBX-5-observation value* provides guidance about dealing with two OBXs with the same observation ID and observation sub IDs. They are sent and replaced as a unit. However, some systems will take this to mean that the set of OBXs is to be combined into one composite observation in the receiving system. We suggest the use of a dot and a string (similar to the Dewey Decimal system) when users wish to distinguish each of the repeats within one type, or results within a cell for editing and correction purposes. Using this system, Figure 7-3 would become 7-4. If there are cases where such nesting occurs at even deeper levels, this approach could be extended.

Figure 7-4. Example of sub-identifier usage

```
OBX|1|CE|880304&ANT|1|T57000^GALLBLADDER^SNM|...<cr>
OBX|2|TX|880304&GDT|1|THIS IS A NORMAL GALL BLADDER|...<cr>
OBX|3|TX|880304&MDT|1|MICROSCOPIC EXAMINATION SHOWS HISTOLOGICALLY
    NORMAL GALLBLADDER TISSUE|...<cr>
OBX|4|CE|880304&IMP|1|M-00100^NML^SNM|...<cr>
OBX|5|CE|880304&ANT|2|T57000^APPENDIX^SNM|...<cr>
OBX|6|TX|880304&GDT|2|THIS IS A RED, INFLAMED APPENDIX|...<cr>
OBX|7|TX|880304&MDT|2|INFLAMMATION WITH MANY PUS CELLS-ACUTE INFLAMMATION|...<cr>
OBX|8|CE|880304&IMP|2.1|M-40000^INFLAMMATION NOS^SNM|...<cr>
OBX|9|CE|880304&IMP|2.2|M-30280^FECALITH^SNM|...<cr>
```

Use a null or 1 when there is no need for multiples.

If the observation includes a number of OBXs with the same value for the observation ID OBX-3, then one must use different values for the sub-ID. This is in fact the case of the repeats depicted in Figure 7-4, but without any need to group sets of OBXs. Three such OBXs could be distinguished by using sub-IDs 1, 2 etc. alternatively, sub-IDs 1.1, 1.2, 1.3 could be used, as shown in Figure 7-4. Figure 7-5 shows and example of an electrocardiograph chest radiograph report with three diagnostic impressions, using 1,2,3 in the sub-ID field to distinguish the three separate results.

Figure 7-5. Example of Sub-ID used to distinguish three independent results with the same observation ID

```
OBX|1|CE|8601-7^EKG IMPRESSION ^LN|1|^atrial fibrillation|...<cr>
OBX|2|CE|8601-7^EKG IMPRESSION ^LN|2|^OLD SEPTAL MYOCARDIAL INFARCT|...<cr>
OBX|3|CE|8601-7^EKG IMPRESSION ^LN|3|^poor R wave progression|...<cr>
```

7.4.2.5 OBX-5 Observation Value (varies) 00573

Definition: This field contains the value observed by the observation producer. *OBX-2-value type* contains the data type for this field according to which observation value is formatted. It is not a required field because some systems will report only the normalcy/abnormalcy (*OBX-8*), especially in product experience reporting. The length of the observation field is variable, depending upon *OBX-3-value type*. This field may repeat for multipart, single answer results with appropriate data types, e.g., CE, TX, and FT data types.

Representation

This field contains the value of *OBX-3-observation identifier* of the same segment. Depending upon the observation, the data type may be a number (e.g., a respiratory rate), a coded answer (e.g., a pathology impression recorded as SNOMED), or a date/time (the date/time that a unit of blood is sent to the ward). An observation value is always represented as the data type specified in *OBX-2-value type* of the same segment. Whether numeric or short text, the answer shall be recorded in ASCII text.

Reporting logically independent observations

The main sections of dictated reports, such as radiologic studies or history and physicals, are reported as separate OBX segments. In addition, each logically independent observation should be reported in a separate OBX segment, i.e. one OBX segment should not contain the **result** of more than one logically independent observation. This requirement is included to assure that the contents of *OBX-6-units*, *OBX-8-abnormal flags*, and *OBX-9-probability* can be interpreted unambiguously. The electrolytes and vital signs batteries, for example, would each be reported as four separate OBX segments. Two diagnostic impressions, e.g., congestive heart failure and pneumonia, would also be reported as two separate OBX segments whether reported as part of a discharge summary or chest X-ray report. Similarly, two bacterial organisms isolated in a single bacterial culture would be reported as two separate OBX segments.

Though two independent diagnostic **statements** cannot be reported in one OBX segment, multiple categorical responses are allowed (usually as CE data types separated by repeat delimiters), so long as they are fragments (modifiers) that together construct one diagnostic statement. Right upper lobe (recorded as one code) and pneumonia (recorded as another code), for example, could be both reported in one OBX segment. Such multiple "values" would be separated by repeat delimiters.

Multiple OBX segments with the same observation ID and Sub ID

In some systems, a single observation may include **fragments** of more than one data type. The most common example is a numeric result followed by coded comments (CE). In this case, the logical observation can be sent in more than one OBX segment. For example, one segment of numeric or string data type for the numeric result and another segment of CE data type for coded comments. If the producer was reporting multiple coded comments they would all be sent in one OBX segment separated by repeat delimiters because they all modified a single logical observation. Multiple OBX segments with the same observation ID and sub ID should always be sent in sequence with the most significant OBX segment (the one that has the normal flag/units and or reference range and status flag) first. The value of *OBX-6 through 12* should be null in any following OBX segments with the same *OBX-3-observation identifier* and *OBX-4-observation sub-ID*. For the purpose of replacement or deletion, multiple OBX segments with the same observation ID and sub ID are treated as a unit. If any are replaced or deleted, they all are replaced.

Coded values

When an OBX segment contains values of CE data types, the observations are stored as a combination of codes and/or text. In Section 7.8.3, "CSS - Clinical Study Data Schedule Segment," examples of results that are represented as CE data types are shown in the first and second OBX segments of OBR 1 and the first and second OBX segments of OBR 2. The observation may be an observation battery ID (for recommended studies), a diagnostic code or finding (for a diagnostic impression), or an anatomic site for a pathology report, or any of the other kinds of coded results.

It is not necessary to always encode the information stored within a coded observation. For example, a chest X-ray impression could be transmitted as pure text even though it has a CE data type. In this case, the test must be recorded as the second component of the **result code,** e.g.,

```
OBX|1|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE.|...<cr>
```

However, separate impressions, recommendations, etc., even if recorded as pure text, should be recorded in separate result segments. That is, congestive heart failure and pneumonia should not be sent as:

```
OBX|1|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE AND PNEUMONIA|...<cr>
```

but as:

```
OBX|1|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE|...<cr>
OBX|2|CE|71020&IMP|2|^PNEUMONIA|....<cr>
```

Even better would be fully-coded results that include computer understandable codes (component 1) instead of, or in addition to, the text description (component 2). One may include multiple values in a CE value and these can be mixtures of code and text, but only when they are needed to construct one diagnosis, impression, or concept. When text follows codes as an independent value it would be taken as a modifier or addenda to the codes. E.g.,

```
OBX|1|CE|710120&IMP^CXR|1|428.0^CONGESTIVE HEART FAILURE^I9C~^MASSIVE HEART|...<cr>
```

The text in component 2 should be an accurate description of the code in component 1. Likewise, if used, the text in component 5 should be an accurate description of the code in component 4.

Insertion of CDA within an OBX:

CDA documents are to be exchanged in the OBX segment. The value of *OBX-2-Value Type* should be set to 'ED'. *OBX-5-Observation Value* contains the MIME package encoded as an encapsulated data type. The components should be valued as follows:

- Set the value of *OBX-5.2-Type of Data* to 'multipart'.
- Set the value of *OBX-5.3-Data Subtype* to 'x-hl7-cda-level-one'
- Set the value of *OBX-5.4-Encoding* to 'A'. (Note that a MIME package is not itself Base64-encoded. Rather entities within the MIME package are Base64-encoded. A MIME package is sent as ASCII text. Therefore, the correct value is 'A' not 'Base64'.
- Set the value of *OBX-5.5-Data* to equal the MIME package. Every entity within the MIME package must be Base64-encoded. As stated in Chapter 2, "the data component must be scanned before transmission for HL7 delimiter characters (and other non-printing ASCII or non-ASCII characters such as LineFeed), and any found must be escaped by using the HL7 escape sequences defined in Section 2.7 'Use of escape sequences in text fields'. On the receiving application, the data field must be de-escaped after being parsed". As a result, CR/LF sequences required in the MIME package need to be escaped (i.e., converted to '\X0D0A\') prior to transmission. The content type of the first MIME entity is set to 'application/x-hl7-cda-level-one+xml', and should contain the CDA document itself. Multimedia objects referenced by the CDA document that need to be transmitted within the CDA document are to be placed in successive entities of the MIME package.

7.4.2.6 OBX-6 Units (CE) 00574

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Background: When an observation's value is measured on a continuous scale, one must report the measurement units within the units field of the OBX segment. Since HL7 Version 2.2 of the specification, all fields that contain units are of data type CE. The default coding system for the units codes consists of the ISO abbreviation for a single case unit (ISO 2955-83) plus extensions that do not collide with ISO abbreviations. We designate this coding system as ISO+ (see Figure 7-9). Both the ISO unit's

abbreviations and the extensions are defined in Section 7.4.2.6.2, "ISO and ANSI customary units abbreviations." The ISO+ abbreviations *are* the codes for the default coding system. Consequently, when ISO+ units are being used, only ISO+ abbreviations need be sent, and the contents of the units field will be backward compatible to HL7 Version 2.1.

7.4.2.6.1 Identifying reporting units

We strongly encourage observation producers to use ISO+ abbreviated units exclusively, but permit the use of other code systems, including US customary units (ANSI X3.50) and locally defined codes where necessary. Local units are designated **L** or 99zzz where z is an alphanumeric character (see Figures 7-2 and 73). ANSI X3.50 - 1986 provides an excellent description of these standards, as well as a table of single case abbreviations for US customary units such as foot or gallon.

We had originally intended to include the ANSI X3.50 - 1986 US customary units in the default ISO+ coding system. However, there are overlaps between ISO's abbreviations and the abbreviations for US customary units. For example, **ft** is the abbreviation for foot in US customary units and for femtotesla in ISO; **pt** is the abbreviation for pint in US customary and for picotesla in ISO. (Be aware that the ANSI document also differs from the ISO document regarding the abbreviation of a few ISO units, as well.) In order to avoid potential ambiguity, we have defined another coding system, designated ANS+ (see Figure 7.7). It includes the U.S. customary units (e.g., feet, pounds) and **ISO** abbreviations defined in ANSI X3.50 - 1986, as well as other non-metric units listed in Figure 7-7 and the ISO combinations of these units. Be aware that a few of the ANSI **ISO** unit abbreviations differ from their abbreviations in ISO (see note at bottom of Figure 7-7).

Because the ANS+ specification includes both **ISO** and US customary units, as well as miscellaneous non-metric units, some of the abbreviations are ambiguous. Although there should be little confusion, in the context of a particular observation, this ambiguity is a good reason for avoiding ANS+ unit codes when possible.

When ANS+ units codes (abbreviations) are being transmitted, **ANS**+ must be included in the third (sixth) component of the field. If the units of distance were transmitted as meters (ISO+) it would be transmitted as **m** because ISO+ is the default coding system for units. However, if transmitted in the US customary units of feet, the units would be transmitted as **ft^^ANS+.** When required, the full text of the units can be sent as the second component in keeping with the CE data type conventions.

Both ISO and ANSI also provide a set of mixed case abbreviations, but these abbreviations cannot be translated to single case without loss of meaning, and should not be used in this specification whose content is required to be case insensitive.

7.4.2.6.2 ISO and ANSI customary units abbreviations

ISO builds its units from seven base dimensions measured as meters, kilograms, seconds, amperes, kelvins, moles and candelas (see Figure 7-6). Other units can be derived from these by adding a prefix to change the scale and/or by creating an algebraic combination of two or more base or derived units. However, some derived units have acquired their own abbreviations (see Figure 7-6). Abbreviations for U.S. customary units are given in Figure 7-6.

The ISO rules, well explained in ANSI X3.50, provide a way to create units of different scales by adding **multiplier** prefixes. These prefixes can be expressed as **words** or abbreviations. In this Standard we are only concerned with the abbreviations.

Figure 7-6. ISO single case units abbreviations

Units	Abbreviation	Units	Abbreviation	Units	Abbreviation
Base units code/abbreviations					

ampere	a	kelvin	k	meter	m
candela	cd	Kilogram	kg	mole	mol
				second	s
Derived units with specified name and abbreviation					
coulomb	c	hour	Hr	pascal	pal
day	d	joule	J	volt	v
degree Celsius	cel	minute (ti)	Min	watt	w
farad	f	newton	N	weber	wb
hertz	hz	ohm	Ohm	year	ann
Other units					
atomic mass unit	u	grey	gy	minute of arc	mnt
Bel	b	henry	h	radian	rad
Decibel	db	liter	l	siemens	sie
Degree	deg	lumen	Lm	steradian	sr
Gram	g	lux	Lx	tesla	t
See ISO 2955-1983 for full set					

The ISO abbreviations for multiplier prefixes are given in Figure 7-12. Prefixes ranging from 10^{-24} (1/billion billionth) to 10^{24} (a billion billion) are available. The single case abbreviation for kilo (x1000) is **k**. A unit consisting of 1000 seconds would be abbreviated as **ks**, 1000 grams as **kg**, 1000 meters as **km**, and so on. Some prefixes share the abbreviation of a base unit. Farad and femto, for example, (10^{-18}) both have the abbreviation of **f**. To avoid confusion, ISO forbids the use of solitary prefixes. It also deprecates the use of two prefixes in one complex unit. Thus, **f** always means farad, **ff** would mean 1 million billionth of a farad. Compound prefixes are not allowed.

A unit can be raised to an exponential power. Positive exponents are represented by a number immediately following a unit's abbreviation, i.e., a square meter would be denoted by m2. Negative exponents are signified by a negative number following the base unit, e.g., **1/m2** would be represented **as m-2.** Fractional exponents are expressed by a numeric fraction in parentheses: the square root of a meter would be expressed as m(1/2). The multiplication of units is signified by a period (.) between the units, e.g., meters X seconds would be denoted **m.s**. Notice that spaces are not permitted. Division is signified by a slash (/) between two units, e.g. meters per second would be denoted as **m/s**. Algebraic combinations of ISO unit abbreviations constructed by dividing, multiplying, or exponentiating base ISO units, are also valid ISO abbreviations units. Exponentiation has precedence over multiplication or division. For example, microvolts squared per hertz (a unit of spectral power) would be denoted **uv2/hz** and evaluated as uv^2/hz while microvolts per square root of hertz (a unit of spectral amplitude) would be denoted uv/hz(1/2) and evaluated as $uv/hz^{½}$. If more than one division operator is included in the expression the associations should be parenthesized to avoid any ambiguity, but the best approach is to convert a/(b/c) to a.c/b or a.c.b-1 to simplify the expression.

The ISO code is a grammar for building units. The rules for building these units are found in Figures 7-6 and 7-8. Figure 7-7 should be used only with English units and should not be used in conjunction with Figure 7-8. The ISO+ table (Figure 7-9) includes the most common such units constructed from this grammar (as well as important non-ISO units). Other ISO units derived from the grammar are valid as well.

Figure 7-7. ANSI+ unit codes for some U.S. customary units

Units	Abbreviation	Units	Abbreviation	Units	Abbreviation
LENGTH		VOLUME		TIME	
inch	in	cubic foot	cft	year	yr
foot	ft	cubic inch	cin	month	mo
mile (statute)	mi	cubic yard	cyd	week	wk
nautical mile	nmi	tablespoon	tbs	day	d
rod	rod	teaspoon	tsp	hour	hr
yard	yd	pint	pt	minute	min
		quart	qt	second	sec
		gallon	gal		
		ounce (fluid)	foz		
AREA		MASS			
square foot	sqf	dram	dr		
square inch	sin	grain	gr (avoir)		
square yard	syd	ounce (weight)	oz		
		pound	lb		
Other ANSI units, derived units, and miscellaneous					
**British thermal unit	btu	**degrees Fahrenheit	degf	**millirad	mrad
cubic feet/minute	cft/min	**feet/minute	ft/min	**RAD	rad
Note: The abbreviations for conventional U.S. units of time are the same as ISO, except for year. ISO = ANN, AMSI = yr. The metric units in X3.50 are the same as ISO, except for: pascal ("pa" in ANSI, "pal" in ISO); ANSI uses "min" for both time and arc while ISO uses "mnt" for minutes of arc; and in ISA seconds are abbreviated "s", in ANSI, "sec".					
Caution: Because the ANS+ specification includes both ISO and US customary units, as well as miscellaneous non-metric units, some of the abbreviations are ambiguous. Although there should be little confusion, in the context of a particular observation, this ambiguity is a good reason for a voiding ANS+ unit codes when possible.					
This list is not exhaustive. Refer to ANSI X3.50-1986, Table 1, for other metric and standard U.S. units.					
**Non-metric units not explicitly listed in ANSI					

Figure 7-8. Single case ISO abbreviations for multiplier prefixes

Prefix		Code	Prefix		Code
yotta*	10^{24}	ya	yocto	10^{-24}	y
zetta*	10^{21}	za	zepto	10^{-21}	z
exa	10^{18}	ex	atto	10^{-18}	a
peta	10^{15}	pe	femto	10^{-15}	f
tera	10^{12}	t	pico	10^{-12}	p
giga	10^{9}	g	nano	10^{-9}	n
mega	10^{6}	ma	micro	10^{-6}	u
kilo	10^{3}	k	milli	10^{-3}	m
hecto	10^{2}	h	centi	10^{-2}	c
deca	10^{1}	da	deci	10^{-1}	d
*These abbreviations are not defined in the ISO specification for single case					

Prefix		Code	Prefix		Code
abbreviations.					

Figure 7-9 lists the abbreviations for common ISO derived units. It also includes standard unit abbreviations for common units, e.g., Milliequivalents, and international units, mm(Hg), and for counting per which we denote by a division sign, a denominator, but no numerator, e.g., /c, that are not part of the above referenced ISO standards. We have extended the units table to better accommodate drug routes and physiologic measures, and otherwise fill in gaps in Version 2.2.

We have generally followed the IUPAC 1995 Silver Book[2] in the definitions of units. However, IUPAC specifies standards for reporting or displaying units and employs 8-bit data sets to distinguish them. This Standard is concerned with the *transmission* of patient information. Therefore, we have restricted ourselves to case insensitive alphabetic characters and a few special characters (e.g., ".", "/", "(", ")", "*", and "_") to avoid any possible confusion in the transmission. Therefore, we use ISO 2955-1983 (Information processing -- representation of SI and other units in systems with limited character sets) and ANSI X3.50-1986 (Representations for U.S. customary, SI, and other units to be used in systems with limited character sets) case insensitive units abbreviations where they are defined. This means that in some cases, IUPAC abbreviations have different abbreviations in ISO+ even when the IUPAC abbreviations use only standard alphabetic characters. For example, **Pascal** is abbreviated **Pa** in IUPAC but **PAL** in ISO+ (following ISO 2955) because **Pa** in a case insensitive context also means **Picoampere**. However, the requirements for transmission do not preclude usage of IUPAC standards for presentation on paper or video display reports to end-users.

All unit abbreviations are case insensitive. One could write milliliters as ML, ml, or mL. In this table we have used lower case for all of the abbreviations except for the letter **L** which we represent in upper case so that readers will not confuse it with the numeral one (1). This is just a change in presentation, not a change in the Standard. Systems should continue to send the codes as upper or lower case as they always have.

Refer to section 7.18.3 for the contents of figure 7-9 - Common ISO derived units & ISO+ extensions.

7.4.2.6.3 Local unit codes

Local codes can be used for the units by indicating the code source of **99zzz** in the third component (where 99zzz is an alpha-numeric string). In the case of local codes, the text name of the codes or the description of the units should also be transmitted (in the second component), so that the receiving system can compare the results with results for the same measurement sent by another service (refer to Chapter 2, Section 2.9, “Data Types”). An "L" should be stored in the third component to indicate that the code is locally defined. More specialized local code designations, as specified in the CE data type definition, can also be employed.

7.4.2.7 OBX-7 References Range (ST) 00575

Components: for numeric values in the format:

a) lower limit-upper limit (when both lower and upper limits are defined, e.g., for potassium 3.5 - 4.5)

b) > lower limit (if no upper limit, e.g., >10)

c) < upper limit (if no lower limit, e.g., <15)

alphabetical values: the normal value may be reported in this location

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.

7.4.2.8 OBX-8 Abnormal Flags (IS) 00576

Definition: This field contains a table lookup indicating the normalcy status of the result. We strongly recommend sending this value when applicable. (See ASTM 1238 - review for more details). Refer to *User-defined Table 0078 - Abnormal flags* for valid entries.

When the laboratory can discern the normal status of a textual report, such as chest X-ray reports or microbiologic culture, these should be reported as N when normal and A when abnormal. Multiple codes, e.g., abnormal and worse, would be separated by a repeat delimiter, e.g., A~W.

User-defined Table 0078 - Abnormal flags

Value	Description	Comment
L	Below low normal	
H	Above high normal	
LL	Below lower panic limits	
HH	Above upper panic limits	
<	Below absolute low-off instrument scale	
>	Above absolute high-off instrument scale	
N	Normal (applies to non-numeric results)	
A	Abnormal (applies to non-numeric results)	
AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)	
null	No range defined, or normal ranges don't apply	
U	Significant change up	
D	Significant change down	
B	Better--use when direction not relevant	
W	Worse--use when direction not relevant	
S	Susceptible. Indicates for microbiology susceptibilities only.	
R	Resistant. Indicates for microbiology susceptibilities only.	
I	Intermediate. Indicates for microbiology susceptibilities only.	
MS	Moderately susceptible. Indicates for microbiology susceptibilities only.	
VS	Very susceptible. Indicates for microbiology susceptibilities only.	

Results may also be reported in **shorthand** by reporting the normalcy status without specifying the exact numeric value of the result. Such shorthand is quite common in clinical notes, where physicians will simply say that **the glucose result was normal.** Such shorthand reporting is also seen in drug experience reporting. In such cases, the result can be reported in the OBX by reporting the normalcy code in *OBX-8-abnormal flags* without specifying any value in *OBX-5-observation value.*

7.4.2.9 OBX-9 Probability (NM) 00577

Definition: This field contains the probability of a result being true for results with categorical values. It mainly applies to discrete coded results. It is a decimal number represented as an ASCII string that must be between 0 and 1, inclusive.

7.4.2.10 OBX-10 Nature of abnormal test (ID) 00578

Definition: This field contains the nature of the abnormal test. Refer to *HL7 Table 0080 - Nature of abnormal testing* for valid values. As many of the codes as apply may be included, separated by repeat delimiters. For example, normal values based on age, sex, and race would be codes as A~S~R.

The constraints on the use of the codes in this table must be consistent with those defined in the PID segment, specifically *PID-35-Species Code, PID-36-Breed Code* and *PID-37-Strain*.

HL7 Table 0080 - Nature of Abnormal Testing

Value	Description	Comment
A	An age-based population	
N	None - generic normal range	
R	A race-based population	
S	A sex-based population	
SP	Species	
B	Breed	
ST	Strain	

7.4.2.11 OBX-11 Observation Result Status (ID) 00579

Definition: This field contains the observation result status. Refer to *HL7 table 0085 - Observation result status codes interpretation* for valid values. This field reflects the current completion status of the results for one Observation Identifier.

It is a required field. Previous versions of HL7 stated this implicitly by defining a default value of "F." Code **F** indicates that the result has been verified to be correct and final. Code **W** indicates that the result has been verified to be wrong (incorrect); a replacement (corrected) result may be transmitted later. Code **C** indicates that data contained in the *OBX-5-observation value* field are to replace previously transmitted (verified and) final result data with the same observation ID (including suffix, if applicable) and observation sub-ID usually because the previous results were wrong. Code **D** indicates that data previously transmitted in a result segment with the same observation ID (including suffix) and observation sub-ID should be deleted. When changing or deleting a result, multiple OBX segments with the same observation ID and observation sub-ID are replaced or deleted as a unit. Normal progression of results through intermediate (e.g., 'gram positive cocci') to final (e.g., 'staphylococcus aureus') should not be transmitted as **C** (correction); they should be transmitted as **P** or **S** (depending upon the specific case) until they are final.

There are situations where the observation battery required for the order needs to be dynamically specified at the time of ordering. That is, this battery is then defined by the set of OBX segments transmitted along with the order and generated by the placing system. For example, timed measurements of serum glucose challenge tests may vary among laboratories. One institution may report them at –30, -15, 0, 30, 60, and 120 minutes, while another may report them at –30, 0, 30, 60, 90, and 120 minutes. Master file entries may exist for each individual element of the battery but not for the battery itself. Another example may be Renin Studies where the specification may be done upon ordering without having a master file definition for each permutation of the possible element. The OBX segments in the ORM message can be used to create dynamic specifications to accommodate these permutations without defining pre-existing master file definitions for the battery itself. The result status field in the OBX can be used to indicate whether the OBX in the ORM message is used to provide a dynamic specification or is used to communicate a result as context to the order. The status of O shall be used to indicate that the OBX segment is used for a dynamic specification of the required result. An OBX used for a dynamic specification must contain the detailed examination code, units, etc., with *OBX-11* valued with O, and *OBX-2* and *OBX-5* valued with null.

HL7 Table 0085 - Observation result status codes interpretation

Value	Description	Comment
C	Record coming over is a correction and thus replaces a final result	
D	Deletes the OBX record	
F	Final results; Can only be changed with a corrected result.	
I	Specimen in lab; results pending	
N	Not asked; used to affirmatively document that the observation identified in the OBX was not sought when the universal service ID in OBR-4 implies that it would be sought.	
O	Order detail description only (no result)	
P	Preliminary results	
R	Results entered -- not verified	

Value	Description	Comment
S	Partial results	
X	Results cannot be obtained for this observation	
U	Results status change to final without retransmitting results already sent as 'preliminary.' E.g., radiology changes status from preliminary to final	
W	Post original as wrong, e.g., transmitted for wrong patient	

7.4.2.12 OBX-12 Effective Date of Reference Range (TS) 00580

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date (and, optionally, the time) on which the values in *OBX-7-reference range* went into effect.

Usage Rule: This field can be valued only if *OBX-7-reference range* is populated.

When this field is present, it facilitates comparison between identical results with different reference ranges. Reference range values may vary because of changes in laboratory practice over time. Such variances could reflect updated practice in laboratory medicine, or the use of updated instrumentation.

7.4.2.13 OBX-13 User Defined Access Checks (ST) 00581

Definition: This field permits the producer to record results-dependent codes for classifying the observation at the receiving system. This field should be needed only rarely, because most classifications are fixed attributes of the observation ID and can be defined in the associated observation master file (see description in Chapter 8).

However, there are a few cases when such controls vary with the value of the observation in a complex way that the receiving system would not want to re-calculate. An example is an antimicrobial susceptibility result. Some systems prefer to display only the susceptibility results of inexpensive antimicrobials depending upon the organism, the source of the specimen and the patient's allergy status. The sending service wants to send all of the susceptibilities so that certain privileged users (e.g., Infectious Disease specialists) can review all of the results but nonprivileged users would see only the "preferred" antimicrobials to which the organism was susceptible. We expect that other cases also occur.

7.4.2.14 OBX-14 Date/Time of the Observation (TS) 00582

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field is required in two circumstances. The first is when the observations reported beneath one report header (OBR) have different dates/times. This could occur in the case of queries, timed test sequences, or clearance studies where one measurement within a battery may have a different time than another measurement.

It is also 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.

7.4.2.15 OBX-15 Producer's ID (CE) 00583

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains a unique identifier of the responsible producing service. It should be reported explicitly when the test results are produced at outside laboratories, for example. When this field is null, the receiving system assumes that the observations were produced by the sending organization. This information supports CLIA regulations in the US. The code for producer ID is recorded as a CE data type. In the US, the Medicare number of the producing service is suggested as the identifier.

