Health Level Seven (HL7) 2.5.1 Specifications for Electronic Laboratory Based Reporting

Guideline for Implementation

Oct 9, 2015

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Document Summary

This document is a guide for the implementation of electronic communication of reportable information from laboratories to the Florida Department of Health (FLDOH), in accordance with Rule 64D-3, Florida Administrative Code. This FLDOH standard is a supplement to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) – February, 2010 with errata (September, 2011).Health Level 7 (HL7) is an accredited and nationally recognized standard of electronic data exchange in healthcare environments, which allows for communication between separate and different types of information systems. The HL7 2.5.1 Standard contains the order and structure of data fields in detail and the HL7 2.5.1 Implementation Guide contains constraints specific to public health reporting and focuses on one type of HL7 Message, the HL7 V2.5.1 ORU^R01 Message. This guide contains FLDOH constraints and exceptions to the HL7 implementation guide as well as additional requirements specific to FLDOH to support electronic interchange of laboratory results of reportable diseases/conditions in the State of Florida.

For sharing laboratory-based reports of Florida public health findings; three coding systems are required by the Florida Department of Health:

1) Logical Observation Identifiers Names and Codes (LOINC®) for laboratory procedure (test) codes/names and laboratory order codes/names.

- LOINC® code databases and value sets can be obtained from the Regenstrief Institute at (www.regenstrief.org). These LOINC® codes facilitate exchange of results and are universal identifiers for laboratory and other clinical observations.

2) Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®) for description of findings, notably organism names, discrete result values, and the description of Specimen sources.

3) Unified Code for Units of Measure (UCUM®) for units of quantitative laboratory results.

Laboratories sending ELR messages to the Florida Department of Health will be required to translate their local code tables to standards codes from these coding systems prior or during testing for acceptance. The most current version of LOINC and SNOMED codes should be used for this translation.

Laboratories unable to meet the HL7 2.5.1 standards at the time of implementation are not exempt from sending HL7 messages for ELR reporting. The FLDOH utilizes an interface engine capable of accepting other versions of HL7. The FLDOH specific requirements defined in this guide can be followed in lower HL7 versions. Exceptions to these requirements will be reviewed on a case by case basis.

For those labs seeking Meaningful Use certification, the HL7 2.5.1 standard is the required messaging format. There are no exceptions to this requirement.

Laboratories are encouraged to use the ELR HL7 V2.5.1 Validation Tool to validate message format and some content requirements at the start of an implementation project. FLDOH will provide feedback on errors generated by the tool; however most errors can be cleared by following the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health formatting rules. The tool can be found at *http://hl7v2-elr-testing.nist.gov/mu-elr/.*

1. Introduction

1.1 Background

Monitoring the occurrence of disease is a cornerstone of public health and is aligned with the mission of the Florida Department of Health. This monitoring, referred to as public health surveillance, can be used to trigger case or outbreak investigations, follow trends, evaluate the effect of prevention measures such as immunizations, and suggest public health priorities. Because disease occurrence and disease trends have the potential to shift rapidly, especially with infectious diseases, surveillance needs to be ongoing, timely, and complete.

The Florida Department of Health has requirements for laboratories to report certain findings to health officials. These requirements are outlined in Rule 64D-3, Florida Administrative Code. With the increasing capacity of laboratories to leverage technology, it is now possible for laboratories to send reportable disease data electronically to the Florida Department of Health. F.A.C. 64D-3 requires laboratories to submit results electronically in Health Level Seven (HL7) messaging format or ASCII delimited flat files, which reflect comparable content to HL7 version 2.5.1 utilized by DOH.

1.2 Scope

This Florida Department of Health specification guide should not be used as a tutorial for either HL7 or electronic interfaces, in general. The reader and laboratory trading partners are expected to have a basic understanding of interface concepts, HL7, and electronic laboratory-based reporting of public health information. This guide is an implementation guide, based on the final release of HL7 version 2.5.1. DOH defined variations from the HL7 standard, are clearly described and clarification of content expectation for the attributes is outlined for participating trading partners.

Please note: ELR does not remove the requirement to report by telephone those diseases with notification timeframes of Suspect Immediately and Immediately in the Table of Reportable Diseases or Conditions to Be Reported (see pages 9-18 in *Laboratory Reporting Guidelines for Reportable Diseases and Conditions in Florida*).

