

The background of the page is a grayscale photograph of a medical professional, likely a doctor or nurse, wearing a white lab coat and glasses. They are sitting at a desk, looking at a computer monitor. In the foreground, a silver stethoscope is resting on a document. The overall scene is a clinical or healthcare setting.

# **Kentucky Health Information Exchange (KHIE)**

## **Reportable Conditions Electronic Laboratory Result (ELR) Reporting**

### **ELR Onboarding Guide**

April 3, 2024

## Document Information

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# 1. Introduction

The Electronic Laboratory Reporting (ELR) onboarding guide contains information on all required data elements, formatting of HL7 messages, resources and best practices for a successful onboarding and submission to the Kentucky Health Information Exchange (KHIE) and the Kentucky Department for Public Health (KDPH). This guide serves as a companion to the HL7 Version 2.5.1 Implementation Guide provided by HL7.org.

In this onboarding guide, the use of the words ‘facility, facilities, organization, organizations, provider, and providers’ is interchangeable with KHIE Participant.

## 2. Kentucky Reportable Diseases and Conditions

As required by Kentucky regulation [902 KAR 0:020](#), health professionals and healthcare facilities resulting reportable diseases laboratories of Kentucky patients are required to submit the data to the KDPH.

Please refer to [Kentucky Reportable Diseases and Conditions](#) for an overview of reportable diseases and conditions in Kentucky.

**Note:** Generally, all positive results should be reported. However, per Kentucky regulation 902 KAR 2:020, there are a few instances in which negative results are required, too. These include:

- Positive and **negative** COVID PCR tests
- Positive and **negative** Hepatitis B and C
- Positive and **negative** HIV results

## 3. KHIE Connectivity Resource

KHIE enables the electronic submission of lab result data via a variety of connectivity and data type options:

- Virtual Private Network (VPN) - Health Language 7 (HL7) messaging
- Web Services (WS) - HL7 messaging
- Secure File Transfer Protocol (SFTP) via MoveIT folder - HL7 messaging, or pipe delimited (|) .txt Flat File
- Direct Data Entry (DDE) - Manually entered via a secure website

The [KHIE Participant Connectivity Guide](#) focuses on the process of onboarding Participants, the KHIE connectivity capabilities, and the information related to the exchange of data with KHIE. This guide is used along with HL7 Global Healthcare Messaging Standard v2.5.1, to exchange information between KHIE, healthcare organizations, and Public Health Registries.

## 3.1 VPN

VPN connectivity establishes a secure IPSec VPN tunnel between the source of the data on the Participant or vendor's network and a KHIE Edge Server. Data is transmitted over a TCP/IP socket connection to a server that is logically dedicated to that Participant.

KHIE will share a [VPN Form](#) that lays out the configurations needed to successfully setup an IPSec tunnel and send messages securely over to KHIE.

## 3.2 Web Services

Web Services connectivity transports messages to a KHIE web services endpoint over the internet. Messages are encrypted and signed using an X509 security certificate to provide privacy and provider authentication.

The Participant must provide the public key certificate and trust chain for the X509 certificate issued by a public trusted certificate authority. No self-signed certificates are accepted.

## 3.3 SFTP- HL7 messaging or Flat-File

To establish an SFTP connection, the Participant must complete the [SFTP Form](#). This form includes essential information such as the NPI, CLIA, and IP address(es). Once the request for folder setup is completed, the Participant will be provided the link to an API and the necessary access credentials, which allow for submission of files. In this route, KHIE accepts both SFTP HL7 file and SFTP flat file.

For the submission of HL7 files via SFTP, KHIE provides a streamlined SFTP Form process. Each HL7 message or result is treated as a separate message. In the case of SFTP flat file submissions, KHIE accepts only files in the Pipe (|) delimited .txt format. Each file contains 67 fields, separated by the pipe character. Although many fields are optional or conditional, certain fields require validation against predefined criteria by KDPH. Additionally, validation checks are performed for patient addresses, phone numbers, ordering provider/facility details, LOINCs in OBR-4/OBX-3 with corresponding descriptions from LOINC.org, SNOMED coded results in OBX-5, and Descriptive Specimen Type in SPM 4. For a successful process, follow the exact column headers.

Please find a sample file.txt with 67 elements, ensuring the exact column headers are maintained to facilitate successful file processing.