7.4.2.16 OBX-16 Responsible Observer (XCN) 00584

```
Components:  <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and
             Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III)
             (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^
             <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^
             <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier
             Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code
             (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^
             <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date
             (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
             <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
             Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From
             Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Name Context (CE):  <Identifier (ST)> & <Text (ST)> & <Name of
             Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
             & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR):  <Range Start Date/Time (TS)> &
             <Range End Date/Time (TS)>

             Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
             <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
             (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
             <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
             System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
             <Original Text (ST)>
```

Definition: When required, this field contains the identifier of the individual directly responsible for the observation (i.e., the person who either performed or verified it). In a nursing service, the observer is usually the professional who performed the observation (e.g., took the blood pressure). In a laboratory, the observer is the technician who performed or verified the analysis. The code for the observer is recorded as a CE data type. If the code is sent as a local code, it should be unique and unambiguous when combined with *OBX-15-producer ID*.

7.4.2.17 OBX-17 Observation Method (CE) 00936

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

This optional field can be used to transmit the method or procedure by which an observation was obtained when the sending system wishes to distinguish among one measurement obtained by different methods and the distinction is not implicit in the test ID. Chemistry laboratories do not usually distinguish between two different methods used to measure a given serum constituent (e.g., serum potassium) as part of the test name. See the LOINC® Users Manual[3] for a more complete discussion of these distinctions. If an observation producing service wanted to report the method used to obtain a particular observation, and the method was NOT embedded in the test name, they can use this field.

The Centers for Disease Control and Prevention (CDC) Method Code (CDCM) (see Figure 7-3) is one candidate code system for reporting methods/instruments. EUCLIDES method codes are another. User-defined tables are an alternative.

7.4.2.18 OBX-18 Equipment Instance Identifier (EI) 01479

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field identifies the Equipment Instance (e.g., Analyzer, Analyzer module, group of Analyzers,...) responsible for the production of the observation. This is the identifier from an institution's master list of equipment, where the institution is specified by the *namespace ID* or if it is blank, then by the "Producer's ID" (OBX-15). It should be possible to retrieve from this master list the equipment type, serial number, etc., however it is not planned to transfer this information with every OBX. The repeating of this field allows for the hierarchical representation of the equipment (lowest level first), e.g., module of an instrument, instrument consisting of modules, cluster of multiple instruments, etc.

7.4.2.19 OBX-19 Date/Time of the Analysis (TS) 01480

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

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).

7.4.3 SPM – Specimen 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 may also be used in limited cases to describe a "virtual" specimen. In particular, to identify the characteristics required for a specimen in the context of a specific observation or test.

---

[3] LOINC® Committee. Logical Observation Identifier Names and Codes. Indianapolis: Regenstrief Institute and LOINC® Committee, 1995. Regenstrief Institute c/o LOINC, 1050 Wishard Blvd., RG-5, Indianapolis, IN 46202. 317/630-7433. Available at http://www:regenstrief.org/loinc/loinc.html. The LOINC® Code System is described in Forrey AW, McDonald CJ, DeMoor G, Huff SM, Leavelle D, Leland D, et.al. Logical Observation Identifier Names and Codes (LOINC®) database: a public use set of codes and names for electronic reporting of clinical laboratory test results. Clinical Chemistry 1996;42:81-90

In summary, SPM represents the attributes specific and unique to a specimen.

HL7 Attribute Table – SPM – Specimen

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	4	SI	O			01754	Set ID – SPM
2	80	EIP	O			01755	Specimen ID
3	80	EIP	O	Y		01756	Specimen Parent IDs
4	250	CWE	R		0487	01900	Specimen Type
5	250	CWE	O	Y	0541	01757	Specimen Type Modifier
6	250	CWE	O	Y	0371	01758	Specimen Additives
7	250	CWE	O		0488	01759	Specimen Collection Method
8	250	CWE	O			01901	Specimen Source Site
9	250	CWE	O	Y	0542	01760	Specimen Source Site Modifier
10	250	CWE	O		0543	01761	Specimen Collection Site
11	250	CWE	O	Y	0369	01762	Specimen Role
12	20	CQ	O			01902	Specimen Collection Amount
13	6	NM	C			01763	Grouped Specimen Count
14	250	ST	O	Y		01764	Specimen Description
15	250	CWE	O	Y	0376	01908	Specimen Handling Code
16	250	CWE	O	Y	0489	01903	Specimen Risk Code
17	26	DR	O			01765	Specimen Collection Date/Time
18	26	TS	O			00248	Specimen Received Date/Time
19	26	TS	O			01904	Specimen Expiration Date/Time
20	1	ID	O		0136	01766	Specimen Availability
21	250	CWE	O	Y	0490	01767	Specimen Reject Reason
22	250	CWE	O		0491	01768	Specimen Quality
23	250	CWE	O		0492	01769	Specimen Appropriateness
24	250	CWE	O	Y	0493	01770	Specimen Condition
25	20	CQ	O			01771	Specimen Current Quantity
26	4	NM	O			01772	Number of Specimen Containers
27	250	CWE	O			01773	Container Type
28	250	CWE	O		0544	01774	Container Condition
29	250	CWE	O		0494	01775	Specimen Child Role

7.4.3.0 SPM field definitions

7.4.3.1 SPM -1 Set ID - SPM (SI) 01754

Definition: This field contains the sequence number. This field is used to identify SPM segment instances in message structures where the SPM segment repeats.

7.4.3.2 SPM-2 Specimen ID (EIP) 01755

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
          <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
          <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains a unique identifier for the specimen as referenced by the Placer application, the Filler application, or both.

This field is not required, as there are use cases in which a unique specimen identifier may not exist. In the first scenario, a placer application may initiate an observation request against an existing specimen without uniquely identifying the specimen. Additionally, in the case of the TCU_U10 message structure, used in Automated equipment test code settings messages, the SPM segment is used to define required characteristics of the specimen. As such, TCU_U10 uses SPM to define a virtual specimen, and a specific specimen ID would not exist. Filler applications would be expected to assign a Specimen ID and populate this field accordingly.

7.4.3.3 SPM-3 Specimen Parent IDs (EIP) 01756

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

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.

7.4.3.4 SPM-4 Specimen Type (CWE) 01900

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)>
```

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 table 0487 – Specimen Type* (replaces *HL7 table 0070 – Specimen source codes*)
- SNOMED, etc.
- Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

HL7 Table 0487 – Specimen Type

Value	Description	Comment

7.4.3.5 SPM-5 Specimen Type Modifier (CWE) 01757

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field contains modifying or qualifying description(s) about the specimen type

The use of this attribute is to modify, qualify or further specify, the entity described by *SPM-4 -Specimen Type*. This is particularly useful when the code set used in *SPM-4-Specimen Type* does not provide the precision required to fully describe the specimen. For example, if the specimen was precisely described as 'capillary venous blood' but the code set employed only provided 'venous blood,' this attribute could be employed to add the modifier 'capillary.'

Refer to *User-Defined Table 0541 Specimen Type Modifier* for suggested values.

User-defined Table 0541 – Specimen Type Modifier

Value	Description	Comment
	No suggested values	

7.4.3.6 SPM-6 Specimen Additives (CWE) 01758

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field identifies any additives introduced to the specimen before or at the time of collection. These additives may be introduced in order to preserve, maintain or enhance the particular nature or component of the specimen. Refer to *HL7 Table 0371 – Additive* for valid values.

7.4.3.7 SPM-7 Specimen Collection Method (CWE) 01759

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: Describes the procedure or process by which the specimen was collected.

Any nationally recognized coding system might be used for this field including SNOMED; alternatively the HL7 defined table 0488 may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.3.8 SPM-8 Specimen Source Site (CWE) 01901

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: specifies the source from which the specimen was obtained. For example, in the case where a liver biopsy is obtained via a percutaneous needle, the source would be 'liver.'

Any nationally recognized coding system might be used for this field including SNOMED; alternatively the HL7 defined table 0070 may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.3.9 SPM-9 Specimen Source Site Modifier (CWE) 01760

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field contains modifying or qualifying description(s) about the specimen source site

The use of this attribute is to modify, qualify or further specify, the entity described by *SPM-8 – Specimen Source Site*. This is particularly useful when the code set used in *SPM-8* does not provide the precision required to fully describe the site from which the specimen originated. For example, if the specimen source site was precisely described as 'left radial vein' but the code set employed only provided 'radial vein,' this attribute could be employed to add the modifier 'left.'

Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.Refer to *User-Defined Table 0542 – Specimen Source Type Modifier* for suggested values.

User-defined Table 0542 – Specimen Source Type Modifier

Value	Description	Comment
	No suggested values	

7.4.3.10 SPM-10 Specimen Collection Site (CWE) 01761

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field differs from *SPM-8-Specimen Source Site* in those cases where the source site must be approached via a particular site (e.g., anatomic location). For example, in the case where a liver biopsy is obtained via a percutaneous needle, the collection site would be the point of entry of the needle. For venous blood collected from the left radial vein, the collection site could be "antecubital fossa".

Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

Refer to *User-Defined Table 0543 – Specimen Collection Site* for suggested values.

User-defined Table 0543 – Specimen Collection Site

Value	Description	Comment
	No suggested values	

7.4.3.11 SPM-11 Specimen Role (CWE) 01762

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

This field indicates the role of the sample. Refer to *User-defined Table 0369 – Specimen role* for suggested values. Each of these values is normally 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 that do not have individual identifiers and upon 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", the repetitions of Parent Specimen ID (SPM-4) represent the individual parent specimens that contribute to the pooled specimen.

Refer to *User-defined Table 0369 – Specimen Role* for suggested values.

User-defined Table 0369 - Specimen Role

Value	Description	Comment
B	Blind Sample	
C	Calibrator, used for initial setting of calibration	
E	Electronic QC, used with manufactured reference providing signals that simulate QC results	
F	Specimen used for testing proficiency of the organization performing the testing (Filler)	
G	Group (where a specimen consists of multiple individual elements that are not individually identified)	
L	Pool (aliquots of individual specimens combined to form a single specimen representing all of the components.)	
O	Specimen used for testing Operator Proficiency	
P	Patient	
Q	Control specimen	
R	Replicate	
V	Verifying Calibrator, used for periodic calibration checks	

7.4.3.12 SPM-12 Specimen Collection Amount (CQ) 01902

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)>
```

Definition: This field specifies the volume or mass of the collected specimen. For laboratory tests, the collection volume is the volume of a specimen. Specifically, units should be expressed in the ISO Standard unit abbreviations (ISO-2955, 1977). This is a results-only field except when the placer or a party has already drawn the specimen. (See Chapter 7 for full details about units.)

7.4.3.13 SPM-13 Grouped Specimen Count (NM) 01763

Definition: This field refers to the number of individual specimens of a particular type represented by this instance of a specimen. The use of this field is restricted to specimens upon which all specimen related attributes are identical. This field would only be valued if the specimen role attribute has the value "G".

7.4.3.14 SPM-14 Specimen Description (ST) 01764

Definition: This is a text field that allows additional information **specifically about the specimen** to be sent in the message

7.4.3.15 SPM-15 Specimen Handling Code (CWE) 01908

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
```

```
Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This describes how the specimen and/or container need to be handled from the time of collection through the initiation of testing. As this field is not required, no assumptions can be made as to meaning when this field is not populated.

Refer to *User-defined Table 0376 – Special Handling Code* for suggested values.

User-defined Table 0376 - Special Handling Code

Code	Description	Comment/Usage Note/Definition
C37	Body temperature	Critical to keep at body temperature: 36 - 38° C.
AMB	Ambient temperature	Keep at ambient (room) temperature, approximately 22 ± 2 degrees C. Accidental refrigeration or freezing is of little consequence
CAMB	Critical ambient temperature	Critical ambient – must not be refrigerated or frozen.
REF	Refrigerated temperature	Keep at refrigerated temperature: 4-8° C. Accidental warming or freezing is of little consequence
CREF	Critical refrigerated temperature	Critical refrigerated – must not be allowed to freeze or warm until immediately prior to testing
FRZ	Frozen temperature	Keep at frozen temperature: -4° C. Accidental thawing is of little consequence
CFRZ	Critical frozen temperature	Critical frozen – must not be allowed to thaw until immediately prior to testing
DFRZ	Deep frozen	Deep frozen: -16 to -20° C.
UFRZ	Ultra frozen	Ultra cold frozen: ~ -75 to -85° C. (ultra cold freezer is typically at temperature of dry ice).
NTR	Liquid nitrogen	Keep in liquid nitrogen.
PRTL	Protect from light	Protect from light (e.g., wrap in aluminum foil).
CATM	Protect from air	Critical. Do not expose to atmosphere. Do not uncap.
DRY	Dry	Keep in a dry environment.
PSO	No shock	Protect from shock.
PSA	Do not shake	Do not shake.
UPR	Upright	Keep upright. Do not turn upside down.
MTLF	Metal Free	Container is free of heavy metals including lead.

7.4.3.16 SPM-16 Specimen Risk Code (CWE) 01903

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This field contains any known or suspected specimen hazards, e.g., exceptionally infectious agent or blood from a hepatitis patient. Either code and/or text may be absent. However, the code is always placed in the first component position and any free text in the second component. Thus, a component delimiter must precede free text without a code. Refer to *User-defined Table 0489 – Risk Codes* for suggested entries

User-defined Table 0489 – Risk Codes

Code	Description	Comment/Usage Note/Definition
BIO	Biological	The dangers associated with normal biological materials. I.e. potential risk of unknown infections. Routine biological materials from living subjects.
COR	Corrosive	Material is corrosive and may cause severe injury to skin, mucous membranes and eyes. Avoid any unprotected contact.
ESC	Escape Risk	The entity is at risk for escaping from containment or control.
AGG	Aggressive	A danger that can be associated with certain living subjects, including humans.

Code	Description	Comment/Usage Note/Definition
IFL	MaterialDangerInflammable	Material is highly inflammable and in certain mixtures (with air) may lead to explosions. Keep away from fire, sparks and excessive heat.
EXP	Explosive	Material is an explosive mixture. Keep away from fire, sparks, and heat.
INF	MaterialDangerInfectious	Material known to be infectious with human pathogenic microorganisms. Those who handle this material must take precautions for their protection.
BHZ	Biohazard	Material contains microorganisms that is an environmental hazard. Must be handled with special care.
INJ	Injury Hazard	Material is solid and sharp (e.g., cannulas.) Dispose in hard container.
POI	Poison	Material is poisonous to humans and/or animals. Special care must be taken to avoid incorporation, even of small amounts.
RAD	Radioactive	Material is a source for ionizing radiation and must be handled with special care to avoid injury of those who handle it and to avoid environmental hazards.

7.4.3.17 SPM-17 Specimen Collection Date/Time (DR) 01765

```
Components:  <Range Start Date/Time (TS)> ^ <Range End Date/Time (TS)>

Subcomponents for Range Start Date/Time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
          Precision (ID)>

Subcomponents for Range End Date/Time (TS):  <Time (DTM)> & <DEPRECATED-Degree of
          Precision (ID)>
```

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, 24-hour urine collection. For specimens collected at a point in time, only the first component (start date/time) will be populated.

7.4.3.18 SPM-18 Specimen Received Date/Time (TS) 00248

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

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-xx Specimen Collection date/time*.

7.4.3.19 SPM-19 Specimen Expiration Date/Time (TS) 01904

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field is the date and time the specimen can no longer be used for the purpose implied by the order. For example, in the Blood Banking environment the specimen can no longer be used for pre-transfusion compatibility testing. The specimen segment will include an *SPM-21-Specimen Reject Reason* of 'EX' indicating 'Expired' for message instances created after this date and time.

7.4.3.20 SPM-20 Specimen Availability (ID) 01766

Definition: This describes whether the specimen, as it exists, is currently available to use in an analysis. Refer to *HL7 Table 0136 Yes/No Indicator* for valid values

7.4.3.21 SPM-21 Specimen Reject Reason (CWE) 01767

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: This describes one or more reasons the specimen is rejected for the specified observation/result/analysis. Refer to *HL7 Table 0490 – Specimen Reject Reason* for valid values.

HL7 Table 0490 – Specimen Reject Reason

Value	Description	Comment
EX	Expired	
QS	Quantity not sufficient	
RB	Broken container	
RC	Clotting	
RD	Missing collection date	
RA	Missing patient ID number	
RE	Missing patient name	
RH	Hemolysis	
RI	Identification problem	
RM	Labeling	
RN	Contamination	
RP	Missing phlebotomist ID	
RR	Improper storage	
RS	Name misspelling	

7.4.3.22 SPM-22 Specimen Quality (CWE) 01768

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: The degree or grade of excellence of the specimen at receipt. The filler populates this attribute. Refer to *User-defined Table 0491 – Specimen Quality* for suggested entries.

User-defined Table 0491 - Specimen Quality

Value	Description	Comment
E	Excellent	
G	Good	
F	Fair	
P	Poor	

7.4.3.23 SPM-23 Specimen Appropriateness (CWE) 01769

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: The suitability of the specimen for the particular planned use as determined by the filler. Refer to *User-defined Table 0492 – Specimen Appropriateness* for suggested entries.

User-defined Table 0492 - Specimen Appropriateness

Value	Description	Comment
P	Preferred	
A	Appropriate	
I	Inappropriate	
??	Inappropriate due to …	

7.4.3.24 SPM-24 Specimen Condition (CWE) 01770

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: A mode or state of being that describes the nature of the specimen. Refer to *User-defined Table 0493 – Specimen Condition* for suggested entries.

User-defined Table 0493 - Specimen Condition

Value	Description	Comment
AUT	Autolyzed	
CLOT	Clotted	
CON	Contaminated	
COOL	Cool	
FROZ	Frozen	
HEM	Hemolyzed	
LIVE	Live	
ROOM	Room temperature	
SNR	Sample not received	

7.4.3.25 SPM-25 Specimen Current Quantity (CQ) 01771

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)>
```

Definition: This attributes contains the amount of specimen that currently exists or is available for use in further testing.

7.4.3.26 SPM-26 Number of Specimen Containers (NM) 01772

Definition: This field identifies the number of containers for a given sample. For sample receipt verification purposes; may be different from the total number of samples that accompany the order.

7.4.3.27 SPM-27 Container Type (CWE) 01773

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: The container in or on which a specimen is transported

7.4.3.28 SPM-28 Container Condition (CWE) 01774

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)>
```

Definition: In chain of custody cases where specimens are moved from lab to lab, the status of the container that the specimen is shipped in must be recorded at each receipt. If the container is compromised in any way (seal broken, container cracked or leaking, etc) then this needs to be recorded for legal reasons.

Refer to *User-defined Table 0544 – Container Condition* for suggested values.

User-defined Table 0544 – Container Condition

Value	Description	Comment
	No suggested values	

7.4.3.29 SPM-29 Specimen Child Role (CWE) 01775

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)>
```

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 Table 0494 – Specimen Child Role* for valid values.

HL7 Table 0494 – Specimen Child Role

Value	Description	Comment
A	Aliquot	
C	Component	
M	Modified from original specimen	

7.5 EXAMPLES OF USE

7.5.1 Query/response

The following is a query of the EKG system for the data for a particular patient number 0123456-1 for reports that have been modified or created since 1/1/88. These examples use LOINC® clinical codes. The response ends with a continuation pointer. A continuation query follows, in reply to which a continuation response is sent.

Query (QRY)

```
MSH|^~\&|CBD||EKG||198905201200||QRY^R02|CDB22222|P|...<cr>

QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES|...<cr>

QRF|EKG||198801010000|...<cr>
```

Response

```
MSH|^~\&|EKG||CDB||198905201201||ORF^R04|X981672|P|...<cr>

MSA|AA|CDB22222|P|...<cr>

QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES|...<cr>

QRF|EKG||198804010000|...<cr>

PID|1||0123456-1||ROBERTSON^JOHN^H|||||||982-1111|...<cr>

OBR|1|43215^OE|98765^EKG|93000^EKG REPORT|
    ||198801111330|||1235^TAYLOR^ROBERT^M||||

    198801111330||P030||||||198801120930||||||P011^PRESLEY^ELVIS^AARON^^^MD|43214^O
    E|...<cr>


OBX|1|ST|8897-1^QRS COMPLEX^LN||91|/MIN|60-100||||F|...<cr>

OBX|2|ST|8894-8^P WAVE^LN||92|/MIN|60-100||||F|...<cr>

OBX|3|ST|8625-6^P-R INTERVAL^LN||0|/MSEC|1.06-.10||||F|...<cr>

OBX|4|ST|8633-0^QRS DURATION^LN||.368|/MSEC|.18-.22||||F|...<cr>

...
```

```
...

...

OBX|8|CE|8601-7^EKG IMPRESSION^LN|1|^ATRIAL FIBRILATION||||||F|...<cr>

OBX|9|CE|8601-7^EKG IMPRESSION^LN|2|^ST DEPRESSION||||||F|...<cr>

OBX|10|FT|93000&ADT^EKG COMMENT||\.in+4\\.ti-4\ 1. When compared with EKG of

    31-oct-88 ventricular rate has increased by 30 bpm.\.sp\\.ti-4\

    2. Criteria for Lateral infarct are no longer present.|||||F|...<cr>

OBR|2|43217^OE|98767^EKG|93000^EKG
    REPORT|||198810311004|||||||198810311004||P030||||||198810311744||||||

    P011^PRESLEY^ELVIS^AARON^^^MD |43213^OE |...<cr>

                    ...

                    ...

                    ...

DSC|1896X22;0123456-1|...<cr>
```

Continuation query

```
MSH|^~\&|CDB||EKG||198905201204||QRY^R02|CDB22289|P|...<cr>

QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES|...<cr>

QRF|EKG||1988040100000|...<cr>

DSC|1896X22;0123456-1|...<cr>
```

Continuation response

```
MSH|^~\&|EKG||CDB||198905201205||ORF^R04|X981672|P|...<cr>

MSA|AA|CDB22289|P|...<cr>

QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES|...<cr>

QRF|EKG||198804010000|...<cr>

PID|1||0123456-1||ROBERTSON^JOHN^H|||||||982-1111|...<cr>

OBR| ...<cr>
```

7.5.2 Unsolicited

The following is an unsolicited transmission of radiology data.

```
MSH|^~\&|XRAY||CDB||200006021411||ORU^R01|K172|P|...<cr>

PID|...<cr>

OBR|1|X89-1501^OE|78912^RD|71020^CHEST XRAY AP \T\
    LATERAL|||19873290800|||9218^MASTERS^JOHN^B|...<cr>

OBX|1|CE|71020&IMP^RADIOLOGIST'S IMPRESSION|4|^MASS LEFT LOWER LOBE|||A|||F|...<cr>

OBX|2|CE|71020&IMP|2|^INFILTRATE RIGHT LOWER LOBE|||A|||F|...<cr>

OBX|3|CE|71020&IMP|3|^HEART SIZE NORMAL|||N|||F|...<cr>

OBX|4|FT|71020&GDT|1|circular density (2 x 2 cm) is seen in the posterior segment
    of

    the LLL.  A second, less well-defined infiltrated circulation density is

    seen in the R mid lung field and appears to cross the minor
    fissure#||||||F|...<cr>

OBX|5|CE|71020&REC|5|71020^Follow up CXR 1 month||30-45||||F|...<cr>
```

7.5.3 Laboratory

Laboratory message: electrolytes, CBC, sed rate, blood cultures and susceptibilities

```
MSH|...<cr>
PID|...<cr>
```

Electrolytes:

```
OBR|1|870930010^OE|CM3562^LAB|2432-6^ELECTROLYTES HCFA 98 PANEL^LN|
    ||198703290800|||
    401-0^INTERN^JOE^^^^MD^L| ||||SER|^SMITH^RICHARD^W.^^^DR.|(319)377-4400|
    This is requestor field #1.|Requestor field #2|Diag.serv.field #1.|
    Diag.serv.field #2.|198703311400|||F|...<cr>
OBX|1|NM|2951-2^SODIUM^LN||150|mmol/L|136-148|H||A|F|19850301|...<cr>
OBX|2|NM|2823-3^POTASSIUM^LN||4.5|mmol/L|3.5-5|N||N|F|19850301|...<cr>
OBX|3|NM|2075-0^CHLORIDE^LN||102|mmol/L|94-105|N||N|F|19850301|...<cr>
OBX|4|NM|2028-9^CARBON DIOXIDE^LN||27|mmol/L|24-31|N||N|F|19850301|...<cr>
```

CBC:

```
OBR|2|870930011^OE|HEM3268^LAB|24359-2HEMOGRAM+DIFFERENTIAL PANEL^LN|
    ||198703290800|||401-0 ^
    INTERN^JOE^^^^MD^L|||||BLDV|^SMITH^RICHARD^W.^^^DR.|(319)377-4400|This is
        requestor field #1.|This is Requestor field #2.|This is lab field #1.|Lab
        field #2.|198703311400|||F|...<cr>

OBX|1|NM|718-7^HEMOGLOBIN^LN||13.4|GM/DL|14-18|N||S|F|19860522|...<cr>
OBX|2|NM|4544-3^HEMATOCRIT^LN||40.3|%|42-52|L||S|F|19860522|...<cr>
OBX|3|NM|789-8^ERYTHROCYTES^LN||4.56|10*6/ml|4.7-6.1|L||S|F|19860522|...<cr>
OBX|4|NM|787-2^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN
   ||88|fl|80-94|N||S|F|19860522|...<cr>
OBX|5|NM|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN
   ||29.5|pg|27-31|N||N|F|19860522|...<cr>
OBX|6|NM|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION:^LN
   ||33|%|33-37|N||N|F|19860522|...<cr>
OBX|7|NM|6690-2^LEUKOCYTES^LN||10.7|10*3/ml|4.8-10.8|N||N|F|19860522|...<cr>
OBX|8|NM|770-8^NEUTROPHILS/100 LEUKOCYTES^LN/100 LEUKOCYTES:^LN||68|%|||||F|...<cr>
OBX|9|NM|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%|||||F|...<cr>
OBX|10|NM|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%|||||F|...<cr>
OBX|11|NM|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%|||||F|...<cr>
```

Sed rate:

```
OBR|3|870930011^OE|HEM3269^LAB|4537-7^ERYTHROCYTE SEDIMENTATION RATE^LN
   |||198703290800|||
    401-0^INTERN^JOE^^^^MD^L|||||BLDV|^SMITH^RICHARD^W.^^^DR.|(319)377-4400|
    This is requestor field #1.|This is Requestor field #2.|This is lab field
    #1.|Lab field #2.|198703311400|||F|...<cr>
OBX|1|NM|4537-7^ERYTHROCYTE SEDIMENTATION RATE:^LN|
```

```
|7|MM/HR|0-10|N||S|F|19860522|...<cr>
```

Parent micro result, identifies organism

```
OBR|4|2740X^OE|BC376^MIC|87040^Blood culture| ||198703290800|||
    99-2^JONES^COLLECTOR||^Hepatitis risk||198703290830|BLDV|
    4010^INTERN^JOE^^^^MD^L|321-4321 X3472^^^^^^^3472|Requestor field 1|Requestor
    field 2|
    Producer's field 1|Producer's field 2|198703301000|35.00|MB|F|...<cr>
OBX|1|CE|600-7^MICROORGANISM IDENTIFIED^LN|1|^E Coli|||A|||F|...<cr>
OBX|2|CE|600-7^MICROORGANISM IDENTIFIED^LN|2|^S Aureus|||A|||F|...<cr>
```

Child micro result, gives antimicrobials susceptibilities for organism identified in first OBX of parent