1.3 Contact

Laboratories should contact the DOH ELR Business Analyst for enrollment information and guidelines to begin the process of meeting this standard in the shortest possible timeframe. Please visit http://floridahealth.gov/meaningfuluse for information on Meaningful Use for ELR.

ELR Business Analyst
Bureau of Epidemiology
Florida Department of Health
4052 Bald Cypress Way, Bin A-12
Tallahassee, FL 32399-1708
DLFDOHReportableLabResultsInquiry@flhealth.gov

2. Definitions

The specifications presented in this guide were developed using HL7 Version 2.5.1

2.1 Message Structure Definitions

Message: A message is the entire unit of data transferred between systems in a single transmission. It is a series of segments in a defined sequence, with a message type and a trigger event.

Segment: A segment is a logical grouping of data fields. Segments within a defined message may be required or optional, may occur only once, or may be allowed to repeat. Each segment is named and is identified by a segment ID, a unique three-character code.

Field: A field is a string of characters. Each field is identified by the segment it is in and the position within the segment (e.g., PID-5 is the fifth field of the PID segment). Optional data fields need not be valued.

Component: A component is one of a logical grouping of items that comprise the contents of a coded or composite field. Within a field having several components, not all components are required to be valued, and some components may be ignored. A component may, in turn, be logically grouped into subcomponents.

Message Syntax: The abstract message is defined in special notation that lists the three letter segment identifiers in the order they will appear in the message. Braces ("{" and "}") indicate that one or more of the enclosed group of segments may repeat. Brackets ("[" and "]" indicate that the enclosed group of segments is optional.

Delimiters: The delimiters to be used for laboratory messages are as follows: "<CR>" – Segment Terminator; "|" – Field Separator; "^" – Component Separator; "&" – Sub-Component Separator; "~" – Repetition Separator; and "\" – Escape Character (see section 1.5 Use of Escape Sequences in Text Fields). Any trailing delimiters found after the last field in a segment, while not accepted, will not cause any errors in the receiving application.

2.2 Message Construction Rules

a. Components, subcomponents, or repetitions that are not valued at the end of a field do not need to be represented by separators.

b. If a data segment that is expected is not included, it will be treated as if all data fields within the segment were not present.

c. If a data segment is included that was not expected, it will be ignored and will not generate an error.

d. If unexpected data fields are found at the end of a data segment, they will be ignored and will not generate an error.

e. Filler values such as “XXX” should be avoided in any field.

f. Exceeding the length of a field/component/subcomponent as listed in the HL7 implementation guide will not generate an error. Exceptions to length requirements should be discussed with FLDOH and agreed prior to implementation.

g. **Lab Result data types shall be restricted to Coded with Exceptions ‘CWE’ for qualitative results and Structured Numeric ‘SN’ for quantitative results.** FLDOH receives ELR from many different facilities that use many different software types and versions. It is impossible to program for all variations found in textual results.

h. Standard vocabulary is required. Such vocabulary coding systems include:

    a. LOINC – Logical Observation Identifiers Names and Codes

    b. SNOMED – Systemized Nomenclature of Medicine

    c. UCUM – Unified Code for Units of Measure

i. Notes or associated result information should be sent in NTE segments not CWE segments. This is to include amplifying information, nurse’s notes, etc.

j. Messages are constrained to include only one patient per message. A message containing more than one PID segment will be rejected.

k. The order group is required and can repeat. This means that multiple ordered tests may be performed on a specimen. FLDOH expects that **each** OBR/OBX grouping must include a single SPM segment.

l. Snapshot processing of the result message involves processing as a snapshot all the repeats of the ORDER_OBSERVATION group together as a group. This is especially important when dealing with parent/child results (such as cultures and sensitivities) which will span multiple ORDER_OBSERVATION groups. All these must be processed from both a message sender and message receiver perspective as a single snapshot.

m. Parent / Child result matching is critical to message processing within FLDOH surveillance systems. Particular attention must be paid to formatting requirements described in section 3.2.8.1 *Additional discussion on OBR Segment (26) - Parent Result* and section 3.2.9.1 *Additional discussion on OBX Segment (4) - Observation Sub-ID*.

n. Multiple results may be associated with an order. There will always be a single OBX in the results group.

o. Additional Clinical information such as Pregnancy Status, Onset Date of Illness, Symptoms, etc. may be sent in an OBR/OBX grouping at the end of a message. Since the actual clinical information may be in the form of a data or string text (TX or ST), these OBX will be the only exception to rule g. and i. above. It must be stated again that

lab result information and general notes concerning the lab test should be sent in an NTE segment. Clinical information OBR/OBX groupings must be discussed and agreed upon prior to implementation.

