AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Preliminary Guidance on Serologic Testing

Vocabulary and HL7 Guidance for Mass Vaccination Event Data Capture

September 2020

Contents

Background

A workgroup of subject matter experts was convened over the course of several weeks in 2020 to determine the technical requirements for an IIS receiving and storing messages containing serologic results as proof of immunity. The effort was initiated proactively to address the potential need for IIS to support documentation of serologic proof of immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19.

Serologic testing may be used to determine an individual's immunity to a specific pathogen. The Advisory Committee on Immunization Practices (ACIP) recognizes serologic testing, reflecting the belief that a therapeutic response may qualify an individual as immune. Test types may vary, and therapeutic response may require a specific threshold or a qualitative result indicating immunity.

> **Preliminary Guidance**
>
> This guidance was published in preliminary format to assist IIS, EHR vendors, and other stakeholders in preparing for the technical requirements of the COVID-19 response. This document will be updated as necessary over the course of the response. See Appendix A for items that have not been clarified and still require community discussion.

A precedent exists for IIS to receive and store serologic proof of immunity for chickenpox, hepatitis B, and other diseases. A survey conducted by the Centers for Disease Control and Prevention with all 64 US and US territory immunization programs indicated that most IIS had some capacity for capturing assertions of serologic proof of immunity. Research of public health laboratory practices related to the receipt and storage of serologic test results indicated persistent use of HL7 messaging to transport this information between electronic health systems and registries.

Policies regarding the acceptability of serologic testing as proof of immunity to COVID-19 may vary among jurisdictions. Many factors may influence the validity of serologic tests, including the uncertainty that the presence of antibodies, even at a level deemed "therapeutic," confirms lasting immunity to COVID-19. This guide does not address the clinical, policy, or interpretive elements related to testing or test results.

The purpose of this guide is to cover the technical aspects of the receipt and storage of serologic test results in an IIS. While this guidance uses COVID-19 as the primary use case example, this document is intended to provide general guidance. Two additional examples of when this could be used are dengue fever (new vaccine under review) and varicella. The scope of this effort is described below.

Scope of Guidance

In scope

The scope of work of the Documenting Serologic Immunity in the IIS Guide includes managing the receipt of HL7 messages including negative, positive, and unknown serologic

test results, both qualitative and quantitative test values, and the date the test results were confirmed. The test type is currently not in scope but may be inherent in the response type. Reference materials include a link to a modeling document produced by Logica Health where various test types can be found.

The table below provides additional explanation for what is included within the scope of the guide.

Table 1 – In scope

Description	In Scope	Notes
Data submission	HL7 messages containing test date, test type, and test results of serologic tests	Annual influenza clinic for a college campus, COVID-19 pandemic vaccine, or vaccination campaign in response to a natural disaster or bioterrorism threat.
Serologic test date	Date of observation (sample collection) Date of analysis (test run)	The IIS should receive and store the date the test results were documented by the health care provider to confirm an individual was tested and test results are available.
Serologic test result types	Quantitative – Examples: single value (ml), range of values Qualitative – Examples: positive, negative, detected, not detected	The IIS should have the capacity to receive and store both quantitative and qualitative test result values in order to accommodate the various test types using each value. The IIS will accept the values as sent, without clinical interpretation.
Lack of serologic test results		The IIS should differentiate between a test given with any result (including negative or indeterminate) and lack of a test so that the IIS can support an individual's test status as unknown.
Type of serologic test	May be included as part of the messaging in observation result (ORU) segments	A variety of serologic tests exist, and differentiating test type supports the validation of the test result values.

Out of scope

The scope of the guidance does not extend to detailed information about the various test types. Manufacturer, trade name, and lot number are not likely to be available from ORU messages and, therefore, are out of scope for the guidance. Viral tests are used to diagnose COVID-19. These tests indicate infection but do not infer immunity. The receipt and storage of diagnostic test results are not included in the guidance. At this time, the capability of the IIS to query for serologic test results or to be queried for serologic test results is not included in the guide.

The table below provides additional explanation for what is not included within the scope of the guide.

Table 2 – Out of scope

Description	Out of Scope	Notes
Query	Inclusion of known serologic test results for a patient as part of a query by parameter (QBP) message from a provider. Health system query of the IIS for response (RSP) containing serologic testing results. IIS query of other systems to obtain serologic testing results.	All may be useful in the future, but the urgency of this guidance prohibits the inclusion of querying of and by the IIS for serologic test data, which is out of scope for this project.
Diagnostic testing	Diagnostic testing does not substitute for serologic testing as a source for inferring immunity.	At this time, ACIP does not indicate that diagnostic testing for COVID-19 can be used to infer immunity for COVID-19.
Manufacturing details of tests	Manufacturer Trade name Lot number	These data are not available from ORU messages and will not be included in HL7 messages.
Use of test results	The downstream uses, including use of the data in forecasting, of the test result data once it is stored.	Whether or not immunity is included in the forecasting recommendations will ultimately be decided by ACIP, and implementation guidance will be covered by CDSi Logic Guidance.