NPI|Patient MRN|SSN|Pt\_Lname|Pt\_Fname|Date\_of\_Birth|Sex|Pt\_Race|Pt\_Race  
 Description|Ethnicity|Ethnicity  
 Desc|Pt\_Phone|Pt\_email|Pt\_St1|Pt\_St2|Pt\_City|Pt\_State|Pt\_Zip|County of  
 Residence|TestName|TestLOINC|Test Result|Unit|Ref\_range|Observation Result Date  
 Time|Order#|Collect\_Date|Ordering Provider Last  
 Name|Dr\_St1|Dr\_St2|Dr\_City|Dr\_State|Dr\_Zip|Dr\_Ph#|Specimen Source|Specimen Type|Onset  
 Date|Symptoms|HCW|Congregate|Hospitalization|First Test(Y/N/U)|ICU?|Pregnant?|Name of Testing  
 Product|Device Identifier|Date Test Ordered|Performing Facility Name|Performing Facility Address  
 1|Performing Facility Address 2|Performing Facility City|Performing Facility State|Performing Facility ZIP  
 Code|Performing Facility Telephone Number|Ordering Facility Name|Ordering Provider NPI|Ordering  
 First Name|Patient Middle Initial|Ordering Facility Address 1|Ordering Facility Address 2|Ordering  
 Facility City|Ordering Facility State|Ordering Facility ZIP Code|Ordering Facility Telephone  
 Number|GISAID|Notes|AbnormalFlag

999999999|TC485066||Qhomson|Phomson|19870606|O|1002-5|AMERICAN INDIAN OR ALASKA  
 NATIVE|H|Hispanic or Latino|(103)193-1234|p.qomson@gmail.com|SWING DOWN ROAD|WELLING  
 TOWN|FRANKFORT|KY|40124|ADAIR|Chlamydia trachomatis culture|10642-7|NOT  
 POSITIVE|Mil|ABC|20200505|5678|20200303|ORDLASTNAME|564 Summer Apt A|HARWARD  
 TOWN|LOUISVILLE|KY|400055|99288394|Perianal|Bone|20220211|Fever|YES|N|No|Y|UNK|7798200  
 6|ABC|TEST|20220707|JENNS CARE|PARK STREET|LAKE  
 MARY|FRANKFORT|KY|40601|2345678911|CAROL HOSP|56789|GEORGE|K|MAIN STREET|NEW  
 TOWN|LEXINGTON|KY|40345|6789654401|GISAID123455|New Variant Notes|Good

### 3.4 Direct Data Entry (DDE)

Direct Data Entry is a secure, web-based reporting application hosted in the Kentucky Health Information Exchange's ePartnerViewer application. It facilitates electronic lab reporting manually using KHIE's online web forms. The platform is easily accessible from most web browsers using a secure internet connection. DDE is the Kentucky Department for Public Health's preferred interim reporting platform.

## 4. Reportable ELR Tracking Spreadsheet

The [Reportable ELR Tracking spreadsheet](#) shall be completed by each reporting facility (KHIE Participant). The reporting facility should provide the ordered and resulted LOINC codes, type of result being used (qualitative or quantitative), SNOMED coded test results, and the specimen source and site.

The completion and return of this spreadsheet are critical milestones to determine the beginning of the onboarding process. Once completed, the KDPH ELR Epidemiologist will review and provide feedback to KHIE to share with the Participant. This document provides an understanding of the program areas that will be onboarded. This document also provides information that assists in identifying whether the KHIE/NEDSS master LOINC or SNOMED code lists require an update.

## 5. HL7 Version 2.5.1 Implementation Guide

The [HL7 Version 2.5.1 Implementation Guide](#) describes the transmission of laboratory-reportable findings to appropriate health agencies using the HL7 2.5.1 ORU^R01 message. This guide contains the necessary specifications for laboratory results reporting to health agencies.

This guide addresses messaging content and dynamics related to the transmission of Laboratory Reportable Result Messages/ELR. Participants will develop and generate HL7 messages that conform to the HL7 2.5.1 Implementation Guide.

## 6. HL7 Format Field Requirements

The following HL7 format fields are required by the state of Kentucky. Participants must adhere to all the required fields. Optional fields are also discussed.