p. RE fields are required, but can be empty if the information is not known. Conformant systems are required to be able to send this information.

q. Batch processing **will be** utilized. Please refer to Table 3-4 in the HL7 Version 2.5.1 IG: Electronic Lab Reporting to Public Health, R1 (US Realm) for Batch Message definition.

r. Preliminary results (P), final results (F), and corrected results (C) are required to be sent by FLDOH and should be properly documented in [OBX-11] (Observation Result Status). Proper serialization must be followed, i.e. a final result cannot precede a preliminary result, and only a corrected result can succeed a final result.

s. Every message must contain one and only one ORC segment and it should precede the first OBR/OBX/SPM group.

t. Acknowledgement messages will not be sent from FLDOH.

u. PD1, TQ1, TQ2, CTD, FTI, and CTI segments are not required by the State of Florida and will be ignored if sent by trading partner. If any of these segments are sent, the segments should be properly formed as described by the normative content. (Please see Table 4-1 in the HL7 implementation guide)

v. [MSH-11] (Processing ID) The value “P” (Production) shall be included when coming from the trading partner’s production system. The value “T” (Training) should be included with coming from the trading partner’s test system. Note: Testing or Training messages should not be sent via a feed that routed to the FLDOH production system.

w. It is expected that ELR will include lab reports for tests performed both in-house and by reference lab facilities with the performing organization appropriately documented in the ELR message. If you are unable to appropriately format the lab results or document the performing organization in the ELR message for those labs sent to reference labs, continuance of paper lab reporting of these lab results will be expected.

x. Data types to be used within ELR messages sent to FLDOH are defined in the HL7 Version 2.5.1 IG: Electronic Lab Reporting to Public Health, R1 (US Realm).

3. Unsolicited Observation Message

Laboratory information is reported through the Observation Report – Unsolicited (ORU) message to public health agencies using event R01. The ORU^R01 message structure required by the Florida Department of Health is outlined below.

3.1 FLDOH required ORU Message Structure

Using the basic "building blocks" of PID, OBR, and OBX segments (in bold type below), a clinical report can be constructed as a three-level hierarchy with the patient information (PID) segment at the upper level, an order record (OBR) at the next level, and one or more observation records (OBX) at the bottom. Note: all segments except the PD1, PV2, TQ1, NTE, and OBX associated with the SPM are required segments on the FLDOH message.

MSH Message Header
{SFT} Software Segment
PID Patient Identification
[PD1] Additional Demographics
[{NTE}] Notes and Comments related to the PID only
{NK1} Next of Kin/Employer/Guardian/ other Associated Parties
PV1 Patient Visit
[PV2] Patient Visit – Additional Information
{*ORDER_OBSERVATION Begin*
[ORC] Order Common
OBR Observations Request
[{NTE}] Notes and Comments related to the OBR
{OBSERVATION *Begin*
OBX Observation related to OBR
[{NTE}] Notes and Comments related to the OBX
} *OBSERVATION Ends*
SPM Specimen Information related to the OBR
[{OBX}] Observation related to Specimen
} *ORDER_ OBSERVATION End*

Messages with data populating non-required fields will not be rejected by the FLDOH interface broker. There is no further discussion of these non-required segments in this implementation guide.

The following deviations from the HL7 Standard Version 2.5.1 message syntax should be noted:

ORU Segment	HL7 Standard Version 2.5.1	FLDOH Laboratory-Based Reporting
Software Segment	Optional Repeating	Repeating
Patient Result Group	Repeating	Single instance
Patient Group	Optional within the Patient Result Group	Required within the Patient Result Group

NK1	Optional Repeating	Repeating
PV1	Optional	Required
ORC	Single Instance Optional within Order Observation Group	Single Instance Required within Order Observation Group. ORC is only contained in the first Order Observation Group
Timing_QTY group	Optional Repeating	Not required for FLDOH, not expected
Observation Group	Repeating Optional within Order Observation	Repeating Required within Order Observation
OBX	Repeating Optional within OBR	Repeating Required within OBR
FTI	Repeating Optional within Order Observation	Not required for FLDOH, not expected
CTI	Repeating Optional within Order Observation	Not required for FLDOH, not expected
DSC	Optional	Not required for FLDOH, not expected

3.2 FLDOH specific Segment Mapping

FLDOH specific requirements, constraints, and exceptions to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, are listed below.