Guidance

Available standards

HL7, AIRA, and CDC have published or are developing a number of interoperability standards and guides which may be relevant to the exchange of patient-level serologic data. The following standards may be relevant to the remainder of the document.

- *HL7 Version 2.5.1 Implementation Guide for Immunization Messaging*
  - This is the current implementation guide (IG) for immunization messaging and contains guidance on transmitting non-discrete serologic and presumed immunity data elements. It is expected that additional functionality regarding discrete lab results will be required in addition to the current requirements in the current IG.
  - https://repository.immregistries.org/files/resources/5bef530428317/hl7_2_5_1_release_1_5__2018_update.pdf
- *AIRA Guidance on Detailed Message Structure and the Use of Specific LOINC Codes*
  - This document clarifies the use of LOINC codes within the messages defined by the Release 1.5 IG. It provides a more thorough description of exchanging serologic evidence of immunity and presumed evidence of immunity as part of a patient-level set of observations.
  - https://repository.immregistries.org/files/resources/5938386822754/message_structure_guidance_document_v1_1__formatted.pdf
- *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health*
  - This is the IG that many electronic health records (EHRs) and lab systems have implemented for exchanging reportable results with Public Health. This standard is currently being used to electronically exchange COVID-19 lab results. Note that several versions of this IG exist, although the basic requirements for the lab results message are the same regardless of version. Also note that the most recent version of this standard was incorporated as a "Public Health Reporting" profile in the context of the larger Laboratory Results Interface (LRI) implementation guide. At this point, we expect that most implementations of reporting to Public Health are using one of the earlier (ELR) specifications rather than the newer LRI specification.
  - *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)*
  - *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)*
  - *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm*
- *HL7 Logica Implementation Guide: Covid-19*
  - Logica is developing a Fast Healthcare Interoperability Resources (FHIR) implementation guide for the purpose of producing information models and

terminology to support exchange of COVID-19 related data. While we don't expect systems to use FHIR to exchange this type of data any time soon, the lab result observation profiles defined by this document may be helpful in associating tests with the relevant LOINC code and result data type.

  o   https://covid-19-ig.logicahealth.org/index.html

Lab result workflow and content

The lab result workflow typically begins with a clinician ordering a test from a catalog of tests offered by the lab. A test ordered may be for a single analyte test, or it may represent a "panel" of tests. For example, when a lipid panel is ordered, it typically results in measurements of total cholesterol, HDLs, LDLs, and triglycerides. Once placed, the order is conveyed from the ordering clinician to the lab which will perform the tests. Depending on the nature of the relationship between the ordering organization and the performing lab, the exchange of order information may be paper based (i.e., a lab requisition form) or electronic, and the amount of metadata (i.e., demographics) about the patient conveyed will vary. Once the test is performed and the results verified, the results will typically be returned electronically to the ordering clinician's EHR system. It is this electronic result message which contains the discrete data potentially of interest to an IIS.

In many workflows, it is possible to cancel a previously placed order, but typically this is allowed only prior to the delivery of test results. That is, once a test is performed and a result captured, the test can no longer be canceled. Because we do not expect IIS to be notified when a test is placed, the cancellation workflow is not of primary importance here.

It is important to understand that lab results can be reported for a patient multiple times. When reporting to the clinician's EHR, preliminary results are often reported followed by an updated message when the results are finalized. Further, even final results may be updated to a status of corrected. This is in contrast to vaccination messages where observations are typically only "final" and are not updated. When consuming lab result messages, it will be important that IIS allow for the update of lab results. As well, the same test may be performed for a given patient multiple times using multiple, independently collected specimens. For example, a serologic test may be ordered and a new specimen collected for a given patient over time to measure if immunity is persisting. It is important for a system to be able to distinguish an updated test result from a repeat of the test for the same patient.

Most discrete lab result results are exchanged as observations using a "question and answer" format. In HL7 v2, this equates to an observation (OBX) segment where the "question" is found in OBX-3 (usually as a LOINC code, although local codes are also possible) and the "answer" is found in OBX-5.