Recommended values are:

- R – Required
- RE – Required but can be empty if not available.
- O – Optional
- C – Conditional
- X – Not used for this profile

Feed Type	Element Name	Recommended Value	Comments
<b>MSH-2</b>	Encoding Characters	R	Literal value: '^~\&'.
<b>MSH-3</b>	Sending Application	R	
<b>MSH-4.1</b>	Sending Facility	R	The MSH segment will include KHIE-defined facility-identifying values for proper message routing to NEDSS.
<b>MSH-4.2</b>	NPI	R	This segment is a 10-digit NPI or Pseudo NPI assigned by KHIE.

<b>MSH-5</b>	Receiving Application	R	
<b>MSH-6</b>	Receiving Facility	R	
<b>MSH-7</b>	Date/Time of Message	R	
<b>MSH-9</b>	Message Type	R	Literal Value: 'ORU^R01^ORU_R01', if v2.5.1.
<b>MSH-11</b>	Processing ID	R	"P" for Production, "T" for Test.
<b>MSH-12</b>	Version ID	R	HL7 v2.5.1 preferred.
<b>MSH-21</b>	Message Profile Identifier	R	"Literal value: 'PHLabReport-NoAck^ELR_Receiver^2.16.840.1.113883.9.11^ISO'
<b>PID-3.1</b>	Pt ID / MRN	R	The Pt ID/MRN must <u>uniquely</u> identify with the associated patient.
<b>PID-3.4</b>	Assigning Authority	R	
<b>PID-3.5</b>	ID Type code /CLIA	R	The ID Type code needs to be ' <u>MR</u> ' by default.
<b>PID-5.1</b>	Pt_Lname	R	
<b>PID-5.2</b>	Pt_Fname	R	
<b>PID-7</b>	Pt_DOB	R	Patient Date of Birth format is <u>YYYYMMDD</u> .
<b>PID-8</b>	Gender	R	
<b>PID-10.1</b>	Pt_Race	R	Pt_Race is required for health equity.
<b>PID-10.2</b>	Pt_Race Description	R	Pt_Race Description is required for health equity.
<b>PID-10.3</b>	Name of Coding System	R	
<b>PID-11</b>	Pt_Address	R	Pt_Address is required for patient follow-up and for proper jurisdiction assignment.
<b>PID-13</b>	Pt_Home Phone Number	R	Pt_Home Phone Number is required to contact for patient follow-up.
<b>PID-22.1</b>	Pt_Ethnicity	R	Pt_Ethnicity is required for Health Equity.
<b>PID-22.2</b>	Pt_Ethnicity Description	R	Pt_Ethnicity Description is required for Health Equity.
<b>PID-22.3</b>	Name of Coding System	R	



<b>PID-29</b>	Patient Death Date/Time	RE	
<b>PV1-1.1</b>	Set ID	R	'1'
<b>PV1-1.2</b>	Patient Class	R	Value Set: HL70004 O=Outpatient, I=Inpatient, E=Emergency...
<b>ORC-2</b>	Placer Order Number	C	Conditional, must match OBR-2.
<b>ORC-3</b>	Filler Order Number (Accession Number)	R	Number uniquely identifies the lab and must be identical to the OBR-3 value.
<b>ORC-12</b>	Ordering Provider	RE	Ordering Provider identifies the provider who ordered the testing being performed. If populated, NPI may be used as the identifier. <b>Note:</b> ORC 12 must contain the same value as OBR-16.
<b>ORC-14</b>	Ordering Provider Callback Phone Number	RE	
<b>ORC-21</b>	Ordering Facility Name	R	Ordering Facility Name is required, as it identifies the name of the facility where the order was placed.
<b>ORC-22</b>	Ordering Facility Address	R	
<b>OBR-3</b>	Filler Order Number (Accession Number)	R	Filler Order Number uniquely identifies the lab and must be identical to the ORC-3 value.
<b>OBR-4.1</b>	LOINC Code	R	Required for usefulness of the data for business partners/stakeholders. Refer to <a href="http://LOINC.org">LOINC.org</a> for recommended LOINC codes.
<b>OBR-4.2</b>	LOINC Description	R	Required for usefulness of the data for business partners/stakeholders. Refer to <a href="http://LOINC.org">LOINC.org</a> for recommended LOINC code descriptions.
<b>OBR-4.3</b>	Name of Coding System	R	
<b>OBR-7</b>	Observation Date/Time	R	OBR-7/OBX-14 is required, as it indicates the created dates when the lab was processed.
<b>OBR-8</b>	Observation End Date/Time	RE	