Note: Segments, fields, and data elements not specifically mentioned in this guide, but required by the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, are still required as defined in the HL7 2.5.1 guide.

3.2.1 MSH segment - Message Header Segment

The Message Header Segment (MSH) contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.

The following are FLDOH specific MSH field requirements:

MSH Field	FLDOH Requirement
MSH-3: Sending Application	The Sending application Name must be the name of the sending application of the FLDOH ELR trading partner. MSH-3.2 should be the sending application OID and MSH-3.3 should be 'ISO.
MSH-4: Sending Facility	The Sending Facility Name must be the text name of the sending lab. The Sending Facility ID must be the CLIA number of the sending lab. The Sending Facility ID Type must be "CLIA ", indicating that the universal ID is a nationally assigned unique identifier. The Department uses the CLIA to map to a standard Name, Address and Phone number for each facility

MSH-5: Receiving Application	The Receiving Application must be "FDOH-ELR^2.16.840.1.114222.4.3.3.8.1.3^ISO".
MSH-6: Receiving Facility	The Receiving Facility must be "FDOH^2.16.840.1.114222.1.3645^ISO".

3.2.2 SFT Segment – Software

The software segment provides information about the sending application or other applications that manipulate the message before the receiving application processes the message. The Laboratory Result Sender actor is required to populate the first SFT segment.

3.2.3 PID Segment – Patient Identification

The PID segment is used as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that is not likely to change frequently.

FLDOH requires the following patient identifying and demographic information in the PID segment:

FLDOH Required Patient Data	HL7 field comments
First name, Last name and Middle initial	PID-5: The Name Type Code (PID-5.7) should always be "L", indicating a legal name.
Address including street, city, state and zip code	PID-11: State or Province field should have a value consistent with the USPS two character State designations. Zip or Postal Code field should have a value consistent with the USPS five digit codes
Phone number, including area code	PID-13: Follow XTN Data type definition; equipment type PID-13.3 required along with components for phone number. This field may also be used to send patient e-mail address in a separate repeat.
Date of Birth	PID-7: Use the abbreviated Timestamp format YYYYMMDD
Gender	PID-8: Gender code from HL7 table 0001. IF the patient's Sex is not available, use "U" to denote sex is unknown
Race	PID-10: Race code from HL7 table 0005. IF the patient's Race is not available, use "U" to denote Race is unknown
Ethnicity (Hispanic/non-Hispanic)	PID-22: Ethnic Group from HL7 table 0189. IF the patient's Ethnicity is not available, use "U" to denote Ethnicity is unknown
Social Security Number	PID-3: repeat with SS as the ID type code
Medical Record Number	PID-3: repeat with MR as the ID type code

3.2.4 NK1 Segment – Next of Kin / Employer

The NK1 segment is used as the primary means of documenting the next of kin of the patient. This is particularly important for lead testing of minors, since the NK1 is used to document information about the parent or guardian. This is also where the employment information for the patient is documented. For animal patients, the NK1 documents the person or organization that owns or is responsible for the animal.

FLDOH requires that any contact information as described above be sent in NK1 segments as in the format as defined in HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health. Particular attention must be paid to the relationship sent in NK1-3 as this is where the distinction is made between an employer and a family member.

FLDOH requires the following minimum data to be sent in the NK1 field if available:

FLDOH Required PV1 Data	HL7 field comments
Name	NK1-2: Name of next of Kin or employer; if employer is the name of a business use NK1-13
Relationship	NK1-3: Use codes from table 0063 HL7version 2.5.1
Address	NK1-4: Address of the next of kin/associated party.
Phone Number	NK1-5: Telephone number of the next of kin/associated party
Organization Name	NK1-13: If next of kin or associated party is an organization use this field
Contact Person's Name	NK1-30: Required if NK1-13 is populated.
Contact Person's Telephone Number	NK1-31: Required if NK1-13 is populated.
Contact Person's Address	NK1-32: Required if NK1-13 is populated.

3.2.5 PV1 Segment - Patient Visit Information

The PV1 segment contains basic inpatient or outpatient encounter information which is useful to FLDOH surveillance efforts.