```
OBR|5|2740X^OE|BC402^MIC|87186^Antibiotic MIC||
   |198703290800||||G|^Hepatitis Risk||198703290830|BLDB
   |401.0^INTERN^JOE^^^^MD^L|321-4321 X3472^^^^^^^3472|||||198703310900|40.00
   |MB|F|600-7&MICROORGANISM IDENTIFIED&LN^1|||2740X&OE^BC376&MIC|...<cr>
OBX|1|ST|28-1^AMIPICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|2|ST|60-4^CARBENICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<16|ug/ml||S|||F|...<cr>
OBX|3|ST|267-5^GENTAMICIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|4|ST|496-0^TETRACYCLINE:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
OBX|5|ST|408-5^PIPERACILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||S|||F|...<cr>
OBX|6|ST|145-3^CEFUROXIME:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|7|ST|161-0^CEPHALOTHIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||S|||F|...<cr>
OBX|8|ST|20-8^AMOXICILLIN+CLAVULANATE:SUSC:PT:ISLT:QN:MIC^LN
   ||<4|ug/ml||S|||F|...<cr>
OBX|9|ST|173-5^CHLORAMPHENICOL:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|10|ST|508-2^TOBRAMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|11|ST|12-5^AMIKACIN:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|12|ST|516-5^TRIMETHOPRIM+SULFMOETHOXAZOLE:SUSC:PT:ISLT:QN:MIC^LN|
   |<2/38|ug/ml||S|||F|...<cr>
OBX|13|ST|76-0^CEFAZOLIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|14|ST|116-4^CEFOXITIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|15|ST|141-2^CEFTRIAXONE:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|16|ST|133-9^CEFTAZIDIME:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|17|ST|185-9^CIPROFLOXACIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
```

Second micro child result, gives susceptibilities or organism identified by Second OBX of parent

```
OBR|6|2740X^OE|BC403^MIC|87186^Antibiotic MIC| ||198703290800||||G|
    ^Hepatitis risk||198703290830|BLDV|401.0^INTERN^JOE^^^^MD^L|321-4321
    X3472^^^^^^^3472|||||
    198703310900|40.00|MB|F|600-7&MICROORGANISM IDENTIFIED &LN^2|
   ||2740X&OE^BC376&MIC|...<cr>
OBX|1|ST|28-1^AMPICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||R|||F|...<cr>
OBX|2|ST|193-3^CLINDAMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<.25|ug/ml||S|||F|...<cr>
OBX|3|ST|267-5^GENTAMICIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
```

```
OBX|4|ST|233-7^ERYTHROMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<.5|ug/ml||S|||F|...<cr>
OBX|5|ST|383-0^OXACILLIN:SUSC:PT:ISLT:QN:MIC^LN||<.5|ug/ml||S|||F|...<cr>
OBX|6|ST|524-9^VANCOMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|7|ST|6932-8^PENICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||R|||F|...<cr>
OBX|8|ST|161-0^CEPHALOTHIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|9|ST|173-5^CHLORAMPHENICOL:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|10|ST|12-5^AMIKACIN:SUSC:PT:ISLT:QN:MIC^LN||<16|ug/ml||S|||F|...<cr>
OBX|11|ST|185-9^CIPROFLOXACIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
OBX|12|ST|428-3^RIFAMPIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
```

7.5.4 Narrative report messages

This example of the body of reports shows the following observation from what are usually free text reports. The text within these examples that begins with **-- and ends with --** are explanatory comments, not a formal part of the message. The following outline shows the segments that are included in this example message.

a) patient identifying record (PID)

b) order record for chest x-ray (OBR)

c) two diagnostic impressions for CXR (OBX)

d) description record for CXR (OBX)

e) a recommendation record for CXR (OBX)

f) an order record for surgical pathology (OBR)

g) a gross description record for pathology showing use of anatomy fields (OBX)

h) a microscopic description record for pathology (OBX)

i) vital signs request (OBR)

j) six vital signs (OBX)

k) part of the physical history (OBR & OBX)

l) end record

```
MSH|...<cr>
PID|...<cr>
```

Order record for CXR

```
OBR|2|P8754^OE|XR1501^XR|24646-2^CXR PA+LAT^LN|||198703290800|||
   401-0^INTERN^JOE^^^^MD^L|...<cr>
```

Two CXR diagnostic impressions

```
OBX|1|CE|24646-2&IMP^CXR PA+LAT^LN
|1|.61^RUL^ACR~.212^Bronchopneumonia^ACR|||A|||F|...<cr>
OBX|2|CE|24646-2&IMP^CXR PA+LAT^LN |2|51.71^Congestive heart
    failure^ACR|||A|||F|...<cr>
```

CXR Description with continuation records

```
OBX|3|TX|24646-2&GDT^CXR PA+LAT^LN||Infiltrate probably representing
    bronchopneumonia in the right
```

```
lower lobe.  Also pulmonary venous congestion cardiomegaly and cephalization,
    indicating early congestive heart failure.|...<cr>
```

Recommendations about CXR report to follow up one month with a repeat CXR

```
OBX|4|CE|24646-2&REC^CXR PA+LAT^LN||71020^Followup CXR 1 month^AS4||||||F|...<cr>
```

Order record for pathology report

```
OBR|3|P8755^OE|SP89-739^SP|11529-5^Surgical Path

Report^LN|||198703290800|||401-0^INTERN^JOE^^^^MD^L|...<cr>

OBX|1|CE|11529-5&ANT^Surgical Path Report^LN|1|Y0480-912001^orbital
    region^SNM||||||F|...<cr>
```

Gross description record (with overflow) for pathology

```
OBX|2|TX|11529-5&GDT^Surgical Path Report^LN1|The specimen is received in four
    containers.  The first is labeled with the patient's name and consists of three
    fragments of reddish-brown tissue each of which measures 2 mm in greatest
    dimension.  They are wrapped in tissue paper and submitted in toto in a single
    cassette|...<cr>
```

Microscopic description record for pathology

```
OBX|3|TX|11529-5&MDT^Surgical Path Report^LN|1|Sections of the first specimen
    received for frozen section diagnosis reveal thick walled, ramifying vessels
    lined by a single layer of flattened endothelial cells.  The thick smooth
    muscle walls exhibit no malignant cytologic features nor do the endothelial
    lining cells.  Within the same specimen are also found fragments of fibrous
    connective tissue, bone, and nerve which are histologically
    unremarkable||||||F|...<cr>
```

Vital signs using LOINC® codes as observation identifiers

```
OBR|4|P8756^OE|N2345^NR|29274-8^VITAL SIGNS^LN| ||198703290800|||401-
    0^INTERN^JOE^^^^MD^L|...<cr>

OBX|1|NM|8462-4^INTRAVASCULAR DIASTOLIC:PRES^LN||90|mm(hg)|60-90||||F|...<cr>

OBX|2|NM|8479-8^INTRAVASCULAR SYSTOLIC:PRES^LN||120|mm(hg)

   |100-160||||F|...<cr>

OBX|3|NM|8478-0^INTRAVASCULAR MEAN:PRES^LN||100|mm(hg)|80-120|N|||F|...<cr>

OBX|4|NM|8867-4^HEART BEAT RATE^LN||74|/min|60-100|N|||F|...<cr>

OBX|5|ST|8357-6^BLOOD PRESSURE METHOD^LN||MANUAL BY CUFF||||||F|...<cr>

OBX|6|ST|8886-4^HEART RATE METHOD^LN||MANUAL BY PALP||||||F|...<cr>
```

Part of the patient's history

```
OBR|5|P8568^OE|HX2230^CLN||2000^HISTORY| ||198703290800||401

0^INTERN^JOE^^^^MD^L||...<cr>

OBX|1|CE|8661-1^CHIEF COMPLAINT^LN||...<cr>

OBX|2|ST|8674-4^HISTORY SOURCE^LN||PATIENT||||||F|...<cr>

OBX|3|TX|8684-3^PRESENT ILLNESS^LN||SUDDEN ONSET OF CHEST PAIN. 2 DAYS,

   PTA ASSOCIATED WITH NAUSEA, VOMITING \T\ SOB.  NO RELIEF WITH ANTACIDS

   OR NTG. NO OTHER SX. NOT PREVIOUSLY ILL.||||||F|...<cr>

    .

    .
```

and so on.

7.5.5 Reporting Cultures and Susceptibilities

7.5.5.1 Culture battery/report representation

Organisms and other observations/tests are reported using multiple OBX segments. The granularity expected for HL7culture reports is one observation per organism.

All OBX segments which have the same observation ID and sub-ID are part of a single observation.

Each organism in a culture battery is assigned a unique *OBX-4-observation sub-ID* (and is therefore a separate observation). The organism name is given in *OBX-5-observation value* (results). It is recommended, but not required, that the organism name may change over time, but the corresponding observation sub-ID never changes. (The observation ID will be identical for all organisms reported.)

Recommended:

```
OBX|1|CE|600-7^Micro Organism Identified^LN|1|^E. Coli||||||F|...<cr>
OBX|2|CE|600-7^Micro Organism Identified^LN |2|^S. Aureus||||||F|...<cr>
```

Not recommended:

```
OBX|1|CE|600-7^Micro Organism Identified^LN |1|^E. Coli||||||F|...<cr>
OBX|2|CE|600-7^Micro Organism Identified^LN |1|^S. Aureus||||||F|...<cr>
```

7.5.5.2 Susceptibility battery/report representation

Each antimicrobial should be reported as a separate (OBX) observation where the Observation ID is a code for the antimicrobial. (OBXs for non-antimicrobials observations and related information may be present in the same battery.)

MIC and disk diffusion (Kirby Bauer) susceptibility results can be combined in the same OBX segment. An OBX can contain a MIC value (in *OBX-5-observation value* (results)) and *OBX-8-abnormal flag* that indicates whether the organism is sensitive, resistant, or intermediate (see *HL7 table 0078- Abnormal flags* under abnormal flag fields).

Or, an OBX can contain a disk diffusion result string (e.g., **sensitive**) in the Observation Results field and the disk diffusion interpretation in *OBX-8-abnormal flags* (e.g., **S**).

A susceptibility battery may only contain results corresponding to a single organism that has been previously reported in a culture battery.

7.5.5.3 Identification of the organism for a susceptibility battery

The following is the preferred, but not required method of organizing data about antimicrobial susceptibility.

A susceptibility battery may only contain results corresponding to a single organism that has been previously reported in a culture battery.

A susceptibility battery is always a child order to a culture battery. *OBR-29-parent* (parent's filler order number) in the susceptibility OBR is equal *to OBR-3-filler order number* in the parent culture OBR and is used to link the two batteries logically.

The susceptibility battery also contains a linkage back to a particular organism in the culture battery. *OBR-26-parent result* of the susceptibility OBR contains two components--*OBX-3-observation identifier* (code only) and *OBX-4-observation sub-ID* of the OBX in the culture battery which contains the organism name.

The identity of an organism/isolate is expected to be refined over time. When an organism identification changes, the parent culture battery can be resent without resending the child susceptibility battery.

The case may occur where a susceptibility battery is reported on an organism which has not yet been identified. In this case, it is required that a placeholder OBX for the organism name be reported in the corresponding culture battery so that *OBR-26-parent result* in the susceptibility OBR will point to a valid organism OBX in the culture battery. Transmission of an organism OBX (in the culture battery) with the Sub-ID field valued must precede the susceptibility battery which uses the identical Sub-ID in *OBR-26-parent result*.

Discussion and examples:

Order micro results (blood culture)

```
MSH|^~\&|LAB1||DESTINATION||19910127105114||ORU^R01|LAB1003929|...<cr>
PID|...<cr>
PV1|...<cr>
ORC|NW|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE^LN|||...<cr>
```

Result for culture

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|SDES^SOURCE||BLOOD-RAPID|||||F|...<cr>
OBX|2|FT|664-3^GRAM STAIN SMEAR^LN||GRAM POSITIVE COCCI IN GROUPS|||||F|...<cr>
OBX|3|FT|600-7^MICROORGANISM IDENTIFIED^LN|1|ISOLATE 1|||||F|...<cr>
```

Result for susceptibility

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29848^LAB1|BT1^SUSCEPTIBILITY BATTERY||||||123^MANSFIELD^CHARLES|
    ||||||||||||||600-7&MICROORGANISM IDENTIFIED&LN
    ^1|||A485388&OE^H29847&LAB1|...<cr>
OBX|1|NM|6932-8^PENICILLIN MIC^LN||0.5|||R|||F|...<cr>
OBX|2|NM|347-5^NAFCILLIN MIC^LN||1|||R|||F|...<cr>
OBX|3|ST|193-3^CLINDAMYCIN MIC^LN||<=0.1|||S|||F|...<cr>
```

Result for Culture ID

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|600-7^ MICROORGANISM IDENTIFIED^LN |1|STAPH EPI|||||F|...<cr>
```

New result for culture ID

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|600-7^MICROORGANISM IDENTIFIED^LN|1|STAPH EPI SERO TYPE 3|||||F|...<cr>
```

Assumptions

1) All OBXs in the parent order must employ the same coding scheme.
2) The Sub-ID of the parent OBXs (result) cannot change.

7.5.6 EKG Results Reporting

Suppose an order has been placed to the EKG system for three EKGs to be performed on successive days. These results can be reported in various ways.

1) The EKG application needs to communicate to anyone the results of the 1st EKG:

ORU message:

```
MSH|...<cr>
PID|...<cr>
```

Order record for EKG

```
OBR|1|P8753^OE|EK5230^EKG|8601-7^EKG impression^LN|||198703290800|||401
0^INTERN^JOE^^^^MD^L|...<cr>
```

Two interpretation records for EKG

```
OBX|1|CE|8601-7^EKG impression^LN|1|^Sinus bradycardia|||A|||F|...<cr>
OBX|2|CE|8601-7^EKG impression^LN |2|^Occasional PVCs|||A|||F|...<cr>
```

Four numeric results for EKG

```
OBX|3|NM|8897-1^QRS COMPLEX RATE ^LN|
   |80|/min|60-100|||||F|...<cr>
OBX|4|NM|8894-8^PULSE RATE^LN||80|/min
   |60-100||||F|...<cr>
OBX|5|NM|8633-0^QRS DURATION ^LN||.08|msec
   |.06-.10||||F|...<cr>
OBX|6|NM|8625-6^P-R INTERVAL ^LN||.22|msec
   |.18-.22||||F|...<cr>
```

- Notice that this report is without reference to the original order.
- No ORC is required because the identifying Fillers Order Number (and other ORC fields) are carried in the OBR segment.
- The EKG application needs to communicate to anyone the original order information, the details of the child orders, the fact of the child spin off, and the results of all three EKGs:

ORU message:

```
MSH|...<cr>
PID|...<cr>
ORC|PA|A226677^OE|89-450^EKG|...<cr>          // original order's ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // original order segment
ORC|CH|A226677^OE|89-451^EKG|...<cr>          // 1st child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // 1st EKG child OBR.
OBX|1|ST|...<cr>                         // 1st EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
```

```
ORC|CH|A226677^OE|89-452^EKG|...<cr>           // 2nd child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>         // 2nd EKG child OBR.
OBX|1|ST|...<cr>                          // 2nd EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
ORC|CH|A226677^OE|89-453^EKG|...<cr>           // 3rd child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>         // 3rd EKG child OBR.
OBX|1|ST|...<cr>                          // 3rd EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
    ...                              // Other parts of message might follow.
```

In this case, we are transmitting the information about the fact of child spin off, the original order and the results all at the same time. Thus, this form of the ORU message reports not only the results of an order, but all of its associated ordering information including the original OBR for three EKGs that was replaced by three separate OBR EKG segments.

7.5.7 Patient-Specific Clinical Data With An Order

Reporting body weight and height with a creatinine clearance.

```
MSH|...<cr>
PID|...<cr>
ORC|NW|...<cr>                          // New order.
OBR|1|P42^PC||2164-2^CREATININE RENAL CLEARANCE: QN^LN|...<cr>
OBX|1|NM|3141-9^BODY WEIGHT^LN||62|kg|...<cr>
OBX|2|NM|3137-7^BODY HEIGHT^LN||190|cm|...<cr>
ORC|NW|...<cr>                          // Next order.
```

7.5.8 Unsolicited Laboratory Observation Message

Analysis results related to a particular container with patient sample.

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
    |OUL^R21|MSG00001|P|2.4|<cr>
PID|1||28514753||Joan^Howard^J||196303241225|F<CR>
SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
    |19980620080037|R^PROCESS COMPLETED<cr>
ORC|RE|5212498721A||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
```

Analysis results related to a particular container with QC sample and the lot and manufacturer information about this sample (see use of SAC-SID segments).

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
    |OUL^R21|MSG00001|P|2.4|<cr>
SAC|||Q092321^LAS|||SER^^^^^^Q |19980620080037|R^PROCESS COMPLETED<cr>
```

```
SID|2951-2^SODIUM^LN|NA-01234567890|9099|MAN_ABC^^Z99<cr>

ORC|RE|5212498721A|||||^^^^^R<CR>

OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER^^^^^^Q<CR>

OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
```

Analysis results of a reflex test for a patient sample with basic identification data (lot, manufacturer, etc.) of the reagent involved in the results generation (see TCD-SID segments).

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
    |OUL^R21|MSG00001|P|2.4|<cr>

PID|1||28514753||Joan^Howard^J||196303241225|F<CR>

SAC|991912376^EXTLAB|01039421^THISLAB|092321A^LAS|092321^LAS||SER
    |19980620080037|R^PROCESS COMPLETED<cr>

ORC|RE|5212498721A|||||^^^^^R<CR>

OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||||SER<CR>

OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>

TCD|2951-2^SODIUM^LN||||||F

SID|2951-2^SODIUM^LN|NA-01234567890|9099|MAN_ABC^^Z99<cr>
```

7.6 CLINICAL TRIALS

Academic medical institutions, academic research coordinating centers, and industry-based research organizations often have computer systems that support registration, compliance and safety monitoring, and outcomes analysis for clinical trials. Patients on these trials may receive their treatment and evaluation at one research facility or at many different medical facilities. Clinical trials systems could message other applications that a patient is registered on a clinical trial. Several functional examples follow: (1) Some of the data required to monitor or analyze outcomes on the trial are generated in other medical computer systems, such as pharmacy, laboratory, or clinical applications. These applications may tag patients on clinical trials so that data may be sent back to the clinical trials system. (2) Order entry systems could also use patient registration information: they could display standard order sets for the protocol or particular treatment/evaluation phases of a complex protocol. They could pass the clinical trials status on to service provider applications to initiate a results report to the clinical trials system. It could also be passed to billing applications that may use specialized procedures for research-related costs. (3) Nursing and pharmacy systems can use information on patients' clinical trials status for care plans or dispensing authorization (auxiliary to the physician's prescription), respectively. There could be many other uses of this message since a patient's involvement on a clinical trial affects all concurrent medical care.

To meet monitoring and analysis requirements, patient registration, treatment, diagnostic, and study summary data are reported to study sponsors like pharmaceutical or medical device companies, regulatory agencies, and data management centers for collaborative studies. Automated procedures must be used to transfer these voluminous data among the participant computer systems in a cost-efficient and timely manner. The following additions to HL7 aim to specify standard messaging transactions to automate such reporting as well as to enable communication of clinical trials registration data to relevant medical applications as described above.

The objectives of the clinical trials messages and segments are to identify that patients are registered on clinical trials, have entered a study-specific phase of treatment or evaluation, or to indicate the study protocol's data schedule. Messages include OBR (Section 4.5.1, "OBR - observation request segment"), OBX (Section 7.4.2, "OBX - Observation/Result Segment"), RXA (Section 4.8.14, "RXA - pharmacy /treatment administration segment"), and RXR (Section 4.8.3, "RXR - pharmacy/treatment route Segment") segments to report observations or drug administration that are relevant to the study. In addition to study-related clinical data, OBX segments may contain the results of study variables according to master code tables such as the Health Outcomes Variables (HL7 Implementation Guide). There are also master segments to describe the clinical trial, its treatment phases, and its scheduled date-time points for message recipients. These are analogous to the Test/Observation Master Segments (Chapter 8), with the trials, phases, or scheduled time points treated as the OMX treats observation identifiers.

7.6.1 Glossary

7.6.1.1 Clinical trial:

A scientifically rigorous study of individual outcomes to some process of healthcare intervention. Clinical trials usually involve medical treatments so this document will use the term *treatment*, rather than the broader term *intervention*. A clinical trial design may randomly assign and compare one treatment approach with another, or generate safety and efficacy data on a single treatment approach. The clinical trial has a protocol for the patient's course of treatment and/or evaluation. There is usually a schedule for collection of data to measure compliance, safety, and outcomes.

7.6.1.2 Phase of a clinical trial:

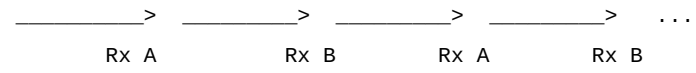
A treatment and/or observation interval of a clinical trial. A phase may represent an interval with a specific treatment regimen assigned randomly or otherwise, with each regimen of a progression of treatments, or with an evaluation component only. Generally, for each phase, there is an explicit patient management, evaluation, and data collection schedule. Each of these phases may have associated safety, outcome, and quality-control variables. A simpler study design need not use the phase structures.

The phase structure serves several purposes in the clinical trials messages. Other computer systems may need to know that the patient has begun a phase with a particular treatment regimen or diagnostic schedule, such as the pharmacy or order entry systems. When reporting study data, observations and variables often describe particular phase instances. For example, each course of treatment may have its own values for the same set of observations or variables. Phase instances may also have distinct data schedules that need to be linked to submitted data.

Several examples follow with each line depicting a phase.

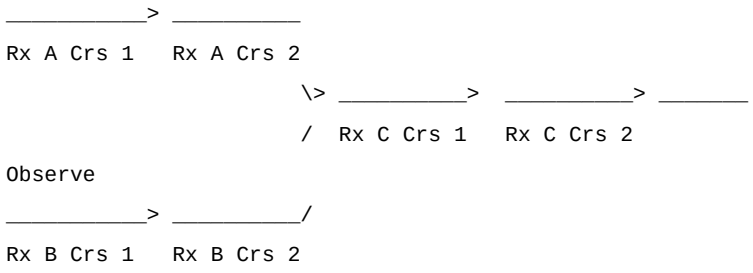
7.6.1.2.1 Example 1

Alternating treatment plus observation intervals:



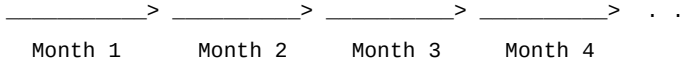
7.6.1.2.2 Example 2

Random assignment to two courses each of treatment A or B, all responding patients to treatment C, continue with observation and a diagnostic regimen after all treatment phases are completed. Treatment phases include the evaluation component for that course of treatment:



7.6.1.2.3 Example 3

Random assignment to placebo or treatment A, both taken daily and evaluated monthly.



7.6.1.3 Data schedule:

The treatment, diagnostic, and procedural requirements, as well as data collection due dates, scheduled on a timeline for most clinical trials. As data are reported, they may need to reflect the scheduled time point that they satisfy. Clinical trials quality control requires attention to compliance between the protocol's schedule and patient data records.

The data schedule will be keyed by time points relative to the study. Some data may be due prior to and at the conclusion of the study and/or one or more of its phases. Some are interim within the study or its phases depending on protocol events such as administration of treatment, arbitrary time intervals instated to make and record assessments, or some clinical milestone such as relapse of disease. Often, multiple data parameters are scheduled at the same time point. Several examples follow:

7.6.1.3.1 Schedule for a randomized cancer prevention trial

Treatment 1st - 3rd Years

	Reg	Rand	Months															
			3	6	9	12	18	24	30	36	42	48	54	60	66	72	78	84
Disease Staging	X																	
H & P	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Assess Adverse Events and Outcome Variables	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Chest PAL X-ray	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CBC, Diff, Plt	X			X	X	X	X	X	X	X		X		X		X		X
SMA 12	X		X	X	X	X	X	X	X	X		X		X		X		X
Cholesterol and Triglyceride	X		X	X	X	X	X	X	X	X								
Electrolytes	X																	
Plasma Retinoic Acid	X	X																
Cotinine Level (nonsmokers)		X																

7.6.1.3.2 Schedule for a cancer chemotherapy trial

		Prior to Each Cycle		Every 3	
	Prestudy		During Cycle	Cycles	End Study
Informed Consent	X	X			
H & P Neurologic	X1				X
Vital Signs	X1		X2		X
Disease Staging	X	X3			X
ECG	X1		X4		
Radiology*		X		X5	X
Chest X-ray	X	X			X
Bone Marrow Bx.	X6				
HCG	X1				
Assess Adverse Events		X			X
CBC, Diff, Plt	X1			X7	X
UA, PT, PTT	X1				X
SMA12, Mg, CEA	X1	X			X

1) Within 3 days prior to start of infusion.
2) At 0,10,30, and 60 minutes after start of drug administration and one-half hour after test drug infusion ends for cycles 1 and 2. For subsequent cycles at 0 and 10 minutes after start of drug administration, and at the end of infusion.
3) Record tumor measurements at the end of every cycle if assessable clinically by physical examination or with simple X-ray.
4) Continuous ECG monitoring during infusion if necessary, due to bradycardia (<50 beats/min) or other significant cardiac findings.
5) When measurable disease requires complex radiologic studies such as CT or radionucleide scans.
6) To be done at baseline (if clinically indicated) at the option of the investigator and also during study if patient has prolonged myelosuppression (WBC<2000 cells/mm3>14 days).
7) Blood counts will be done twice weekly during cycles 1 and 2, then weekly.
8) * Radionucleide scan and X-ray of the bones, CT scans of the chest, pelvis, and brain only when clinically indicated.

7.6.1.3.3 Schedule for a randomized pain medication trial

	Day 1 Before RX	Day 1 After RX	Daily	Day 30
H & P	X			X
Creat, Bili, SGOT	X			
Urinalysis	X			
Pain Diagnosis	X			
Opioid Dose Strand	X	X	X	X
Non-opioid Analgesic		X	X	X
Medications for Side Effects		X	X	X
Phone Report: Pain and Side Effects			X	
Visual Analog Scales	X	X	X	X
Pain Evaluation Form	X			X

7.7 CLINICAL TRIALS - TRIGGER EVENTS AND MESSAGE DEFINITIONS

The event type will be carried in the message header segment.

7.7.1 CRM - Clinical Study Registration Message (Events C01-C08)

The data are entered in a clinical trials or other patient data system and broadcast to other facility systems such as order entry, pharmacy, accounting, and nursing systems. They can be transmitted in batch mode or broadcast to outside-facility computer systems, including diagnostic and patient management systems. It is assumed that proper routing and security mechanisms are in place.

Event	Description
C01	Register a patient on a clinical trial
C02	Cancel a patient registration on clinical trial (for clerical mistakes since an intended registration should not be canceled)

Event	Description
C03	Correct/update registration information
C04	Patient has gone off a clinical trial
C05	Patient enters phase of clinical trial
C06	Cancel patient entering a phase (clerical mistake)
C07	Correct/update phase information
C08	Patient has gone off phase of clinical trial

CRM^C01-C08^CRM_C01	Clinical Study Registration Message	Status	Chapter
MSH	Message Header		2
[{ SFT }]	Software Segment		2
{	--- PATIENT begin		
PID	Patient Identification		3
[PV1]	Patient Visit		3
CSR	Clinical Study Registration		7
{[CSP]}	Clinical Study Phase		7
}	--- PATIENT end		

7.7.2 CSU - Unsolicited Study Data Message (Events C09-C12)

Data are entered in the clinical trials system or may reside in laboratory, pathology, radiology, pharmacy and/or other clinical applications. Most clinical trials data - clinical observations and study variables - will be communicated in OBR and OBX segments. The CSR, CSP, and CSS segments will identify the specific association these OBR and OBX have to the clinical trial. Data can be broadcast or transmitted in batch mode to study sponsors or the data management center for collaborative studies.