<b>OBR-16</b>	Ordering Provider	RE	Ordering Provider identifies the provider who ordered the testing being performed. If populated, NPI may be used as the identifier. <b>Note:</b> OBR-16 must contain the same value as ORC 12.
<b>OB-17</b>	Order Callback Phone Number	RE	
<b>OBR-22</b>	Result Rpt/ Status Change Date/Time	R	OBR-22 is required, as it indicates the updated dates and the most recent changes.
<b>OB-25</b>	Result Status	R	NEDSS only accepts values of P, C, or F
<b>OBX-2</b>	Value Type	R	Value Type is required, as it identifies the <i>data type</i> used for OBX-5. A few of the data types include CE, CWE, ST, SN or TX.
<b>OBX-3.1</b>	LOINC Code	R	LOINC Code is required for usefulness of the data for business partners/stakeholders. Refer to <a href="http://LOINC.org">LOINC.org</a> for recommended LOINC codes.
<b>OBX-3.2</b>	LOINC Description	R	LOINC Description is required for usefulness of the data for business partners/stakeholders. Refer to <a href="http://LOINC.org">LOINC.org</a> for recommended LOINC code descriptions.
<b>OBX-3.3</b>	Name of Coding System	R	
<b>OBX-5</b>	Observation Value / Test Result	R	Observation Value/Test Result is required for usefulness of the data for business partners/stakeholders. The test results need to be SNOMED coded. Refer to <a href="http://SNOMED CT.org">SNOMED CT.org</a>
<b>OBX-6</b>	Units	C	OBX-6 is conditional based upon the OBX-5. If OBX-5 is a <i>Quantitative value</i> (Number) then OBX-6 should be populated.
<b>OBX-7</b>	Reference Range	RE	Reference Range is required if it exists, but it may be empty.
<b>OBX-8</b>	Abnormal Flags	O	OBX-8 indicates the normalcy of the result found in OBX-5. It is populated if any abnormalities are present in the result (OBX-5), <b>Value Set HL70078</b> .
<b>OBX-11</b>	Observation Result Status	R	NEDSS only accepts values of P, C, or F

<b>OBX-14</b>	Date/Time of Observation	R	OBR-7/OBX-14 is required, as it indicates the created dates when the lab was processed.
<b>OBX-19</b>	Date/Time of Analysis	R	
<b>OBX-23</b>	Performing Organization Name	R	
<b>OBX-24</b>	Performing Organization Address	R	
<b>OBX-25</b>	Performing Organization Medical Director	RE	
<b>DG1-3.1/ DG1-3.4</b>	Diagnosis Segment	X	Diagnosis Segment is not applicable for LABs.
<b>NTE-3</b>	Comment	O	May be populated with comments and additional information not directly related to the clinical finding.
<b>SPM-2.1</b>	Specimen ID	R	The specimen or accession identifier should be placed in SPM-2.
<b>SPM-4</b>	Specimen Type	R	SPM-4 is required, as it indicates the description of the precise nature of the specimen that is the source for the observation. The specimen type needs to be SNOMED coded. Refer to <a href="http://SNOMED CT.org">SNOMED CT.org</a>
<b>SPM-8</b>	Specimen Source Site	RE	SPM-8 indicates the source from which the specimen was obtained. If populated, it may be the location of the source of the specimen such as an anatomical site.

## 7. Segment Order Table

For successful processing of your messages, please adhere to the following segment order requirements:

MSH
PID
ORC
OBR
OBX
NTE 1 L Onset:
NTE 2 L Symptoms:
NTE 3 L HCW: Yes
NTE 4 L Congregate:

