

ELR 2.5.1 Clarification Document for EHR Technology Certification

V1.2

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And

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Revision History

Date	Version	Description
3/22/2013	1.2	Revised Clarification of OBX.4 (Observation Sub-ID),NONOBX.5_CWE.9 (original text) and PID.34 (Last Update Facility) condition predicates. Added NIST_ELR-34 to the NIST Tool Implementation Decisions table. This clarification document has been updated as part of an updated release of the NIST 2014 Certification Tool.

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Introduction:

This supplement, “ELR 2.5.1 Clarification Document for EHR Technology Certification V1.1, October 2012” supersedes the earlier document “ELR 2.5.1 Clarification Document for EHR Technology Certification, July 2012”. Like its predecessor, it clarifies conformance requirements and other aspects of the HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 implementation guide (the ELR Implementation Guide or ‘ELR IG’) and its accompanying Errata and Clarifications document. The supplement does not specify additional requirements. Rather, it clarifies existing requirements given in the ELR IG and the related Errata and Clarifications document. It also identifies areas where the ELR IG was ambiguous or contradictory for testing tool implementation. Therefore, this supplement also documents the implementation decisions made in collaboration with National Institute of Standards and Technology (NIST) and during the creation of the NIST ELR Conformance Test Tool. These issues and additional errata are identified for a future “Release 2” of the ELR IG by HL7.

Generally, the ELR IG’s scope is more comprehensive than Electronic Health Record (EHR) technology certification requires. Thus, the parts of the ELR IG (such as conformance profiles) that are applicable in the context of EHR technology certification include the ELR Receiver Usage. Note that even though the name of this conformance profile is “ELR Receiver Usage,” in the EHR technology certification context this conformance profile is one to which the “Sender”, i.e., the EHR technology is required to conform.

Section 1: Condition Predicates

This section is intended to list and clarify the conditional usage predicates into machine processable statements for the many elements listed in the guide. It is divided up into three tables that cover the data types, segment field elements, and message structure elements respectively. Footnotes provide further explanation, where required.

Table 1: Condition Predicates for Data types

Data type Element	ELR IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
CNN.10	CE	C(R/X)	".... ELR Condition predicate: Required if component 1 (ID Number) is populated."	If CNN.1 (Identifier) is valued.

¹ Representation of Conditional usage has been pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Please refer to the base standard documentation for a full explanation of conformance concepts

Data type Element	ELR IG Usage	Usage based on reference text¹	Reference Text from ELR IG	Condition Predicate based on Text
CNN.11	CE	C(R/X)	"ELR Condition predicate: This component is required if a value is present in component 10 (Assigning Authority – Universal ID.)...."	If CNN.10 (Assigning Authority - Universal ID) is valued.
NONOBX5_CWE.2	CE	C(RE/X)	"It is strongly recommended that text be sent to accompany any identifier. ELR Condition predicate: If the Identifier component is empty, then this component must be empty."	If CWE.1 (Identifier) is valued.
NONOBX5_CWE.3	CE	C(R/X)	"Harmonized condition predicate: Required if an identifier is provided in component 1...."	If CWE.1 (Identifier) is valued.
NONOBX5_CWE.5	CE	C(RE/X)	"It is strongly recommended that alternate text be sent to accompany any alternate identifier...ELR Condition predicate: If the alternate Identifier component is empty, then this component must be empty."	If CWE.4 (Identifier) is valued.
NONOBX5_CWE.6	CE	C(R/X)	"Harmonized condition predicate: Required if an alternate identifier is provided in component 4...."	If CWE.4 (Identifier) is valued.
NONOBX5_CWE.9	CE	C(R/RE)	".... ELR Condition predicate: If no identifier and alternate identifier are present, then this component is required."	If CWE.1 (Identifier) AND CWE.4 (alternate identifier) are not valued.
OBX5.6	CE	C(R/X)	"Harmonized condition predicate: Required if an alternate identifier is provided in component 4...."	If CWE.4 (Identifier) is valued.
XCN.9	CE	C(R/X)	". Harmonized condition predicate: Required if component 1 (ID Number) is populated."	XCN.9 (Assigning Authority) IF XCN.1 (ID Number) is valued.
XCN.13	CE	C(R/X)	"ELR Condition predicate. Required if component 1 (ID Number) is populated."	IF XCN.1 (ID Number) is valued.
XON.1	CE	C(R/RE)	"ELR Condition predicate: Must be present if there is no Organization Identifier in component 10. Send it if you have it."	IF XON.10 (ID Number) is not valued.
XON.6	CE	C(R/X)	".... ELR & Lab to EHR Condition predicate: Required if component 10 (Organization Identifier) is populated."	IF XON.10 (ID Number) is valued.
XON.7	CE	C(R/X)	"ELR Condition predicate: Required if component 10 (Organization Identifier) is populated."	IF XON.10 (ID Number) is valued.
XTN.4	CE	C(R/X)	"ELR Condition predicate: Required if component 7 (local number) is not present."	IF XTN.7 (local number) is not valued.
XTN.5	CE	C(RE/X)	"ELR Condition predicate: This component is required or empty (RE) if component 7 (Local Number) is present otherwise it must be empty."	IF XTN.7 (local number) is valued.
XTN.6	CE	C(RE/X)	"ELR Condition predicate: This component is required or empty (RE) if component 7 (Local Number) is present otherwise it must be empty."	IF XTN.7 (local number) is valued.

Data type Element	ELR IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
XTN.7	CE	C(R/X)	"ELR Condition predicate: Required if component 4 (Email Address) is not present. Component 7 (Local Number) must be empty if component 4 (Email Address) is present."	IF XTN.4 (Email Address) is not valued.
XTN.8	CE	C(RE/X)	"ELR Condition predicate: This component is required or empty (RE) if component 7 (Local Number) is present otherwise it must be empty."	IF XTN.7 (Local Number) is valued.

Table 2: Condition Predicates for Segment field elements

Message Element	IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
MSH-15	CE	C(R/RE)	"Harmonized condition predicate: Required when MSH-21 profile id is PHLabReport-Ack or USLabReport, otherwise it may be empty or "NE"."	If the first component (Entity Identifier) of one occurrence of MSH-21 (Message Profile Identifier) is 'PHLabReport-Ack'.
MSH-16	CE	C(R/RE)	Harmonized condition predicate: Required when MSH-21 profile id is PHLabReport-Ack or USLabReport, otherwise it may be empty or "NE"...."	If the first component (Entity Identifier) of one occurrence of MSH-21 (Message Profile Identifier) is 'PHLabReport-Ack'.
PID-34	CE	C(R/O)	".... ELR: Condition predicate: If PID-33 is present this is required."	IF PID-33 (Last Update Date/Time) is valued.
NK1-2	CE	C(R/X)	".... ELR Condition predicate: If next of kin or associated party is a person use this field, otherwise, use field NK1-13"	IF NK1-13 (Organization Name – NK1) is not valued.
NK1-13	CE	C(R/X)	"ELR Condition predicate: If next of kin or associated party is an organization use this field, otherwise, use field NK1-2."	IF NK1-2 (Name) is NOT valued.

Message Element	IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
NK1-30	CE	C(R/X)	"ELR Condition predicate: Required if NK1-13 is populated."	IF NK1-13 (Organization Name) is valued.
ORC-2	CE	C(R/X)	"ELR & Lab to EHR Condition predicate: If OBR-2 Placer Order Number is populated; this field must contain the same value as OBR-2."	IF OBR-2 (Placer Order Number) within same Order_Observation Group is valued.
ORC-12	CE	C(R/X)	"ELR Condition predicate: If OBR.16 Ordering Provider is populated, this field will contain the same value."	IF OBR-16 (Placer Order Number) within same Order_Observation Group is valued.
ORC-14	CE	C(R/X)	"ELR Condition predicate: If OBR-17 Callback Phone Number is populated, this field will contain the same value...."	IF OBR-17 (Order Callback Phone Number) within same Order_Observation Group is valued.
OBR-8	CE	C(R/X)	"...ELR Condition predicate: This field must contain the same value as the second component of SPM-17 Specimen Collection Date/Time."	IF SPM-17.2 is valued.
OBR-26 ²	CE	N/A	"... Harmonized condition predicate: This field is required when linking child sensitivities to the parent culture."	Condition Predicate NOT derivable from message.
OBR-29 ²	CE	N/A	"...Harmonized condition predicate: This field is required if OBR-24 carries the value "MB" and OBR-4 indicates the ordered test is a culture and sensitivity...."	Condition Predicate NOT derivable from message.
OBX-2	CE	C(R/X)	"... Conditional statement: If OBX-5 is populated, OBX-2 is required..."	IF OBX-5 (Observation Value) is valued.
OBX-4	CE	C(R/RE)	"Harmonized condition predicate: Required if there is more than one OBX with the same OBX-3 Observation Identifier associated with the same OBR...."	If there are multiple OBX segments associated with the

² The condition predicate for this element is not clear enough in the ELR IG to create a machine processable statement. It will need to be reviewed and clarified in a future release of the Implementation Guide. In the NIST tool implementation this element conforms to RE usage.