Event	Description
C09	Automated time intervals for reporting, like monthly
C10	Patient completes the clinical trial
C11	Patient completes a phase of the clinical trial
C12	Update/correction of patient order/result information

CSU^C09-C12^CSU_C09	Unsolicited Study Data Message	Status	Chapter
MSH	Message Header		2
[{SFT}]	Software Segment		2
{	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and comments		2

CSU^C09-C12^CSU_C09	Unsolicited Study Data Message	Status	Chapter
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
]	--- VISIT End		
CSR	Clinical Study Registration		7
{	--- STUDY_PHASE begin		
[CSP]	Clinical Study Phase		7
{	--- STUDY_SCHEDULE begin		
[CSS]	Clinical Study Data Schedule		7
{	--- STUDY_OBSERVATION begin		
[ORC]	Common Order		4
OBR	Observation Battery		7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{OBX}	Observation Results		7
}	--- STUDY_OBSERVATION end		
{	--- STUDY_PHARM begin		
[ORC]	Common Order		4
{	--- RX_ADMIN begin		
RXA	Pharmacy Administration		4
RXR	Pharmacy Route		4
}	--- RX_ADMIN end		
}	--- STUDY_PHARM end		
}	--- STUDY_SCHEDULE end		
}	--- STUDY_PHASE end		
}	--- PATIENT end		

7.8 CLINICAL TRIALS – SEGMENT DEFINITIONS

7.8.1 CSR - Clinical Study Registration Segment

The CSR segment will contain fundamental administrative and regulatory information required to document a patient's enrollment on a clinical trial. This segment is all that is required if one needs to message another system that an enrollment has taken place, i.e., from clinical trials to pharmacy, accounting, or order entry systems. The CSR segment may also be used to identify that OBR, OBX, RXA, and RXR segments that follow represent data applicable to the identified study.

HL7 Attribute Table – CSR – Clinical Study Registration

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	EI	R			01011	Sponsor Study ID
2	60	EI	O			01036	Alternate Study ID
3	250	CE	O			01037	Institution Registering the Patient
4	30	CX	R			01038	Sponsor Patient ID
5	30	CX	O			01039	Alternate Patient ID - CSR
6	26	TS	R			01040	Date/Time Of Patient Study Registration
7	250	XCN	O	Y		01041	Person Performing Study Registration
8	250	XCN	R	Y		01042	Study Authorizing Provider
9	26	TS	C			01043	Date/time Patient Study Consent Signed
10	250	CE	C			01044	Patient Study Eligibility Status
11	26	TS	O	Y/3		01045	Study Randomization Date/time
12	250	CE	O	Y/3		01046	Randomized Study Arm
13	250	CE	O	Y/3		01047	Stratum for Study Randomization
14	250	CE	C			01048	Patient Evaluability Status
15	26	TS	C			01049	Date/time Ended Study
16	250	CE	C			01050	Reason Ended Study

7.8.1.0 CSR field definitions

7.8.1.1 CSR-1 Sponsor Study ID (EI) 01011

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The field contains the universal identifier for the clinical trial. Since many clinical trials are collaborative and multi-centered, and since one goal of these standards is to promote automated data exchange among sites, the primary identifier should come from the sponsor. The coding system component may reference the sponsor. Example:

```
T93-0807^NCI (where NCI refers to the National Cancer Institute).
```

7.8.1.2 CSR-2 Alternate Study ID (EI) 01036

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains an alternate identifier that may be used as agreed upon by messaging parties. For example, the sending application may code its internal study number here.

7.8.1.3 CSR-3 Institution Registering the Patient (CE) 01037

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field distinguishes the institution where registration occurred. The legal approval to give patients access to a trial lies with the Internal Review Board for the institution. Universal healthcare provider facility codes should be used when they exist. Currently coding systems must be devised by users.

7.8.1.4 CSR-4 Sponsor Patient ID (CX) 01038

```
Components:  <ID Number (ST)> ^ <Check Digit (ST)> ^ <Check Digit Scheme  (ID)> ^
             <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^ <Assigning
             Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)> ^
             <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
             <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
             (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
             <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
             System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
             <Original Text (ST)>
```

Definition: This field contains the main patient identification for the study. The sponsor patient ID allows automation of records on patients treated at various institutions. The sponsor patient ID should be unique for each patient participating on the study identified in *CSR-1-sponsor study ID*.

7.8.1.5 CSR-5 Alternate Patient ID - CSR (CX) 01039

```
Components:  <ID Number (ST)> ^ <Check Digit (ST)> ^ <Check Digit Scheme  (ID)> ^
             <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^ <Assigning
             Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)> ^
             <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
             <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
             (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
             <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
             System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
             <Original Text (ST)>
```

Definition: This field may be the sending application's patient identification. Coding conventions may be used as agreed upon by users.

7.8.1.6 CSR-6 Date/Time Patient of Patient Study Registration (TS) 01040

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date of the patient registration is mandatory. The time component is optional. The time stamp for a registration may be useful. For example, patients may be randomized at the pharmacy according to the order in which they were registered.

7.8.1.7 CSR-7 Person Performing Study Registration (XCN) 01041

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Definition: This field contains the healthcare facility employee who actually phoned, submitted a form, or interactively registered the patient on the clinical trial. This is generally done under authorization from the attending physician or a principal or collaborating investigator.

7.8.1.8 CSR-8 Study Authorizing Provider (XCN) 01042

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

```
Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Name Context (CE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR):  <Range Start Date/Time (TS)> &
          <Range End Date/Time (TS)>

          Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
          (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
          Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)>
```

Definition: This field contains the healthcare provider, generally the attending physician, who is accountable that the patient is eligible for the trial and has signed an informed consent. National standard healthcare provider codes should be used when they exist. This field is required for the patient registration trigger event (C01).

7.8.1.9 CSR-9 Date/Time Patient Study Consent Signed (TS) 01043

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the consent form signing date is collected to provide a checkpoint that the consent form was obtained. Since many trials involve unapproved drugs and other treatment modalities, the consent form is highly important to document and store. This field is required for the patient registration trigger event (C01). The time component is optional.

7.8.1.10 CSR-10 Patient Study Eligibility Status (CE) 01044

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)>
```

Definition: This field indicates whether the patient was an appropriate candidate for the trial. It is important for quality control and data analysis. The code set will vary among clinical trials. An example answer set is: ***Yes, No, By Approval, Not Assessed, Unknown***. This field is required for the patient registration trigger event (C01).

7.8.1.11 CSR-11 Study randomization date/time (TS) 01045

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the patient was randomized. The time component is optional. Up to three randomizations are supported. Sequential randomizations are listed in chronological order.

7.8.1.12 CSR-12 Randomized Study Arm (CE) 01046

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)>
```

Definition: This field contains codes that must be developed by users. The blind treatment assignment may be communicated as a dummy text: **^blind** or if a coded treatment assignment must also be communicated**: 1^blind^local_code**. If more than one randomization occurs, the second and third repetitions will correspond to the second and third repetitions of *CSR-11-study randomization date/time*, if they exist.

7.8.1.13 CSR-13 Stratum for Study Randomization (CE) 01047

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: Many studies have stratified randomization schemas. The strata codes must be developed for each clinical trial. This field is important for statistical analysis of the study results. The second and third repetitions will correspond to the second and third repetitions of *CSR-11-study randomization date/time* and *CSR-12-randomized study arm*, if they exist.

7.8.1.14 CSR-14 Patient Evaluability Status (CE) 01048

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field categorizes the inclusion of this patient's data for various analyses. The patient's data may be evaluable for analysis of adverse events but not for outcomes. Or it may be evaluable for some outcomes and not others. The coding systems will vary among trials. This field is required for the off-study trigger event (C04).

7.8.1.15 CSR-15 Date/Time Ended Study (TS) 01049

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the patient completes or is otherwise removed from the study. This field is required for the off-study event (C04). The time component is optional.

7.8.1.16 CSR-16 Reason Ended Study (CE) 01050

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This information is important for quality control and data analysis. The coding systems will vary among trials. An example answer set is: **Adverse Events, Completed Trial, Death, Drug Resistance, Intercurrent Illness, Lost to Follow up, No Response to Therapy, Noncompliance, Progression of Disease, Protocol Violation, Refused Further Therapy**. This field is required for the off-study trigger event (C04).

7.8.2 CSP - Clinical Study Phase Segment

The CSP segment contains information on a patient's status for a particular phase of the study. This segment is optional and is useful when a study has different evaluation intervals within it. (See Section 0, "HL7 Attribute Table – CSR – Clinical Study RegistrationPhase of a Clinical Trial." The CSP segment is implemented on a study-specific basis for messaging purposes. The fact that the patient has entered a phase of the study that represents a certain treatment approach may need to be messaged to other systems, like pharmacy, nursing, or order entry. It is also important to sponsors and data management centers for tracking patient progress through the study and monitoring the data schedule defined for each phase. It may subsume OBR and OBX segments that follow it to indicate that these data describe the phase.

HL7 Attribute Table – CSP – Clinical Study Phase

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	250	CE	R			01022	Study Phase Identifier
2	26	TS	R			01052	Date/time Study Phase Began
3	26	TS	O			01053	Date/time Study Phase Ended
4	250	CE	C			01054	Study Phase Evaluability

7.8.2.0 CSP field definitions

7.8.2.1 CSP-1 Study phase Identifier (CE) 01022

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field identifies the phase of the study that a patient has entered. The set of codes will generally be developed for each clinical trial, although there are patterns that trials in particular disease or prevention categories may follow. The phase structure will be based on data collation and reporting needs for the study. It is an operational structure and need not be discussed in the clinical trial protocol documentation or even made known to patient care or data collection personnel. The coding system will usually be developed by the sponsor for multicentered clinical trials to standardize the receipt of automated data. Local codes could be added if an additional local message is desired. Otherwise, local coding conventions will be used. Example: `2^Init Rx, Crs 1^NCI T93-0807 Phases`

7.8.2.2 CSP-2 Date/Time Study Phase Began (TS) 01052

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the patient began this phase interval. The time is optional.

7.8.2.3 CSP-3 Date/Time Study Phase Ended (TS) 01053

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the patient ended this phase interval.

7.8.2.4 CSP-4 Study Phase Evaluability (CE) 01054

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the disposition of the patient's data for this phase interval for quality control and data analysis purposes. The set of codes will vary across clinical trials. An example answer set: **Complete, Adverse Events Only, Outcome Only, None, Unknown**.

7.8.3 CSS - Clinical Study Data Schedule Segment

The Clinical Study Data Schedule (CSS) segment is optional depending on whether messaging of study data needs to be linked to the scheduled data time points for the study. (See Section 7.6.1.3, "data schedule.") The CSS segment enables communication of data schedules and adherence that ranges from the basic to the elaborate. Use of the segment must be planned for each implementation. Each CSS segment will subsume observation and drug administration segments that follow, indicating that they satisfy this scheduled time point.

HL7 Attribute Table – CSS – Clinical Study Data Schedule Segment

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	250	CE	R			01055	Study Scheduled Time Point

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
2	26	TS	O			01056	Study Scheduled Patient Time Point
3	250	CE	O	Y/3		01057	Study Quality Control Codes

7.8.3.0 CSS field definitions

7.8.3.1 CSS-1 Study Scheduled Time Point (CE) 01055

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the time point for which some instance of data for the clinical trial was scheduled. The time point may be expressed in any coded format. Some examples of time point values are: **Prestudy, Pretreatment, 4 times/day, Weekly, Every 3 days, Every course, At Relapse, At Off Study.** Alternatively, frequency values from Section 2.A.81.2, "Interval component (RI)," (the Interval component of the TQ Timing/Quantity data type could be used; however, note that as of version 2.5, the TQ data type is retained only for backward compatibility). Time point naming conventions and usage must be specified by implementers.

7.8.3.2 CSS-2 Study Scheduled Patient Time Point (TS) 01056

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date/time that the scheduled time point should occur for this patient. The date/time may be used for a reference in reviewing the actual dates on which scheduled items that follow in OBR segments occur for the patient. The time component is optional.

7.8.3.3 CSS-3 Study Quality Control Codes (CE) 01057

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: In clinical settings, the **actual** date of a treatment or procedure may vary considerably from the **due** date. Various coding systems may be used to evaluate the adherence to the schedule or acceptability of the data. Coding systems will vary among trials.

7.8.4 CTI - Clinical Trial Identification Segment

The CTI segment is an optional segment that contains information to identify the clinical trial, phase and time point with which an order or result is associated.

HL7 Attribute Table – CTI – Clinical Trial Identification

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	EI	R			01011	Sponsor Study ID
2	250	CE	C			01022	Study Phase Identifier
3	250	CE	O			01055	Study Scheduled Time Point

7.8.4.0 CTI field definitions

7.8.4.1 CTI-1 Sponsor Study ID (EI) 01011

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains the universal identifier for the clinical trial. The coding system is as described in *CSR-1-sponsor study ID*.

7.8.4.2 CTI-2 Study Phase Identifier (CE) 01022

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field identifies the phase of the study that a patient has entered. See *CSP-1-study phase identifier* for details of coding systems.

7.8.4.3 CTI-3 Study Scheduled Time Point (CE) 01055

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field identifies a time point in the clinical trial phase. *CTI-2-study phase identifier* must be valued if *CTI-3-study scheduled time point* is valued. Should correspond to *CSS-1-study scheduled time point*.

7.8.5 CM0 Clinical Study Master Segment

The clinical study master segment (CMO) is described in Chapter 8 section 8.11.2.

7.8.6 CM1 Clinical Study Phase Master Segment

The clinical study phase master segment (CMI) is described in Chapter 8, section 8.11.3.

7.8.7 CM2 Clinical Study Schedule Master Segment

The clinical study schedule master segment is described in Chapter 8, section 8.11.4.

7.9 CLINICAL TRIALS – EXAMPLES OF USE

7.9.1 CRM - Message When Patient Registered on a Clinical Trial

```
MSH|^~\&|PDMS|MDACC|ORDER ENTRY|MDACC|200006021649||CRM^C01|...<cr>

PID|1||223892||King^Sally^Brown||19530117|...<cr>

CSR|DM94-004^MDACC||MDACC|3||19941013||342^^^^^^^PDMS|
    |||||1005^^^^^^^MDACC|19941013|Y^Meets All Requirements^PDMS|...<cr>
```

7.9.2 CRM - Message When Patient Begins a Phase of a Clinical Trial

```
MSH|^~\&|PDMS|MDACC|PHARM|MDACC|200006050925||CRM^C05|...<cr>

PID|1||352352||West^Mary^L.||19230213|...<cr>

CSR|ID91-025^MDACC||MDACC|301||19941005||342^^^^^^^PDMS |||19941201|2^blind^PDMS|
        12^Smoker,Stage II,<60^PDMS|...<cr>

CSP|2^Treatment^PDMS|19941201|...<cr>
```

7.9.3 CSU - Message Reporting Monthly Patient Data Updates to the Sponsor

```
MSH|^~\&|PDMS|MDACC|CTMS|NCI|200006050927||CSU^C09|...<cr>

PID|1||235925||J^F^M||19350616|...<cr>
             [note:anonymous]

CSR|T93-080^NCI|ID93-030^^MDACC|MDACC|14||19941205|...<cr>
```

```
CSS|^Prestudy|19941204|C^compliant^NCI<cr>

OBR|1|1234|1234|3^EligibilChecklist^StudyFormsList|||19941205|...<cr>
```

Note: The clinical trials section probably needs its own definition of OBR. OBR-2&3 have condition rules indicating that the placer and filler numbers must be present in either the ORC or the OBR. Since an ORC is not present, then these fields must be populated in the OBR. My guess is that clinical trials aren't interested in the placer and filler number.

```
OBX|1|CE|ELIG1^Elig Crit 1^NCI|Text Elig Crit 1|Y|...<cr>

OBX|2|CE|ELIG2^Elig Crit 2^NCI||Y|...<cr>

OBR|2|1235|1235|4^Prestudy Form^StudyFormsList|||19941205|...<cr>

OBX|1|CE|QOL^Quality of Life^NCI||2\T\3\T\2\T\4\T\2^SPITZER|...<cr>

OBX|2|CE|PRICHEM^Prior Chemo^NCI||Yes|...<cr>

OBX|3|CE|PRIBIOL^Prior Biologics^NCI||No|...<cr>

OBX|4|NM|NUMREM^Number Prior Remissions^NCI||2|...<cr>

OBR|3|932^OE|243789^LAB|88304^SURG PATH REPORT|||19940101|...<cr>

OBX|1|CE|88304&ANT|1|9999^PANCREAS^SNM|...<cr>

OBX|2|CE|88304&IMP|2|9999^ADENOCARCINOMA^SNM|...<cr>

OBR|4|933^OE|243790^LAB|85022^CBC|||199412050800|...<cr>

OBX|1|NM|718-7^HEMOGLOBIN:^LN||13.4|GM/DL|14-18|N||S|F|19860522|...<cr>
```

[cbc values]

```
OBX|2|NM|4544-3^HEMATOCRIT:^LN||40.3|%|42-52|L||S|F|19860522|...<cr>

OBX|3|NM|789-8^ERYTHROCYTES:^LN||4.56|10*6/ml|4.7-6.1|L||S|F|19860522|...<cr>

OBX|4|NM|787-22^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN||88|fl   |80-
    94|N||S|F|19860522|...<cr>

OBX|5|NM|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN||29.5|pg   |27-
    31|N||N|F|19860522|...<cr>

OBX|6|NM|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN
    CONCENTRATION:^LN||33|%|33-37|N||N|F|19860522|...<cr>

OBX|7|NM|6690-2^LEUKOCYTES:^LN||10.7|10*3/ml|4.8-10.8|N||N|F|19860522|...<cr>

OBX|8|NM|764-1^NEUTROPHILS BAND FORM/100 LEUKOCYTES:^LN||2|%|||||F|...<cr>

OBX|9|NM|769-0^NEUTROPHILS SEGMENTED/100 LEUKOCYTES:^LN||67|%|||||F |...<cr>

OBX|10|NM|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%|||||F|...<cr>

OBX|11|NM|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%|||||F|...<cr>

OBX|12|NM|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%|||||F|...<cr>

OBR|5|934^OE|243791^LAB|80004^ELECTROLYTES|||199412050800|...<cr>

OBX|1|NM|2947-0^SODIUM:^LN||150|mmol/l|136-148|H||A|F|19850301 |...<cr>

OBX|2|NM|2823-3^POTASSIUM:^LN||4.5|mmol/l|3.5-5|N||N|F|19850301|...<cr>
```

[electrolytes values]

```
OBX|3|NM|2069-3^CHLORIDE:^LN||102|mmol/l|94-105|N||N|F|19850301|...<cr>

OBX|4|NM|2028-9^CARBON DIOXIDE.TOTAL:^LN||27|mmol/l|24-31|N||N|F
    |19850301|...<cr>

CSP|^Course 1|19941205|19950120|Y^Toxicity and Response^NCI |...<cr>

CSS|^Course Completion|19950120|...<cr>

OBR|1|935^OE|243791^LAB|2039-6^CARCINOEMBRYONIC AG:^LN|||19941008|...<cr>
```

```
                OBX|1|NM|2039-6^CARCINOEMBRYONIC AG:^LN||15.2|IU |...<cr>
OBR|2|1236|1236|10^Course Completion Form^StudyPhaseFormsList|||19950120 |...<cr>
OBX|1|CE|CRSRESP^Course Response^NCI||4^Partial Response|...<cr>
OBX|2|NM|DRUGDISP^Capsules Dispensed^NCI||60|...<cr>
OBX|3|NM|DRUGRETN^Capsules Returned^NCI||5|...<cr>
OBX|4|ID|DXCOMP^Diagnostic Tests Compliance^NCI||Y|...<cr>
OBX|5|CE|PERSTAT^Performance Status^NCI||3^ZUBRODS|...<cr>
OBR|3|1237|1237|9999^Adverse Events|...<cr>
OBX|1|CE|9999&EVENT|1|45^Vomiting^NCI|...<cr>
OBX|2|DT|9999&ONSET|1|19941215|...<cr>
OBX|3|DT|9999&RESOLUTION|1|19941217|...<cr>
OBX|4|CE|9999&GRADE|1|M^MODERATE|...<cr>
OBX|5|CE|9999&RELATION_TO_RX|1|L^LIKELY|...<cr>
OBX|6|CE|9999&EVENT|2|303^Dyspnea^NCI|...<cr>
OBX|7|DT|9999&ONSET|2|19941231|...<cr>
OBX|8|DT|9999&RESOLUTION|2|...<cr>
OBX|9|CE|9999&GRADE|2|MI^MILD|...<cr>
OBX|10|CE|9999&RELATION_TO_RX|2|U^UNLIKELY|...<cr>
```

[Note: Needs to maintain compatibility with ongoing product experience message efforts.]

[Note2: There are other possible OBX suffixes defined by FDA: APEX/ NADIR, ACTION, THERAPY, OUTCOME, RECHALLENGE.]

7.10 PRODUCT EXPERIENCE

Patients experience symptoms, manifest signs or develop diseases or syndromes while exposed to medical devices and/or drugs. Evidence suggests that some of these symptoms, signs, diseases or syndromes may develop as a consequence of the products used. Examples include the development of clear cell adenocarcinoma of the vagina in the daughters of mothers treated with diethylstilbestrol during pregnancy and gastrointestinal bleeding in patients treated with non-steroidal anti-inflammatory drugs. While it is difficult to prove causality, strong evidence exists in many cases.

It is important to document such experiences during the development and testing of products to identify potential adverse effects but also during routine use of the product to identify serious adverse effects which occur infrequently. The latter is the realm of pharmacoepidemiology and post-marketing surveillance.

Adverse events are important for product manufacturers as signal generating hypotheses concerning drug kinetics or dynamics, often in special populations of patients. Adverse events are important for regulators in ensuring that manufacturers protect the public health in assessments of risk and benefits, including special populations, and that they promptly and thoroughly investigate individual events and clusters of events. Adverse events are especially important for practitioners and patients who always deal with a special population of one individual who may be having an event and a practitioner seeking information about related events seen with the same or similar products.

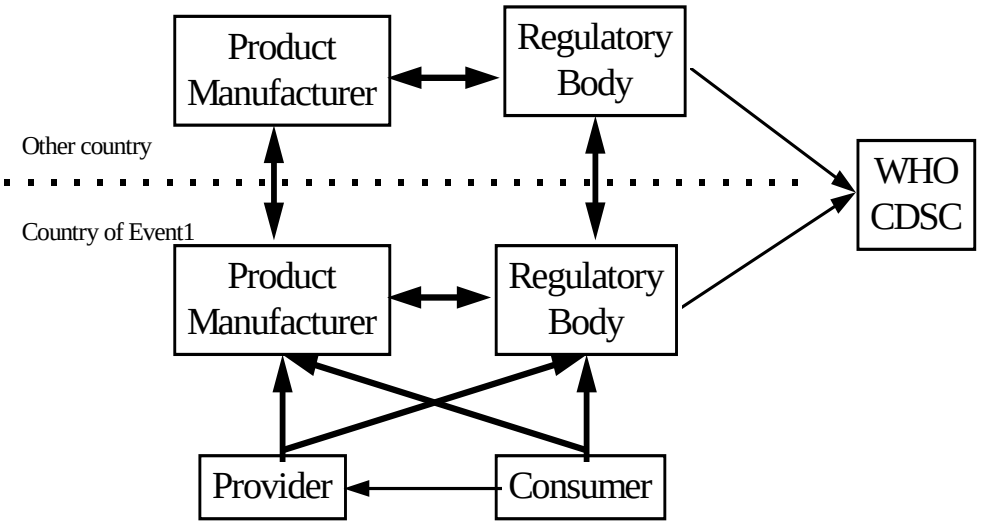
Reporting has usually focused on *serious* and *unexpected* events. Serious, if defined unambiguously, focuses attention on those events of most importance to the patient and practitioner. Expected events are those which prior experience has demonstrated to be probabilistically linked to the product and are generally included in product labeling.

Because of the risks associated with the uses of drugs and medical devices, a system of surveillance has been established in most developed countries. With globalization of the marketplace, the need to share this information across national boundaries has increased. Currently most reporting is performed using a series of forms, including CIOMS, yellow cards, the FDA's 1639 and MedWatch forms and the Japanese form, which are sent:

- from identified reporting sources to regulatory bodies

- from identified reporting sources to product manufacturers
- between regulatory bodies
- within product manufacturers
- within regulatory bodies
- from product manufacturers to regulatory bodies
- from regulatory bodies to the WHO Collaborative Drug Surveillance Center

Figure 7-8. - Flow of product experience information



Regardless of who originates a drug experience report, documentation of the experience eventually reaches the regulatory agencies. The manufacturer is mandated to alert the regulatory agency.

Electronic interchange of these data would reduce errors, decrease costs and speed communications.

7.10.1 Glossary

7.10.1.1 Drug:

Any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition, for the relief of pain or suffering, or to control or improve any physiological condition (Dorland's Illustrated Medical Dictionary 27th edition).

7.10.1.2 Medical device:

Something contrived for or used in the diagnosis (vascular catheters), treatment (thermotherapy units) or prevention of disease or other abnormal condition, for the relief of pain or suffering or to control or improve any physiologic condition, including instrumentation and implanted devices (prosthetic cardiac valves, pacemakers, hip prostheses).

7.10.1.3 Product:

A drug or medical device.

7.10.1.4 Non-proprietary (generic) name:

Drug name that is not protected by a trademark, usually descriptive of its chemical structure; sometimes called a public name. In the US, most generic drug names are assigned by the US Adopted Name Council (USAN). Other generic names in common use are the National Formulary (NF) and the US Pharmacopoeia (USP) names. Figure 7-3 lists other available drug coding systems.

7.10.1.5 Trade (brand) name:

Proprietary names that are registered to protect the name for the sole use of the manufacturer holding the trademark.

7.10.1.6 Adverse event/adverse experience:

- Pre-marketing: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

- Post-marketing/European Union: Any undesirable experience occurring to a patient treated with a pharmaceutical product whether or not considered related to the medicinal product.

- Post-marketing/US: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose; an adverse event occurring from drug withdrawal; and any failure of expected pharmacologic action.

- WHO: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this product.

7.10.1.7 Adverse drug reaction:

- Pre-marketing: All noxious and unintended responses to a medicinal product related to any dose.

- Post-marketing/WHO: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function

- Post-marketing/European Union: A reaction which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or treatment of disease or the modification of physiological function.

- Post-marketing/US: Any undesirable effect reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable.

7.10.1.8 Causation:

An exposure which truly does increase or decrease the probability of a certain outcome.

7.10.1.9 Causal relationship:

When an event occurs a product may be suspected as causing the event but rarely can it be proven particularly at an early stage of the product's life. Certain information about the relationship between the product and the event can reinforce the belief in a causal relationship between the product and the event while others can decrease the probability that there is a causal relationship.

7.10.1.10 Regulatory agency:

Many geopolitical entities have established agencies/authority responsible for regulating products used in health care. The agencies are collectively referred to as regulatory agencies.

7.10.1.11 Product manufacturer:

The organization which is responsible for the manufacture of a product. This will usually be the entity, which holds the marketing authorization for the product.

7.10.1.12 Holder of marketing authorization:

The organization which holds the authority to market a product. This will often be the organization, which manufactures the product.

7.10.1.13 Serious adverse product reaction:

An adverse product reaction which:

- is fatal (results in death)
- is life threatening
- requires hospitalization or prolongation of a hospitalization
- results in persistent or significant disability/incapacity
- results in a congenital anomaly/birth defect.

Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life threatening or result in hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

7.10.1.14 Expected adverse product reaction:

Expected events are those which prior experience has demonstrated to be probabilistically linked to the product and are generally included in product labeling.

Pre-marketing: An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product).

Post-marketing/European Union: This relates to an adverse reaction which is not mentioned in any EC summary of product characteristics (SPC). In the absence of any European SPC, an international document prepared by the marketing authorization holder containing all relevant safety information which the marketing authorization holder considers should be listed for the medicinal product in all countries where the medicinal product is marketed (Care Data Sheet).

Post-marketing/US current: Unexpected means an adverse drug experience that is not listed in the current labeling for the drug product and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling but differs from the event because of greater severity or specificity.