NTE 5 L Hospitalization:
SPM

## 8. Sample HL7 Message

```

MSH|^~\&|TestLAB|TESTLAB^999999999^DNS|KHIE|KHIE|20230520112927||ORU^R01^ORU_R01|8
11111111|P|2.5.1|||NE|NE|||||PHLabReport-NoAck^HL7^2.16.840.1.113883.9.11^ISO

SFT|||||

PID|1||PTMRN0000^^^TESTLAB^MR||LNAME^FNAME^X^^^L||19900909|M||2106-
3^White^HL70005^WH^White^L|1 Whitaker
Rd^^LEXINGTON^KY^40508^USA^H^^|^PRN^PH^^1^859^1111111|||||||2186-5^Not Hispanic or
Latino^HL70189|||||||N|||202306140945-0400

PV1|1|O

ORC|RE|8111111^TESTLAB^^ISO|0101:S00025R^TESTLAB||CM||||||1194700000^DOCLNAME^DOCF
NAME^D^^^PA^^^L^^^NPI^^^L^^^PA|^WPN^PH^^1^859^3333333^^Hospital Line|||||Test
Clinic^L^^^L^^^18D0000001|500 Manhattan
Ave^^Lexington^Ky^40508^USA^B^^21071|^WPN^PH^^1^859^3333333|

OBR|1|8111111^TESTLAB^^ISO|0101:S00025R^TESTLAB|24363-4^Acute hepatitis 2000 panel -
Serum^LN|||202305200945|202305200945||||||1194700000^DOCLNAME^DOCFNAME^D^^^PA^^
^L^^^NPI^^^L^^^PA|^WPN^PH^^1^859^3333333^^Hospital Line|||||202306140945|||F

OBX|1|CWE|24113-3^Hepatitis B virus core IgM Ab [Presence] in Serum or Plasma by
Immunoassay^LN||260385009^Negative^SCT||Negative||||F||202305200945|||||202305200945||
||TESTCLIN^D^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^18D0000009|500 Manhattan
Ave^^Lexington^Ky^40508^USA^B^^21071|^Director^Medical^L^^^MD^^^L^^^NPI^^^L^^^MD
OBX|2|CWE|5196-1^Hepatitis B virus surface Ag [Presence] in Serum or Plasma by
Immunoassay^LN||260385009^Negative^SCT||Negative||||F||202305200945|||||202305200945||
||TESTCLIN^D^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^18D0000009|500 Manhattan
Ave^^Lexington^Ky^40508^USA^B^^21071|^Director^Medical^L^^^MD^^^L^^^NPI^^^L^^^MD
OBX|3|CWE|72376-7^Hepatitis C virus Ab [Presence] in Serum, Plasma or Blood by Rapid
immunoassay^LN||10828004^Positive^SCT||Negative||||F||202305200945|||||202305200945|||
TESTCLIN^D^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^18D0000009|500 Manhattan
Ave^^Lexington^Ky^40508^USA^B^^21071|^Director^Medical^L^^^MD^^^L^^^NPI^^^L^^^MD

SPM|1|8111111^|0101:S00025R^|119364003^Serum
specimen^SCT||||||||||202305200945^202305200945|202305200945|||||||||

```

## 9. LOINC and SNOMED codes

Appropriately mapped LOINC and SNOMED codes are essential in the routing of reportable conditions from the KHIE environment to the NEDSS environment. These codes must be mapped correctly within the messages to ensure the KDPH data quality standards are met.

The reportable LOINC and SNOMED codes are categorized by Program Area. This detail becomes pivotal through the ELR validation process since NEDSS typically requires 10 message accessions per Program Area for each round of validation. The reportable LOINC is populated in the OBX-3.1/Observation ID, which KHIE monitors to identify and forwards the reportable labs to the NEDSS endpoint.

Below are the latest LOINC/SNOMED codes that KHIE and KDPH use. These lists are subject to change and Participants should check <https://khie.ky.gov/Public-Health/Pages/default.aspx> to stay up to date.

## 10. HL7 Mapping Tips

Please note the following tips:

### 10.1 PID 10 Race Formatting

Primarily from HL7 table HL70005:

Race (PID.10.1)	Race Description (PID.10.2)
1002-5	American Indian or Alaska Native
2028-9	Asian
2054-5	Black or African American
2076-8	Native Hawaiian or Other Pacific Islander
2106-3	White
2131-1	Other Race
U	Asked but Unknown
U	Unknown

Example:

**1002-5^American Indian or Alaska Native^HL70005**

(OR)

**1002-5^American Indian or Alaska Native^CDCREC**

**Note (1):** Blank Race fields will result in an error in the NEDSS system.

**Note (2):** Highlighted, non-standard values must only occur at or below 20% of the total volume of messages to pass NEDSS/DPH validation.