We expect that the data type of the answer in OBX-5 (as indicated in OBX-2) will vary by the test performed, although it should be consistent for any given test. We expect that most COVID-19 related tests will be reported as either a qualitative or quantitative result. Qualitative results will likely use a coded data v2 data type (CE, CWE, etc.) with values such

as positive/negative or detected/not detected/inconclusive. Quantitative results will use a numeric data type (NM or SN).

Being relatively rare, the SN (structured numeric) data type may not be familiar to many people, but it is important to be prepared to receive this data type in the OBX segment, as the use of a ratio may be common when using serologic tests. The SN data type is used to exchange discrete numeric results with qualifications. For example, SN is used to indicate a result as a ratio (e.g., 1:2), range (e.g., 5-6), or open-ended range (e.g., <5). When used in OBX-5, the SN data type may be composed of up to four elements consisting of:

- Comparator (=, >, <, <=, >= or <>)
- Number
- Separator (+, -, / or :)
- Number

For example, a value of <5 in OBX-5 appears as <^5 while a ratio of 1:2 appears a ^1^:^2

If receiving data in the SN data type format, it is important that the receiving system understand how the results will be used downstream and be prepared to store the data elements either discretely or as a string depending on subsequent needs. Please review the HL7 base standard for a more thorough description of the SN data type.

Regardless of the context in which an OBX segment is found, the content of the segment itself is expected to be very similar, if not identical. That is, it doesn't matter if the OBX segment containing a lab result is part of a vaccination event message (VXU) or a lab result message (ORU); the OBX itself should be consistently formatted and populated.

A further discussion of data elements in the OBX segment which can be expected in a typical lab result can be found in the Common Important Data Elements section later in the document.

Sources of data

Lab tests can be run by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a. This includes either high or medium complexity tests. Additionally, tests can be run in patient care settings that are operating under a CLIA Certificate of Waiver. When lab tests are run by high or medium complexity laboratories, the patient sample may be collected in a patient care setting, and test results may be returned to the patient care provider.

As a result, there are two main sources of first-party data:

- CLIA-certified laboratories (electronic laboratory reporting (ELR) systems)
- Patient care providers (including physicians with EHR systems and other non-traditional providers such as pharmacies or nursing services)

Additionally, third-party data may be available from:

- Public Health

- o State or jurisdictional disease surveillance systems
- o State-to-state IIS data exchange
- Health information exchanges (HIEs)
- Payors, such as Medicaid/Medicare or private health plans

It is important not to add burden to existing systems and data feeds. One option to allow the IIS to receive data without increasing the burden on lab systems would be to split the feed that is directed to the state or jurisdiction disease surveillance system. With this approach, an ORU would be redirected to the IIS, and the IIS could consume it as an ORU or convert it to a VXU (vaccination record update) and then consume.

VXU^V04 message structure

Most readers of this document will be familiar with the basic structure of the VXU message type; however, a brief summary will be provided to facilitate a comparison to the ORU message type typically used for lab results.

For the purposes of reporting vaccination events, the key segments within the VXU message as defined by the Release 1.5 IG are:

- MSH – Message header
- PID – Patient identifier
- PD1 – Patient demographics
- NK1 – Next of kin
- ORC – Order request
- RXA – Administration
- RXR – Route
- OBX - Observation result

The data central to the vaccination event is contained with the ORC/RXA/RXR group, but additional related data may be included as observations in repetitions of the OBX segment. Where the observation is associated with a vaccination event (e.g., the patient's eligibility status or an adverse reaction), the OBX segment follows the ORC/RXA/RXR group describing that vaccination event. However, some observations, such as evidence of immunity, are not linked to a vaccination event and are grouped as part of a set of patient-level observations as described in the *AIRA Guidance on Detailed Message Structure and the Use of Specific LOINC Codes*. It is expected that any discrete laboratory results transmitted in a VXU message would be exchanged as OBX segments in the patient-level group.

ORU^R01 message structure

Typically, lab results are exchanged using an ORU^R01. This message structure shares many segments with the VXU message and should look familiar to most readers. For the purposes of reporting laboratory results, the key segments within the ORU message as defined by the *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health* are:

- MSH – Message header

- PID – Patient identifier
- NK1 – Next of kin
- PV1 – Patient visit
- ORC – Order request
- OBR – Observations request
- TQ1 – Timing/quantity
- OBX – Observation result
- NTE – Notes and comments
- SPM – Specimen

While the ORU message does contain several types of segments not found in a VXU message (e.g., PV1, TQ1, and SPM), we expect that these segments will not significantly impact the logic executed by an IIS when considering the impact of COVID-19 test results on vaccine recommendations.