Message Element	IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
				same OBR segment that have the same OBX-3 (Observation Identifier) values for (OBX-3.1 and OBX-3.3) or (OBX-3.4 and OBX-3.6).
OBX-5 ³	CE	C(RE/X)	".... Harmonized Condition predicate: Either OBX-5 or OBX-8 (Abnormal flags) must be present in the message except if OBX-11 is 'X', result cannot be obtained."	IF OBX-11 (Observation Result Status) is not valued 'X'.
OBX-6	CE	C(R/X)	".... Harmonized Conditional statement: If the data type in OBX 2 is "NM" or "SN" and the OBX-11 observation result status is not 'X' then this field is required."	IF OBX-2 (Value Type) is valued 'NM' , 'SN' AND OBX-11 (Observation Result Status) is not valued 'X'.
OBX-8 ³	CE	C(RE/X)	"...ELR Condition predicate: Required if OBX-5 is empty and the OBX-11 observation result status is not 'X', result cannot be obtained..."	IF OBX-11 (Observation Result Status) is not valued 'X'.
OBX-14 ²	CE	N/A	"...ELR Condition predicate: For observations related to the testing of a specimen, OBX-14 (Date/Time of the Observation) shall contain specimen collection time and will be the same value as OBR-7 and SPM-17.1...."	Condition Predicate NOT derivable from message.

³ Condition Predicate for OBX-5 and OBX-8 has been split into a Condition Predicate and a conformance statement (ELR-065 and ELR-066 respectively) for each element, in order to be able to test all possible use cases as outlined below:

Valid structure:

- Case 1: OBX.5 populated, OBX.8 empty and OBX.11 <> X
- Case 2: OBX.5 empty, OBX.8 populated and OBX.11 <> X
- Case 3: OBX.5 populated, OBX.5 populated and OBX.11 <> X
- Case 4: OBX.5 empty, OBX.8 empty and OBX.11 = X

Invalid structure:

- Case 5, 6 and 7: OBX.5 and/or OBX.8 populated and OBX.11 = X
- Case 8: OBX.8 empty, OBX.5 empty and OBX.11 <> X

Table 3: Condition Predicates for Message Structure

Segment in Standard	ELR IG Usage	Usage based on reference text ¹	Reference Text from ELR IG	Condition Predicate based on Text
ORC ⁴	CE	N/A	"... ELR Condition predicate: The first Order_Observation Group must contain an ORC segment (containing ordering facility information) if no ordering provider information is present in OBR-16 or OBR-17."	Condition Predicate NOT derivable from message.
OBSERVATION Group Begin	CE	C(R/RE)	"... Harmonized condition predicate: May be empty for OBR-25 Result statuses of "O," "I," "S" and "X"; otherwise, it is required."	OBSERVATION Group Begin: Condition Predicate: IF OBR.25 (Result Status) is valued "A", "C", "F", "P", or "R".
SPECIMEN Group Begin ⁵	CE	N/A	"...ELR & NHSN Condition predicate: The Specimen Group is required for the parent Order_Observation Group in the message...."	Condition Predicate NOT derivable from message.

⁴ The ORC condition predicate is not clear enough in the ELR IG to create a machine processable statement. It will need to be reviewed and clarified in a future release of the Implementation Guide. In the NIST tool implementation this element conforms to RE usage.

⁵ Unable to test SPM Group Conditional usage based on existing predicate statement since application can't identify the "parent" Order_Observation Group (not based upon another element in message). However implicit in this comment is that there needs to be at least one SPM segment in the message, therefore conformance statement ELR-064 was added below. In the NIST tool implementation this element conforms to RE usage

Section 2: Conformance Statements:

This section is intended to explicitly state the conformance statements as machine processable statements. These conformance statements are gleaned from the text body, table description, and other sections of the ELR IG.⁶ It is divided up into three tables that cover the data types, segment field elements and message structure elements respectively. Footnotes provide further explanation, where required. Several areas in the 'Reference Text from Implementation Guide' column have italic and underlined text. This formatting occurs if more than one conformance statement was generated from the text.

Table 1: Conformance Statements for Data Types:

Datatype Element	Reference Text from ELR IG	Conformance Statement based on Text
ST, TX, FT.	<p>"2.2 USE OF ESCAPE SEQUENCES IN TEXT FIELDS Senders and receivers using this profile shall handle escape sequence processing as described in HL7 Version 2.5.1, Chapter 2, Section 2.7.4 (Special Characters). This requirement applies to the ST, TX and FT data types. Implementers shall not support escape sequences described in Sections 2.7.2 (Escape sequences supporting multiple character sets), 2.7.3 (Highlighting), 2.7.5 (Hexadecimal), 2.7.6 (Formatted Text) and 2.7.7 (Local). This restriction applies to the TX and FT data types."</p>	<p>ELR-001: The ST, TX, FT Data types Shall support only the following escape sequences: \F\ field separator for " " \S\ component separator for "^" \T\ subcomponent separator for "&" \R\ repetition separator for "~" \E\ escape character "\"</p>
NONOBX5_CWE.1	<p>1) (from OBR.4) Identifier code for the requested observation/test/ battery. <i>Strongly recommend Laboratory Order Value Set, which is based on LOINC.</i> 2) (from OBX.3) Unique identifier for the type of observation. This field provides a code for the type of observation. OBX-3 in conjunction with OBX-4 Observation Sub-ID should uniquely identify this OBX from all other OBXs associated with this OBR. <i>LOINC is used as the coding system for this field except where the test being reported has no equivalent LOINC code.</i> In this case, use of local codes is allowed. This should only occur for new tests that have yet been coded by LOINC. <i>When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear.</i> Lab to EHR - LOINC® is an HL7 approved code system and shall be used for the Observation Identifier as described in the appropriate HITSP Interoperability Specification. Use of LOINC codes for additional tests is strongly encouraged.</p>	<p>ELR-069: NONOBX5_CWE.1 (Identifier) If NONOBX5_CWE.3 (Name of Coding System) value is "LN", SHALL be a valid LOINC code identifier format.</p>

⁶ The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in RFC 2119 (<http://www.ietf.org/rfc/rfc2119.txt>). The following definitions are excerpted from the RFC:
 MUST or the terms "REQUIRED" or "SHALL", mean that the definition is an absolute requirement of the specification.
 MUST NOT or the phrase "SHALL NOT", mean that the definition is an absolute prohibition of the specification.

Datatype Element	Reference Text from ELR IG	Conformance Statement based on Text
NONOBX5_CWE.4	<p>1) (from OBR.4) Identifier code for the requested observation/test/ battery. <i>Strongly recommend Laboratory Order Value Set, which is based on LOINC.</i></p> <p>2) (from OBX.3) Unique identifier for the type of observation. This field provides a code for the type of observation. OBX-3 in conjunction with OBX-4 Observation Sub-ID should uniquely identify this OBX from all other OBXs associated with this OBR. <i>LOINC is used as the coding system for this field except where the test being reported has no equivalent LOINC code.</i> In this case, use of local codes is allowed. This should only occur for new tests that have yet been coded by LOINC. <i>When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear.</i> Lab to EHR - LOINC® is an HL7 approved code system and shall be used for the Observation Identifier as described in the appropriate HITSP Interoperability Specification. Use of LOINC codes for additional tests is strongly encouraged.</p>	<p>ELR-070: NONOBX5_CWE.4 (Alternate Identifier) If NONOBX5_CWE.6 (Name of AlternateCoding System) value is "LN", SHALL be a valid LOINC code identifier format.</p>
CNN.10	"Must be an OID. ..."	<p>ELR-002: CNN.10 (Assigning Authority - Universal ID) SHALL be valued with an ISO-compliant OID.</p>
CNN.11	"... Constrained to the value 'ISO'."	<p>ELR-003: CNN.11 (Assigning Authority - Universal ID Type) SHALL contain the value "ISO".</p>
EI.3	"Must be an OID."	<p>ELR-004: EI.3 (Universal ID) SHALL be valued with an ISO-compliant OID.</p>
EI.4	"Constrained to the value 'ISO'."	<p>ELR-005: EI.4 (Universal ID Type) SHALL contain the value "ISO".</p>
HD.2	"Must be an OID except for ELR Receiver for MSH-3 where a CLIA identifier is allowed."	<p>ELR-062: HD.2 (Universal ID) If HD.3 (Universal ID type) value is "CLIA", SHALL be a valid CLIA identifier format.</p>
HD.2	"Must be an OID except for ELR Receiver for MSH-3 where a CLIA identifier is allowed."	<p>ELR-063: HD.2 (Universal ID) If HD.3 (Universal ID type) value is "ISO", SHALL be a valid ISO OID format.</p>
HD.3	"Constrained to the value 'ISO' except for ELR Receiver for MSH-4 where the value 'CLIA' is allowed."	<p>ELR-007: HD.3 (Universal ID Type) IF element is MSH-4.3 (Universal ID type) , then HD.3 (Universal ID type) SHALL contain the value "ISO" OR "CLIA", ELSE HD.3 (Universal ID type) SHALL contain the value "ISO"</p>

Datatype Element	Reference Text from ELR IG	Conformance Statement based on Text
SN.1	"Component that must be one of ">" or "<" or ">=" or "<=" or "=" or "<>".	ELR-008: If valued, SN.1 (Comparator) SHALL contain the value ">" or "<" or ">=" or "<=" or "=" or "<>".
SN.3	"Component that must be one of "-" or "+" or "/" or "." or ":"."	ELR-009: If valued, SN.3 (Separator/Suffix) SHALL contain the value "-" or "+" or "/" or "." or ":".
XAD.4	"Identifies addresses within the United States are recorded using the FIPS 5-2 two-letter alphabetic codes for the State, District of Columbia, or an outlying area of the United States or associated area. http://www.itl.nist.gov/fipspubs/fip5-2.htm "	ELR-010: XAD.4 (State or Province) SHALL use the FIPS 5-2 two letter alphabetic codes.
XAD.5	"In the US, the zip code takes the form 99999[-9999], while the Canadian postal code takes the form A9A9A9."	ELR-011: XAD.5 (Zip or Postal Code) SHALL be formatted as 99999[-9999] for US Zip or ZIP +4 codes or as A9A9A9 for Canadian postal codes.
XAD.9	"PHVS_County_FIPS_6-4"	ELR-067: XAD.9 (County/Parish Code) SHALL be formatted as 99999.