Post-marketing/US (proposed): The applicant's core safety data sheet shall be a document prepared by the applicant that contains all relevant safety information, including adverse drug experiences, which the applicant believes should e listed for the drug in all countries where the drug is marketed. It may be used

by the applicant as the reference document by which an adverse drug experience is judged to be expected or unexpected for purposes of this post-marketing periodic report.

Post-marketing/WHO: An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

7.10.2 References

Gabrielli ER. Standard specification for drug therapy documentation. ASTM Committee E31.12 July (1993).

Kessler DA. Introducing MEDWatch. JAMA 269: 2765-2768(1993).

Kurata JH, Overhage JM, Gabrielli E, Jones JK. International Data Standards for Hospital-based Drug Surveillance. M.D. Computing 12(1) 50-57 (1995).

Moore N, Montera d, Coulson R, DeAbajo F, Kreft-Jais C, Biron A, Monteaugudo J. The single case format: proposal for a structured message for the telematic transmission of information on individual case reports in pharmacovigilance. Pharmacoepidemiology and Drug Safety 3: 157-162 (1994)

Thompson WL. A modest proposal for enhancing the safety and effectiveness of use of human drugs, biologics and devices and animal health products with human health implications through cost-effective health informatics tools supporting a global database of safety reports as a joint ICH E2, M1 and M2 initiative. Private communication. March (1995)

7.11 PRODUCT EXPERIENCE - TRIGGER EVENTS AND MESSAGE DEFINITIONS

The message header segment will care one of three event types at *MSH-9-message type*.

Event	Description
P07	PEX - Unsolicited initial individual product experience report
P08	PEX - Unsolicited update individual product experience report
P09	SUR - Summary product experience report

7.11.1 PEX - Product Experience Message (Events P07, P08)

The primary application of this message is to transfer information related to an adverse event occurring while a patient was exposed to a product.

PEX^P07-P08^PEX_P07	Product Experience Message	Status	Chapter
MSH	Message Header		2
[{SFT}]	Software Segment		2
EVN	Event Type		3
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{NTE}]	Notes and comments		2
[	--- VISIT begin		

PEX^P07-P08^PEX_P07	Product Experience Message	Status	Chapter
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
]	--- VISIT end		
{	--- EXPERIENCE begin		
PES	Product Experience Sender		7
{	--- PEX_OBSERVATION begin		
PEO	Product Experience Observation		7
{	--- PEX_CAUSE begin		
PCR	Potential Causal Relationship		7
[	--- RX_ORDER begin		
RXE	Pharmacy/Treatment Encoded Order		4
{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}	--- TIMING_QTY end		
[{RXR}]	Pharmacy/Treatment Route		4
]	--- RX_ORDER end		
[{	--- RX_ADMINISTRATION begin		
RXA	Pharmacy/Treatment Administration		4
[RXR]	Pharmacy/Treatment Route		4
}]	--- RX_ADMINISTRATION end		
[{PRB}]	Detail problem segment		12
[{OBX}]	Observation/Result Segment		7
[{NTE}]	Notes and comments		2
[	--- ASSOCIATED_PERSON begin		
NK1	Associated parties segment		2
[	--- ASSOCIATED_RX_ORDER begin		
RXE	Pharmacy/Treatment Encoded Order		4
{	--- NK1_TIMING_QTY begin		

PEX^P07-P08^PEX_P07	Product Experience Message	Status	Chapter
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}	--- NK1_TIMING_QTY end		
[{RXR}]	Pharmacy/Treatment Route		4
]	--- ASSOCIATED_RX_ORDER end		
[{	--- ASSOCIATED_RX_ADMIN begin		
RXA	Pharmacy/Treatment Administration		4
[RXR]	Pharmacy/Treatment Route		4
}]	--- ASSOCIATED_RX_ADMIN end		
[{PRB}]	Detail Problem Segment		12
[{OBX}]	Observation/Results Segment		7
]	--- ASSOCIATED_PERSON end		
[{	--- STUDY begin		
CSR	Clinical study registration		7
[{CSP}]	Clinical study phase segment		7
}]	--- STUDY end		
}	--- PEX_CAUSE end		
}	--- PEX_OBSERVATION end		
}	--- EXPERIENCE end		

The PID segment provides the patient identification information including institutional identification numbers, date of birth and in the case of patients who die, information about their death. Patients are frequently identified only by their initials which can be represented in the PID segment, e.g. the initials JMO would appear as J^M^O in the name field of the PID segment. The EVN segment identifies the type of transaction that is being sent -- primarily it specifies who the sender is and implies which information is expected to be included in the message. A message sent from a healthcare provider, for example, might contain minimal information, while a message from a pharmaceutical manufacturer might contain nearly complete information.

The PES or Product Experience Sender segment provides information about the message sender and its knowledge of the event. The heart of the product experience message is the product experience observation (PEO) segment and the PCR segments clustered under it. The PEO segment identifies a clinical event and the PCR segments identify products which are potentially causally related to the event. There may be more than one product which is potentially related to the event so multiple PCR segments can be included. RXE and RXR segments can be repeated and provide information about the products the patient was exposed to at the time of the event (typically excluding those used to treat the event). Details about the administration of the products identified in the PCR segments should be described with RXE and RXR segments. Repeated PRB segments provide information about diagnoses which represent comorbid conditions. The repeated OBX segments are used to send patient observations such as height, weight, last menstrual period,

and laboratory results. Analytical commentary can be included in the NTE segment. This commentary will typically be the sender's analysis of the event and the potentially causally related products. Finally, the CSR and CSP segments can optionally be included if the event occurred during a formal clinical trial in order to describe the trial.

When a product experience relates to an exposure which occurred indirectly (transmammary or transplacentally for example), the individual experiencing the adverse effect — the fetus or child — would be described in the PID segment and the individual via which they are exposed in the NK1 segment. The first set of RXE segments would typically indicate the drugs which to which the fetus or child was exposed. Additional codes for the route are defined in this Appendix to allow the suspected routes of exposure to be represented. The second set of RXE/RXR segment - those clustered under the NK1 segment - would represent the route by which the mother or father was exposed to the drug. Early spontaneous abortion would normally be treated as an adverse effect on the mother rather than on the fetus, and the PID would refer to the mother. The second set of PRB/OBX segments reflects the problems/observations associated with the individual via which they were exposed.

Each message contains information about a single case including one patient (PID), at least one sender (PES), one or more events (PEO) and one or more suspected products (PCR and RXE/RXA) for a minimal message. The structure of the message allows actual administration information to be sent in the RXA if known; if administration information is unavailable, or the adverse reaction cannot be related to a single administration event, the RXE segment can be used to send prescription level information. Additional information may be included based on availability and regulatory requirements.

The MSH segment specifies the character set (*MSH-18*) and the language (*MSH-19*) used in the PEX message.

The PEX message is designed to accommodate required reporting of adverse product events to the responsible regulatory agencies. In the United States, the paper version of this report is Medwatch.

7.11.2 SUR - Summary Product Experience Report (Event P09)

Sending summary reports related to products constitutes a P09 event.

This message and event is deprecated for v2.5: This message is not consistent with most message definitions and appears flawed for the following reasons:

The SUR message structure has no optional segments. Even the NTE is defined as required.

The message contains an invalid ED segment.

The Message contains sequences of segments that would be difficult if not impossible to parse. For example the PSH segment is a child of an FAC segment followed by a second PSH that is the parent of another FAC segment.

This Technical Committee invites users of the existing message and/or domain experts to submit a formal proposal for a replacement message, event and use cases that can be considered for the next v2.x ballot.

SUR^P09^SUR_P09	Summary Product Experience Report	Status	Chapter
MSH	Message Header		2
{			
FAC	Facility		7
{			
PSH	Product Summary Header		7

SUR^P09^SUR_P09	Summary Product Experience Report	Status	Chapter
PDC	Product Detail Country		7
}			
PSH	Product Summary Header		7
{			
FAC	Facility		7
PDC	Product Detail Country		7
NTE	Notes (for PCR)		2
}			
ED	Encapsulated Data		2
}			

The Summary Product Experience Report message can be divided into two separate parts. Part 1 consists of a Facility segment which identifies the reporting organization, a Product Summary Header segment which provides summary information about the products and manufacturers, and a Product Detail Country segment which provides country specific product identification and marketing information. Part 2 consists of a repeating series of segments. These segments could be used to represent data about each model of a medical device (Part 2 of FDA Form 3417, for example). The Product Summary Header segment provides manufacturer's data, under which repeating sets of Facility segments (representing multiple manufacturing sites), a Product Detail Country segment (representing marketing and product identification data) and the Note segment (for other commentary) may follow. Finally, the Encapsulated Data (ED) segment can be used to transmit images of documents, including any of the MIME (Multimedia Internet Mail Extension) support formats such as JPEG, GIF, and FAX.

Regulatory agencies require a variety of reports that are centered on the product, not on a single patient. Some of these reports request information just about the product, and some request information about the product combined with a summary of the product experience reports on that product. These are used by regulatory agencies to provide totals against which they can verify that they have received and processed all of the relevant reports, and to calculate denominators for computing event rates. If manufacturers begin to transmit these reports electronically and regulatory agencies in turn electronically confirm the receipt of such reports, the need for some of these summary reports will decline.

The SUR message provides a mechanism for sending a variety of different summary reports. In the United States, the Medical Device Reporting Annual Certification and the Medical Device Reporting Baseline Report are examples of such reports. Below, we use these two medical device reports to illustrate how one would map the contents of this kind of report to the SUR message.

Manufacturers are required to submit a Baseline Report (FDA Form 3417 of October, 1995 (when a device is first released. The focus of this report is a single product. The first part requests information about the manufacturer of the product (Questions 2a through 2g), e.g., the firm's name, street address, city, country, type of firm (e.g., manufacturer, distributor, both); the manufacturer's contact (Questions 3a through 3g). e.g., title, street address, city, state, phone number, and whether the firm is an organization of a foreign manufacturer. Most of this information can be transmitted as fields within the FAC (Facility segment - the first segment in the SUR message following the MSH). Question 1 (which asks the type of baseline report - initial or annual update) and Question 7 (the date of the report) are reported in the PSH (Product Summary Header) segment that follows the FAC segment in the SUR message. The second part of the Baseline Report form also includes information about the device name (Question 2), generic name (Question 3), device model number (Question 4), device catalogue number (Question 5), other device identifier (Question 6), product code (Question 7), and device family (Question 8), related device information (Question 9), the

basis for marketing the device (Question 10), device life (Question 11), the date the device was first marketed (Question 12), the date the device ceased being marketed (Question 13), whether the device was the subject of a 522 study (Question 14), and the number of devices manufactured, distributed, and in current use (Question 15). All of these questions with the exception of #9 are represented in the PDC segment. Questions 16a and 16b are represented by nested PSH segments.

The Medical Device Reporting Annual Certification form consists of two parts. Part 12 transmits information describing the firm submitting the report (Questions 2a through 2h) and the individual who completed the report (Questions 3a through 3g). These questions are represented in the FAC segment. Question 1 (period covered by the certification) corresponds to the PSH segment. Part 2, Question 3, which details one or more individual devices, can be transmitted in the repeating FAC and PSH segments. Figure 7-19 summarizes the mapping between questions on these two FDA forms and the SUR message.

Figure 7-9. Mapping of FDA medical device reports to SUR message

Baseline Report	Annual Certification	SUR
		MSH
Part 1 Questions 2a-2g, 3a-3g	Part 1 Questions 2,3	{ FAC
Part 1 Questions 1, 7	Part 1 Question 1	{PSH
		PDC
		}
Part 2 Questions 16a, 16b	Part 2 Question 3	PSH
Part 2 Questions 1a, 1b	Part 2 Question 3	{ FAC
Part 2 Questions 2-15		PDC
		NTE
		}
Part 2 Alternative transmission method - image file rather than text		ED
		}

7.12 PRODUCT EXPERIENCE – SEGMENT DEFINITIONS

7.12.1 PES - Product Experience Sender Segment

HL7 Attribute Table - PES – Product Experience Sender

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	250	XON	O	Y		01059	Sender Organization Name
2	250	XCN	O	Y		01060	Sender Individual Name
3	250	XAD	O	Y		01062	Sender Address
4	250	XTN	O	Y		01063	Sender Telephone
5	75	EI	O			01064	Sender Event Identifier
6	2	NM	O			01065	Sender Sequence Number
7	600	FT	O	Y		01066	Sender Event Description

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
8	600	FT	O			01067	Sender Comment
9	26	TS	O			01068	Sender Aware Date/Time
10	26	TS	R			01069	Event Report Date
11	3	ID	O	Y/2	0234	01070	Event Report Timing/Type
12	1	ID	O		0235	01071	Event Report Source
13	1	ID	O	Y	0236	01072	Event Reported To

7.12.1.0 PES - field definitions

7.12.1.1 PES-1 Sender Organization Name (XON) 01059

Components: <Organization Name (ST)> ^ <Organization Name Type Code (IS)> ^ <DEPRECATED-ID Number (NM)> ^ <Check Digit (NM)> ^ <Check Digit Scheme (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Organization Identifier (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the name of the organization sending the message. Coded lists of manufacturers such as that from the World Health Organization database might be used in the component of the coded name to identify the source code type. If sent from an individual, this field may not be sent.

7.12.1.2 PES-2 Sender Individual Name (XCN) 01060

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate

```
            Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
            Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
            Text (ST)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
            (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
            <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
            System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
            <Original Text (ST)>
```

Definition: This field contains the name of the contact individual. If sent by an organization, the individuals in the organization who serve as primary contact points correspondence regarding this event.

7.12.1.3 PES-3 Sender Address (XAD) 01062

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
            or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
            Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
            (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^
            <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^
            <Expiration Date (TS)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
            Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR):  <Range Start Date/Time
            (TS)> & <Range End Date/Time (TS)>

            Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
            (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
            Precision (ID)>
```

Definition: This field contains the postal address of the message sender to which correspondence regarding the experience being reported should be directed.

7.12.1.4 PES-4 Sender Telephone (XTN) 01063

```
Components:  <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^
            <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country
            Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension
            (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)>
            ^ <Unformatted Telephone number  (ST)>
```

Definition: This field contains the telephone number of the message sender to which telephone communications regarding the experience being reported should be directed. An electronic mail address can be specified in this field.

7.12.1.5 PES-5 Sender Event Identifier (EI) 01064

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
            <Universal ID Type (ID)>
```

Definition: The first component of this field contains the product manufacturer's unique alphanumeric identifier for this specific event. This identifier will be used on all subsequent communications regarding this event. For events reported to the FDA, the identifier is: the FDA assigned manufacturer or distributor number; a hyphen; the 4-digit year; a hyphen; and a consecutive 5-digit sequence number for each report filled by the sender that year. For example, the event identifier for the third event reported in 1996 by a manufacturer whose FDA-assigned registration number is 1234567 would be 1234567-1993-3. Organizations without a FDA-assigned registration number should use 0000000 until assigned a number. Reports from other facilities should use the 10-digit HCFA number left padded with zeros in place of the FDA-assigned registration number. The second through fourth components are defined in exactly the same way as the three components of the hierarchic designator (HD) data type (Section 2.8.18, "HD - hierarchic designator").

7.12.1.6 PES-6 Sender Sequence Number (NM) 01065

Definition: This field contains sequentially assigned integer values which distinguish messages which share the same sender event identification element. 0 for initial report, 1 for second, and so on.

7.12.1.7 PES-7 Sender Event Description (FT) 01066

Definition: This field contains the summary narrative text description of the event that occurred written by the sender, which may include a description of the nature of the event, how the product was involved, any environmental conditions that may have influenced the event, and patient follow-up or required treatment. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative. By representing clinical information in OBX segments rather than in the narrative, these data become much more useful and flexible.

7.12.1.8 PES-8 Sender Comment (FT) 01067

Definition: This field contains the text commentary regarding the report being made, such as disclaimers, which is not necessarily part of the report.

7.12.1.9 PES-9 Sender Aware Date/Time (TS) 01068

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field identifies the date the sender became aware of the event.

7.12.1.10 PES-10 Event Report Date (TS) 01069

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the message was originally sent to the regulatory agency.

7.12.1.11 PES-11 Event Report Timing/Type (ID) 01070

Definition: This field contains the timing type of report as required by regulatory agency. Refer to *HL7 Table 0234 - Report Timing* for valid values.

HL7 Table 0234 - Report timing

Value	Description	Comment
CO	Correction	
AD	Additional information	
RQ	Requested information	
DE	Device evaluation	
PD	Periodic	
3D	3 day report	
7D	7 day report	
10D	10 day report	
15D	15 day report	
30D	30 day report	

7.12.1.12 PES-12 Event report source (ID) 01071

Definition: This field identifies the source from which the sender learned about the event. Multiple sources may be reported by repeating the element.

If the source of the report is a clinical trial, the CSR and CSP segments can be included to define the study. Refer to *HL7 Table 0235 - Report Source* for valid values.

HL7 Table 0235 - Report source

Value	Description	Comment
C	Clinical trial	
L	Literature	
H	Health professional	
R	Regulatory agency	
D	Database/registry/poison control center	
N	Non-healthcare professional	
P	Patient	
M	Manufacturer/marketing authority holder	
E	Distributor	
O	Other	

7.12.1.13 PES-13 Event Reported To (ID) 01072

Definition: This field indicates all the entities to whom the entity submitting the report has reported the event. Repeat the element if the report was submitted to more than one entity. Refer to *HL7 Table 0236 - Event reported to* for valid values.

HL7 Table 0236 - Event Reported To

Value	Description	Comment
M	Manufacturer	
L	Local facility/user facility	
R	Regulatory agency	
D	Distributor	

7.12.2 PEO - Product Experience Observation Segment

Details related to a particular clinical experience or event are embodied in the PEO segment. This segment can be used to characterize an event which might be attributed to a product to which the patient was exposed. Products with a possible causal relationship to the observed experience are described in the following PCR (possible causal relationship) segments. The message format was designed to be robust and includes many optional elements which may not be required for a particular regulatory purpose but allow a complete representation of the drug experience if needed.

A PEX message can contain multiple PEO segments if the patient experienced more than one event but must contain at least one PEO segment.

HL7 Attribute Table – PEO – Product Experience Observation

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	250	CE	O	Y		01073	Event Identifiers Used
2	250	CE	O	Y		01074	Event Symptom/Diagnosis Code
3	26	TS	R			01075	Event Onset Date/Time
4	26	TS	O			01076	Event Exacerbation Date/Time
5	26	TS	O			01077	Event Improved Date/Time
6	26	TS	O			01078	Event Ended Data/Time
7	250	XAD	O	Y		01079	Event Location Occurred Address
8	1	ID	O	Y	0237	01080	Event Qualification
9	1	ID	O		0238	01081	Event Serious
10	1	ID	O		0239	01082	Event Expected
11	1	ID	O	Y	0240	01083	Event Outcome
12	1	ID	O		0241	01084	Patient Outcome

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
13	600	FT	O	Y		01085	Event Description From Others
14	600	FT	O	Y		01086	Event From Original Reporter
15	600	FT	O	Y		01087	Event Description From Patient
16	600	FT	O	Y		01088	Event Description From Practitioner
17	600	FT	O	Y		01089	Event Description From Autopsy
18	250	CE	O	Y		01090	Cause Of Death
19	250	XPN	O	Y		01091	Primary Observer Name
20	250	XAD	O	Y		01092	Primary Observer Address
21	250	XTN	O	Y		01093	Primary Observer Telephone
22	1	ID	O		0242	01094	Primary Observer's Qualification
23	1	ID	O		0242	01095	Confirmation Provided By
24	26	TS	O			01096	Primary Observer Aware Date/Time
25	1	ID	O		0243	01097	Primary Observer's identity May Be Divulged

7.12.2.0 PEO field definitions

7.12.2.1 PEO-1 Event Identifiers Used (CE) 01073

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field may be used to transmit the event identifier used by other entities for this event. The entry would typically contain a unique alphanumeric identifier assigned by an entity with the text component null or repeating the unique alphanumeric identifier followed by the organization's identifier. An event identifier might be GB1234^GB1234^PharmaGiant for example.

7.12.2.2 PEO-2 Event Symptom/Diagnosis Code (CE) 01074

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field is the coded diagnosis or problem description which best describes the event. A text representation of the coded item should routinely be included. MEDDRA and WHO-ART are examples of appropriate coding schemes, as are the patient and device codes included in the FDA Center for Devices and Radiologic Health's coding manual for Form 3500A.

7.12.2.3 PEO-3 Event Onset Date/Time (TS) 01075

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains a report or best estimate of the date/time of onset of the event. The date/time can be recorded to any level of precision it is known (hour, day, month, year).

7.12.2.4 PEO-4 Event Exacerbation Date/Time (TS) 01076

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field identifies the best estimate of the date/time the event was exacerbated.

7.12.2.5 PEO-5 Event Improved Date/Time (TS) 01077

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field identifies the best estimate of the date/time the event improved.

7.12.2.6 PEO-6 Event Ended Data/Time (TS) 01078

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field identifies the best estimate of the date/time the event resolved.

7.12.2.7 PEO-7 Event Location Occurred Address (XAD) 01079

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
             or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
             Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
             (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^
             <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^
             <Expiration Date (TS)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
             Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR):  <Range Start Date/Time
             (TS)> & <Range End Date/Time (TS)>

             Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>
```

Definition: This field identifies the location at which the event started. Often this will specify only the country in which the event started.

7.12.2.8 PEO-8 Event Qualification (ID) 01080

Definition: This field is contains a classification of the type of product experience this event is considered to represent. Refer to *HL7 Table 0237 - Event Qualification* for valid values.

HL7 Table 0237 - Event Qualification

Value	Description	Comment
I	Interaction	
O	Overdose	
A	Abuse	
M	Misuse	
D	Dependency	
L	Lack of expect therapeutic effect	
W	Drug withdrawal	
B	Unexpected beneficial effect	

Unexpected beneficial effects would not often be reported but are required by certain countries.

7.12.2.9 PEO-9 Event Serious (ID) 01081

Definition: This field indicates whether the event was judged as serious. If the event did not meet the criteria for seriousness but the sender judges the event significant on other grounds, the event can be identified as significant [*but not serious*]. Refer to *HL7 Table 0238 - Event Seriousness* for valid values.

HL7 Table 0238 - Event Seriousness

Value	Description	Comment
Y	Yes	
S	Significant	
N	No	

7.12.2.10 PEO-10 Event Expected (ID) 01082

Definition: This field indicates whether the observed event was expected or unexpected as judged. Refer to *HL7 Table 0239 - Event Expected* for valid values.

HL7 Table 0239 - Event Expected

Value	Description	Comment
Y	Yes	
N	No	
U	Unknown	

7.12.2.11 PEO-11 Event Outcome (ID) 01083

Definition: This field identifies the consequence of the event on the patient. If the consequence of the event is not understood or not available, the patient outcome element may be used although neither is required. May be repeated if more than one is appropriate. Refer to *HL7 Table 0240 - Event consequence* for valid values.

HL7 Table 0240 - Event Consequence

Value	Description	Comment
D	Death	
L	Life threatening	
H	Caused hospitalized	
P	Prolonged hospitalization	
C	Congenital anomaly/birth defect	
I	Incapacity which is significant, persistent or permanent	
J	Disability which is significant, persistent or permanent	
R	Required intervention to prevent permanent impairment/damage	
O	Other	

7.12.2.12 PEO-12 Patient Outcome (ID) 01084

When an event specific outcome is not available, the patient outcome element may be used to represent the patient's overall outcome if that information is known. Refer to *HL7 Table 0241 - Patient outcome* for valid values.

HL7 Table 0241 - Patient Outcome

Value	Description	Comment
D	Died	
R	Recovering	
N	Not recovering/unchanged	
W	Worsening	
S	Sequelae	
F	Fully recovered	
U	Unknown	

7.12.2.13 PEO-13 Event Description from Others (FT) 01085

Definition: This field contains a summary narrative text description of the event that occurred written by the sender. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative. By representing clinical information in OBX segments rather than in the narrative, these data become much more useful and flexible.

7.12.2.14 PEO-14 Event Description from Original Reporter (FT) 01086

Definition: This field contains a summary narrative text description of the event provided by the original reporter. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.15 PEO-15 Event Description from Patient (FT) 01087

Definition: This field contains a summary narrative text description of the event obtained directly from the patient. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative, which will allow the data to be more readily represented and manipulated.

7.12.2.16 PEO-16 Event Description from Practitioner (FT) 01088

Definition: This field contains a summary narrative text description of the event provided by the practitioner most familiar with the event. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.17 PEO-17 Event Description from Autopsy (FT) 01089

Definition: This field contains a summary narrative text description of the autopsy results. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.18 PEO-18 Cause of Death (CE) 01090

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)>

Definition: This field identifies the coded cause of death. May be repeated as necessary to list multiple contributing causes. A text description can be included by including text but no code or coding system. For example, if the cause of death is to be determined at autopsy but results are not yet available, the cause of death element could be ^Pending autopsy^. The date/time of death can be sent in the PID and the autopsy results sent in the event description from autopsy element of the PEO segment.

7.12.2.19 PEO-19 Primary Observer Name (XPN) 01091

Components: <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Name Type Code (ID)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Definition: This field identifies the name of the person who initially described the event.

7.12.2.20 PEO-20 Primary Observer Address (XAD) 01092

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
             or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
             Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
             (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^
             <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^
             <Expiration Date (TS)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
             Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR):  <Range Start Date/Time
             (TS)> & <Range End Date/Time (TS)>

             Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>
```

Definition: This field identifies the address of the person who initially described the event.

7.12.2.21 PEO-21 Primary Observer Telephone (XTN) 01093

```
Components:  <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^
             <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country
             Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension
             (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)>
             ^ <Unformatted Telephone number  (ST)>
```

Definition: This field identifies the telephone number of the person who initially described the event.

7.12.2.22 PEO-22 Primary Observer's Qualification (ID) 01094

Definition: This field contains the qualification of the primary observer which may assist in assessing the validity of the observations. Refer to *HL7 Table 0242 - Primary Observer's Qualification* for valid values.

HL7 Table 0242 - Primary Observer's Qualification

Value	Description	Comment
P	Physician (osteopath, homeopath)	
R	Pharmacist	
M	Mid-level professional (nurse, nurse practitioner, physician's assistant)	
H	Other health professional	
C	Health care consumer/patient	
L	Lawyer/attorney	
O	Other non-health professional	

7.12.2.23 PEO-23 Confirmation Provided By (ID) 01095

Definition: This field contains the qualification of the health professional who confirmed the observation if the primary observer was not a health professional. Refer to *HL7 Table 0242 - Primary observer's qualification* for valid values.

7.12.2.24 PEO-24 Primary Observer Aware Date/Time (TS) 01096

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field identifies the date/time the primary observer became aware of event.

7.12.2.25 PEO-25 Primary Observer's Identity May Be Divulged (ID) 01097

Definition: Indicates whether or not the primary observer, if known to the sender, grants permission to disclose his or her identity to the product manufacturer for the purpose of further investigating the event. If the element is absent, the assumption should be made that permission is not granted. Refer to *HL7 Table 0243 - Identity May Be Divulged* for valid values.

HL7 Table 0243 - Identity May Be Divulged

Value	Description	Comment
Y	Yes	
N	No	
NA	Not applicable	

7.12.3 PCR - Possible Causal Relationship Segment

The PCR segment is used to communicate a potential or suspected relationship between a product (drug or device) or test and an event with detrimental effect on a patient. This segment identifies a potential causal relationship between the product identified in this segment and the event identified in the PEO segment.

More than one PCR segment can be included in the message if more than one product is possibly causally related to the event.

