

ELR 2.5.1 Clarification Document for EHR Technology Certification

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Table of Contents

Section 1: Condition Predicates..... 3

 Table 1: Condition Predicates for Data types 3

 Table 2: Condition Predicates for Segment field elements 5

 Table 3: Condition Predicates for Message Structure 7

Section 2: Conformance Statements: 8

 Table 1: Conformance Statements for Data Types: 8

 Table 2: Message Detail Conformance Statements: 9

 Table 3: Conformance Statements for the Message Structure: 17

Section 3: Clarifications of Cardinality 18

Section 4: Additional Errata identified in Guide 19

Introduction:

This supplement, “ELR 2.5.1 Clarification Document for EHR Technology Certification” 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 Implementation Guide) and its accompanying Errata and Clarifications document. The supplement does not specify additional requirements. Rather, it clarifies existing requirements given in the ELR implementation guide and the related Errata and Clarifications document.

Generally, the Implementation Guide’s scope is more comprehensive than EHR technology certification requires. Thus, the parts of the Implementation Guide (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 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.

Table 1: Condition Predicates for Data types

Data type Element	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
CNN.10	CE	"Must be an OID. ELR Condition predicate: Required if component 1 (ID Number) is populated."	If CNN.1 (Identifier) is valued.
CNN.11	CE	"ELR Condition predicate: This component is required if a value is present in component 10 (Assigning Authority – Universal ID.) Constrained to the value ‘ISO’."	If CNN.10 (Assigning Authority - Universal ID) is valued.
NONOBX5_CWE.2	CE	“It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text attribute is used to carry the text, not the text component. 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	Harmonized condition predicate: Required if an identifier is provided in component 1. See section 6 for description of the use of coding systems in this implementation guide.	If CWE.1 (Identifier) is valued.
NONOBX5_CWE.5	CE	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.

Data type Element	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
NONOBX5_CWE.6	CE	Harmonized condition predicate: Required if an alternate identifier is provided in component 4. See section 6 for description of the use of coding systems in this implementation guide.	If CWE.4 (Identifier) is valued.
NONOBX5_CWE.9	CE	1) "Either original Text is used to convey the text that was the basis for coding, or when there is no code to be sent, only free text. ELR Condition predicate: If no identifier and alternate identifier are present, then this component is required." 2) "It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text attribute is used to carry the text, not the text component."	If CWE.1 (Identifier) AND CWE.4 (alternate identifier) are not valued.
OBX5.6	CE	Harmonized condition predicate: Required if an alternate identifier is provided in component 4. See section 6 for description of the use of coding systems in this implementation guide.	IF CWE.4 (Identifier) is valued.
XCN.9	CE	The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1. 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	ELR Condition predicate. Required if component 1 (ID Number) is populated.	IF XCN.1 (ID Number) is valued.
XON.1	CE	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	"The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10. ELR & Lab to EHR Condition predicate: Required if component 10 (Organization Identifier) is populated."	IF XON.10 (ID Number) is valued.
XON.7	CE	ELR Condition predicate: Required if component 10 (Organization Identifier) is populated.	IF XON.10 (ID Number) is valued.
XTN.4	CE	ELR Condition predicate: Required if component 7 (local number) is not present. Component 4 (Email Address) must be empty if component 7 (Local Number) is present.	IF XTN.7 (local number) is not valued.
XTN.5	CE	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	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.7	CE	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	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	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
MSH-15	CE	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	Harmonized condition predicate: Required when MSH-21 profile id is PHLabReport-Ack or USLabReport, otherwise it may be empty or "NE". Refer to Error! Reference source not found. – HL7 Table 0155 – Accept/Application Acknowledgment Conditions for valid values.	If the first component (Entity Identifier) of one occurrence of MSH-21 (Message Profile Identifier) is 'PHLabReport-ACK'.
PID-34	CE	"This is the facility that originated the demographic update. ELR: Condition predicate: If PID-33 is present this is required."	IF PID.33 (Last Update Date/Time) is valued.
NK1-2	CE	"Name of the next of kin or associated party. Multiple names for the same entity are allowed, but the legal name must be sent in the first sequence. If the legal name is not sent, the repeat delimiter must be sent in the first sequence. 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	"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.
NK1-30	CE	"ELR Condition predicate: Required if NK1-13 is populated."	IF NK1.13 (Organization Name) is valued.
ORC-2	CE	"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	"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	"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."	IF OBR.17 (Order Callback Phone Number) within same Order_Observation Group is valued.
OBR-8	CE	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.	IF SPM-17.2 is valued.