Table 2: Message Detail Conformance Statements:

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
MSH-1	"Character to be used as the field separator for the rest of the message. Literal value: ' ' [ASCII (124)]".	ELR-012: MSH-1 (Field Separator) SHALL contain the constant value ' '.
MSH-2	"Five characters, always appearing in the same order: ^~\&# . Literal value: '^~\&#'."	ELR-013: MSH-2 (Encoding Characters) SHALL contain the constant value '^~\&#'.
MSH-7	"Field containing the date/time the message was created by the sending system. Format: YYYYMMDDHHMMSS[S[S[S[S]]]]+/-ZZZZ. Note that the time zone offset is required, and the minimum granularity is to the second, although more precise time stamps are allowed."	ELR-014: MSH-7 (Date/Time Of Message) SHALL follow the format YYYYMMDDHHMMSS[S[S[S[S]]]]+/-ZZZZ
MSH-9.1	"For the result message Literal Value: 'ORU^R01^ORU_R01'."	ELR-015: MSH-9.1 (Message Code) SHALL contain the constant value 'ORU'
MSH-9.2	"For the result message Literal Value: 'ORU^R01^ORU_R01'."	ELR-016: MSH-9.2 (Trigger Event) SHALL contain the constant value 'R01'

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
MSH-9.3	"For the result message Literal Value: 'ORU^R01^ORU_R01'."	ELR-017: MSH-9.3 (Message Structure) SHALL contain the constant value 'ORU_R01'
MSH-12.1	"Restricted to 2.5.1 in this guide. Literal value: '2.5.1'"	ELR-018: MSH-12.1 (Version ID) SHALL contain the constant value '2.5.1'
MSH-15	1) "Harmonized condition predicate: Required when MSH-21 profile id is PHLabReport-Ack or USLabReport, otherwise it may be empty or "NE"." 2) refer to Table 3-2, Table 3-3, and Table 3-4	ELR-019: MSH-15 (Accept Acknowledgment Type) SHALL contain the constant value 'AL' IF any occurrence of MSH-21.1 (Entity Identifier) is 'PHLabReport-Ack', ELSE, if valued, SHALL contain the constant value 'NE'.
MSH-16	1) "Harmonized condition predicate: Required when MSH-21 profile id is PHLabReport-Ack or USLabReport, otherwise it may be empty or "NE"." 2) refer to Table 3-2, Table 3-3, and Table 3-4	ELR-020: MSH-16 (Application Acknowledgement Type) SHALL contain 'AL', 'NE', 'ER', or 'SU', IF any occurrence of MSH-21.1 (Entity Identifier) is 'PHLabReport-Ack', ELSE, if valued, SHALL contain the constant value 'NE'.
MSH-21.1	2) refer to Table 3-2, Table 3-3, and Table 3-4	ELR-021: The first component (Entity Identifier) of one occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with 'PHLabReport-Ack' OR 'PHLabReport-NoAck' OR 'PHLabReport-Batch'
MSH-21.3	1) "Must be an OID." 2) From Errata "Table 3-2 Added Profile Assigning Authority Universal ID - ELR Receiver row with value 2.16.840.1.113883.9.11Table 3-3 Added Profile Assigning Authority Universal ID - ELR Receiver row with value 2.16.840.1.113883.9.11 ...Table 3-4 Added Profile Assigning Authority Universal ID - ELR Receiver row with value 2.16.840.1.113883.9.11 "	ELR-022: The third component (Universal ID) of one occurrence of MSH-21 (Message Profile Identifier) SHALL contain the value "2.16.840.1.113883.9.11"
SFT-6	from DTM datatype Comments "Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] "	ELR-023: SFT-6 (Software Install Date) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]
PID-1	Literal Value: '1'.	ELR-024: PID-1 (Set ID – PID) SHALL contain the constant value '1'.
PID- 6.7	"May be included for identification purposes. Name type code is constrained to the value "M." "	ELR-025: If valued, PID- 6.7 (Name Type Code) SHALL contain the constant value 'M'.

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
PID-7	<i>"Patient's date of birth. The time zone component is optional. Note that the granularity of the birth date may be important. For a newborn, birth date may be known down to the minute, while for adults it may be known only to the date. Birth date may be used by the lab to calculate an age for the patient, which may affect what normal ranges apply to particular test results. Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Note: If a birth date is not provided in the PID, then the patient age at specimen collection must be reported as an observation associated with the specimen."</i>	ELR-026: If valued, PID-7 (Date/Time of Birth) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ].
PID-7	<i>"Patient's date of birth. The time zone component is optional. Note that the granularity of the birth date may be important. For a newborn, birth date may be known down to the minute, while for adults it may be known only to the date. Birth date may be used by the lab to calculate an age for the patient, which may affect what normal ranges apply to particular test results. Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Note: If a birth date is not provided in the PID, then the patient age at specimen collection must be reported as an observation associated with the specimen."</i>	ELR-027: If PID-7 (Date/Time of Birth) is not valued, then an OBX segment associated with the SPM segment SHALL be present to report patient age at specimen collection.
PID-29	"Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]"	ELR-028: PID-29 (Patient Death Date and Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]
PID-33	"Note: Used to indicate when demographics were last updated. Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]"	ELR-029: PID-33 (Last Update Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]
PV1-1	Literal Value: '1'.	ELR-030: PV1-1 (Set ID - PV1) SHALL contain the constant value '1'.
PV1-44	from DTM datatype Comments "Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]"	ELR-031: PV1-44 (Admit Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]
PV1-45	1) "Date and time patient services ended ELR and NHSN Cardinality: ELR and NHSN currently support a single discharge date/time." 2) from DTM datatype Comments "Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]"	ELR-032: PV1-45 (Discharge Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]
NK1-1	"For the first repeat of the NK1 segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc."	ELR-033: NK1-1 (Set ID – NK1) SHALL be valued sequentially starting with the value '1'
ORC-1	See Table: 3-5	ELR-034: ORC-1 (Order Control) SHALL contain the constant value 'RE'.

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
ORC-2	"ELR & Lab to EHR Condition predicate: If OBR-2 Placer Order Number is populated; this field must contain the same value as OBR-2."	ELR-035: ORC-2 (Placer Order Number) SHALL be the same value as OBR-2 within same Order_Observation Group.
ORC-3	"This field must contain the same value as OBR-3 Filler Order Number. Note: In the circumstance where some of the lab results are generated by the lab, but others are performed by a reference lab, the sending lab can choose what filler order number to use, but whatever is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in ORC-3."	ELR-036: ORC-3 (Filler Order Number) SHALL be the same value as OBR-3 (Filler Order Number) within same Order_Observation Group.
ORC-12	"ELR Condition predicate: If OBR.16 Ordering Provider is populated, this field will contain the same value."	ELR-037: ORC-12 (Ordering Provider) SHALL be the same value as OBR-16 within same Order_Observation Group.
ORC-14	"ELR Condition predicate: If OBR-17 Callback Phone Number is populated, this field will contain the same value. This should be a phone number associated with the original order placer. ELR Cardinality: ELR currently supports up to 2 call back phone numbers."	ELR-038: ORC-14 (Call Back Phone Number) SHALL be the same value as OBR-17 within same Order_Observation Group.
OBR-1	"For the first repeat of the OBR segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc."	ELR-039: OBR-1 (Set ID - OBR) SHALL be valued sequentially starting with the value '1'
OBR-3	"Order number associated with the Filling Application. This number is assigned to the test by the organization performing the test. This field should not contain the accession number or specimen identifier for a specimen unless these identifiers meet the criteria for a filler order number. The specimen or accession identifier should be placed in SPM-2. <u>The Filler Order Number identifies this order as distinct from all other orders being processed by this filler where an order is interpreted to be the testing identified in a single OBR segment. Normally, this is a type of system identifier assigned by the filler software application. The Filler Order Number, along with the Placer Order Number, is essentially foreign keys exchanged between applications for uniquely identifying orders and the associated results across applications. In messages containing multiple OBRs, each OBR must be identified by a unique Filler Order Number.</u> This is critical for making parent/child results relationships work properly. Microbiology cultures and sensitivities are linked in this fashion in this profile. See Appendix A, Section A.4. Linking Parent and Child Results, of this document for more information on linking parent/child results."	ELR-040: OBR-3 (Filler Order Number) SHALL NOT contain the same value as another occurrence of OBR-3 (Filler Order Number) in the message.