## 10.2 PID 13: Patient Phone Number

- Format: |^PRN^PH^^1^270^1111111|

## 10.3 PID 22: Patient Ethnicity

Primarily from HL7 table HL70189:

Value	Description
H	Hispanic or Latino
N	Not Hispanic or Latino
U	Unknown

**Example:**

**2135-2^Hispanic or Latino^HL70189**

**(OR)**

**H^Hispanic or Latino^HL70189**

**Note (1):** Blank Ethnicity fields will result in an error in the NEDSS system.

**Note (2):** The highlighted, non-standard value must only occur at or below 20% of the total volume of messages to pass NEDSS/DPH validation.

## 10.4 OBX-5/Observation Value, Non-Micro Results

The highlighted SNOMED Codes are preferred.

Result_CD	Result_Description
10828004	POSITIVE
260373001	Detected
260385009	NEGATIVE
260415000	Not Detected
281296001	Result comments

373121007	Test not done (qualifier value)
419984006	Inconclusive
42425007	Equivocal
720735008	Presumptive positive
82334004	Indeterminate
89925002	Canceled (qualifier value)

- Example: | 10828004^POSITIVE^SCT|

## 10.5 SPM-4/Specimen Type

Value (SPM.4.1)	Description (SPM.4.2)
119371008	Abscess
119295008	Aspirate
258607008	BAL (bronchoalveolar lavage)
119297000	Blood
122552005	Blood (arterial)
122554006	Blood (capillary)
122556008	Blood (cord)
122555007	Blood (venous)
258580003	Blood (whole)
258450006	Cerebrospinal fluid
258524009	Cervical swab
119368000	Cyst
122574004	Duodenal fluid
258508008	Genital swab
309049000	Lesion
258500001	Nasopharyngeal swab
461911000124106	Oropharyngeal swab
168359007	Penile swab
119361006	Plasma
258528007	Rectal swab
119342007	Saliva
119364003	Serum
119334006	Sputum
119339001	Stool
119332005	Synovial fluid (joint fluid)

119376003	Tissue
119369008	Ulcer
258530009	Urethral swab
122575003	Urine
122880004	Urine clean catch
119394009	Vaginal swab
119365002	Wound

**Example:**

**258500001^Nasopharyngeal swab^SCT**

**Note: For COVID Labs**, acceptable specimen types include Saliva, Sputum, Nasopharyngeal Swab, Nasal Swab, but not Upper Respiratory Sample.

## 11. Other Key Validation Tips

- There is a validation process with KHIE and KDPH.
- Participant must submit LIVE (PROD) to Test data for validation. Therefore, labs must be actively resulting tests to complete validation.
- Interim reporting will be required until validation is complete. This will be facilitated with KDPH.
- Participant must capture correct race and ethnicity values. High percentages of unknown or other values for race and ethnicity fields will not pass KDPH validation.
- An accurate patient address and patient phone number are required for validation.
- Participant must commit to a weekly scheduled ½ hour data validation meeting.
- Participant must complete the Reportable ELR Tracking spreadsheet.
- Unique Accessions/Requisitions for each OBR-3. **Must be minimum 7 characters, preferably alpha-numeric, maximum 22 characters.**
- KDPH will not accept **local codes** in OBX-3.4.5 and .6
- Only during the validation process, if added volume is needed to meet requirements, KDPH will accept positive and negative results for all reportable conditions. They will also accept historical volume, if applicable.



## 12. HIV Onboarding and Related Information

KHIE is the public health reporting authority for the state of KY. HIV results data are routed through KHIE to KDPH only for the purpose of public health reporting. HIV results data are not shared with the health information exchange Participants.

Facilities can report HIV results data electronically through KHIE to the KDPH HIV program. Only Participants that have executed the most current reportable condition addendum are allowed to submit. There is an additional layer of validation that occurs with the KDPH HIV Program Epidemiologists.

The appropriate HIV tab in the Reportable ELR Tracking spreadsheet in Section 4 must be completed. This tab is reviewed; feedback is provided.

The KDPH HIV program team determines if a Participant's data meets HIV standards for ELR onboarding.