FLDOH requires the following minimum data to be sent in the PV1 field:

FLDOH Required PV1 Data	HL7 field comments
Patient Class	PV1-2:
Assigned Patient Location	PV1-3: required only if PV1-2 is 'Inpatient'
Discharge Disposition	PV1-36
Admit Date/Time	PV1-44
Discharge Date/Time	PV1-45

3.2.6 PV2 Segment – Additional Patient Visit Information

The PV2 segment is a continuation of information contained on the PV2 segment.

FLDOH requires the following minimum data to be sent in the PV2 field:

FLDOH Required PV2 Data	HL7 field comments
Admit Reason	PV2-3
Employment Illness Related Indicator	PV2-15

3.2.7 ORC Segment – Test Order

The ORC segment is used as the primary means of communicating test order related information. This segment contains test order and ordering provider information which are important to the public health community.

FLDOH requires the following data to be sent in the ORC segment:

FLDOH Required ORC Data	HL7 field comments
Placer Order Number	ORC-2: In the second component (Namespace ID) use the Hospital name or acronym. In the third component (Universal ID) use the Hospital or Enterprise OID rather than the software OID. These two elements, help make the Placer Order Number unique between facilities.
Filler Order Number	ORC-3: In the second component (Namespace ID) use the Hospital name or acronym. In the third component (Universal ID) use the Hospital or Enterprise OID rather than the software OID. These two elements, help make the Filler Order Number unique between facilities.
Ordering Provider Name	ORC-12: The National Provider Identifier (NPI) should be used as the identifier in ORC-12.1.
Ordering Provider Phone Number	ORC-14: Follow XTN Data type definition; equipment type ORC-14.3 required along with components for phone number. This field may also be used to send the ordering provider's e-mail address in a separate repeat.
Ordering Facility Name	ORC -21: IF the test ordered is not from a hospital or identifiable medical facility, the value should reflect the name of the ordering medical doctor or clinical care provider who ordered the test. The National Provider Identifier (NPI) or CLIA should be used as the identifier in ORC-21.10.
Ordering Facility Address	ORC-22: State or Province field should have a value consistent with the USPS two character State designations. Zip or Postal Code field should have a value consistent with the USPS five digit codes

Ordering Facility Phone Number	ORC-23: Follow XTN Data type definition; equipment type ORC-23.3 required along with components for phone number. This field may also be used to send patient e-mail address in a separate repeat.
Ordering Provider Address	ORC-24: State or Province field should have a value consistent with the USPS two character State designations. Zip or Postal Code field should have a value consistent with the USPS five digit codes

3.2.8 OBR Segment – Observation Request

The Observation Request (OBR) segment is used to transmit information specific to an order for a diagnostic study or observation, physical exam, or assessment. The OBR defines the attributes of a particular request for diagnostic services or clinical observations. For laboratory-based reporting, the OBR defines the attributes of the original request for laboratory testing.

FLDOH requires the following data to be sent in the OBR segment:

FLDOH Required OBR Data	HL7 field comments
Placer Order Number	OBR-2: In the second component (Namespace ID) use the Hospital name or acronym. In the third component (Universal ID) use the Hospital or Enterprise OID rather than the software OID. These two elements, help make the Placer Order Number unique between facilities.
Filler Order Number	OBR-3: In the second component (Namespace ID) use the Hospital name or acronym. In the third component (Universal ID) use the Hospital or Enterprise OID rather than the software OID. These two elements, help make the Filler Order Number unique between facilities.
Specimen collected date/time	OBR-7: Use of the abbreviated Timestamp format YYYYMMDD is permitted.
Specimen collected end date/time	OBR-8: This field should only be populated if a specimen is collected over a period of time. Not normally populated for Public Health lab result reporting to FLDOH.
Ordering Provider Name	OBR-16: The National Provider Identifier (NPI) should be used as the identifier in OBR-16.1.
Ordering Provider Phone Number	OBR-17: Follow XTN Data type definition; equipment type OBR-17.3 required along with components for phone number. This field may also be used to send ordering provider's e-mail address in a separate repeat.
Order Status	OBR-25: This status should pertain to the entire order.