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
OBR-7 ⁷	<p><i>"For specimen-based observations, the date/time the specimen was collected. A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000". If the SPM is sent, this field must contain the same value as the first component of SPM-17 Specimen Collection Date/Time. HL7 requires this field in an OBR in a result message. For OBXs related to this OBR and related to the testing of a specimen, OBX-14 (Date/Time of the Observation) SHALL contain the same value as this field. Format: YYYYMMDD[HH[MM[SS[S[S[S[S]]]]]]][+/-ZZZZ] except when reporting an unknown date of '0000"</i></p>	<p>ELR-041: OBR-7 (Observation Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000" when the collection date/time is unknown.</p>
OBR-8	<p>1) "For specimen-based observations where the specimen was collected over a period of time, this represents the end point in time when the specimen was collected. ELR Condition predicate: This field must contain the same value as the second component of SPM-17 Specimen Collection Date/Time." 2) From SPM.17.2 <i>"A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000". Format: /YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]+/-ZZZZ]^YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]+/-ZZZZ] "</i></p>	<p>ELR-043: OBR-8 (Observation End Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZZ]OR contain the value "0000" when the collection date/time is unknown.</p>
OBR-22 ⁸	<p>"Required field in this message. Applies to the entire report. Receipt of a subsequent message with the same Filler Number and a different status in this field implies that processing may need to occur at the receiving application level to update a previous report. Format: YYYYMMDDHHMM[SS.SS]+/-ZZZZ"</p>	<p>ELR-047: OBR-22 (Results Rpt/Status Chng - Date/Time) SHALL follow the format YYYYMMDDHHMM[SS.S[S[S[S]]]]+/-ZZZZ.</p>
OBX-1	<p>"For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc."</p>	<p>ELR-048: OBX-1 (Set ID – OBX) SHALL be valued sequentially starting with the value '1' within a given Order_Observation Group. (OBX following the OBR).</p>
OBX-1	<p>"For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc."</p>	<p>ELR-068: OBX-1 (Set ID – OBX) SHALL be valued sequentially starting with the value '1' within a given Specimen Group (OBX following the SPM).</p>

⁷ Corrected date/Time format - see Additional Errata #7

⁸ Corrected date/Time format - see Additional Errata #6

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
OBX-5 ³	<p>1) "Field that documents each specific, allowed data type. See Section 6.1.1.1, HL7 Table 0125 for the data types that will be supported for this field. Harmonized Condition predicate: <i>Either OBX-5 or OBX-8 (Abnormal flags) must be present in the message except if OBX-11 is 'X', result cannot be obtained.</i>"</p> <p>2) "Those OBX's associated with quantitative LOINC identifiers should be using OBX-5 with either the NM (numeric), SN (structured numeric), TS (timestamp), DT (date) or TM (time) data types. These quantitative results can be accompanied by an interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL7 table 0078...."</p> <p>3) Table 5-13.</p>	<p>ELR-065: OBX-5(Observation Value) Must be valued IF OBX-8 (Abnormal Flags) is empty AND OBX-11 (Observation Result Status) is not valued 'X'.</p>
OBX-8 ³	<p>1) "Indicator of the normalcy of the result found in OBX-5... ELR-Note that this IG is adopting HL70078 form 2.7...ELR Condition predicate: <i>Required if OBX-5 is empty and the OBX-11 observation result status is not 'X', result cannot be obtained....</i>"</p> <p>2) "Those OBX's associated with quantitative LOINC identifiers should be using OBX-5 with either the NM (numeric), SN (structured numeric), TS (timestamp), DT (date) or TM (time) data types. These quantitative results can be accompanied by an interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL7 table 0078...."</p> <p>3) Table 5-13.</p>	<p>ELR-066: OBX-8 (Abnormal Flags) Must be valued IF OBX-5 (Observation Value) is empty AND OBX-11 (Observation Result Status) is not valued 'X'.</p>
OBX-14 ⁷	<p>"The date/time of observation is intended to carry the clinically relevant time of the observation. For specimen-based laboratory reporting, the specimen collection date and time. For observations carried out directly on a patient for instance, such as a blood pressure, the time the observation was performed also happens to be the clinically relevant time of the observation. The date/time the testing was performed should be reported in OBX-19 ELR Condition predicate: For observations related to the testing of a specimen, OBX-14 (Date/Time of the Observation) SHALL contain specimen collection time and will be the same value as OBR-7 and SPM-17.1. <u>Format:</u> <u>YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] except when reporting an unknown date of '0000'...."</u></p>	<p>ELR-049: OBX-14 (Date/Time of the Observation) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000" when the collection date/time is unknown.</p>

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
OBX-14	<p>"The date/time of observation is intended to carry the clinically relevant time of the observation. For specimen-based laboratory reporting, the specimen collection date and time. For observations carried out directly on a patient for instance, such as a blood pressure, the time the observation was performed also happens to be the clinically relevant time of the observation. The date/time the testing was performed should be reported in OBX-19 ELR Condition predicate: <u>For observations related to the testing of a specimen, OBX-14 (Date/Time of the Observation) SHALL contain specimen collection time and will be the same value as OBR-7 and SPM-17.1.</u> Format: YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]]+/-ZZZZ] except when reporting an unknown date of '0000'...."</p>	<p>ELR-051: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), SHALL be identical to OBR-7 (Observation Date/Time) value within the same Order_Observation Group.</p>
OBX-19	<p>1) "Time at which the testing was performed. Note that in the past; OBX-14 was often used to carry the time of testing a specimen, even though HL7 clearly stated it should be the specimen collection date/time in that case. In this IG, the time the testing was performed will be carried in OBX-19, and OBX-14 will be used for its HL7 intended purpose." 2) from DTM data type Comments <u>"Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]]+/-ZZZZ]"</u></p>	<p>ELR-052: OBX-19 (Date/Time of the Analysis) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]]+/-ZZZZ]</p>
NTE-1	<p>"For the first repeat of the NTE segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc."</p>	<p>ELR-053: NTE-1 (Set ID – NTE) SHALL be valued sequentially starting with the value '1' within a given segment group.</p>
SPM-1	<p>1) "For the first repeat of the SPM segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc." 2)(from Specimen Group) "Each specimen group documents a single sample. Note that for ELR, the message has been constrained to support a single SPECIMEN group per OBR, meaning only a single specimen can be associated with the OBR. "</p>	<p>ELR-054: SPM-1 (Set ID – SPM) SHALL contain the constant value '1'.</p>
SPM-17.1	<p>"Time range over which the sample was collected, as opposed to the time the sample collection device was recovered. The first component of the date range must match OBR-7 Observation Date/Time. The second component must match OBR-8 Observation End Date/Time. For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of this field. <u>A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000".</u> Format: <u>[YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]]]]+/-ZZZZ]^YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]]+/-ZZZZ]"</u></p>	<p>ELR-055: SPM-17.1 (Range Start Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]]+/-ZZZZ]OR contain the value "0000" when the collection date/time is unknown.</p>

Message Element	Reference Text from ELR IG	Conformance Statement based on Text
SPM-17.1	<p>"Time range over which the sample was collected, as opposed to the time the sample collection device was recovered. <u>The first component of the date range must match OBR-7 Observation Date/Time.</u> The second component must match OBR-8 Observation End Date/Time. For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of this field. A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000". Format: YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]^YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] "</p>	<p>ELR-057: SPM-17.1 (Range Start Date/Time) SHALL be identical to OBR-7 (Observation Date/Time) value within the same Order_Observation Group.</p>
SPM-17.2	<p>"Time range over which the sample was collected, as opposed to the time the sample collection device was recovered. The first component of the date range must match OBR-7 Observation Date/Time. The second component must match OBR-8 Observation End Date/Time. For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of this field. <u>A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000". Format:</u> YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]^YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] "</p>	<p>ELR-058: SPM-17.2 (Range End Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000".</p>
SPM-17.2	<p>"Time range over which the sample was collected, as opposed to the time the sample collection device was recovered. The first component of the date range must match OBR-7 Observation Date/Time. <u>The second component must match OBR-8 Observation End Date/Time.</u> For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of this field. A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000". Format: YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]^YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] "</p>	<p>ELR-059: SPM-17.2 (Range End Date/Time) SHALL be identical to OBR-8 (Observation End Date/Time) value within the same Order_Observation Group.</p>
SPM-18	<p>"Time the specimen was 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. <u>Format: YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]"</u></p>	<p>ELR-060: SPM-18 (Specimen Received Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ].</p>

Table 3: Conformance Statements for the Message Structure:

Segment in Standard	Reference Text from ELR IG	Conformance Statement based on Text
message processing	<p>"2.1.4 Snapshot processing HL7 distinguishes between two methods of update: the "snapshot" and the "action code/unique identifier" modes. Both modes apply to repeating segments and repeating segment groups. For repeating fields, only snapshot processing applies. For the purpose of this guide, only snapshot processing is supported for segments, segment groups and fields. "</p>	<p>ELR-061: Only Snapshot processing SHALL be supported</p>
SPECIMEN group	<p>The Specimen group is conditionally required in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. It also provides a place for the specimen number. Each specimen group documents a single sample. Note that for ELR, the message has been constrained to support a single SPECIMEN group per OBR, meaning only a single specimen can be associated with the OBR.</p> <p>ELR & NHSN Cardinality: These profiles currently support a single SPM segment. Per the harmonization strategy the receiver must pick from a message instance which repeat they will use for the profile. <u><i>“ELR & NHSN Condition predicate: The specimen group is required for the parent Order Observation Group in the message.”</i></u></p>	<p>ELR-064: Specimen (Specimen Group) SHALL be present in at least one occurrence of one Order_Observation Group.</p>

Section 3: Clarifications of Cardinality

There are several instances where the cardinality is specified for ELR in the Comments and Description and may be ambiguous. This section is intended to highlight and clarify the cardinality in these cases.

Table 1: Message Cardinality Statements

Message Element	Reference Text from ELR IG	Cardinality Statement based on Text
PV1-45	1) "Date and time patient services ended ELR and NHSN <u>Cardinality: ELR and NHSN currently support a single discharge date/time.</u> 2) from DTM data type Comments "Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] "	PV1-45 (Discharge Date/Time) SHALL be limited to a single occurrence (Cardinality = [1..1]).
ORC-14	"ELR Condition predicate: If OBR-17 Callback Phone Number is populated, this field will contain the same value. This should be a phone number associated with the original order placer. <u>ELR Cardinality: ELR currently supports up to 2 call back phone numbers.</u> "	ORC-14 (Call Back Phone Number) SHALL be limited to 2 occurrences (Cardinality = [0..2]).
ORC-21	"ELR Cardinality: ELR supports a single ordering facility name."	ORC-21 (Ordering Facility Name) SHALL be limited to single occurrence (Cardinality = [1..1]).
ORC-22	"The address of the facility where the order was placed. ELR Cardinality: ELR supports a single ordering facility address"	ORC-22 (Ordering Facility Address) SHALL be limited to single occurrence (Cardinality = [1..1]).