Message Element	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
		ELR Condition predicate: This field must contain the same value as the second component of SPM-17 Specimen Collection Date/Time.	
OBX-2	CE	1)"This field identifies the data type used for OBX-5. Conditional statement: If OBX-5 is populated, OBX-2 is required. See Section 6.1.1.1, HL7 Table 0125 for the data types that will be supported for this field and OBX-5." 2) Table 2-2 3) Table 6-3	IF OBX.5 (Observation Value) is valued.
OBX-4	CE	"Harmonized condition predicate: Required if there is more than one OBX with the same OBX-3 Observation Identifier associated with the same OBR. Normally, this field is populated with a number, but text values may be used also."	If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 values for (OBX-3.1 and OBX-3.3) or (OBX-3.4 and OBX-3.6).
OBX-5	CE	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: Either OBX-5 or OBX-8 (Abnormal flags) must be present in the message except if OBX-11 is 'X', result cannot be obtained." 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...." 3) Table 5-13.	IF OBX.11 (Observation Result Status) is not valued 'X' AND OBX.8 (Abnormal flags) is not valued.
OBX-6	CE	1) "UCUM® is an HL7-approved code system and shall be used for units as described in the appropriate HITSP Interoperability Specification. The UCUM unit of measure for values without a unit of measure is "1". 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." 2) Table 5-13.	IF OBX.2 (Value Type) is valued 'NM' , 'SN' AND OBX.11 (Observation Result Status) is not valued 'X'.
OBX-8	CE	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: Required if OBX-5 is empty and the OBX-11 observation result status is not 'X', result cannot be obtained...." 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	IF OBX.11 (Observation Result Status) is not valued 'X' AND OBX.5 (Observation Value) is not valued.

Message Element	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
		should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL7 table 0078...." 3) Table 5-13.	

Table 3: Condition Predicates for Message Structure

Segment in Standard	Usage	Reference Text from Implementation Guide	Condition Predicate based on Text
ORC	CE	"The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc. 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."	IF OBR.16 and OBR.17 are not valued.
OBSERVATION Group Begin	CE	1) "Multiple results may be associated with an order. There will always be a single OBX in the results group. Snapshot processing: Since the OBX segment in 2.5.1 does not contain a unique instance identifier, it is assumed that the repeating observation group will contain a complete set of observations (OBXs) associated with the OBR. Where a single OBX is being updated, all the OBXs related to the OBR must accompany the updated OBX, i.e., a full snapshot is sent. Harmonized condition predicate: May be empty for OBR-25 Result statuses of "O," "I," "S" and "X"; otherwise, it is required." 2) HL7 Table 0123	OBSERVATION Group Begin: Condition Predicate: IF OBR.25 (Result Status) is valued "A", "C", "F", "P", or "R".

Section 2: Conformance Statements:

This section is intended to list explicitly the conformance statements for ELR that are described the text body, table description, and other sections of the ELR guide. It is divided up into three tables that cover the data types, segment field elements and message structure elements respectively. 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 Implementation Guide	Conformance Statement based on Text
ST, TX, FT.	"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."	ELR-001: "ELR-XXX: The ST, TX, FT Data types Shall support only the following escape sequences: \F field separator " " \S component separator "^" \T subcomponent separator "&" \R repetition separator "~" \E escape character "\"
CNN.10	"Must be an OID. ELR Condition predicate: Required if component 1 (ID Number) is populated."	ELR-002: CNN.10 (Assigning Authority - Universal ID) SHALL be valued with an ISO-compliant OID.
CNN.11	"ELR Condition predicate: This component is required if a value is present in component 10 (Assigning Authority – Universal ID.) Constrained to the value 'ISO'."	ELR-003: CNN.11 (Assigning Authority - Universal ID Type) SHALL contain the value "ISO".
EI.3	Must be an OID.	ELR-004: EI.3 (Universal ID) SHALL be valued with an ISO-compliant OID.
EI.4	"Constrained to the value 'ISO'."	ELR-005: EI.4 (Universal ID Type) SHALL contain the value "ISO".
HD.2	"Must be an OID except for ELR Receiver for MSH-3 where a CLIA identifier is allowed."	ELR-006: HD.2 (Universal ID) IF element is MSH-4.2 (Universal ID) , then HD.2 (Universal ID) SHALL be valued with an ISO-compliant OID OR CLIA identifier, ELSE HD.2 (Universal ID) SHALL be valued with an ISO-compliant OID.