### 12.1 Abbott (or Alere) Determine HIV Test

**Background:** The Abbott Determine (sometimes called the Alere Determine) is a newer generation point-of-care test that tests for HIV 1/2 antibodies and p24 Antigen. Unlike earlier point-of-care tests, it differentiates between a positive Antibody result and a positive Antigen result, yielding four possible result options. (Note: It does NOT differentiate between HIV 1 vs HIV 2 antibodies.)

- 1) + Ab – Ag
- 2) – Ag + Ab
- 3) + Ab +Ag
- 4) – Ab – Ag

To process these labs, one LOINC code must be used (75666-8). The four different result options are differentiated via SNOMED code (see table).

LOINC	LOINC Long Name	Result	SCT
75666-8	HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay	Ab positive only	<b>1 OBX segment</b> [259855002^Human immunodeficiency virus antibody^SCT]
		Ag (p24) positive only	<b>1 OBX segment</b> [713008009^Human immunodeficiency virus p24 antigen positive^SCT]
		Ab positive and Ag (p24) positive	<b>[report as 2 OBX segments with the same LOINC code, one for [259855002^Human immunodeficiency virus antibody^SCT] and one for [713008009^Human immunodeficiency virus p24 antigen positive^SCT]</b>
		Negative	<b>1 OBX segment</b> [260385009^Negative^SCT]

### Sample HL7 of HIV Results

#### Example 1: Ab (+) Ag (-)

```
OBX|1|CWE|75666-8^HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay^LN^^^2.73||259855002^
Human immunodeficiency virus antibody^SCT^^^^^Reactive||Non-Reactive|A||F||20231129145800||||20231129150020||||BAPTIST
HEALTH LA GRANGE LABORATORY^D^^^^CLIA&1.2.3.4.5.6&ISO^XX^^18D0030411|<BR>1025 NEW MOODY LANE^^LAGRANGE^KY^40031^USA^B|1982877528
^MCKEE^SUSAN^WILLIAMS^^^^^NPI^^^^NPI
```

#### Example 2: Ab (-) Ag (+)

```
OBX|1|CWE|75666-8^HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay^LN^^^2.73||713008009^
```

HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN DETECTED^SCT^^^^^Reactive||Non-Reactive|A||F|||20231129150000|||20231129150205|||  
 BAPTIST HEALTH LA GRANGE LABORATORY^D^^^^CLIA&1.2.3.4.5.6&ISO^XX^^^18D0030411|<BR>1025 NEW MOODY LANE^^LAGRANGE^KY^40031^USA^B|  
 1982877528^MCKEE^SUSAN^WILLIAMS^^^^^NPI^^^NPI

### Example 3: Ab (+) Ag (+)

OBX|1|CWE|75666-8^HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay^LN^^^^2.73||259855002^  
 Human immunodeficiency virus antibody^SCT^^^^^Reactive||Non-Reactive|A||F|||20231129150200|||20231129155921|||BAPTIST HEALTH  
 LA GRANGE LABORATORY^D^^^^CLIA&1.2.3.4.5.6&ISO^XX^^^18D0030411|<BR>1025 NEW MOODY LANE^^LAGRANGE^KY^40031^USA^B|1982877528^  
 MCKEE^SUSAN^WILLIAMS^^^^^NPI^^^NPI  
 OBX|2|CWE|75666-8^HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay^LN^^^^2.73||713008009^  
 HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN DETECTED^SCT^^^^^Reactive||Non-Reactive|A||F|||20231129150200|||20231129155921|||  
 BAPTIST HEALTH LA GRANGE LABORATORY^D^^^^CLIA&1.2.3.4.5.6&ISO^XX^^^18D0030411|<BR>1025 NEW MOODY LANE^^LAGRANGE^KY^40031^USA^B|  
 1982877528^MCKEE^SUSAN^WILLIAMS^^^^^NPI^^^NPI

### Example 4: Ab (-) Ag (-)

OBX|1|CWE|75666-8^HIV 1+2 Ab and HIV1 p24 Ag [Identifier] in Serum, Plasma or Blood by Rapid immunoassay^LN^^^^2.73||260385009^  
 Negative^SCT^^^^^Non-Reactive||Non-Reactive|||F|||20231129160100|||20231129160217|||BAPTIST HEALTH LA GRANGE LABORATORY^D  
 ^^^^CLIA&1.2.3.4.5.6&ISO^XX^^^18D0030411|<BR>1025 NEW MOODY LANE^^LAGRANGE^KY^40031^USA^B|1982877528^MCKEE^SUSAN^WILLIAMS^^^^^  
 NPI^^^NPI

## 13. Appendix

### 13.1 Appendix A: Susceptibility Results – Parent-Child Messaging

The purpose of a parent-child relationship is to link together a “child” sensitivity panel to the “parent” culture results. This means that there can be many child results for a single parent result. This is important in public health surveillance to determine the resistance of organisms to different types of medications.