Table 2: Message Structure Cardinality Statements

Segment in Standard	Reference Text from ELR IG	Cardinality Statement based on Text
Specimen Group Begin	"The specimen group is conditionally required in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. It also provides a place for the specimen number. Each specimen group documents a single sample. Note that for ELR, the message has been constrained to support a single SPECIMEN group per OBR, meaning only a single specimen can be associated with the OBR. ELR & NHSN Condition predicate: The specimen group is required for the parent Order_Observation Group in the message. <u>ELR & NHSN Cardinality: These profiles currently support a single SPM segment.</u> Per the harmonization strategy the receiver must pick from a message instance which repeat they will use for the profile."	Specimen Group Begin: SHALL be limited to one Specimen Group occurrence for each Order_Observation Group. (Cardinality = [0..1]).

Section 4: Additional Errata identified in ELR IG

There are additional errata identified in the ELR IG. These will be brought to the attention of the HL7 Public Health Emergency Response (PHER) working group in order to ballot and publish a second Errata document.

- 1) OBR-2 (Placer Order Number): Cardinality should be [0..1] instead of [1..1] as published.
- 2) HD.2 (Universal ID): Comment should read: Must be an OID except for ELR Sending Facility for MSH-4 where a CLIA identifier is allowed, instead of “for ELR Receiver for MSH-3 where a CLIA identifier is allowed.”
- 3) HD.3 (Universal ID Type): Comment should read: Constrained to the value ‘ISO’ except for ELR Sending Facility for MSH-4 where the value ‘CLIA’ is allowed, instead of “for ELR Receiver for MSH-4 where the value ‘CLIA’ is allowed.”
- 4) MSH-2 (Encoding characters): Although the truncation character (#) is present in MSH-2, it is not used in the ELR v2.5.1 message as such. This is confusing and should be removed in the next release.
- 5) TQ1 segment (Timing/Quantity): ELR guide erroneously marked as ‘O’ optional, but it is a required segment per the underlying HL7 v2.5.1 standard. This has no bearing on the testing as it is part of an optional group, but it should be corrected in the next release.
- 6) OBR-22 (Results Rpt/Status Chng - Date/Time): Need to correct the error in the timestamp notation to YYYYMMDDHHMM[SS[.S[S[S[S]]]])+/-ZZZZ
- 7) Typographical error in Implementation Guide in Comments field for Timestamp format in OBR.7 and OBX.14. Should be changed to YYYYMMDD[HH[MM[SS[.S[S[S[S]]]])]]+/-ZZZZ.
- 8) CE datatype usage is O in Table 6.1.1.1 but X in Table 2-2 and not defined for ELR –Receiver in table 2-3.
- 9) The value set listed in the ELR IG for PRL.1 should be “Laboratory Observation Identifier Value Set” instead of “Laboratory Observation Value Set”.
- 10) SPM-1 Add text to reflect the constraint for ELR to 1 specimen per message as outlined in the specimen group “For ELR: Literal Value ‘1’”
- 11) In the table 2.3.17 HD – Hierarchic Designator the term “Local” should be removed from the first row of the “Value Set” column since it does not describe a defined value set.
- 12) In Table 6.1 the value set for OBX-5 coded values is named “Laboratory Coded Observation Value Set” while in Table 5.12 the same value set is named “Laboratory Coded Observation Value Set” – this should be changed in Table 5.12 to “Laboratory Coded Observation Value Set”.
- 13) 6.1.1.4 HL7 Table 0301 - Universal ID Type represents the V2.5.1 table instead of the V2.7 as is listed in table 6-1 and therefore is missing “CLIA” as an O Usage for MSH-4.3. Change 6.1.1.4 HL7 Table 0301 to V2.7 value set and set “CLIA” as an O Usage for MSH-4.3.

Section 5: Vocabulary

Vocabulary clarifications are provided in this section to ensure that value sets referenced in Table 6.1 of the ELR IG are cross referenced with the ELR251 Value Sets from the PHIN vocabulary access and distribution system (VADS). This table includes values sets from all data elements including those with “O” Usage and has been reformatted to fit this document – the complete reference table is accessible here:

<https://phinvads.cdc.gov/vads/DownloadHotTopicDetailFile.action?filename=368D12BD-1514-E211-989D-001A4BE7FA90>

PHINVADS provides all ELR related value sets collected into a view that can be accessed here:

[http://phinvads.cdc.gov/vads/ViewView.action?name=Electronic%20Laboratory%20Reporting%20\(ELR\)%20to%20Public%20Health%20-%20HL7%20Version%202.5.1](http://phinvads.cdc.gov/vads/ViewView.action?name=Electronic%20Laboratory%20Reporting%20(ELR)%20to%20Public%20Health%20-%20HL7%20Version%202.5.1)

For the value sets;

- “Reason for Study Value Set “
- “Laboratory Observation Identifier Values”
- “Laboratory Coded Observation Value Set”
- “Specimen Type”
- “Specimen Collection Method Value Set”,

where the ELR IG lists “TBD” for the Value Sets/Code System source, PHIN VADS has created some suggested value sets based on the comments in Table 6.1 of the ELR IG. Implementation decisions for the purposes of NIST validation testing for these six value sets are documented in Section 5 below.

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Name of Coding System	CE.3	HL70396	PHVS_CodingSystem_HL7_2x_Table0396	2.16.840.1.114222.4.11.3338	
Degree	CNN.7	HL70360	PHVS_DegreeLicenseCertificate_HL7_2x	2.16.840.1.114222.4.11.808	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Units	CQ.2	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Identifier Type Code	CX.5	HL70203	PHVS_IdentifierType_CDC	2.16.840.1.114222.4.11.999	
Type of Data	ED.2	HL70191	PHVS_TypeOfReferencedData_HL7_2x	2.16.840.1.114222.4.11.3345	
Type of Data	ED.2	HL70834 (2.7)	PHVS_MIME_MediaType_IANA	2.16.840.1.114222.4.11.1012	
Data Subtype	ED.3	HL70291 (2.7)	PHVS_MIME_MediaSubType_IANA	2.16.840.1.114222.4.11.1011	
Encoding	ED.4	HL70299	PHVS_Encoding_HL7_2x	2.16.840.1.114222.4.11.986	
Universal ID Type	EI.4	HL70301	PHVS_UniversalIdType_HL7_2x_ELRL	2.16.840.1.114222.4.11.6067	
HL7 Error Code	ERR.3	HL70357	PHVS_MessageErrorConditionCodes_HL7_2x	2.16.840.1.114222.4.11.974	
Severity	ERR.4	HL70516	PHVS_ErrorSeverity_HL7_2x	2.16.840.1.114222.4.11.993	
Application Error Code	ERR.5	HL70533			HL7 empty table - to be filled locally
Acknowledgment Code	MSA.1	HL70008	PHVS_AcknowledgmentCode_HL7_2x	2.16.840.1.114222.4.11.958	
Message Code	MSG.1	HL70076	PHVS_MessageType_HL7_2x	2.16.840.1.114222.4.11.3341	
Trigger Event	MSG.2	HL70003	PHVS_EventType_HL7_2x	2.16.840.1.114222.4.11.3337	
Message Structure	MSG.3	HL70354	PHVS_MessageStructure_HL7_2x	2.16.840.1.114222.4.11.3349	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Accept Acknowledgment Type	MSH-15	HL70155	PHVS_AcceptApplicationAcknowledgmentConditions_HL7	2.16.840.1.114222.4.11.3344	
Accept Acknowledgment Type	MSH-16	HL70155	PHVS_AcceptApplicationAcknowledgmentConditions_HL7	2.16.840.1.114222.4.11.3344	
Country Code	MSH-17	Country Value Set	PHVS_Country_ISO_3166-1	2.16.840.1.114222.4.11.828	
Character Set	MSH-18	HL70211	PHVS_AlternateCharacterSets_HL7_2x	2.16.840.1.114222.4.11.3347	
Alternate Character Set Handling Scheme	MSH-20	HL70356	PHVS_AlternateCharacterSetHandlingScheme_HL7_2x	2.16.840.1.114222.4.11.3350	
Primary Language	NK1-20	PHVS_Language_ISO_639-2_Alpha3	PHVS_Language_ISO_639-2_Alpha3	2.16.840.1.114222.4.11.831	
Relationship	NK1-3	HL70063	PHVS_Relationship_HL7_2x	2.16.840.1.114222.4.11.813	
Source of Comment	NTE-2	HL70105	PHVS_SourceOfComment_HL7_2x	2.16.840.1.114222.4.11.3014	
Comment Type	NTE-4	HL70364	PHVS_CommentType_CDC	2.16.840.1.114222.4.11.975	
Specimen Action Code	OBR-11	HL70065	PHVS_SpecimenActionCode_HL7_2x	2.16.840.1.114222.4.11.3340	
Diagnostic Serv Sect ID	OBR-24	HL70074	PHVS_DiagnosticServiceSectionID_HL7_2x	2.16.840.1.114222.4.11.922	
Result Status	OBR-25	HL70123	PHVS_ResultStatus_HL7_2x	2.16.840.1.114222.4.11.815	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Reason For Study Value Set	OBR-31	TBD			Reason for Study. Union of concepts from PHVS_AdministrativeDiagnosis_CDC_ICD-9CM and ICD-10. Note: HITSP apparently has stopped using ICD-9 for diagnosis and focused on using value sets from SNOMED CT.
Reason For Study Value Set	OBR-31	PHVS_AdministrativeDiagnosis_CDC_ICD-9CM	PHVS_AdministrativeDiagnosis_CDC_ICD-9CM	2.16.840.1.114222.4.11.856	
Reason For Study Value Set	OBR-31	HITSP Problem list	PHVS_ProblemList_HITSP	2.16.840.1.113883.3.88.12.3221.7.4	HITSP Problem list includes a broader set of concepts such as diagnosis, diseases, finding, symptoms and signs.
Laboratory Order Value Set	OBR-4	HITSP C-80,20090708 V1.1, 2.16.840.1.113883.3.88.12.80.25, See comments from ELR IG.	PHVS_LabTestOrderables_CDC	2.16.840.1.114222.4.11.1004	This identifies the laboratory order. From the LOINC® database, Laboratory order concepts can be extracted by using the following filter: CLASSTYPE=1 and ORDER_OBS= order
Procedure Code	OBR-44	HL70088			HL7 Tables - Empty
Procedure Code Modifier	OBR-45	HL70340			HL7 Tables - Empty
Placer Supplemental Service Information	OBR-46	HL70411			HL7 Tables - Empty
Medically Necessary Duplicate	OBR-48	HL70476			HL7 Tables - Empty