HL7 Attribute Table – PCR – Possible Causal Relationship

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	250	CE	R			01098	Implicated Product
2	1	IS	O		0249	01099	Generic Product
3	250	CE	O			01100	Product Class
4	8	CQ	O			01101	Total Duration Of Therapy
5	26	TS	O			01102	Product Manufacture Date
6	26	TS	O			01103	Product Expiration Date
7	26	TS	O			01104	Product Implantation Date
8	26	TS	O			01105	Product Explantation Date
9	8	IS	O		0244	01106	Single Use Device
10	250	CE	O			01107	Indication For Product Use
11	8	IS	O		0245	01108	Product Problem
12	30	ST	O	Y/3		01109	Product Serial/Lot Number
13	1	IS	O		0246	01110	Product Available For Inspection
14	250	CE	O			01111	Product Evaluation Performed
15	250	CE	O		0247	01112	Product Evaluation Status
16	250	CE	O			01113	Product Evaluation Results
17	8	ID	O		0248	01114	Evaluated Product Source
18	26	TS	O			01115	Date Product Returned To Manufacturer
19	1	ID	O		0242	01116	Device Operator Qualifications
20	1	ID	O		0250	01117	Relatedness Assessment
21	2	ID	O	Y/6	0251	01118	Action Taken In Response To The Event
22	2	ID	O	Y/6	0252	01119	Event Causality Observations
23	1	ID	O	Y/3	0253	01120	Indirect Exposure Mechanism

7.12.3.0 PCR field definitions

7.12.3.1 PCR-1 Implicated Product (CE) 01098

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the coded identity of the product (drug, device, etc.) which is possibly causally related to the event. Includes the product identity number such as NDC, model or catalogue numbers. If a coded value is not available for the product a text description can be included as the second component of the CE data. See Chapter 2 for a listing of some recognized coding systems for drugs and devices.

7.12.3.2 PRC-2 Generic Product (IS) 01099

Definition: This field indicates whether the product used was a generic or a branded product. Refer to *User-defined Table 0249 – Generic product* for suggested values.

User-defined Table 0249 – Generic Product

Value	Description	Comment
	No suggested values defined	

7.12.3.3 PCR-3 Product Class (CE) 01100

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the coded classification of the implicated product. For drugs, this would usually be the drug class - calcium channel blocking agents for nifedipine for example. For other products it would be the generic type of device, e.g., urinary catheter, cardiac pacemaker. If a coded value is not available for the class, a text description can be included.

7.12.3.4 PCR-4 Total Duration of Therapy (CQ) 01101

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
             System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
             of Alternate Coding System (ID)>
```

Definition: This field represents the total duration of therapy with product listed. The treatment at the current dose and schedule are indicted in the quantity timing attribute of the RXE segment but the patient may have been treated for some time previously at a different dose or on a different schedule. The quantity in the second component of the CQ should be a time quantity.

7.12.3.5 PCR-5 Product Manufacture Date (TS) 01102

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field indicates the date the product was manufactured.

7.12.3.6 PCR-6 Product Expiration Date (TS) 01103

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the expiration date indicated on the product packaging.

7.12.3.7 PCR-7 Product Implantation Date (TS) 01104

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: If an implantable medical device, this field identifies the date device was implanted.

7.12.3.8 PCR-8 Product Explantation Date (TS) 01105

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: If an implantable medical device and it was removed, the field identifies the date it was removed.

7.12.3.9 PCR-9 Single Use Device (IS) 01106

Definition: This field indicates whether the product was designed for a single use. Refer to *User-defined Table 0244 – Single use device* for suggested values.

User-defined Table 0244 – Single Use Device

Value	Description	Comment
	No suggested values defined	

7.12.3.10 PCR-10 Indication for Product Use (CE) 01107

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains coded representation of the problem or diagnosis for which the product was used. See Chapter 2 for some coding systems which might be chosen to transmit diagnoses or problems.

7.12.3.11 PCR-11 Product Problem (IS) 01108

Definition: A product problem would exist if a product malfunction could lead to death or serious injury. Refer to *User-defined Table 0245 - Product problem* for suggested values.

User-defined Table 0245 – Product Problem

Value	Description	Comment
	No suggested values defined	

7.12.3.12 PCR-12 Product Serial/Lot Number (ST) 01109

Definition: This field is an alphanumeric descriptor which identifies the specific item or lot of drug. This descriptor would normally be obtained from the package labeling or item itself.

7.12.3.13 PCR-16 Product Available for Inspection (IS) 01110

Definition: This field indicates that the product is available for analysis. *User-defined Table 0246 -Product available for inspection is used as the HL7 identifier for the user-defined table of values for this field*. If the product was returned to the manufacturer, this would be indicated by including the date it was returned in the date product returned to manufacturer element.

User-defined Table 0246 – Product Available for Inspection

Value	Description	Comment
	No suggested values defined	

7.12.3.14 PCR-14 Product Evaluation Performed (CE) 01111

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field indicates the type of product evaluation performed. The evaluation codes listed in SubPart B of the Coding Manual for FDA Form 3500A, "Type of Evaluation Performed" may be used. If no codes are available, text may be sent in the second component of the field.

7.12.3.15 PCR-15 Product Evaluation Status (CE) 01112

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field identifies the status of product evaluation. Subpart A Item H.3 of the Coding Manual for FDA Form 3500A may also be used. If no codes are available, text may be sent in the second component of the field. Refer to *HL7 Table 0247 - Status of evaluation* for valid values.

HL7 Table 0247 - Status of Evaluation

Value	Description	Comment
Y	Evaluation completed	
P	Evaluation in progress	
K	Problem already known, no evaluation necessary	
X	Product not made by company	
A	Evaluation anticipated, but not yet begun	
D	Product discarded -- unable to follow up	
C	Product received in condition which made analysis impossible	
I	Product remains implanted -- unable to follow up	
U	Product unavailable for follow up investigation	
Q	Product under quarantine -- unable to follow up	
R	Product under recall/corrective action	
O	Other	

7.12.3.16 PCR-16 Product Evaluation Results (CE) 01113

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)>
```

Definition: This field contains the results of the product evaluation.

7.12.3.17 PCR-17 Evaluated Product Source (ID) 01114

Definition: This field contains the source of the product evaluated. Refer to *HL7 Table 0248 - Product source* for valid values.

HL7 Table 0248 - Product source

Value	Description	Comment
A	Actual product involved in incident was evaluated	
L	A product from the same lot as the actual product involved was evaluated	
R	A product from a reserve sample was evaluated	
N	A product from a controlled/non-related inventory was evaluated	

7.12.3.18 PCR-18 Date Product Returned to Manufacturer (TS) 01115

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: If the product was returned to the manufacturer, this field contains the date it was returned may be reported.

7.12.3.19 PCR-19 Device Operator Qualifications (ID) 01116

Definition: This field identifies the qualification of the person operating the device when the event occurred. Refer to *HL7 Table 0242 - Primary observer's qualification* for valid values.

7.12.3.20 PCR-20 Relatedness Assessment (ID) 01117

Definition: This field represents the assessment of relatedness of the product to the event. Refer to *HL7 Table 0250 - Relatedness assessment* for valid values.

HL7 Table 0250 - Relatedness Assessment

Value	Description	Comment
H	Highly probable	
M	Moderately probable	
S	Somewhat probable	
I	Improbable	
N	Not related	

7.12.3.21 PCR-21 Action Taken in Response to the Event (ID) 01118

Definition: This field indicates the action taken as a result of the event. Segment may repeat if multiple categories of evidence are relevant. Refer to *HL7 Table 0251 - Action taken in response to the event* for valid values.

HL7 Table 0251 - Action Taken in Response to the Event

Value	Description	Comment
WP	Product withdrawn permanently	
WT	Product withdrawn temporarily	
DR	Product dose or frequency of use reduced	
DI	Product dose or frequency of use increased	
OT	Other	
N	None	

7.12.3.22 PCR-22 Event Causality Observations (ID) 01119

Definition: This field contains observations made about the event which may bear on causality. Refer to *HL7 Table 0252 - Causality observations* for valid values. Segment may repeat if multiple categories of evidence are relevant.

HL7 Table 0252 - Causality Observations

Value	Description	Comment
AW	Abatement of event after product withdrawn	
BE	Event recurred after product reintroduced	
LI	Literature reports association of product with event	
IN	Event occurred after product introduced	
EX	Alternative explanations for the event available	
PL	Effect observed when patient receives placebo	
TC	Toxic levels of product documented in blood or body fluids	
DR	Dose response observed	
SE	Similar events in past for this patient	
OE	Occurrence of event was confirmed by objective evidence	
OT	Other	

7.12.3.23 PCR-23 Indirect Exposure Mechanism (ID) 01120

Definition: The patient identified in the PID segment, who experienced the event, might have been exposed to the potential causal product via an intermediary, e.g., a child might be exposed to a product through the placenta or in breast milk, or a transfusion recipient might be exposed via a blood product. If this is the case, the mechanism of product transmission is identified in this field, using the valid values in *HL7 Table 0253 - Indirect exposure mechanism*. If this field is populated, the identity of the person through whom the product was transmitted is contained in NK1 and RXE segments which follow.

HL7 Table 0253 - Indirect exposure mechanism

Value	Description	Comment
B	Breast milk	
P	Transplacental	
F	Father	
X	Blood product	
O	Other	

7.12.4 PSH - Product Summary Header Segment

HL7 Attribute Table – PSH –Product Summary Header

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	60	ST	R			01233	Report Type
2	60	ST	O			01297	Report Form Identifier
3	26	TS	R			01235	Report Date
4	26	TS	O			01236	Report Interval Start Date
5	26	TS	O			01237	Report Interval End Date
6	12	CQ	O			01238	Quantity Manufactured
7	12	CQ	O			01239	Quantity Distributed
8	1	ID	O		0329	01240	Quantity Distributed Method
9	600	FT	O			01241	Quantity Distributed Comment
10	12	CQ	O			01242	Quantity in Use
11	1	ID	O		0329	01243	Quantity in Use Method
12	600	FT	O			01244	Quantity in Use Comment
13	2	NM	O	Y/8		01245	Number of Product Experience Reports Filed by Facility
14	2	NM	O	Y/8		01246	Number of Product Experience Reports Filed by Distributor

7.12.4.0 PSH field definitions

7.12.4.1 PSH-1 Report Type (ST) 01233

Definition: This field contains the name, title, or other description of the report. Typically, the field will include the agency name (e.g., FDA), agency component if applicable (e.g., CDRH) and the report type (e.g., Medical Device Reporting Baseline Report).

7.12.4.2 PSH-2 Report Form Identifier (ST) 01297

Definition: This field contains the form descriptor which describes the report. Typically, the field will include the agency name (e.g., FDA), agency component if applicable (e.g., CDRH) and the form number (e.g., 3417).

7.12.4.3 PSH-3 Report Date (TS) 01235

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date as assigned by the sender.

7.12.4.4 PSH-4 Report Interval Start Date (TS) 01236

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date that marks the beginning of the time interval covered by the current report.

7.12.4.5 PSH-5 Report Interval End Date (TS) 01237

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date which marks the inclusive end of the time interval covered by the current report.

7.12.4.6 PSH-6 Quantity Manufactured (CQ) 01238

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)>
```

Definition: This field is used to send the number of units of the product manufactured during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.7 PSH-7 Quantity Distributed (CQ) 01239

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)>
```

Definition: This field is used to send the number of units of the product which was distributed during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.8 PSH-8 Quantity Distributed Method (ID) 01240

Definition: This field is used for measuring the quantity distributed. An explanation of the method used for estimation can be included in *PSH-9-quantity distributed comment*. Refer to *HL7 Table 0329 - Quantity method* for valid values.

HL7 Table 0329 - Quantity method

Value	Description	Comment
A	Actual count	
E	Estimated (see comment)	

7.12.4.9 PSH-9 Quantity Distributed Comment (FT) 01241

Definition: This field is used for any explanatory text needed but in particular should provide a description of the estimation method used. If referring to the description used in a previous report, the comment should include the product identifier and data of that report.

7.12.4.10 PSH-10 Quantity In Use (CQ) 01242

```
Components:  <Quantity (NM)> ^ <Units (CE)>
```

```
Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)>
```

Definition: This field is used to send the number of units of the product which were in use during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.11 PSH-11 Quantity In Use Method (ID) 01243

Definition: This field contains the method used for measuring the quantity in use. An explanation of the method used for estimation can be included in *PSH-12-quantity in use comment*. Refer to *HL7 Table 0329 - Quantity method* for valid values.

7.12.4.12 PSH-12 Quantity In Use Comment (FT) 01244

Definition: This field can be used for any explanatory text needed but in particular should provide a description of the estimation method used. If referring to the description used in a previous report, the comment should include the product identifier and data of the report.

7.12.4.13 PSH-13 Number of product experience reports filed by facility (NM) 01245

Definition: The field contains the number of product experience reports filed by facility.

7.12.4.14 PSH-14 Number of product experience reports filed by distributor (NM) 01246

Definition: This field contains the number of product experience reports filed by distributor.

7.12.5 PDC - Product Detail Country Segment

HL7 Attribute Table – PDC – Product Detail Country

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	250	XON	R	Y		01247	Manufacturer/Distributor
2	250	CE	R			01248	Country
3	60	ST	R			01249	Brand Name
4	60	ST	O			01250	Device Family Name
5	250	CE	O			01251	Generic Name
6	60	ST	O	Y		01252	Model Identifier
7	60	ST	O			01253	Catalogue Identifier
8	60	ST	O	Y		01254	Other Identifier
9	250	CE	O			01255	Product Code
10	4	ID	O		0330	01256	Marketing Basis
11	60	ST	O			01257	Marketing Approval ID
12	12	CQ	O			01258	Labeled Shelf Life
13	12	CQ	O			01259	Expected Shelf Life
14	26	TS	O			01260	Date First Marketed
15	26	TS	O			01261	Date Last Marketed

7.12.5.0 PDC field definitions

7.12.5.1 PDC-1 Manufacturer/Distributor (XON) 01247

```
Components:  <Organization Name (ST)> ^ <Organization Name Type Code (IS)> ^
          <DEPRECATED-ID Number (NM)> ^ <Check Digit (NM)> ^ <Check Digit Scheme
          (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
```

```
            <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^
            <Organization Identifier (ST)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
            & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
            & <Universal ID Type (ID)>
```

Definition: This field contains the identity of the manufacturer/distributor.

7.12.5.2 PDC-2 Country (CE) 01248

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)>
```

Definition: This field contains the country to which this product detail is relevant. ISO 3166 provides a list of country codes that may be used.

7.12.5.3 PDC-3 Brand Name (ST) 01249

Definition: This field contains the name under which the product is marketed by this manufacturer.

7.12.5.4 PDC-4 Device Family Name (ST) 01250

Definition: This field contains the name used by the manufacturer to describe the family of products to which this product belongs.

7.12.5.5 PDC-5 Generic Name (CE) 01251

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)>
```

Definition: This field contains the name generically used to identify the product.

7.12.5.6 PDC-6 Model Identifier (ST) 01252

Definition: This field contains the manufacturer's model identifier for the product.

7.12.5.7 PDC-7 Catalogue Identifier (ST) 01253

Definition: This field contains the manufacturer's catalogue identifier for the product.

7.12.5.8 PDC-8 Other Identifier (ST) 01254

Definition: This field contains any other identifier used to for the product.

7.12.5.9 PDC-9 Product Code (CE) 01255

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)>
```

Definition: This field contains the product code from an external coding system such as that used by the CDRH at the FDA.

7.12.5.10 PDC-10 Marketing Basis (ID) 01256

Definition: This field contains the basis for marketing approval. Refer to *HL7 Table 0330 - Marketing basis* for valid values.

HL7 Table 0330 - Marketing basis

Value	Description	Comment
510K	510 (K)	
510E	510 (K) exempt	
PMA	Premarketing authorization	
PRE	Preamendment	
TXN	Transitional	
522S	Post marketing study (522)	

7.12.5.11 PDC-11 Marketing Approval ID (ST) 01257

Definition: This field contains the designation or description of the marketing basis.

7.12.5.12 PDC-12 Labeled Shelf Life (CQ) 01258

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)>
```

Definition: This field contains the shelf life of the product as labeled. This will usually be in months or years. If there is no shelf life indicated in the product labeling, this field will be empty.

7.12.5.13 PDC-13 Expected Shelf Life (CQ) 01259

```
Components:  <Quantity (NM)> ^ <Units (CE)>

Subcomponents for Units (CE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)>
```

Definition: This field contains the shelf life of the product expected by the manufacturer. This will usually be in months or years.

7.12.5.14 PDC-14 Date First Marketed (TS) 01260

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the product was first marketed in the country.

7.12.5.15 PDC-15 Date Last Marketed (TS) 01261

```
Components:  <Time (DTM)> ^ <DEPRECATED-Degree of Precision (ID)>
```

Definition: This field contains the date the product was last marketed in the country. This field will be omitted if the product is still being marketed.

7.12.6 FAC - Facility Segment

HL7 Attribute Table – FAC – Facility

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	20	EI	R			01262	Facility ID-FAC
2	1	ID	O		0331	01263	Facility Type
3	250	XAD	R	Y		01264	Facility Address
4	250	XTN	R			01265	Facility Telecommunication
5	250	XCN	O	Y		01266	Contact Person
6	60	ST	O	Y		01267	Contact Title
7	250	XAD	O	Y		01166	Contact Address

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
8	250	XTN	O	Y		01269	Contact Telecommunication
9	250	XCN	R	Y		01270	Signature Authority
10	60	ST	O			01271	Signature Authority Title
11	250	XAD	O	Y		01272	Signature Authority Address
12	250	XTN	O			01273	Signature Authority Telecommunication

7.12.6.0 FAC field definitions

7.12.6.1 FAC-1 Facility ID-FAC (EI) 01262

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains the facility identifier.

7.12.6.2 FAC-2 Facility Type (ID) 01263

Definition: This field contains the type of facility. Refer to *HL7 Table 0331 - Facility type* for valid values.

HL7 Table 0331 - Facility type

Value	Description	Comment
U	User	
M	Manufacturer	
D	Distributor	
A	Agent for a foreign manufacturer	

7.12.6.3 FAC-3 Facility Address (XAD) 01264

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
             or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
             Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
             (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^
             <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^
             <Expiration Date (TS)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
             Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR):  <Range Start Date/Time
             (TS)> & <Range End Date/Time (TS)>

             Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of Precision
             (ID)>

Subcomponents for Expiration Date (TS):  <Time (DTM)> & <DEPRECATED-Degree of
             Precision (ID)>
```

Definition: This field contains the facility's address.

7.12.6.4 FAC-4 Facility Telecommunication (XTN) 01265

```
Components:  <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^
             <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country
             Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension
             (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)>
             ^ <Unformatted Telephone number  (ST)>
```

Definition: This field contains the facility's telecommunication information.

7.12.6.5 FAC-5 Contact Person (XCN) 01266

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Definition: This field contains the primary contact person's name.

7.12.6.6 FAC-6 Contact Title (ST) 01267

Definition: This field contains the primary contact person's title.

7.12.6.7 FAC-7 Contact Address (XAD) 01166

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^ <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Definition: This field contains the primary contact person's address.

7.12.6.8 FAC-8 Contact Telecommunication (XTN) 01269

Components: <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)>

Definition: This field contains the primary contact person's telecommunication information.

7.12.6.9 FAC-9 Signature Authority (XCN) 01270

Components: <ID Number (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <DEPRECATED-Degree (e.g., MD) (IS)> ^ <Source Table (IS)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CE)> ^ <DEPRECATED-Name Validity Range (DR)> ^ <Name Assembly Order (ID)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix From Partner/Spouse (ST)> & <Surname From Partner/Spouse (ST)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)>

Subcomponents for DEPRECATED-Name Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)>

Definition: This field contains the name of the individual with signature authority or who is responsible for the report.

7.12.6.10 FAC-10 Signature Authority Title (ST) 01271

Definition: This field contains the title of the individual with signature authority or who is responsible for this report.

7.12.6.11 FAC-11 Signature Authority Address (XAD) 01272

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^ <DEPRECATED-Address Validity Range (DR)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for DEPRECATED-Address Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Note subcomponent contains sub-subcomponents

Subcomponents for Effective Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <DEPRECATED-Degree of Precision (ID)>

Definition: This field contains the address of the individual with signature authority or who is responsible for this report.

7.12.6.12 FAC-12 Signature Authority Telecommunication (XTN) 01273

Components: <DEPRECATED-Telephone Number (ST)> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Email Address (ST)> ^ <Country Code (NM)> ^ <Area/City Code (NM)> ^ <Local Number (NM)> ^ <Extension (NM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)>

Definition: This field contains the telecommunication information of the individual with signature authority of who is responsible for this report.

7.13 PRODUCT EXPERIENCE – EXAMPLES OF USE

```
MSH|^-&|SAP||RAP||200006051512||PEX^P07|...<cr>

EVN|...<cr>

PID|1||""|A^A^A||19230616|F|||||||||||||||Y|...<cr>
```

Note: This section probably needs to have its own definition of the PID. PID-3 is a required field in chapter 3, but in the context of this section probably shouldn't be required. I also removed PID-23, Birthplace (19950710). A date is not a birthplace.

```
PES|Eli Lilly and Company||Lilly Corporate Center^^Indianapolis^IN^46285||
    GB95070448A|0|||19950704|19950710|10D|...<cr>

PEO||^Awaiting results of autopsy|19950704||||^^^^^GB||S|N|D~H~O||Patient
    admitted via casualty with increased shortness of breath and left sided chest
    pain on 04 JUL 95 for assessment.~11-JUL-95 Patient admitted 09-JUL-95 at
    11:30 PM with an 18 hour history of diarrhoea followed by collapse. On
    admission, patient was exhausted and dehydrated. She had a rash on both
    breasts and abdomen. Patient found to have deteriorating renal function.
    Patient commenced IV fluid, however patient was found dead on 10-JUL-95
    morning. Query vomited and aspirated. Post mortem requested. Events possibly
    related to study drug.|...<cr>

PCR|xxxxx^Wonder Drug 1^ATC|N|^antineoplastic|||||||^NON SMALL CELL LUNG
    CANCER|...<cr>
```

```
RXE|1^^^19950629^19950710|xxxxx^Wonder Drug
    1^ATC|1||TAB|||||||||||||||M1|3||||NON SMALL CELL LUNG CANCER|...<cr>

RXR|PO|...<cr>
```

Note: The message structure for the PEX does not allow repeating RXE/RXR groups within a PCR group. This is probably a mistake in the message definition table for the PEX messages.