Parent Result	OBR-26: This field is used for Parent/child linking. It should be filled in only for Orders pertaining to a generated or reflex order with parent order/observation group in the same message. For Public Health lab results parent result is populated for drug sensitivity test orders. See FLDOH specific requirements for parent/child linking in section 3.2.8.1
Parent Order and Filler Order Numbers	OBR-29: This field should be filled in for the same reasoning as OBR-26 above. The first component should be the Parent Placer Order Number. The second component should be the Parent Filler Order Number. If the Parent Placer Order Number is empty in the OBR-2 field of the parent order, then the first component in this field should be empty.
Reason for Study	OBR-31: Include ICD9 or ICD10 codes associated with symptoms listed as reason for testing. This field should also be used to send ICD9 or ICD10 codes indicating the test is part of a pregnancy panel or that the patient is pregnant when appropriate.

3.2.8.1 Additional discussion on OBR Segment (26) – Parent Result

This field provides linkages to results describing previously performed tests on the same message. This important information, together with the information in OBR-29 Parent (the identifiers associated with the parent placer and filler), uniquely identifies the OBX segment from the previously performed test that is related to this order (description of OBX segment provided below). The value reported in this OBR segment in the parent result is the organism or chemical species about which this battery reports. For example, if the current battery (as designated in OBR-4) is an antimicrobial susceptibility test, the parent result in OBR-26 may contain a result from a previously performed culture test, which identified the organism on which the current susceptibility was run. While the HL7 implementation guide indicates that the first two components of the Parent result are required and the third component is optional, **FLDOH requires all three components as follows:**

The first component of the Parent Result shall contain the full OBX-3 component in the Parent organism OBX. The subcomponents shall be separated by an '&'.

The second component of the Parent Result shall contain the sub-ID found in the Parent organism OBX-4.

The third component of the Parent Result shall contain the result description in the parent organism OBX-5.2. If the parent organism OBX-5.2 is empty the OBX-5.5 description shall be used.

Example ParentResult:
|600-7&Microorganism identified&LN&CULT&Culture&L^1.1^Streptococcus pneumoniae|
The First component <600-7&Microorganism identified&LN&CULT&Culture&L > consists of the test codes/descriptions for a microbial culture that appeared in the parent organism OBX-3.
The second component of this field <1.1> is the sub-ID in the parent organism OBX-4.
The third component is the result description <Streptococcus pneumonia> of the parent organism. As stated above the result description should come from the parent organism OBX-5.2 component, but may come from the parent organism OBX-5.5 if the OBX-5.2 is empty.

3.2.9 OBX Segment – Observation / Result

The OBX segment is used to transmit a single observation fragment. It represents the smallest indivisible unit of a report. The principal mission of this segment is to carry information about observations in report messages. Whereas the OBR segment gives general information about the order of the test, the OBX segment gives the specific, individual tests performed (OBX-3) and the specific results for each test (OBX-5). Laboratory-based reporting to public health agencies focuses on OBX-3 and OBX-5 as the most informative elements of the message; thus, every effort should be made to make OBX-3 and OBX-5 as informative and unambiguous as possible.

Since FLDOH receives ELR from many different laboratories using different sending applications, **it is required that OBX-5 results be restricted to coded and numerical results**. Reporting of Non-numerical test results should be in the form of discrete data such as: Positive, Negative, Detected, Not Detected, Reactive, Non-Reactive, etc. These discrete results are in turn sent as Coded results in the 'CWE' data type format. Numerical results will be sent in 'SN' data type format. Any additional comments or interpretive data should be not be sent in an OBX segment, but rather in an NTE segment associated with the results (OBX) or order (OBR) whichever is appropriate. Exceptions to this rule will be done on a case by case basis and must be discussed with FLDOH prior to the start of implementation.

FLDOH requires the following data to be sent in the OBX segment:

FLDOH Required OBR Data	HL7 Field Comments
Data Type	OBX-2: FLDOH requires 'CWE' for discrete results and 'SN' for numerical results. Exceptions must be agreed upon prior to implementation.
Test Codes and Names	OBX-3: FLDOH requires the use of LOINC® (Logical Observation Identifiers Names and Codes) as the "universal" procedure identifiers in OBX-3.1 and 3.2, the ID type of 'LN' denoting LOINC codes should be sent in OBX-3.3. Local test codes/descriptions should be sent in OBX-3.4 and 3.5 with an ID type of 'L' denoting local codes in OBX-3.6. Laboratories that have not mapped their local test codes to LOINC codes are encouraged to do so prior to the start of ELR message testing. The Florida Department of Health has its own table of Florida specific Notifiable Conditions and can assist with the mapping of LOINC Codes if the laboratory cannot determine a specific LOINC code to use. It is strongly recommended that OBX-3 be populated with as specific a LOINC code as possible to prevent any misinterpretation of results. Mismatches between LOINC code and results such as Culture tests with Antigen results should be checked prior to sending test messages.
Observation Sub-ID	OBX-4: Required when there are multiple observations for an order. FLDOH requires the use of decimals in the sub-ID field. See the explanation in section 3.2.9.1 for details.