Datatype Element	Reference Text from Implementation Guide	Conformance Statement based on Text
HD.3	"Constrained to the value 'ISO' except for ELR Receiver for MSH-4 where the value 'CLIA' is allowed."	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 "OID" OR "CLIA", ELSE HD.3 (Universal ID type) SHALL contain the value "ISO"
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.

Table 2: Message Detail Conformance Statements:

Message Element	Reference Text from Implementation Guide	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'

Message Element	Reference Text from Implementation Guide	Conformance Statement based on Text
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'
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 the constant value '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 Implementation Guide	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	"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] <u>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.</u> "	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	Table:3-5	ELR-034: ORC-1 (Order Control) SHALL contain the constant value 'RE'.

Message Element	Reference Text from Implementation Guide	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 Implementation Guide	Conformance Statement based on Text
OBR-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-7	<p>"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". <u>If the SPM is sent, this field must contain the same value as the first component of SPM-17 Specimen Collection Date/Time.</u> 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" "</p>	<p>ELR-042: OBR-7 (Observation Date/Time) SHALL be the identical to SPM-17.1 (Range Start Date/Time) value if SPM segment present within the same Order_Observation Group.</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 "<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: YYYYMMDD[HH[MM[SS[S[S[S[S]]]]]]]]+/-ZZZZ ^YYYYMMDD[HH[MM[SS[S[S[S[S]]]]]]]]+/-ZZZZ </u> "</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-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: <u>This field must contain the same value as the second component of SPM-17 Specimen Collection Date/Time.</u>" 2) From SPM.17.2 "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-044: OBR-8 (Observation End Date/Time) SHALL be the identical to SPM-17.2 (Range End Date/Time) value if SPM segment present within the same Order_Observation Group.</p>

Message Element	Reference Text from Implementation Guide	Conformance Statement based on Text
OBR-16	"Identifier of the provider who ordered the testing being performed. The National Provider Identifier (NPI) may be used as the identifier. Note that ORC-12 Ordering Provider is constrained to contain the same value as this field."	ELR-045: OBR-16 (Ordering Provider) SHALL be the same value as ORC-12 (Ordering Provider) within the same Order_Observation Group.
OBR-17	"This is the number the laboratory can call with questions regarding the order. This should be a phone number associated with the original order placer. Note that ORC.14 Call Back Phone Number is constrained to contain the same value as this field."	ELR-046: OBR-17 (Order Callback Phone Number) SHALL be the same value as ORC-14 (Call Back Phone Number) within the same Order_Observation Group.
OBR-22	"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"	ELR-047: OBR-22 (Results Rpt/Status Chng - Date/Time) SHALL follow the format YYYYMMDDHHMM[SS.SSS]+/-ZZZZ.
OBX-1	"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."	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). OBX.1 (Set ID – OBX) SHALL be valued sequentially starting with the value '1' within a given Specimen Group (OBX following the SPM).
OBX-14	"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>	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.

Message Element	Reference Text from Implementation Guide	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-050: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), SHALL be the identical to SPM-17.1 (Range Start Date/Time) value if SPM segment present within the same Order_Observation Group.</p>
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 NTE segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc." 2) "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>

Message Element	Reference Text from Implementation Guide	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. 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> <u> YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ]^YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ] "</u></p>	<p>ELR-055: SPM-17.1 (Range Start Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ] OR contain the value "0000" when the collection date/time is unknown..</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. <u>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]]]]]]][+/-ZZZ]^YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ] "</u></p>	<p>ELR-056: SPM-17.1 (Range Start Date/Time) SHALL be identical to all OBX-14 (Date/Time of Observation) values for observation related to testing of specimen (OBX's following the OBR) within the same Order_Observaton Group.</p>
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: <u> YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ]^YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZ] "</u></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_Observaton Group.</p>

Message Element	Reference Text from Implementation Guide	Conformance Statement based on Text
SPM-17.2	"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: YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZZ]^YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZZ] "</u>	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".
SPM-17.2	"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] "	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.
SPM-18	"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>	ELR-060: SPM-18 (Specimen Received Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS.S[S[S[S]]]]]]][+/-ZZZZ].

Table 3: Conformance Statements for the Message Structure:

Segment in Standard	Reference Text from Implementation Guide	Conformance Statement based on Text
message processing	"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. "	ELR-061: Only Snapshot processing SHALL be supported

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 Implementation Guide	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]]]]]]][+/-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	Description	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 Guide

There are additional errata identified in the guide. 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.”