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Procedure Reason					
Result Handling	OBR-49	HL70507	PHVS_ObservationResultHandling_HL7_2x	2.16.840.1.114222.4.11.3357	
Nature of Abnormal Test	OBX-10	HL70080	PHVS_NatureOfAbnormalTesting_HL7_2x	2.16.840.1.114222.4.11.1017	
Observation Result Status	OBX-11	HL70085	PHVS_ObservationResultStatus_HL7_2x	2.16.840.1.114222.4.11.811	
Observation Method	OBX-17	HL7 V3 Observation Method	PHVS_LabTestMethods_CDC	2.16.840.1.114222.4.11.1003	
Value Type	OBX-2	HL70125	PHVS_ValueType_ELR	2.16.840.1.114222.4.11.6064	This is the constrained value set as per the ELR IG
Laboratory Observation Identifier Value Set	OBX-3	TBD			Unique identifiers for the type of observations. Values must be drawn from LOINC. This value set is the union of the following value sets: <ul style="list-style-type: none"> • Laboratory Test Result Value Set • ELR Reportable Laboratory Observation Identifier Value Set • NHSN Lab test id value set (TBD)
Laboratory Observation Identifier Value Set	OBX-3	Laboratory Test Result Value Set	PHVS_LabTestName_CDC	2.16.840.1.114222.4.11.1002	Broader super set of all the Lab LOINC codes that could come in OBX-3. Does not include panels (n=40,000 codes)

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Laboratory Observation Identifier Value Set	OBX-3	ELR Reportable Laboratory Observation Identifier Value Set	PHVS_LabTestName_ReportableConditions	2.16.840.1.114222.4.11.6053	This includes all the LOINC codes (OBX-3) from Reportable Condition Mapping Table (RCMT). This set is a smaller subset that includes only the LOINC lab test codes related to reportable conditions (n=5569 codes)
Laboratory Coded Observation Value Set	OBX-5	TBD			Drawn from SNOMED CT. At a minimum, it will contain the SNOMED CT® Laboratory Test Finding (118246004) hierarchy and the SNOMED CT® Microorganism (264395009) sub-tree. It may also need to contain various modifiers and qualifiers as identified in PHVS_ModifierOrQualifier_CDC value set. The HITSP C80 Laboratory Observation Value Set covers only the Laboratory Test Findings portion of this value set, and really needs to be expanded to cover at least microorganisms and commonly use qualifiers and modifiers.
Laboratory Coded Observation Value Set	OBX-5	Laboratory Coded Observation Value Set	PHVS_LabTestResult_ReportableConditions	2.16.840.1.114222.4.11.6054	This includes all the SNOMED CT – codes (OBX-5) from Reportable Condition Mapping Table (RCMT). This set is a smaller subset that includes only the SNOMED CT codes related to reportable conditions (n=2402 codes) It does not contain the and commonly use qualifiers and modifiers for resulting qualitative tests.

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Laboratory Coded Observation Value Set	OBX-5	SNOMED CT® Laboratory Test Finding (118246004) hierarchy	PHVS_EvaluationFinding_CDC	2.16.840.1.114222.4.11.3359	
Laboratory Coded Observation Value Set	OBX-5	SNOMED CT® Microorganism (264395009) sub-tree	PHVS_Microorganism_CDC	2.16.840.1.114222.4.11.1009	
Laboratory Coded Observation Value Set	OBX-5	PHVS_ModifierOrQualifier_CDC	PHVS_ModifierOrQualifier_CDC	2.16.840.1.114222.4.11.1014	
Units	OBX-6	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Abnormal Flags	OBX-8	ELR- HL70078 (2.7)	PHVS_AbnormalFlag_HL7_27	2.16.840.1.114222.4.11.3343	
Order Control	ORC-1	HL70119	PHVS_OrderControlCodes_HL7_2x	2.16.840.1.114222.4.11.923	
Confidentiality Code	ORC-28	HL70177	PHVS_ConfidentialityCode_HL7_2x	2.16.840.1.114222.4.11.976	
Order Type	ORC-29	HL70482	PHVS_OrderType_HL7_2x	2.16.840.1.114222.4.11.3354	
Enterer Authorization Mode	ORC-30	HL70483	PHVS_AuthorizationMode_HL7_2x	2.16.840.1.114222.4.11.3355	
Order Status	ORC-5	HL70038	PHVS_OrderStatus_HL7_2x	2.16.840.1.114222.4.11.1025	
Response Flag	ORC-6	HL70121	PHVS_ResponseFlag_HL7_2x	2.16.840.1.114222.4.11.1023	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Race	PID-10	HL70005	PHVS_Race_HL7_2x	2.16.840.1.114222.4.11.6065	
Primary Language	PID-15	PHVS_Language_ISO_639-2_Alpha3	PHVS_Language_ISO_639-2_Alpha3	2.16.840.1.114222.4.11.831	
Marital Status	PID-16	HL70002	PHVS_MaritalStatus_HL7_2x	2.16.840.1.114222.4.11.809	
Religion	PID-17	HL70006	PHVS_Religion_HL7_2x	2.16.840.1.114222.4.11.814	
Ethnic Group	PID-22	HL70189	PHVS_EthnicGroup_HL7_2x	2.16.840.1.114222.4.11.6066	
Multiple Birth Indicator	PID-24	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Citizenship	PID-26	HL70171	PHVS_BirthCountry_CDC	PHVS_BirthCountry_CD C	
Veterans Military Status	PID-27	HL70172			HL7 Tables - Empty
Patient Death Indicator	PID-30	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Identity Unknown Indicator	PID-31	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Identity Reliability Code	PID-32	HL70445	PHVS_IdentityReliabilityCode_HL7_2x	2.16.840.1.114222.4.11.1000	
Species Code	PID-35	PHVS_Animal_CDC	PHVS_Animal_CDC	2.16.840.1.114222.4.11.1074	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Production Class Code	PID-38	HL70429	PHVS_ProductionClass_HL7_2x	2.16.840.1.114222.4.11.812	
Tribal Citizenship	PID-39	TBD			HL7 recommends using Bureau of Indian Affairs (BIA) Tribal Identity List. The following is a link to the current live list: http://www.usa.gov/Government/Tribal_Sites/index.shtml This is a link to the most recent official static list: http://edocket.access.gpo.gov/2008/E8-6968.htm
Administrative Sex	PID-8	HL70001	PHVS_AdministrativeSex_HL7_2x	2.16.840.1.114222.4.11.927	
Location Status	PL.5	HL70306			HL7 Tables - Empty
Person Location Type	PL.6	PH_HealthcareService Loc_HL7_V3	NHSNHealthcareServiceLocationCode	2.16.840.1.113883.13.19	
Building	PL.7	HL70307			HL7 Tables - Empty
Floor	PL.8	HL70308			HL7 Tables - Empty
Processing ID	PT.1	HL70103	PHVS_ProcessingID_HL7_2x	2.16.840.1.114222.4.11.1028	
Processing Mode	PT.2	HL70207	PHVS_ProcessingMode_HL7_2x	2.16.840.1.114222.4.11.1029	
Preadmit Test Indicator	PV1-12	HL70087			HL7 Tables - Empty
Admit Source	PV1-14	HL70023	PHVS_AdmitSource_HL7_2x	2.16.840.1.114222.4.11.918	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Patient Type	PV1-18	HL70018			HL7 Tables - Empty
Patient Class	PV1-2	HL70004	PHVS_PatientClass_HL7_2x	2.16.840.1.114222.4.11.917	
Bad Debt Agency Code	PV1-31	HL70021			HL7 Tables - Empty
Delete Account Indicator	PV1-34	HL70111			HL7 Tables - Empty
Discharge Disposition	PV1-36	HL70112	PHVS_DischargeDisposition_HL7_2x	2.16.840.1.114222.4.11.915	
Diet Type	PV1-38	HL70114			HL7 Tables - Empty
Servicing Facility	PV1-39	HL70115			HL7 Tables - Empty
Admission Type	PV1-4	Admission Type Value Set	PHVS_AdmissionType_HL7_2x	2.16.840.1.114222.4.11.913	
Account Status	PV1-41	HL70117			HL7 Tables - Empty
Visit Indicator	PV1-51	HL70326	PHVS_VisitIndicator_HL7_2x	2.16.840.1.114222.4.11.3348	
Employment Illness Related Indicator	PV2-15	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Admission Level of Care Code	PV2-40	HL70432	PHVS_AdmissionLevelOfCareCode_HL7_2x	2.16.840.1.114222.4.11.912	
Specimen Collection Site	SPM-10	HL70543			HL7 Tables - Empty