To allow for the appropriate processing of parent-child results messages, please follow the list below:

- 1) There should be one and only one ORC segment in the HL7 v2.5.1 message that contains parent-child information.
- 2) There should be only one SPM segment in the message which should be placed at the end of the HL7 v2.5.1 message.
- 3) OBR-29 in the parent OBR should be null.
- 4) Every OBR segment should have at least one following OBX segment. Only one parent OBR segment (*which can have multiple OBX segments*) should be sent.
- 5) Child and parent results should satisfy the following criteria:
  - a. Child OBR-26.1 = OBX-3 from the parent OBX  
(Each of the **OBX-3 components (OBX-3.1, OBX-3.2, etc.)** from parent should be concatenated with an ampersand and populated in child’s OBR-26.1.)
  - b. Child OBR-26.2 = OBX-4 from parent OBX, OBX-4 (Observation SubID) is optional in HL7 for Parent Result
  - c. Child OBR-26.3 = Parent OBX-5.2 (if this is a CE/CWE) or the complete OBX-5, if this is a string/text result
  - d. Child OBR-29.1 = Parent OBR-2  
(Each of the OBR-2 components (OBR-2.1, OBR-2.2, etc.) from parent should be concatenated with an ampersand and populated in child’s OBR-29.1.)
  - e. Child OBR-29.2 = Parent OBR-3  
(Each of the OBR-3 components (OBR-3.1, OBR-3.2, etc.) from parent should be concatenated with an ampersand and populated in child’s OBR-29.2.)

Please refer to the [NEDSS HL7 Parent-Child](#) document for a better understanding of parent-child susceptibility issues in micro results through the sample messages and examples present in the document.

## 13.2 Acronyms

CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendment
ELR	Electronic Laboratory Reporting
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven
ISO	International Organization for Standards
KDPH	Kentucky Department for Public Health
KHIE	Kentucky Health Information Exchange
LOINC	Logical Observation Identifiers Names and Codes
MRN	Medical Record Number
NEDSS	National Electronic Disease Surveillance System
NPI	National Provider Identifier
ORU	Observational Report - Unsolicited
SNOMED	Systemized Nomenclature of Medicine, Clinic Terms

## 14. Appendix

### 14.1 Appendix B: Requirements for Onboarding and Data Validation

Participants (reporting facilities) shall onboard and validate ELR data when the following conditions are met\*:

The Participant reporting facility:

- is a new Participant (unique MSH 4.1 and MSH 4.2 value) and has never submitted ELR data
- has undergone an EHR/EMR vendor change
- has undergone a Laboratory Information System (LIS) change

Participants (reporting facilities) shall inform KHIE's ELR team at [KHIELabSupport@ky.gov](mailto:KHIELabSupport@ky.gov) when any of the following conditions occur in association with the connection to KHIE:

- EHR version or upgrade change
- interface change or upgrade
- interface connection has been down for more than 90 days
- cyber incident occurs
- there is a chance of interruption of mapping within the EHR, LIS, or other system(s) that could impact the data quality of the ELR messages
- addition of a new reportable condition laboratory test, LOINC, or SNOMED coding to your laboratory testing catalog
- any regulatory change(s) regarding reportable conditions that impact reporting and require the addition of laboratory test result(s)
- addition of new reportable condition laboratory tests to complete onboarding because you originally onboarded for COVID-19 results reporting only

On behalf of KDPH, KHIE reserves the right to request the Participant facility to onboard and validate reportable condition laboratory resulting for any reason deemed to negatively impact data quality, the KHIE or NEDSS systems, and/or any other issues.

After notification by KHIE of persistent data quality issues, failures in NEDSS, or other unresolved issues, and upon recommendation by KDPH, KHIE reserves the right to request the Participant to return to the test environment for data revalidation.

\*The KHIE ELR/KDPH team may request a meeting to evaluate the need for onboarding and validation.