Results	OBX-5: FLDOH requires the use of SNOMED CT® (Systematized Nomenclature of Medicine--Clinical Terms) as the "universal" observation values in OBX-5.1 and 5.2 for discrete non-numerical results, the ID type of 'SCT' denoting SNOMED CT codes should be sent in OBX-5.3. Local result codes/descriptions should be sent in OBX-5.4 and 5.5 with an ID type of 'L' denoting local codes in OBX-5.6. Laboratories that have not mapped their local result codes to SNOMED CT codes are encouraged to do so prior to the start of ELR message testing. The Florida Department of Health can assist with the mapping of SNOMED CT Codes if the laboratory cannot determine a specific SNOMED CT code to use.
Units	OBX-6: Units should be reported in all scenarios in which it is relevant to the interpretation of a numeric observation value.
Reference Ranges	OBX-7: Reference Range should be reported in all scenarios in which it is relevant to the interpretation of a numeric observation value, including titer results. If the reference range information for a specific test is more textual in nature, for example it contains positive, equivocal and negative ranges or interpretation data, then this info should be sent in an NTE segment rather than the OBX-7 field.
Abnormal Flags	OBX-8: This field contains the interpretation of numerical results as well as microbiology sensitivity interpretations. While the HL7 standard version 2.5.1 permits repetitions, laboratory-based reporting only expects one abnormal flag.
Observation Result Status	OBX-11
Specimen Collected Date	OBX-14: Use the abbreviated Timestamp format YYYYMMDD is permitted.
Observation Method	OBX-17: If the LOINC code in OBX-3 (Observation Identifier) is method less, this field should be populated.
Date/Time of the Observation	OBX-19: Use of the abbreviated Timestamp format YYYYMMDD is permitted.
Performing Organization Name	OBX-23: Performing Site name shall be sent in first component and CLIA for performing site shall be sent in tenth component of this field
Performing Organization Address	OBX-24: if available

3.2.9.1 Additional discussion on OBX Segment (4) – Sub-ID

FLDOH uses this field to distinguish between and group multiple OBX segments organized under one OBR.

- OBX (4) Sub –ID is required when multiple OBX segments are reported within a single OBR segment.
- FLDOH requires that decimals be used in the sub-ID field so as to differentiate results for independent observations, match observations for the same organism, and match Child results in subsequent OBR/OBX groupings to their parent result.
- FLDOH has adapted the use of decimals in the sub-ID field. When two or more OBX segments in the same OBR grouping relate to the same observation result, their OBX (4) values must have the same whole number while their decimals should be different so as to indicate individual result segments, yet have a group linkage. If they relate to independent observation results, the whole number portion of the OBX (4) values must be different also. This allows for the reporting of multiple results with multiple OBS segments.
- For example, if there are four OBX segments in the same OBR grouping where the first two OBXs relate to one result, and the third and fourth relate to another result, then the Observation Sub_ID for the first two should be 1.1 and 1.2 respectively, and for the third and fourth , should be 2.1 and 2.2 respectively.
- Here what this Example of sub-identifier usage would look like:
    - OBX|1|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**1.1**|66543000^Campylobacter jejuni^SCT^^^^January 2007||||||F…..
    - OBX|2|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**1.2**|^10000^-^90000|1^^UCUM^^^^1.6|||||F….. Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI
    - OBX|3|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**2.1**|302620005^Salmonella group B phase 1 a-e^SCT^^^^January 2007||||||F…..
    - OBX|4|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**2.2**|>^10000|1^^UCUM^^^^1.6|||||F…
- The example above has two OBX segments for each organism found in the culture test of the report, one for the organism and one for the colony count. Segments that apply to the Campylobacter Jejuni finding all have the sub-identifier with a whole number of 1. Segments that apply to the Salmonella group B all have sub-identifier with a whole number of 2. The use of the decimal in the sub ID to distinguish repeating OBXs for the same observation ID is really a special case of using the sub ID to group related subdivisions of information within the overall observation category. In the example above the decimals in each sub-ID provide a unique identifying number within the finding group. This unique id can be further used to match follow-up testing such as Drug Susceptibility tests which might be reported on the same message. Its use must be carefully structured to avoid introducing ambiguities.