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Specimen Role	SPM-11	HL70369	PHVS_SpecimenRole_CDC	2.16.840.1.114222.4.11.1046	
Specimen Collection Amount	SPM-12	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Specimen Handling Code	SPM-15	HL70376	PHVS_EntityHandling_CDC	2.16.840.1.114222.4.11.990	
Specimen Risk Code	SPM-16	HL70489	PHVS_RiskCodes_HL7_2x	2.16.840.1.114222.4.11.3356	
Specimen Availability	SPM-20	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Specimen Reject Reason	SPM-21	HL70490	PHVS_SpecimenRejectReason_HL7_2x	2.16.840.1.114222.4.11.1044	
Specimen Quality	SPM-22	HL70491	PHVS_SpecimenQuality_HL7_2x	2.16.840.1.114222.4.11.1043	
Specimen Appropriateness	SPM-23	HL70492	PHVS_SpecimenAppropriateness_HL7_2x	2.16.840.1.114222.4.11.1039	
Specimen Condition	SPM-24	HL70493	PHVS_SpecimenCondition_CDC	2.16.840.1.114222.4.11.1042	
Specimen Current Quantity	SPM-25	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Container Condition	SPM-28	HL70544			HL7 Tables - Empty
Specimen Child Role	SPM-29	HL70494	PHVS_SpecimenChildRole_HL7_2x	2.16.840.1.114222.4.11.1040	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Specimen Type	SPM-4	TBD			Union of HL70487 and SNOMED CT Specimen sub-tree (12303009)
Specimen Type	SPM-4	HL70487 (Specimen Type Value Set)	PHVS_SpecimenType_HL7_2x	2.16.840.1.114222.4.11.6046	
Specimen Type	SPM-4	SNOMED CT Specimen sub-tree (12303009)	PHVS_Specimen_CDC	2.16.840.1.114222.4.11.946	
Specimen Type Modifier	SPM-5	PHVS_ModifierOrQualifier_CDC	PHVS_ModifierOrQualifier_CDC	2.16.840.1.114222.4.11.1014	
Specimen Additives	SPM-6	HL70371	PHVS_AdditiveOrPreservative_HL7_2x	2.16.840.1.114222.4.11.960	
Specimen Collection Method	SPM-7	TBD			Specimen Collection Method. Union of HL7 Table 0488 and SNOMED CT Specimen Collection (17636008) sub-tree.
Specimen Collection Method	SPM-7	HL70488 (Specimen Collection Method Value Set)	PHVS_SpecimenCollectionMethod_HL7_2x	2.16.840.1.114222.4.11.1041	
Specimen Collection Method	SPM-7	SNOMED CT Specimen Collection (17636008) sub-tree	PHVS_SpecimenCollectionMethod_CD C	2.16.840.1.114222.4.11.3282	
Specimen Source Site	SPM-8	Body Site Value Set	PHVS_BodySite_HITSP	2.16.840.1.113883.3.88.12.3221.8.9	
Specimen Source Site Modifier	SPM-9	PHVS_ModifierOrQualifier_CDC	PHVS_ModifierOrQualifier_CDC	2.16.840.1.114222.4.11.1014	
Conjunction	TQ1-12	HL70472	PHVS_TQConjunctionID_HL7_2x	2.16.840.1.114222.4.11.3353	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Occurrence duration	TQ1-13	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Quantity	TQ1-2	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Service Duration	TQ1-5	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Relative Time and Units	TQ1-6	Unified Code for Units of Measure (UCUM)	PHVS_UnitsOfMeasure_CDC	2.16.840.1.114222.4.11.838	
Priority	TQ1-9	HL70485	PHVS_ExtendedPriorityCodes_HL7_2x	2.16.840.1.114222.4.11.1024	
Version ID	VID.1	HL70104	PHVS_VersionID_HL7_2x	2.16.840.1.114222.4.11.3342	
International ization Code	VID.2	Country Value Set	PHVS_Country_ISO_3166-1	2.16.840.1.114222.4.11.828	
Census Tract	XAD.10	HL70288			Need to get the Census Tract codes from Census Website - http://www.census.gov/geo/www/tractez.html
State or Province	XAD.4	State Value Set	PHVS_State_FIPS_5-2	2.16.840.1.114222.4.11.830	
Zip or Postal Code	XAD.5	Postal Code Value Set			Zipcodes need to be downloaded from USPS website.
Country	XAD.6	Country Value Set	PHVS_Country_ISO_3166-1	2.16.840.1.114222.4.11.828	
Address Type	XAD.7	HL70190	PHVS_AddressType_HL7_2x	2.16.840.1.114222.4.11.801	
County/Parish Code	XAD.9	PHVS_County_FIPS_6-4	PHVS_County_FIPS_6-4	2.16.840.1.114222.4.11.829	

ELR Implementation Guide information regarding coded data elements and value sets			CDC Vocabulary Server - PHIN VADS Information about value sets		
Data Element Name from ELR IG	HL7 Segment - Field	Value Set information from ELR IG	PHIN VADS Value Set Name	PHIN VADS Value Set OID	Comments
Name Type Code	XCN.10	HL70200	PHVS_NameType_HL7_2x	2.16.840.1.114222.4.11.810	
Check Digit Scheme	XCN.12	HL70061	PHVS_CheckDigitScheme_HL7_2x	2.16.840.1.114222.4.11.3339	
Name Representation Code	XCN.15	HL70465	PHVS_NameAddressRepresentation_HL7_2x	2.16.840.1.114222.4.11.3352	
Name Context	XCN-16	HL70448			HL7 Tables - Empty
Name Assembly Order	XCN-18	HL70444	PHVS_NameAssemblyOrder_HL7_2x	2.16.840.1.114222.4.11.3351	
Source Table	XCN-8	HL70297			HL7 Tables - Empty
Organization Name Type Code	XON-2	HL70204	PHVS_TypeOfOrganizationalNameType_HL7_2x	2.16.840.1.114222.4.11.3346	
Telecommunication Use Code	XTN-2	HL70201	PHVS_TelecommunicationUseCode_HL7_2x	2.16.840.1.114222.4.11.818	
Telecommunication Equipment Type	XTN-3	HL70202	PHVS_TelecommunicationEquipmentType_HL7_2x	2.16.840.1.114222.4.11.817	

Section 6: NIST Tool Implementation Decisions

This section documents the implementation decisions made during the creation of the NIST Technical Certification testing tool.

Decision Number	Message Element	Description	Decision
NIST_ELR-1	Message	There are four profiles in the ELR IG, but only the ELR Receiver Usage Profile is normative and in use.	Support only the ELR Receiver Usage Profile
NIST_ELR-2	MSH-7 SFT-6 PID-7 PID-29 PID-33 PV1-44 PV1-45 OBR-7 OBR-8 OBR-22 OBX-14 OBX-19 SPM-17.1 SPM-17.2 SPM-18	Time zone offset is strongly recommended but not required for all timestamps except for MSH.7 and OBR.22. Per HL7 standard use MSH.7 as default timestamp for all other timestamps where timestamp not provided.	For Context-based test messages the Time zone offset in MSH.7 will be "-0500" Other timezone offset in message will be Test Story based. Therefore the timezones offset may not match in these messages. NIST tool will test for content but not validate content for consistency.
NIST_ELR-3	ORC OBSERVATION Group Begin SPECIMEN Group Begin MSH-15 MSH-16 PID-34 NK1-2 NK1-13 NK1-30 ORC-2 ORC-12 ORC-14 OBR-8 OBR-26 OBR-29	All conditional elements in the ELR IG were listed as CE. CE as defined by the HL7 2.5.1 standard is C(RE/X) 1. In many cases, this contradicts the comments in the ELR IG.	The Conditional usage was based on the ELR IG text and represented and implemented based upon the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5)1. If no guidance was given when the predicate was not met, the usage followed the base standard , i.e. "X" Not Supported. This is reflected in Section 1 above.

Decision Number	Message Element	Description	Decision
	OBX-2 OBX-4 OBX-5 OBX-6 OBX-8 OBX-14 CNN.10 CNN.11 NONOBX5_CWE.2 NONOBX5_CWE.3 NONOBX5_CWE.5 NONOBX5_CWE.6 NONOBX5_CWE.9 OBX-5.6 XCN.9 XCN.13 XON.1 XON.6 XON.7 XTN.4 XTN.5 XTN.6 XTN.7 XTN.8		
NIST_ELR-4	OBR-26 OBR-29 OBX-14 ORC SPECIMEN Group Begin	Several Conditional Predicates in the ELR IG were not testable based on information available in the message.	The NIST tool Treats these elements as conforming to the Usage RE. This is reflected in the tables in Section 1 by the entry "N/A".
NIST_ELR-5	Specimen Group	The Conditional usage for the Specimen Group is not testable however the Specimen group is required in the message.	A conformance statement was created to require that at least one Specimen group is present in the message.
NIST_ELR-6	PID-10 (Race)	The ELR IG defines HL70005 as a value set for Race, however this value set is identical to and derived from the CDCREC value set.	For the Race Value Set, the Name of Coding System can be either "CDCREC" or "HL70005".