```
PRB|AD|19950704|705^DYSPNEA^MEDR|...<cr>

PRB|AD|19950710|20143^DEATH^MEDR|...<cr>

PRB|AD|19950704|18330^CHEST PAIN^MEDR|...<cr>

PRB|AD|19950709|21197^DIARRHEA^MEDR|...<cr>

PRB|AD|19950709|6432^SYNCOPE^MEDR|...<cr>

PRB|AD|19950709|4966^DEHYDRATION^MEDR|...<cr>

PRB|AD|19950709|20544^KIDNEY FUNCTION ABNORMAL^MEDR|...<cr>

OBX|1|NM|804-5^lEUKOCYTES^LN||2300|10*3/ml|||||F|19940704|...<cr>

OBX|2|NM|770-8^NEUTROPHILS/100 LEUKOCYTES^LN||1.9|%|||||F|19950704|...<cr>

OBX|3|NM|6299-2^UREA NITROGEN^LN||22.3|mg%|||||F|19950709|...<cr>

OBX|4|NM|2160-0^CREATININE^LN||247|mmole|||||F|19950709|...<cr>

NTE|||Additional details must be obtained from the affiliate in order to assess
    causality. A three day alert phone call was made to the FDA on 12-JUL-
    95|...<cr>
```

7.14 WAVEFORM

HL7 support for waveform data is intended to provide access to waveform data in a variety of situations. Needs include remote access to waveform data, research, and input to clinical decision making, as well as obtaining snippets of waveform data to complete waveform data sets. In some cases, predominantly in research oriented environments, a physician may want to manually interpret, scale the raw data, and/or apply alternative algorithms to the raw data values. In these environments, the review of waveform data includes the processing of the raw data. The HL7 waveform data capabilities allow for these applications, including data collection information such as skew between channels, in-band with the waveform.

Waveform observations, like other results, can be transmitted in solicited mode (in response to a query) or in unsolicited mode - see Section 7.15.1, “W01 - Waveform Result, Unsolicited Transmission Of Requested Information,” for discussion. In either mode of transmission the timing information, channel definition, annotations, and digital time series data in the waveform recording are treated as individual “observations” within a result “battery.” For a given “battery,” each of the result fragments is transmitted in a separate OBX segment, where the Observation ID suffix for the OBX is used to identify the result fragment. To reduce ambiguity, an explicit framework for defining the structure of waveform result messages is provided. The elements of that framework include the following:

- Waveform specific data types which enable transmission of channel definition and waveform data. See Section 2.16 for data type definitions.
- Waveform specific Observation ID suffixes (OBX-3-observation identifier) which uniquely identify the category of waveform result in a given OBX segment
- Fixed rules for combining OBX segments of each category in the waveform response messages
- Explicit definition of which OBX fields may be populated for each category of waveform result

- Unique trigger events which identify result messages which contain batteries of waveform result OBX segments

7.14.1 Specific Observation Id Suffixes

Each waveform channel in a recording contains timing, channel definition and digital time series data. The category of waveform result transmitted in a given OBX segment is determined by the Observation ID Suffix contained in *OBX-3-observation identifier*. Four suffixes are provided for the different categories of waveform result:

Observation	Suffix	Data Type
Timing Information	TIM	TS
Channel Definition	CHN	CD
Waveform Data	WAV	NA or MA
Waveform Annotation	ANO	CE

The Observation Sub-ID is used to associate the TIM, CHN, and subsequent WAV, and ANO category result segments for a given channel or channels in a waveform response message.

7.14.1.1 Timing information (TIM)

Definition: The TIM category OBX result segment establishes the date and time of the first data point in a given Observation Sub-ID grouping of waveform channels. If there is a gap in the time sequence of waveform data, this should be indicated by the transmission of a new TIM category result segment prior to subsequent WAV category result segments with the same Observation Sub-ID. The data type is TS.

7.14.1.2 Channel definition data (CHN)

Definition: The CHN category OBX result segment defines recording channels for digitally sampled time-series waveforms. Subsequent WAV category result segments carry the actual waveform samples. Each CHN category result segment defines one or more channels; the *OBX-5-Observation Value* field may repeat to define additional channels. Each instance or repetition is formatted as a CD data type.

Each channel has a number (which generally defines its position in a multichannel display) and an optional name or label (also used in displays). One or two named waveform sources may also be associated with a channel (providing for the use of differential amplifiers with two inputs). A channel also has an associated sensitivity, calibration parameters (sensitivity correction factor, baseline, and time skew), sampling frequency, and minimum and maximum values. The sampling frequency refers to the number of samples per unit time for the data reported in the subsequent WAV category result segments.

When multiple channels are defined within a single CHN category result segment, if the channel sensitivity/units (third component), sensitivity correction factor (first subcomponent of component 4), baseline (second subcomponent), time skew (third subcomponent), sampling frequency (fifth component), minimum data value (first subcomponent of component 6), or maximum data value (second subcomponent) is not present in any repetition of the *OBX-5-observation value* field, the value given in the last repetition in which the item *was* present may used by the receiver system. This is referred to as a "sticky default." For example, if all channels have the same sensitivity, sensitivity correction factor/baseline/time skew, sampling frequency, and minimum/maximum data values, these may be specified for the first channel but omitted in all subsequent channel definitions in the same CHN category result segment, thus reducing the length of the segment. If the sensitivity correction factor, baseline, or time skew is not present in the first channel being defined, values of 1, 0, and 0 (respectively) may be used. No other default values are assumed for components which are not present.

7.14.1.3 Waveform digital data (WAV)

Definition: The WAV category OBX result segment is used to transmit the actual waveform data (the time-series digitized values from an analog-to-digital converter (ADC) or other source of sampled digital data). WAV category result segments are associated with their corresponding channel definitions (CHN category OBX result segment) via the Observation Sub-ID. The number of channels defined in the CHN category result segment specifies the number of channels of multiplexed data contained in the WAV category result segments associated with it. For example, if a CHN category result segment contains only a single channel definition, then each WAV category result segment with the same Observation Sub-ID contains only one channel of data. However, if a CHN category result segment contains three channel definitions then each WAV category result segment with the same Observation Sub-ID must contain three channels of data. A given set of waveform data for all channels and at multiple successive times may be transmitted in a single WAV category result segment (provided that the length of the observation value field does not exceed the maximum defined field length for OBX segments, 65536), or in multiple successive WAV category result segments, possibly with interspersed result segments of other types (for example, containing annotations, or comments).

The data type of the WAV category result segment can be NA (Numeric Array) or MA (Multiplexed Array). Using the NA data type, the data values are formatted in "channel-block", or "unmultiplexed" format. The digital samples for each channel are separated using component delimiters, and successive channels are separated using the repeat delimiter. Using the MA data type, the data values are formatted in "channel multiplexed" format, i.e., the values for the first time sample (all channels) are transmitted first, then the values for the second time sample (all channels) are transmitted, and so on until all samples have been transmitted. The digital samples for each channel are separated by the component delimiter, and successive samples are separated by the repeat delimiter. Channel multiplexed format can only be used if all of the multiplexed channels have the same effective sampling frequency.

7.14.1.4 Waveform annotation (ANO)

Definition: The ANO category OBX segment is used to transmit waveform annotations (coded entry associated with a given point in time during the waveform recording). The ANO category result segments are referenced to their corresponding channel definitions (CHN category OBX result segment) via the Observation Sub-ID. The number of channels defined in the CHN category result segment specifies the number of channels of annotation contained in any ANO category result segments associated with it. For example, if a CHN category result segment contains only a single channel definition, then any ANO category result segments with the same Observation Sub-ID will contain only one annotation coded entry. However, if a CHN category result segment contains three channel definitions then any ANO category result segments with the same Observation Sub-ID must contain three separate annotation coded entries.

The data type of the ANO category result segment is CE. The annotation coded entries for successive channels are separated using the repeat delimiter. Adjacent repeat delimiters are used when there is no annotation coded entry for a channel in a multichannel result segment. Refer to *User defined Table 0317 - Annotations* for suggested values.

User-defined Table 0317 - Annotations

Value	Description	Comment
9900	Pace spike	
9901	SAS marker	
9902	Sense marker	
9903	Beat marker	
9904	etc.	

7.15 WAVEFORM – TRIGGER EVENTS & MESSAGE DEFINITIONS

Response messages containing waveform results are identified by the trigger event provided in the message header segment (MSH-09, second component of message type). Separate trigger events have been defined to differentiate the solicited and unsolicited modes of transmission.

7.15.1 W01 - Waveform Result, Unsolicited Transmission Of Requested Information

The waveform response unsolicited trigger event identifies ORU messages used to transmit waveform data which are results of an ordered test or series of observations. The W01 trigger event may also be used to identify ORU messages sent as the eventual response to a QRY message specifying a deferred mode query for waveform results/observations with record-oriented format (similar to the deferred response display mode DSR message type described in Chapter 2). One or more ORU messages with the W01 trigger event may result from this type of QRY message.

7.15.2 W02 - Waveform Result, Response To Query

The W02 trigger event identifies QRF messages which are a response to a QRY message specifying an immediate mode query for waveform results/observations with record-oriented format.

7.16 WAVEFORM – SEGMENT DEFINITIONS

7.16.1 Combining Rules For Waveform Obx Segments

A waveform result "battery" may contain one or more channels of digital waveform data. The Observation Sub-ID is used to logically associate the TIM, CHN and WAV category OBX segments which pertain to a given set of channels in the result "battery." Each Sub-ID group must contain at least one TIM, one CHN and one WAV category segment and at least one of the TIM category result segments must precede the first WAV category result segment in that group.

7.16.2 Restrictions on Valuation of OBX Segment Fields

The result category for a given OBX segment determines how specific fields in that segment are valued. The following tables indicate the use of the OBX segment for waveform components. The data types, lengths, optionality, and repeat values listed do not replace the basic definition of the OBX segment in Section 7.4.2.

The OPT/X column can take the values of R = Required, O = Optional, or X = Ignored and not valued. **OBX Fields marked with an X should not be valued in Waveform response messages of specified Suffix type.** Valuation of the fields must match the value provided in the associated wave category OBX segments, i.e., OBX with the same sub-ID must share the same result status.

7.16.3 OBX Segment - TIM Category

When using the OBX for the TIM category, *OBX-2* should be valued to TS. Consequently, *OBX-5* should have a length of 26 given the format of the TS data type. Note the expectations on which fields are required as well as the fields that should not be valued.

HL7 Attribute Table – OBX – Observation/Result Example - TIM Category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID – OBX
2	2	ID	R		0125	00570	Value Type
3	250	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	26	TS	R			00573	Observation Value
6	250	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	5	IS	X	Y	0078	00576	Abnormal Flags
9	5	NM	X			00577	Probability
10	2	ID	X	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observation Result Status
12	26	TS	X			00580	Effective Date of Reference Range Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	250	CE	X			00583	Producer's ID
16	250	XCN	X	Y		00584	Responsible Observer
17	250	CE	X	Y		00936	Observation Method
18	22	EI	O	Y		01479	Equipment Instance Identifier
19	26	TS	O			01480	Date/Time of the Analysis

7.16.4 OBX Segment - CHN Category

When using the OBX for the CHN category, *OBX-2* should be valued to CD. Consequently, *OBX-5* could have a length of up to 65536 given the format of the CD data type. Note the expectations on which fields are required as well as the fields that should not be valued.

HL7 Attribute Table - OBX – Observation/Result Example - CHN Category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID – OBX
2	2	ID	R		0125	00570	Value Type
3	250	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	65536	CD	R			00573	Observation Value
6	250	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	5	ID	X	Y	0078	00576	Abnormal Flags
9	5	NM	X			00577	Probability
10	2	ID	X	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observation Result Status
12	26	TS	X			00580	Effective Date of Reference Range Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	250	CE	X			00583	Producer's ID
16	250	XCN	X	Y		00584	Responsible Observer
17	250	CE	X	Y		00936	Observation Method
18	22	EI	O	Y		01479	Equipment Instance Identifier
19	26	TS	O			01480	Date/Time of the Analysis

Note: The length of the observation value field is variable, depending upon number of channels defined.

7.16.5 OBX Segment - WAV Category

When using the OBX for the WAV category, *OBX-2* can be valued as either NM or MA. Consequently, *OBX-5* could have a length of up to 65536 given the format of the data types. Note the expectations on which fields are required as well as the fields that should not be valued.

HL7 Attribute Table – OBX – Observation/Result Example - WAV Category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID – OBX
2	2	ID	R		0125	00570	Value Type
3	250	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	65536	NA or MA	C			00573	Observation Value
6	250	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	5	ID	O	Y	0078	00576	Abnormal Flags
9	5	NM	X			00577	Probability
10	2	ID	X	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observation Result Status
12	26	TS	X			00580	Effective Date of Reference Range Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	250	CE	X			00583	Producer's ID
16	250	XCN	O	Y		00584	Responsible Observer
17	250	CE	X	Y		00936	Observation Method
18	22	EI	O	Y		01479	Equipment Instance Identifier
19	26	TS	O			01480	Date/Time of the Analysis

Notes:

1. The length of the observation value field is variable, depending upon number of channels and number of data points sampled.

2. Fields 8, 11 and 16 apply exclusively to the set of data points in the OBX. They do not map to a particular data point or channel.

7.16.6 OBX Segment – ANO Category

When using the OBX for the ANO category, *OBX-2* should be valued to CE. Consequently, *OBX-5* could have a length of up the 65536 given the format of the data types. Note the expectations on which fields are required as well as the fields that should not be valued.

HL7 Attribute Table – OBX - Observation/Result Example - ANO Category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID – OBX
2	2	ID	R		0125	00570	Value Type
3	250	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	250	CE	C			00573	Observation Value

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
6	250	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	5	ID	O	Y	0078	00576	Abnormal Flags
9	5	NM	X			00577	Probability
10	2	ID	X	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observation Result Status
12	26	TS	X			00580	Effective Date of Reference Range Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	O			00582	Date/Time of the Observation
15	250	CE	X			00583	Producer's ID
16	250	XCN	O	Y		00584	Responsible Observer
17	250	CE	X	Y		00936	Observation Method
18	22	EI	O	Y		01479	Equipment Instance Identifier
19	26	TS	O			01480	Date/Time of the Analysis

Note: The length of the observation value field is variable, depending upon number of channels defined.

7.17 WAVEFORM – EXAMPLES OF USE

This section gives four example messages of type ORU (unsolicited) that each contain a three-channel waveform recording, with the same waveform in each channel. These examples contain data for one patient. In these example message transmissions, **<cr>** indicates an ASCII carriage return character (ASCII 13).

The following is a detailed explanation of each of the segments contained in the example messages:

Message Header (MSH) Segment - This specifies the delimiters (|^~**&**), sending application (**SVL,** meaning Sunnyville Laboratory), receiving application (**SVC**, meaning Sunnyville Clinic), date and time of transmission (March 24, 1990 at 10:12:15), message type (**ORU**) and trigger event (**W01**), a message control ID that identifies this message uniquely among all messages transmitted by this sender (**19264**), processing ID (**P**, meaning production), and specification version ID (**2.3**).

Patient ID (PID) Segment - This contains a sequence number (**1**), external and internal patient IDs (both **4567890**), and a patient name (**Mr. John Q Doe, Jr**).

Order (OBR) Segment - This contains a sequence number (**1**), placer order number (**5678**) and placer ID (**SVC**, meaning Sunnyville Clinic), filler order number (**1234**) and filler ID (**SVL**, meaning Sunnyville Laboratory), and test/observation ID (**5**, using a local coding system that is known to the intended receiver, meaning a three-channel waveform recording).

CHN Category Result (OBX) Segments - Using a value type of **CD** (channel definition), these define each of the three data channels by number and specify a label (waveform source) for each. The channel sensitivity (**0.5 mV**), sampling frequency (**200**), and minimum and maximum data values (**-2048** to **2047**) are specified for each channel in examples 1 and 2 and 4. In example 3, these are specified only for channel 1, but apply by default to all subsequent channels. No baseline or calibration parameters are specified, so defaults are used for all channels.

TIM Category Result (OBX) Segments - Using the data type TS (time stamp), these define the start of the waveform data at a time 525 ms past 8:12:37 on March 24, 1990.

WAV Category Result (OBX) Segments - The data may be transmitted in either "channel-block" (unmultiplexed) format using the NA data type, or in "channel-multiplexed" format using the MA data type. The three examples demonstrate different ways of transmitting 3 waveform channels, with 25 samples from each waveform channel. Note that in these examples, each waveform channel is identical.

ANO Category Result (OBX) Segments - Annotation segments with a single channel definition contain a single annotation string. Annotation segments with multiple channel definitions contain a separate annotation string for each defined channel - successive annotation strings are separated from each other by the repeat delimiter. In the

following examples, channel 1 has been annotated at a time 565 ms past 8:12:37 on March 24, 1990; channel 3 has been annotated at a time 605 ms past 8:12:37 on March 24, 1990.

7.17.1 Example 1: "channel-block" format, using three separate sets of TIM, CHN, WAV and category OBX segments:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|...<cr>

PID|1||4567890||Doe^John^Q^Jr^Mr|...<cr>

OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^99SVL|...<cr>

OBX|1|CD|5&CHN^^99SVL|1|1^ONE^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|2|TS|5&TIM^^99SVL|1|19900324081237.525||||||F|...<cr>

OBX|3|NA|5&WAV^^99SVL|1|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-
    8||||||F|...<cr>

OBX|4|CE|5&ANO^^99SVL|1|^Channel passing through
    maxima||||||F|||19900324081237.565|...<cr>

OBX|5|CD|5&CHN^^99SVL|2|2^TWO^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|6|TS|5&TIM^^99SVL|2|19900324081237.525||||||F|...<cr>

OBX|7|NA|5&WAV^^99SVL|2|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-
    8||||||F|...<cr>

OBX|8|CD|5&CHN^^99SVL|3|3^THREE^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|9|TS|5&TIM^^99SVL|3|19900324081237.525||||||F|...<cr>

OBX|10|NA|5&WAV^^99SVL|3|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-
    8||||||F|...<cr>

OBX|11|CE|5&ANO^^99SVL|3|^Channel passing through
    zero||||||F|||19900324081237.605|...<cr>

...
```

7.17.2 Example 2: "Channel-Block" Format, Using a Single Set of TIM, CHN, WAV and Category OBX Segments, With Multiple Channels Within the one WAV Category Result Segment:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|...<cr>

PID|1||4567890||Doe^John^Q^Jr^Mr|...<cr>

OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^99SVL|...<cr>

OBX|1|CD|5&CHN^^99SVL|1|1^ONE^0.5&mv^^200^-2048&2047~2^TWO^0.5&mv^^200^-
    2048&2047~3^THREE^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|2|TS|5&TIM^^99SVL|1|19900324081237.525||||||F|...<cr>

OBX|3|NA|5&WAV^^99SVL|1|

0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8~

0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8~

0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8||||||F|...<cr>

OBX|4|CE|5&ANO^^99SVL|1|^Channel passing through
    maxima||||||F|||19900324081237.565|...<cr>

OBX|5|CE|5&ANO^^99SVL|1|~~^Channel passing through
    zero||||||F|||19900324081237.605|...<cr>
```

Note: This is an illegal construct per the message construction rules from chapter 1: the repetition separator is used only if more than one occurrence is transmitted. There is only one occurrence being sent here.

```
...
```

7.17.3 Example 3: "Channel-Multiplexed" Format, With Multiple Channels Within the one WAV Category Result Segment:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|...<cr>

PID|1||4567890||Doe^John^Q^Jr^Mr|...<cr>

OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^99SVL|...<cr>

OBX|1|CD|5&CHN^^99SVL|1|1^ONE^0.5&mv^^200^-2048&2047~2^TWO~3^THREE||||||F|...<cr>

OBX|2|TS|5&TIM^^99SVL|1|19900324081237.525||||||F|...<cr>

OBX|3|MA|5&WAV^^99SVL|1|0^0^0~1^1^1~2^2^2~3^3^3~4^4^4~5^5^5~6^6^6~7^7^7~8^8^8~7^7
    ^7~6^6^6~5^5^5~4^4^4~3^3^3~2^2^2~1^1^1~0^0^0~-1^-1^-1~-2^-2^-2~-3^-3^-3~-4^-
    4^-4~-5^-5^-5~-6^-6^-6~-7^-7^-7~-8^-8^-8||||||F|...<cr>

OBX|4|CE|5&ANO^^99SVL|1|^Channel passing through
    maxima||||||F|||19900324081237.565|...<cr>

OBX|5|CE|5&ANO^^99SVL|1|~~^Channel passing through
    zero||||||F|||19900324081237.605|...<cr>
```

Note: This is an illegal construct per the message construction rules from chapter 1: "the repetition separator is used only if more than one occurrence is transmitted." There is only one occurrence being sent here.

```
...
```

7.17.4 Example 4: "Channel-Block" Format, Using Three Separate Sets of TIM, CHN, WAV and Category OBX Segments With a Break in Waveform Data Used to Pinpoint Waveform Annotations for Channels One and Three:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|...<cr>

PID|1||4567890||Doe^John^Q^Jr^Mr|...<cr>

OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^99SVL|...<cr>

OBX|1|CD|5&CHN^^99SVL|1|1^ONE^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|2|TS|5&TIM^^99SVL|1|19900324081237.525||||||F|...<cr>

OBX|3|NA|5&WAV^^99SVL|1|0^1^2^3^4^5^6^7^8||||||F|...<cr>

OBX|4|CE|5&ANO^^99SVL|1|^Channel passing through
    maxima||||||F|||19900324081237.565|...<cr>

OBX|5|NA|5&WAV^^99SVL|1|7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8||||||F|...<cr>

OBX|6|CD|5&CHN^^99SVL|2|2^TWO^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|7|TS|5&TIM^^99SVL|2|19900324081237.525||||||F|...<cr>

OBX|8|NA|5&WAV^^99SVL|2|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-
    8||||||F|...<cr>

OBX|9|CD|5&CHN^^99SVL|3|3^THREE^0.5&mv^^200^-2048&2047||||||F|...<cr>

OBX|10|TS|5&TIM^^99SVL|3|19900324081237.525||||||F|...<cr>

OBX|11|NA|5&WAV^^99SVL|3|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0||||||F|...<cr>

OBX|12|CE|5&ANO^^99SVL|3|^Channel passing through
    zero||||||F|||19900324081237.605|...<cr>

OBX|13|NA|5&WAV^^99SVL|3|-1^-2^-3^-4^-5^-6^-7^-8||||||F|...<cr>

...
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7.18 TABLES LISTINGS

7.18.1 HL7 Table 0163 – Body Site

Referenced in 2.17.5 Coding Schemes

HL7 Table 0163 - Body site

Value	Description	Comment
BE	Bilateral Ears	
OU	Bilateral Eyes	
BN	Bilateral Nares	
BU	Buttock	
CT	Chest Tube	
LA	Left Arm	
LAC	Left Anterior Chest	
LACF	Left Antecubital Fossa	
LD	Left Deltoid	
LE	Left Ear	
LEJ	Left External Jugular	
OS	Left Eye	
LF	Left Foot	
LG	Left Gluteus Medius	
LH	Left Hand	
LIJ	Left Internal Jugular	
LLAQ	Left Lower Abd Quadrant	
LLFA	Left Lower Forearm	
LMFA	Left Mid Forearm	
LN	Left Naris	
LPC	Left Posterior Chest	
LSC	Left Subclavian	
LT	Left Thigh	
LUA	Left Upper Arm	
LUAQ	Left Upper Abd Quadrant	
LUFA	Left Upper Forearm	
LVG	Left Ventragluteal	
LVL	Left Vastus Lateralis	
NB	Nebulized	
PA	Perianal	
PERIN	Perineal	
RA	Right Arm	
RAC	Right Anterior Chest	
RACF	Right Antecubital Fossa	
RD	Right Deltoid	
RE	Right Ear	
REJ	Right External Jugular	
OD	Right Eye	
RF	Right Foot	
RG	Right Gluteus Medius	
RH	Right Hand	
RIJ	Right Internal Jugular	
RLAQ	Rt Lower Abd Quadrant	
RLFA	Right Lower Forearm	
RMFA	Right Mid Forearm	
RN	Right Naris	
RPC	Right Posterior Chest	

Value	Description	Comment
RSC	Right Subclavian	
RT	Right Thigh	
RUA	Right Upper Arm	
RUAQ	Right Upper Abd Quadrant	
RUFA	Right Upper Forearm	
RVL	Right Vastus Lateralis	
RVG	Right Ventragluteal	

7.18.2 HL7 Table 0070 – Specimen Source Codes

Referenced in 2.17.5 Coding Schemes

HL7 Table 0070 - Specimen Source Codes

Value	Description	Comment
ABS	Abscess	
AMN	Amniotic fluid	
ASP	Aspirate	
BPH	Basophils	
BIFL	Bile fluid	
BLDA	Blood arterial	
BBL	Blood bag	
BLDC	Blood capillary	
BPU	Blood product unit	
BLDV	Blood venous	
BON	Bone	
BRTH	Breath (use EXHLD)	
BRO	Bronchial	
BRN	Burn	
CALC	Calculus (=Stone)	
CDM	Cardiac muscle	
CNL	Cannula	
CTP	Catheter tip	
CSF	Cerebral spinal fluid	
CVM	Cervical mucus	
CVX	Cervix	
COL	Colostrum	
BLDCO	Cord blood	
CNJT	Conjunctiva	
CUR	Curettage	
CYST	Cyst	
DIAF	Dialysis fluid	
DOSE	Dose med or substance	
DRN	Drain	
DUFL	Duodenal fluid	
EAR	Ear	
EARW	Ear wax (cerumen)	
ELT	Electrode	
ENDC	Endocardium	
ENDM	Endometrium	
EOS	Eosinophils	
RBC	Erythrocytes	
EYE	Eye	
EXG	Exhaled gas (=breath)	
FIB	Fibroblasts	

Value	Description	Comment
FLT	Filter	
FIST	Fistula	
FLU	Body fluid, unsp	
GAS	Gas	
GAST	Gastric fluid/contents	
GEN	Genital	
GENC	Genital cervix	
GENL	Genital lochia	
GENV	Genital vaginal	
HAR	Hair	
IHG	Inhaled Gas	
IT	Intubation tube	
ISLT	Isolate	
LAM	Lamella	
WBC	Leukocytes	
LN	Line	
LNA	Line arterial	
LNV	Line venous	
LIQ	Liquid NOS	
LYM	Lymphocytes	
MAC	Macrophages	
MAR	Marrow	
MEC	Meconium	
MBLD	Menstrual blood	
MLK	Milk	
MILK	Breast milk	
NAIL	Nail	
NOS	Nose (nasal passage)	
ORH	Other	
PAFL	Pancreatic fluid	
PAT	Patient	
PRT	Peritoneal fluid /ascites	
PLC	Placenta	
PLAS	Plasma	
PLB	Plasma bag	
PLR	Pleural fluid (thoracentesis fld)	
PMN	Polymorphonuclear neutrophils	
PPP	Platelet poor plasma	
PRP	Platelet rich plasma	
PUS	Pus	
RT	Route of medicine	
SAL	Saliva	
SMN	Seminal fluid	
SER	Serum	
SKN	Skin	
SKM	Skeletal muscle	
SPRM	Spermatozoa	
SPT	Sputum	
SPTC	Sputum - coughed	
SPTT	Sputum - tracheal aspirate	
STON	Stone (use CALC)	
STL	Stool = Fecal	
SWT	Sweat	
SNV	Synovial fluid (Joint fluid)	
TEAR	Tears	

Value	Description	Comment
THRT	Throat	
THRB	Thrombocyte (platelet)	
TISS	Tissue	
TISG	Tissue gall bladder	
TLGI	Tissue large intestine	
TLNG	Tissue lung	
TISPL	Tissue placenta	
TSMI	Tissue small intestine	
TISU	Tissue ulcer	
TUB	Tube NOS	
ULC	Ulcer	
UMB	Umbilical blood	
UMED	Unknown medicine	
URTH	Urethra	
UR	Urine	
URC	Urine clean catch	
URT	Urine catheter	
URNS	Urine sediment	
USUB	Unknown substance	
VITF	Vitreous Fluid	
VOM	Vomitus	
BLD	Whole blood	
BDY	Whole body	
WAT	Water	
WICK	Wick	
WND	Wound	
WNDA	Wound abscess	
WNDE	Wound exudate	
WNDD	Wound drainage	
XXX	To be specified in another part of the message	

7.18.3 Figure 7-9 – Common ISO Derived Units & ISO+ Extensions

Referenced in Section 7.4.2.6.2.

Figure 7-9. Common ISO derived units and ISO+ extensions

Code/Abbr.	Name
/(arb_u)	*1 / arbitrary unit
/iu	*1 / international unit
/kg	*1 / kilogram
/L	1 / liter
1/mL	*1 / milliliter
10.L/min	*10 x liter / minute
10.L /(min.m2)	*10 x (liter / minute) / meter^2 = liter / (minute × meter^2)
10*3/mm3	*10^3 / cubic millimeter (e.g., white blood cell count)
10*3/L	*10^3 / Liter
10*3/mL	*10^3 / milliliter
10*6/mm3	*10^6 / millimeter^3
10*6/L	*10^6 / Liter

Code/Abbr.	Name
10*6/mL	*10^6 / milliliter
10*9/mm3	*10^9 / millimeter^3
10*9/L	*10^9 / Liter
10*9/mL	*10^9 / milliliter
10*12/L	*10^{12} / Liter
10*3(rbc)	*1000 red blood cells†
a/m	Ampere per meter
(arb_u)	*Arbitrary unit
bar	Bar (pressure; 1 bar = 100 kilopascals)
/min	Beats or Other Events Per Minute
bq	Becquerel
(bdsk_u)	*Bodansky Units
(bsa)	*Body surface area
(cal)	*Calorie
1	*Catalytic Fraction
/L	Cells / Liter
cm	Centimeter
cm_h20	* Centimeters of water =H_20 (pressure)
cm_h20.s/L	Centimeters H_20 / (liter / second) = (centimeters H_20 × second) / liter (e.g., mean pulmonary resistance)
cm_h20/(s.m)	(Centimeters H_20 / second) / meter = centimeters H_20 / (second × meter) (e.g., pulmonary pressure time product)
(cfu)	*Colony Forming Units
m3/s	Cubic meter per second
d	Day
db	Decibels
dba	*Decibels a Scale
cel	Degrees Celsius
deg	Degrees of Angle
(drop)	Drop
10.un.s/cm5	Dyne × Second / centimeter^5 (1 dyne = 10 micronewton = 10 un) (e.g., systemic vascular resistance)
10.un.s/(cm5.m2)	((Dyne × second) / centimeter^5) / meter^2 = (Dyne × second) / (centimeter^5 × meter^2) (1 dyne = 10 micronewton = 10 un) (e.g., systemic vascular resistance/body surface area)
ev	Electron volts (1 electron volt = 160.217 zeptojoules)
eq	Equivalent
f	Farad (capacitance)
fg	Femtogram
fL	Femtoliter
fmol	Femtomole

Code/Abbr.	Name
/mL	*Fibers / milliliter
g	Gram
g/d	*Gram / Day
g/dL	Gram / Deciliter
g/hr	Gram / Hour
g/(8.hr)	*Gram / 8 Hour Shift
g/kg	Gram / Kilogram (e.g., mass dose of medication per body weight)
g/(kg.d)	(Gram / Kilogram) / Day = gram / (kilogram × day) (e.g., mass dose of medication per body weight per day)
g/(kg.hr)	(Gram / Kilogram) / Hour = gram / (kilogram × hour) (e.g., mass dose of medication per body weight per hour)
g/(8.kg.hr)	(Gram / Kilogram) /8 Hour Shift = gram / (kilogram × 8 hour shift) (e.g., mass dose of medication per body weight per 8 hour shift)
g/(kg.min)	(Gram / Kilogram) / Minute = gram / (kilogram × minute) (e.g., mass dose of medication per body weight per minute)
g/L	Gram / Liter
g/m2	Gram / $Meter^2$ (e.g., mass does of medication per body surface area)
g/min	Gram / Minute
g.m/(hb)	Gram × meter / heart beat (e.g., ventricular stroke work)
g.m/((hb).m2)	(Gram × meter/ heartbeat) / $meter^2$ = (gram × meter) / (heartbeat × $meter^2$) (e.g., ventricular stroke work/body surface area, ventricular stroke work index)
g(creat)	*Gram creatinine
g(hgb)	*Gram hemoglobin
g.m	Gram meter
g(tot_nit)	*Gram total nitrogen
g(tot_prot)	*Gram total protein
g(wet_tis)	*Gram wet weight tissue
gy	Grey (absorbed radiation dose)
hL	Hectaliter = 10^2 liter
h	Henry
in	Inches
in_hg	Inches of Mercury (=Hg)
iu	*International Unit
iu/d	*International Unit / Day
iu/hr	*International Unit / Hour
iu/kg	International Unit / Kilogram
iu/L	*International Unit / Liter
iu/mL	*International Unit / Milliliter
iu/min	*International Unit / Minute
j/L	Joule/liter (e.g., work of breathing)