3.2.9.2 Antimicrobial Susceptibility Results

- Antimicrobial susceptibility results should provide the quantitative value (MIC or zone diameter), the test method performed (can be in the test code as an appropriate LOINC), the interpretation (Susceptible, Intermediate, Resistant, Susceptible-Dose Dependent) and appropriate reference range used to determine the interpretation. For more discussion on antimicrobial susceptibility testing, please see Appendix 1.

3.2.10 SPM Segment – Specimen

The Specimen Information Segment (SPM) describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it and some basic characteristics of the specimen.

FLDOH requires the following minimum data to be sent in the SPM segment:

FLDOH Required OBR Data	HL7 Field Comments
Specimen ID	SPM-2: The first component should be the Placer Order Number. The second component should be the Filler Order Number. If the Placer Order Number (OBR-2) is empty, then the first component in this field should be empty.
Specimen Type	SPM-4: FLDOH requires the use of SNOMED CT® (Systematized Nomenclature of Medicine--Clinical Terms) as the “universal” specimen values in SPM-4.1 and 4.2; the ID type of ‘SCT’ denoting SNOMED CT codes should be sent in SPM-4.3. Local specimen codes/descriptions should be sent in SPM-4.4 and 4.5 with an ID type of ‘L’ denoting local codes in SPM-4.6.
Specimen Source Site	SPM-8: FLDOH requires that this field represent the anatomical site from which the specimen in SPM-4 was collected. The use of SNOMED codes is required in this field.
Specimen Collection Date/Time	SPM-17: The HL7 2.5.1 guide indicates the data in this field should include the time range over which the sample was collected. If the range is a single instance in time, that instance shall be sent in the first component of this field and may be repeated in the second component or the second component may be empty. Use of the abbreviated Timestamp format YYYYMMDD is permitted.
Specimen Received Date/Time	SPM-18: Use of the abbreviated Timestamp format YYYYMMDD is permitted.

4. CONCLUSION

The Florida Department of Health continues to work with CDC and other national organizations as part of the ongoing efforts related to electronic laboratory based reporting of public health information using HL7 messaging. The industry standards such as LOINC® and SNOMED® codes are subject to routine updates to which it is the responsibility of participating agencies and trading partners to update and maintain those code sets.

The Florida Department of Health recognizes that updates to the HL7 standard version and/or updates to the segment attributes may occur. These changes will be examined in coordination with all the Department's trading partners to ensure that the integrity of the electronic laboratory based reporting is maintained.

Appendix 1 - Antimicrobial Susceptibility Testing

Testing Method

When sending antimicrobial susceptibility testing, use standardized codes (LOINC®) that denote the testing method (i.e. disk diffusion, MIC, Etest, etc). The ability to compare methodology allows DOH to appropriately note differences in analysis and interpretations when aggregating data using different testing methods.

Results

Quantitative values are required for any antimicrobial susceptibility test results. These values, such as minimum inhibitory concentrations (MIC), zone diameters or other test results are the basis of the interpretations.

- Quantitative values should be discrete values rather than ranges such as ≤1 or ≥4 whenever possible based on software and laboratory capability. Results reported as being in a range can't be readily included in analysis.
- Quantitative values are needed to reinterpret or align breakpoints used by differing software, laboratory procedures, or equipment. It is also necessary to have appropriate quantitative values to analyze historic trend data as breakpoints change over time.
- The importance of including quantitative values is stressed in CLSI M39-A4 Analysis and Presentation of Cumulative Antimicrobial Susceptibility Tests Data.
- DOH also requires quantitative values to allow for isolates to align with current standards for benchmarking to other sources of antimicrobial susceptibility data such as CDC, FDA or other surveillance systems. DOH can ensure isolates meet case and surveillance definitions for resistance when comparing and using data from other sources.
- Facilities participating or wishing to participate in CDC's National Healthcare Safety Network (NHSN) Antimicrobial Use and Resistance (AUR) module are also required to submit quantitative values to that system.

Reference Ranges

Reference ranges for values can be concurrent with CLSI recommendations or specific to different labs. These values are necessary in defining quantitative values that may fall outside of the ranges (i.e. values >4 MIC). Reference ranges are used to check the breakpoints used at the time of interpretation with the ability to accurately distinguish laboratories using the same ranges.