Decision Number	Message Element	Description	Decision
NIST_ELR-7	SPM-21 (Specimen Reject Reason) PRL.2 (Parent Observation sub-identifier)	SPM.21 (Specimen Reject Reason) and PRL.2 (Parent Observation sub-identifier) is not tested for in context specific tool since not covered by any Test Story.	SPM-21 (Specimen Reject Reason) and PRL.2 (Parent Observation sub-identifier) will not be tested for in context specific tool due to scope and time constraints.
NIST_ELR-8	Parent/Child Relationship messaging	Test case scenario 4 was designed to Demonstrate ability to support a culture and susceptibilities using multiple Order_Observation groups in a parent child structure.	Limited the scenario to multiple child observations on one parent observation - did not test the parent child messaging when more than one parent result has child-observations (multiple organisms isolated and tested for antimicrobial susceptibility).
NIST_ELR-9	Reflex test messaging	Test case scenario 5 was designed to Demonstrate ability to support a reflex test – there are several valid message options at this time: Adding additional OBX segments under the same OBR Or Using a parent-child relationship linkage Or Creating a new accession	Created two message structure options for test case scenario 5: 5A – additional OBXes under the same OBR 5B – Parent-child linkage Testing procedure will need to acknowledge other valid structure possibilities.
NIST_ELR-10	SFT NTE(Notes/Comments) NK1 OBX following SPM NK1-2 (Name) NK1-4 (Address) NK1-5 (Phone Number) PID-10 (Race) ORC-23 (Ordering Facility Phone Number) PID-22 (Ethnic Group) NK1-30 (Contact Person’s Name) NK1-31 (Contact Person’s Telephone Number) NK1-32 (Contact Person’s Address) ORC-12 (Ordering Provider)	Several repeating elements listed in ELR IG are not tested for in Context-based Validation tool.	For the Context-based Validation testing, the repeats in the following elements were selected to be tested: OBR OBX PID-3 (Patient Identifier List) PID-5 (Patient Name) PID-11 (Patient Address) PID-13 (Phone Number Home) ORC-14 (Call Back Phone Number) OBR-17 (Order Callback Phone Number) PID-14 (Phone Number Business). Assumption is that if a system can support repeats in these elements then systems should be able to support repeats in others, when required by the guide. However, multiple repeats are supported

Decision Number	Message Element	Description	Decision
	ORC-24 (Ordering Provider Address)		for all fields in the Context-free Validation tool.
NIST_ELR-11	NTE(Notes/Comments) following PID NTE(Notes/Comments) following OBR NTE(Notes/Comments) following OBX	For the Context-based Validation testing tool, unable to properly validate a maximally populated message Test Story in Test Scenario 1 which would contain the NTE following PID, the NTE following OBR, and the NTE following OBX.	For the Context-based Validation testing these three occurrences of the NTE segment are present in separate test scenarios: NTE following PID -T01, NTE following OBR - T02, the NTE following OBX -T05a, T05b, T07, and T09. However, all NTE segments are supported in the Context-free Validation tool
NIST_ELR-12	CE (Coded Element)	CE datatype is supported in guide but conformance usage not defined.	At the time of publication of this document, CE data type usage has been defined as RE for all components.
NIST_ELR-13	OBR-4, OBX-3, PRL.1	Laboratory Order Value Set and Laboratory Observation identifier Value Set are marked TBD in the ELR IG. PHIN VADS provides several options for these value sets, but they are either too large to implement or too constrained.	Implementation approach for the Context-based implementation tool will be to use the constrained LOINC CODE list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation based upon the value sets.
NIST_ELR-14	OBX-5	The Laboratory Coded Observation Value Set is marked TBD in the ELR IG. PHIN VADS provides several options for this value set, but they are either too large to implement or too constrained.	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation based upon the value sets.
NIST_ELR-15	SPECIMEN/OBX-3, SPECIMEN/OBX-5	The value sets listed above and in the ELR IG for OBX-3 and OBX-5 are only for OBSERVATION/OBX content since these Value Sets are in the context of laboratory related observations. Value Sets for SPECIMEN/OBX-3 and SPECIMEN/OBX-5 have not been defined and ultimately will be an implementation decision by each jurisdiction.	At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation.

Decision Number	Message Element	Description	Decision
NIST_ELR-16	SPM-4	The Specimen Type Value Set was marked TBD in the ELR guide, but the comments describe it as a union of HL70487 and SNOMED CT from the specimen hierarchy.	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the user stories. The validation tool will validate the content of SPM.4 (Specimen Type) against both value sets in the Context-free validation.
NIST_ELR-17	SPM-7	The Specimen Collection Method Value Set was marked TBD in the ELR guide, but the comments describe it as a union of HL70488 and SNOMED CT from the specimen collection hierarchy	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the Test Stories. The validation tool will validate the content of SPM.7 (Specimen Collection Method) against both value sets in the Context-free validation.
NIST_ELR-18	OBX-5, SPM-5, SPM-9	The PHVS_ModifierOrQualifier_CDC Value Set is too large to be implemented.	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation based upon the value sets.
NIST_ELR-19	PID-25	The PHVS_Animal_CDC Value Set is too large to be implemented.	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation based upon the value sets.
NIST_ELR-20	OBR-31	PHINVADS does not have the "Reason for study value set", as it is identified in the guide. It does have PHVS_AdministrativeDiagnosis_CDC_ICD-9CM. No ICD10 codes in PHINVADS value sets until 2014. In addition, there are several potentially valid coding systems. for "Reason For Study Value Set" in	Implementation approach for the Context-based implementation tool will be to use the constrained list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements in the Context-free validation based upon

Decision Number	Message Element	Description	Decision
		OBR.31.3 from HL7 Table 0396 including <ul style="list-style-type: none"> • I10 = ICD-10 • I9 = ICD9 • I9C = ICD-9CM I9CDX = ICD9CM Diagnosis Code.	the value sets.
NIST_ELR-21	XAD.9	The PHVS_County_FIPS_6-4 Value Set is too large to be implemented.	At the time of publication of this document, the validation tool will not validate content of these elements based upon the value sets. The tool however will validate that the proper format is used (ELR-067).
NIST_ELR-22	XAD.5	The Postal Code Value Set is too large to be implemented.	At the time of publication of this document, the validation tool will not validate content of these elements based upon the value sets. The tool however will validate that the proper format is used (ELR-011).
NIST_ELR-23	Message	Pregnancy information needs to be tested to support EPI PH needs,	Not supported in tool. Needs to be addressed in the Implementation guide.
NIST_ELR-24	Message	Test case Scenario for Acute and Convalescent sera (paired Sera Results) not covered	Not supported in tool. Needs to be addressed in the Implementation guide.
NIST_ELR-25	Message	Test case Scenario for when testing lab and sending lab are different (reference or pass through testing)	Not supported in tool. Needs to be addressed in the Implementation guide.
NIST_ELR-26	Message	Snap-shot processing (prelim and final, final and corrected) test case scenarios not covered.	Not supported in tool at this time.
NIST_ELR-27	Message	Test case scenario for bi-directional messaging (ACK) not covered	Not supported in tool at this time.
NIST_ELR-28	XAD.4	PHIN VADS FIPS state Value Set, PHVS_State_FIPS_5-2_V1, contains both 2 character numeric codes in the "Concept Code" column and 2 character alpha codes in the "Preferred Alternate Code" column. Per ELR-010 above, the 2 character alpha codes shall be used.	Use ONLY the "alternate preferred code" in content validation of this Value set based on conformance statement ELR-010.

Decision Number	Message Element	Description	Decision
NIST_ELR-29	CWE.7, CWE.8	Minimum SNOMED-CT and LOINC coding system version identified in MU2 final ruling.	Validation of LOINC and SNOMED version not supported in tool.
NIST_ELR-30	PID-35, OBX-5, SPM-4, SPM-5, SPM-7, SPM-8, SPM-9	In PHIN VADS all SNOMED related Value Sets, contains both SNOMED-CT numeric "ConceptId" in the "Concept Code" column and the alphanumeric SNOMEDID in the "Preferred Alternate Code" column. Per ELR IG and MU2 final rules only SNOMED-CT shall be used. ⁹	Use ONLY the numeric "ConceptId" from the VADS "Concept Code" column when validating for SNOMED-CT content.
NIST_ELR-31	Message	How undefined elements (conformance usage = "O") are handled in when present in a test message.	The tool will validate undefined elements with respect to the base HL7 251 standard requirements including content validation. If the base standard specifies and defines a value set for a particular element then this check will be performed.
NIST_ELR-32	OBX/SPM for PID-7 = "0000"	For ELR-027: If PID-7 (Date/Time of Birth) is not valued, then an OBX segment associated with the SPM segment SHALL be present to report patient age at specimen collection.	For Context-free validation the validation tool is only checking for the presence of the SPECIMEN/OBX.
NIST_ELR-33	SPM-8	SPM-8 (Specimen Source Site) Body Site Value Set is too large to be implemented.	Implementation approach for the Context-based implementation tool will be to use the constrained SNOMED CODE list based on the Test Stories. At the time of publication of this document, the validation tool will not validate content of these elements based upon the value sets.

⁹ Each SNOMED CT Concept has a permanent unique **numeric Identifier** which is known as the ConceptId. From Section 3.1.2. Concept Identifiers SNOMED CT User Guide- July 2012 International Release (US English), (www.snomed.org/ug.pdf).

SNOMED-CT international currently has 2 release formats – RF1 and RF2. Both formats include concept identifiers (formatted as digits only) and description identifiers (formatted as digits only). ONLY the concept identifiers are allowed to be messaged. In the RF1 format, which is going to be phased out soon, the alpha numeric codes from SNOMED (before creation of SNOMED CT) are still included, as they are widely implemented to aid with cross-mapping. In RF2, which will be the only supported format going forward, those codes are no longer available. In line with the future direction of SNOMED the NIST tool will test for capability to transmit the concept identifiers when the declared code system in CWE.3 or CWE.6 is SCT. If jurisdictions allow use of alphanumeric codes, the name of the coding system should be SCT2 in CWE.3 or CWE.6 instead of SCT. Use of SNM as declared code system in CWE.3 or CWE.6 would indicate use of the SNOMED version from 1996.

Decision Number	Message Element	Description	Decision
NIST_ELR-34	OBX.4, NONOBX5_CWE.9	For these elements the conformance usage was changed from C(R/X) to C(R/RE).	These elements will not be tested for usage, when the condition is not met.
NIST_ELR-35	PID-34	For these elements the conformance usage was changed from C(R/X) to C(R/O)	This element will not be tested for usage, when the condition is not met.