Code/Abbr.	Name
kat	*Katal
kat/kg	*Katal / Kilogram
kat/L	*Katal / Liter
k/watt	Kelvin per watt
(kcal)	Kilocalorie (1 kcal = 6.693 kilojoule)
(kcal)/d	*Kilocalorie / Day
(kcal)/hr	*Kilocalorie / Hour
(kcal)/(8.hr)	*Kilocalorie / 8 Hours Shift
kg	Kilogram
kg(body_wt)	* kilogram body weight
kg/m3	Kilogram per cubic meter
kh/h	Kilogram per hour
kg/L	Kilogram / liter
kg/min	Kilogram per minute
kg/mol	Kilogram / mole
kg/s	Kilogram / second
kg/(s.m2)	(Kilogram / second)/ $meter^2$ = kilogram / (second × $meter^2$)
kg/ms	Kilogram per square meter
kg.m/s	Kilogram meter per second
kpa	Kilopascal (1 mmHg = 0.1333 kilopascals)
ks	Kilosecond
(ka_u)	King-Armstrong Unit
(knk_u)	*Kunkel Units
L	Liter
L/d	*Liter / Day
L/hr	Liter / hour
L/(8.hr)	*Liter / 8 hour shift
L/kg	Liter / kilogram
L/min	Liter / minute
L/(min.m2)	(Liter / minute) / $meter^2$ = liter / (minute × $meter^2$) (e.g., cardiac output/body surface area = cardiac index)
L/s	Liter / second (e.g., peak expiratory flow)
L.s	Liter / second / $second^2$ = liter × second
lm	Lumen
lm/m2	Lumen / $Meter^2$
(mclg_u)	*MacLagan Units
mas	Megasecond
m	Meter

Code/Abbr.	Name
m2	Meter^2 (e.g., body surface area)
m/s	Meter / Second
m/s2	Meter / Second^2
ueq	*Microequivalents
ug	Microgram
ug/d	Microgram / Day
ug/dL	Microgram / Deciliter
ug/g	Microgram / Gram
ug/hr	*Microgram / Hour
ug(8hr)	Microgram / 8 Hour Shift
ug/kg	Microgram / Kilogram
ug/(kg.d)	(Microgram / Kilogram) /Day = microgram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
ug/(kg.hr)	(Microgram / Kilogram) / Hour = microgram / (kilogram × hours) (e.g., mass dose of medication per patient body weight per hour)
ug/(8.hr.kg)	(Microgram / Kilogram) / 8 hour shift = microgram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)
ug/(kg.min)	(Microgram / Kilogram) / Minute = microgram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per minute)
ug/L	Microgram / Liter
ug/m2	Microgram / Meter^2 (e.g., mass dose of medication per patient body surface area)
ug/min	Microgram / Minute
uiu	*Micro international unit
ukat	*Microkatel
um	Micrometer (Micron)
umol	Micromole
umol/d	Micromole / Day
umol/L	Micromole / Liter
umol/min	Micromole / Minute
us	Microsecond
uv	Microvolt
mbar	Millibar (1 millibar = 100 pascals)
mbar.s/L	Millibar / (liter / second) =(millibar × second) / liter (e.g., expiratory resistance)
meq	*Milliequivalent
meq/d	*Milliequivalent / Day
meq/hr	*Milliequivalent / Hour
meq/(8.hr)	Milliequivalent / 8 Hour Shift
meq/kg	Milliequivalent / Kilogram (e.g., dose of medication in milliequivalents per patient body weight)

Code/Abbr.	Name
meq/(kg.d)	(Milliequivalents / Kilogram) / Day = milliequivalents / (kilogram × day) (e.g., dose of medication in milliequivalents per patient body weight per day)
meq/(kg.hr)	(Milliequivalents / Kilogram) / Hour = milliequivalents / (kilogram × hour) (e.g., dose of medication in milliequivalents per patient body weight per hour)
meq/(8.hr.kg)	(Milliequivalents / Kilogram) / 8 Hour Shift = milliequivalents / (kilogram × 8 hour shift) (e.g., dose of medication in milliequivalents per patient body weight per 8 hour shift)
meq/(kg.min)	(Milliequivalents / Kilogram) / Minute = milliequivalents / (kilogram × minute) (e.g., dose of medication in milliequivalents per patient body weight per minute)
meq/L	Milliequivalent / Liter
	Milliequivalent / Meter^2 (e.g., dose of medication in milliequivalents per patient body surface area)
meq/min	Milliequivalent / Minute
mg	Milligram
mg/m3	Milligram / Meter^3
mg/d	Milligram / Day
mg/dL	Milligram / Deciliter
mg/hr	Milligram / Hour
mg/(8.hr)	Milligram / 8 Hour shift
mg/kg	Milligram / Kilogram
mg/(kg.d)	(Milligram / Kilogram) / Day = milligram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
mg/(kg.hr)	(Milligram / Kilogram) / Hour = milligram/ (kilogram × hour) (e.g., mass dose of medication per patient body weight per hour)
mg/(8.hr.kg)	(Milligram / Kilogram) /8 Hour Shift = milligram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)
mg/(kg.min)	(Milligram / Kilogram) / Minute = milligram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per hour)
mg/L	Milligram / Liter
mg/m2	Milligram / Meter^2 (e.g., mass dose of medication per patient body surface area)
mg/min	Milligram / Minute
mL	Milliliter
mL/cm_h20	Milliliter / Centimeters of Water (H_20) (e.g., dynamic lung compliance)
mL/d	*Milliliter / Day
mL/(hb)	Milliliter / Heart Beat (e.g., stroke volume)
mL/((hb).m2)	(Milliliter / Heart Beat) / Meter^2 = Milliliter / (Heart Beat × Meter^2) (e.g., ventricular stroke volume index)
mL/hr	*Milliliter / Hour
mL/(8.hr)	*Milliliter / 8 Hour Shift
mL/kg	Milliliter / Kilogram (e.g., volume dose of medication or treatment per patient body weight)
mL/(kg.d)	(Milliliter / Kilogram) / Day = milliliter / (kilogram × day) (e.g., volume dose of medication or treatment per patient body weight per day)
mL/(kg.hr)	(Milliliter / Kilogram) / Hour = milliliter / (kilogram × hour) (e.g., volume dose of medication or treatment per patient body weight per hour)

Code/Abbr.	Name
mL/(8.hr.kg)	(Milliliter / Kilogram) / 8 Hour Shift = milliliter / (kilogram × 8 hour shift) (e.g., volume dose of medication or treatment per body weight per 8 hour shift)
mL/(kg.min)	(Milliliter / Kilogram) / Minute = milliliter / (kilogram × minute) (e.g., volume dose of medication or treatment per patient body weight per minute)
mL/m2	Milliliter / $Meter^2$ (e.g., volume of medication or other treatment per patient body surface area)
mL/mbar	Milliliter / Millibar (e.g., dynamic lung compliance)
mL/min	Milliliter / Minute
mL/(min.m2)	(Milliliter / Minute) / $Meter^2$ = milliliter / (minute × $meter^2$) (e.g., milliliters of prescribed infusion per body surface area; oxygen consumption index)
mL/s	Milliliter / Second
mm	Millimeter
mm(hg)	*Millimeter (HG) (1 mm Hg = 133.322 kilopascals)
mm/hr	Millimeter/ Hour
mmol/kg	Millimole / Kilogram (e.g., molar dose of medication per patient body weight)
mmol/(kg.d)	(Millimole / Kilogram) / Day = millimole / (kilogram × day) (e.g., molar dose of medication per patient body weight per day)
mmol/(kg.hr)	(Millimole / Kilogram) / Hour = millimole / (kilogram × hour) (e.g., molar dose of medication per patient body weight per hour)
mmol/(8.hr.kg)	(Millimole / Kilogram) / 8 Hour Shift = millimole / (kilogram × 8 hour shift) (e.g., molar dose of medication per patient body weight per 8 hour shift)
mmol/(kg.min)	(Millimole / Kilogram) / Minute = millimole / (kilogram × minute) (e.g., molar dose of medication per patient body weight per minute)
mmol/L	Millimole / Liter
mmol/hr	Millimole / Hour
mmol/(8hr)	Millimole / 8 Hour Shift
mmol/min	Millimole / Minute
mmol/m2	Millimole / $Meter^2$ (e.g., molar dose of medication per patient body surface area)
mosm/L	*Milliosmole / Liter
ms	Milliseconds
mv	Millivolts
miu/mL	*Milliunit / Milliliter
mol/m3	Mole per cubic meter
mol/kg	Mole / Kilogram
mol/(kg.s)	(Mole / Kilogram) / Second = mole / (kilogram × second)
mol/L	Mole / Liter
mol/s	Mole / Second
ng	Nanogram
ng/d	Nanogram / Day
ng/hr	*Nanogram / Hour
ng/(8.hr)	Nanogram / 8 Hour shift
ng/L	Nanogram / Liter

Code/Abbr.	Name
ng/kg	Nanogram / Kilogram (e.g., mass dose of medication per patient body weight)
ng/(kg.d)	(Nanogram / Kilogram) / Day = nanogram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
ng/(kg.hr)	(Nanogram / Kilogram) / Hour = nanogram / (kilogram × hour) (e.g., mass dose of medication per patient body weight per hour)
ng/(8.hr.kg)	(Nanogram / Kilogram) / 8 Hour Shift = nanogram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)
ng/(kg.min)	(Nanogram / Kilogram) / Minute = nanogram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per minute)
ng/m2	Nanogram / Meter^2 (e.g., mass dose of medication per patient body surface area)
ng/mL	Nanogram / Milliliter
ng/min	*Nanogram / Minute
ng/s	*Nanogram / Second
nkat	*Nanokatel
nm	Nanometer
nmol/s	Nanomole / Second
ns	Nanosecond
n	Newton (force)
n.s	Newton second
(od)	*O.D. (optical density)
ohm	Ohm (electrical resistance)
ohm.m	Ohm meter
osmol	Osmole
osmol/kg	Osmole per kilogram
osmol/L	Osmole per liter
/m3	*Particles / Meter^3
/L	*Particles / Liter
/(tot)	*Particles / Total Count
(ppb)	*Parts Per Billion
(ppm)	*Parts Per Million
(ppth)	Parts per thousand
(ppt)	Parts per trillion (10^12)
pal	Pascal (pressure)
/(hpf)	*Per High Power Field
(ph)	*pH
pa	Picoampere
pg	Picogram
pg/L	Picogram / Liter
pg/mL	Picogram / Milliliter
pkat	*Picokatel

Code/Abbr.	Name
pm	Picometer
pmol	*Picomole
ps	Picosecond
pt	Picotesla
(pu)	*P.U.
%	Percent
dm2/s2	Rem (roentgen equivalent man) = 10^{-2} $meter^2$ / $second^2$ = $decimeter^2$ / $second^2$ Dose of ionizing radiation equivalent to 1 rad of x-ray or gamma ray) [From Dorland's Medical Dictionary]
sec	Seconds of arc
sie	Siemens (electrical conductance)
sv	Sievert
m2/s	Square meter / second
cm2/s	Square centimeter / second
t	Tesla (magnetic flux density)
(td_u)	Todd Unit
v	Volt (electric potential difference)
1	Volume Fraction
wb	Weber (magnetic flux)
*Starred items are not genuine ISO, but do not conflict. †This approach to units is discouraged by IUPAC. We leave them solely for backward compatibility	

7.18.4 HL7 Table 0487 – Specimen Type

HL7 table 0487 – Specimen Type

Value	Description	Comment
ABS	Abscess	
PELVA	Abscess, Pelvic	Condition
PERIA	Abscess, Perianal	Condition, Abcess & Body Part
RECTA	Abscess, Rectal	Condition
SCROA	Abscess, Scrotal	Condition
SUBMA	Abscess, Submandibular	Condition
SUBMX	Abscess, Submaxillary	Condition
TSTES	Abscess, Testicular	Condition
AIRS	Air Sample	Environment
ALL	Allograft	Tissue
AMP	Amputation	Tissue
GASAN	Antrum, Gastric	Tissue
ASP	Aspirate	
ETA	Aspirate, Endotrach	Aspirate
GASA	Aspirate, Gastric	Aspirate
NGASP	Aspirate, Nasogastric	Aspirate
TASP	Aspirate, Tracheal	Aspirate
TTRA	Aspirate, Transtracheal	Aspirate

Value	Description	Comment
AUTP	Autopsy	Tissue
BX	Biopsy	Tissue
GSPEC	Biopsy, Gastric	Tissue
SKBP	Biopsy, Skin	Tissue
CONE	Biospy, Cone	Tissue
BITE	Bite	Conditions
CBITE	Bite, Cat	Conditions
DBITE	Bite, Dog	Conditions
HBITE	Bite, Human	Conditions
IBITE	Bite, Insect	Conditions
RBITE	Bite, Reptile	Conditions
BLEB	Bleb	Condition, Fluid/Tissue
BLIST	Blister	Condition, Fluid/Tissue
BBL	Blood bag	Blood
BPU	Blood product unit	Blood
HBLUD	Blood, Autopsy	Blood
CSVR	Blood, Cell Saver	Transfusion
FBLOOD	Blood, Fetal	Blood
MBLD	Blood, Menstrual	Blood
WB	Blood, Whole	Blood
BOIL	Boil	Condition
BON	Bone	
BOWL	Bowel contents	Condition
BRTH	Breath (use EXHLD)	
BRSH	Brush	Product; Brush or brushing (these may be 2 separate entries as in a physical brush or a portion thereof vs the substance obtained after a surface has been brushed)
EBRUSH	Brush, Esophageal	Product
BRUS	Brushing	Product
GASBR	Brushing, Gastric	Product
BUB	Bubo	Condition
BULLA	Bulla/Bullae	Condition
BRN	Burn	
CALC	Calculus (=Stone)	
CARBU	Carbuncle	Condition
CAT	Catheter	Device
CSITE	Catheter Insertion Site	Device
CTP	Catheter tip	Device
ANGI	Catheter Tip, Angio	Device
ARTC	Catheter Tip, Arterial	Device
CVPT	Catheter Tip, CVP	Device
ETTP	Catheter Tip, Endotracheal	Device
FOLEY	Catheter Tip, Foley	Device
HEMAQ	Catheter Tip, Hemaquit	Device
HEMO	Catheter Tip, Hemovac	Device
IDC	Catheter Tip, Indwelling	Device
INTRD	Catheter Tip, Introducer	Device

Value	Description	Comment
IVCAT	Catheter Tip, IV	Device
MAHUR	Catheter Tip, Makurkour	Device
SCLV	Catheter Tip, Subclavian	Device
SPRP	Catheter Tip, Suprapubic	Device
SWGZ	Catheter Tip, Swan Gantz	Device
VASTIP	Catheter Tip, Vas	Device
VENT	Catheter Tip, Ventricular	Device
GROSH	Catheter, Groshong	Device
HIC	Catheter, Hickman	Device
PORTA	Catheter, Porta	Device
SPRPB	Cathether Tip, Suprapubic	Device
TLC	Cathether Tip, Triple Lumen	Device
CLIPP	Clippings	Condition
COL	Colostrum	
CNJT	Conjunctiva	
LENS1	Contact Lens	Device
LENS2	Contact Lens Case	Device
CYST	Cyst	
BCYST	Cyst, Baker's	Condition
ICYST	Cyst, Inclusion	Condition
PILOC	Cyst, Pilonidal	Condition
RENALC	Cyst, Renal	Condition
DIA	Dialysate	Condition
DISCHG	Discharge	Condition
DIV	Diverticulum	Condition
DRN	Drain	
DRN	Drain	Device
HEV	Drain, Hemovac	Device
GTUBE	Drainage Tube, Drainage (Gastrostomy)	Condition
GASD	Drainage, Gastric	Condition
ILEO	Drainage, Ileostomy	Condition
JP	Drainage, Jackson Pratt	Condition
JEJU	Drainage, Jejunal	Condition
NASDR	Drainage, Nasal	Condition
NGAST	Drainage, Nasogastric	Condition
PND	Drainage, Penile	Condition
DRNGP	Drainage, Penrose	Condition
RECT	Drainage, Rectal	Condition
SUMP	Drainage, Sump	Condition
DRNG	Drainage, Tube	Device
EARW	Ear wax (cerumen)	
EFFUS	Effusion	Condition
ELT	Electrode	
AUTOC	Environment, Attest	Environment
ATTE	Environmental, Autoclave Ampule	Environment
AUTOC	Environmental, Autoclave Capsule	Environment
EFF	Environmental, Effluent	Environment
EEYE	Environmental, Eye Wash	Environment

Value	Description	Comment
EFOD	Environmental, Food	Environment
EISO	Environmental, Isolette	Environment
EOTH	Environmental, Other Substance	Environment; (Substance is Known but not in code Table)
ESOI	Environmental, Soil	Environment
ESOS	Environmental, Solution (Sterile)	Environment
SPS	Environmental, Spore Strip	Environment
STER	Environmental, Sterrad	Environment
ENVIR	Environmental, Unidentified Substance	Environment
WWA	Environmental, Water	Environment
DEION	Environmental, Water (Deionized)	Environment
WWT	Environmental, Water (Tap)	Environment
FAW	Environmental, Water (Well)	Environment
WWO	Environmental, Water (Ocean)	
EWHI	Environmental, Whirlpool	Environment
EXUDTE	Exudate	Condition
FLT	Filter	
FIST	Fistula	
FLUID	Fluid	Fluid
FGA	Fluid, Abdomen	Fluid
CSMY	Fluid, Cystostomy Tube	Fluid
ACNFLD	Fluid, Acne	Fluid
FLU	Fluid, Body unsp	
CST	Fluid, Cyst	Fluid
HYDC	Fluid, Hydrocele	Fluid
IVFLD	Fluid, IV	Fluid
JNTFLD	Fluid, Joint	Fluid
KIDFLD	Fluid, Kidney	Fluid
LSAC	Fluid, Lumbar Sac	Fluid
FLD	Fluid, Other	Fluid
PCFL	Fluid, Pericardial	
RENC	Fluid, Renal Cyst	Fluid
FRS	Fluid, Respiratory	Fluid
SHUNF	Fluid, Shunt	Fluid
SNV	Fluid, synovial (Joint fluid)	
GAST	Fluid/contents, Gastric	
FUR	Furuncle	Condition
GAS	Gas	
EXG	Gas, exhaled (=breath)	
IHG	Gas, Inhaled	
GENV	Genital vaginal	
GRAFT	Graft	Condition
GRAFT	Graft Site	Condition
POPGS	Graft Site, Popliteal	Condition
POPLG	Graft, Popliteal	Condition
GRANU	Granuloma	Condition
IMP	Implant	Device
INFIL	Infiltrate	Condition

Value	Description	Comment
INS	Insect	Object
IUD	Intrauterine Device	Device (Common Usage)
IT	Intubation tube	
KELOI	Lavage	Product
LAVG	Lavage, Bronhial	Product
LAVGG	Lavage, Gastric	Product
LAVGP	Lavage, Peritoneal	Product
LAVPG	Lavage, Pre-Bronch	Product
LESN	Lesion	Condition
ORL	Lesion, Oral	Condition (Common Usage)
PENIL	Lesion, Penile	Condition (Common Usage)
LIQO	Liquid, Other	
LIQ	Liquid, Unspecified	
MASS	Mass	Condition
SMM	Mass, Sub-Mandibular	Condition
MUCOS	Mucosa	Condition
MUCUS	Mucus	Condition
NEDL	Needle	Device
NODUL	Nodule(s)	Condition
CYN	Nodule, Cystic	Condition
ORH	Other	
PACEM	Pacemaker	Device
PLAN	Plant Material	Object
PLAS	Plasma	Blood
PLB	Plasma bag	Blood
PPP	Plasma, Platelet poor	Blood
PRP	Plasma, Platelet rich	Blood
POL	Polyps	Condition
PROST	Prosthetic Device	Device
PSC	Pseudocyst	Condition
PUS	Pus	
PUST	Pus	Condition
PUSFR	Pustule	Condition
QC3	Quality Control	Environment
RES	Respiratory	Condition (Ambiguous)
SAL	Saliva	
FSCLP	Scalp, Fetal	Condition
CSCR	Scratch, Cat	Condition
SECRE	Secretion(s)	Fluid/Secretion
NSECR	Secretion, Nasal	Condition
SER	Serum	
ASERU	Serum, Acute	Blood
CSERU	Serum, Convalescent	Blood
PLEVS	Serum, Peak Level	Blood
TSERU	Serum, Trough	Blood
SHUNT	Shunt	Condition
EXS	Shunt, External	Condition
SITE	Site	Site

Value	Description	Comment
CVPS	Site, CVP	Site
INCI	Site, Incision/Surgical	Site
NGS	Site, Naso/Gastric	Site
NEPH	Site, Nephrostomy	Site
PIS	Site, Pacemaker Insetion	Site
PDSIT	Site, Peritoneal Dialysis	Site
PDTS	Site, Peritoneal Dialysis Tunnel	Site
PINS	Site, Pin	Site
POPLV	Site, Popliteal Vein	Site
SHU	Site, Shunt	Site
TRAC	Site, Tracheostomy	Site
SKN	Skin	
TZANC	Smear, Tzanck	
GSOL	Solution, Gastrostomy	Product
ILLEG	Source of Specimen Is Illegible	
OTH	Source, Other	
UDENT	Source, Unidentified	
USPEC	Source, Unspecified	
SPRM	Spermatozoa	
SPT	Sputum	
SPTC	Sputum - coughed	
SPTT	Sputum - tracheal aspirate	
DCS	Sputum, Deep Cough	Condition
SPUTIN	Sputum, Inducted	Condition
SPUT1	Sputum, Simulated	Condition
SPUTSP	Sputum, Spontaneous	Condition
STONE	Stone, Kidney	Condition
STL	Stool = Fecal	
SUP	Suprapubic Tap	Product
SUTUR	Suture	Object
TISS	Tissue	
TISU	Tissue ulcer	
ACNE	Tissue, Acne	Tissue
HERNI	Tissue, Herniated	Tissue
SCAR	Tissue, Keloid (Scar)	Tissue
TRANS	Transudate	Condition
ETTUB	Tube, Endotracheal	Device
GT	Tube, Gastric	Device
TUBES	Tubes	Device
IVTIP	Tubing Tip, IV	Device
TUMOR	Tumor	Condition
DEC	Ulcer, Decubitus	Condition
UR	Urine	
URT	Urine catheter	
URC	Urine clean catch	
URINB	Urine, Bladder Washings	Condition
URINC	Urine, Catheterized	Condition
USCOP	Urine, Cystoscopy	Condition

Value	Description	Comment
URINM	Urine, Midstream	Condition
URINN	Urine, Nephrostomy	Condition
URINP	Urine, Pedibag	Device
RANDU	Urine, Random	Condition
VITF	Vitreous Fluid	
VOM	Vomitus	
WRT	Wart	Tissue
WASH	Wash	Product
WASI	Washing, e.g. bronchial washing	Product
WAT	Water	
WEN	Wen	Tissue
WICK	Wick	
WORM	Worm	Object
WND	Wound	
WNDA	Wound abscess	
WNDD	Wound drainage	
WNDE	Wound exudate	
PUNCT	Wound, Puncture	Condition

7.18.5 HL7 Table 0371 – Additive/Preservative

HL7 Table 0371 – Additive/Preservative

Value	Description	Comment
F10	10% Formalin	Tissue preservative
C32	3.2% Citrate	Blue top tube
C38	3.8% Citrate	Blue top tube
HCL6	6N HCL	24 HR Urine Additive
ACDA	ACD Solution A	Yellow top tube
ACDB	ACD Solution B	Yellow top tube
ACET	Acetic Acid	Urine preservative
AMIES	Amies transport medium	Protozoa
HEPA	Ammonium heparin	Green top tube
BACTM	Bacterial Transport medium	Microbiological culture
BOR	Borate Boric Acid	24HR Urine Additive
BOUIN	Bouin's solution	Tissue
BF10	Buffered 10% formalin	Tissue
WEST	Buffered Citrate (Westergren Sedimentation Rate)	Black top tube
BSKM	Buffered skim milk	Viral isolation
CARS	Carson's Modified 10% formalin	Tissue
CARY	Cary Blair Medium	Stool Cultures
CHLTM	Chlamydia transport medium	Chlamydia culture
CTAD	CTAD (this should be spelled out if not universally understood)	Blue top tube
ENT	Enteric bacteria transport medium	Bacterial culture
ENT+	Enteric plus	Stool Cultures
JKM	Jones Kendrick Medium	Bordetella pertussis
KARN	Karnovsky's fixative	Tissue
LIA	Lithium iodoacetate	Gray top tube
HEPL	Lithium/Li Heparin	Green top tube
M4	M4	Microbiological culture
M4RT	M4-RT	Microbiological culture
M5	M5	Microbiological culture

MICHTM	Michel's transport medium	IF tests
MMDTM	MMD transport medium	Immunofluorescence
HNO3	Nitric Acid	Urine
NONE	None	Red or Pink top tube
PAGE	Pages's Saline	Acanthaoemba
PHENOL	Phenol	24 Hr Urine Additive
KOX	Potassium Oxalate	Gray top tube
EDTK	Potassium/K EDTA	Deprecated. Replaced by EDTK15 and EDTK75
EDTK15	Potassium/K EDTA 15%	Purple top tube
EDTK75	Potassium/K EDTA 7.5%	Purple top tube
PVA	PVA (polyvinylalcohol)	O&P
RLM	Reagan Lowe Medium	Bordetella pertussis cultures
SST	Serum Separator Tube (Polymer Gel)	'Tiger' Top tube
SILICA	Siliceous earth, 12 mg	Gray top tube
NAF	Sodium Fluoride	Gray top tube
FL100	Sodium Fluoride, 100mg	Urine
FL10	Sodium Fluoride, 10mg	Urine
NAPS	Sodium polyanethol sulfonate 0.35% in 0.85% sodium chloride	Yellow (Blood Culture)
HEPN	Sodium/Na Heparin	Green top tube
EDTN	Sodium/Na EDTA	Dark Blue top tube
SPS	SPS(this should be spelled out if not universally understood)	Anticoagulant w/o bacteriocidal properties
STUTM	Stuart transport medium	Bacterial culture
THROM	Thrombin	Orange or Grey/Yellow (STAT Chem)
FDP	Thrombin NIH; soybean trypsin inhibitor (Fibrin Degradation Products)	Dark Blue top tube
THYMOL	Thymol	24 Hr Urine Additive
THYO	Thyoglycollate broth	Bacterial Isolation
TOLU	Toluene	24 Hr Urine Additive
URETM	Ureaplasma transport medium	Ureaplasma culture
VIRTM	Viral Transport medium	Virus cultures

7.18.6 HL7 Table 0488 – Specimen Collection Method

HL7 table 0488 – Specimen Collection Method

Value	Description	Comment
FNA	Aspiration, Fine Needle	
PNA	Aterial puncture	
BIO	Biopsy	
BCAE	Blood Culture, Aerobic Bottle	
BCAN	Blood Culture, Anaerobic Bottle	
BCPD	Blood Culture, Pediatric Bottle	
CAP	Capillary Specimen	
CATH	Catheterized	
EPLA	Environmental, Plate	
ESWA	Environmental, Swab	
LNA	Line, Arterial	
CVP	Line, CVP	
LNV	Line, Venous	
MARTL	Martin-Lewis Agar	
ML11	Mod. Martin-Lewis Agar	
PACE	Pace, Gen-Probe	
PIN	Pinworm Prep	
KOFFP	Plate, Cough	

Value	Description	Comment
MLP	Plate, Martin-Lewis	
NYP	Plate, New York City	
TMP	Plate, Thayer-Martin	
ANP	Plates, Anaerobic	
BAP	Plates, Blood Agar	
PRIME	Pump Prime	
PUMP	Pump Specimen	
QC5	Quality Control For Micro	
SCLP	Scalp, Fetal Vein	
SCRAPS	Scrapings	
SHA	Shaving	
SWA	Swab	
SWD	Swab, Dacron tipped	
WOOD	Swab, Wooden Shaft	
TMOT	Transport Media,	
TMAN	Transport Media, Anaerobic	
TMCH	Transport Media, Chalamydia	
TMM4	Transport Media, M4	
TMMY	Transport Media, Mycoplasma	
TMPV	Transport Media, PVA	
TMSC	Transport Media, Stool Culture	
TMUP	Transport Media, Ureaplasma	
TMVI	Transport Media, Viral	
VENIP	Venipuncture	

7.19 OUTSTANDING ISSUES

None.