The OBR segment in the ORU message in many ways is akin to the RXA (pharmacy/treatment administration) segment of the VXU message. The OBR segment will typically contain both the placer and filler identifiers associated with the order (note that these are also found in the ORC segment) as well as the test ordered (be it a panel or an individual test). One OBX segment should be present for each individual test performed. To return to the lipid panel example from above, the OBR segment will contain a code in OBR-4 representing the lipid panel that was ordered, and the message would be expected to contain four OBX segments, one for each analyte (total cholesterol, LDL, HDL, and triglycerides). For expected IIS purposes, it is the content of the OBX segments (the actual results) and not the OBR segment (the test orders) which will be of importance.

While less common, it is also possible that an NTE segment may follow an OBX segment. When this happens, the NTE typically contains a comment relating to the result in the preceding OBX segment. The comment may describe a particularly complex reference range for the test or provide additional data about the result. Regardless of the exact content of the NTE, this segment is unlikely to contain discrete data useful for automated forecasting functions. When implementing the ability to receive lab results, it is worth exploring the contents of the NTE segment for the specific use cases being implemented.

As will be described in the following section, the contents of the core PID, ORC, and OBX segments are expected to be relatively similar between the VXU and ORU message types.

It is important to note that, while many labs and EHRs have implemented support for the ELR standard, not all reportable result messages flowing to Public Health strictly abide by this standard and that there may be local variation in message content. However, we expect that the core data element used for patient matching (in PID) and the discrete lab result (in OBX) will be found in most messages. Still, receiving systems should be validating the completeness of the results received.

Common important data elements

As noted above, the contents of the critical message segments (PID and OBX) should be relatively similar between the VXU and PID message types.

It is expected that the contents of the PID segment will primarily be used for patient matching purposes. Most of the demographic elements used for this purpose are included in both message types. It should be noted that, depending on the workflow that transmits ordering information from the clinician to the lab, sometimes only minimal patient demographic data will be available in the result (ORU) message. This may impact the IIS's ability to perform patient matching. Based on past experience and input from commercial labs, we expect that most result messages will consistently contain the patient name, date of birth, and gender and that additional demographics, such as address and phone number, will be included when they are available to the lab.

Table 3 - PID data elements

PID Data Element	VXU Profile Usage	ORU Profile Usage	Comments
PID-3 (patient identifier)	R [1..*]	R [1..*]	The patient ID received from vaccination submitters and the lab might not be the same for a given patient.
PID-5 (patient name)	R [1..*]	R [1..*]	
PID-6 (mother's maiden name)	RE [0..1]	RE [0..1]	Mother's maiden name is less likely to be available on a lab result.
PID-7 (date/time of birth)	R [1..1]	RE [0..1]	
PID-8 (administrative sex)	RE [0..1]	RE [0..1]	
PID-10 (race)	RE [0..*]	RE [0..*]	
PID-11 (address)	RE [0..*]	RE [0..*]	
PID-13 (home phone)	RE [0..*]	RE [0..*]	
PID-22 (ethnic group)	RE [0..1]	RE [0..*]	
PID-24 (multiple birth order)	RE [0..1]	O [0..1]	
PID-25 (birth order)	RE [0..1]	O [0..1]	

The ORC segment from the lab result message should contain similar data elements as found in VXU messages. This order-level information is important for deduplication of test results.

Table 4 – ORC data elements

ORC Data Element	VXU Profile Usage	ORU Profile Usage	Lab Results Comments
ORC-1 (control code)	R [1..1]	R [1..1]	VXU messages and the majority of ORU messages will have a value of "RE" in ORC-1, but cancel messages are included in the scope of the exchange (see above); values of "CA" or "OC" may be possible.
ORC-2 (placer order number)	RE [0..1]	RE [0..1]	
ORC_3 (filler order number)	R [1..1]	R [1..1]	Different orders will have different filler IDs. An update to a previous result should have the same filler ID.
ORC-12 (ordering provider)	RE [0..1]	RE [0..1]	
ORC_17 (entering organization)	RE [0..1]	O [0..1]	

The OBX segment from the lab result message will likely contain additional data elements not typically found in VXU messages; however, the core OBX fields should be similar.

Table 5 – OBX data elements

OBX Data Element	VXU Profile Usage	ORU Profile Usage	Lab Results Comments
OBX-2 (value type)	R [1..1]	R [1..1]	This indicates the data type of the result in OBX-5.
OBX-3 (observation identifier)	R [1..1]	R [1..1]	This will contain the test code, typically using LOINC.
OBX-4 (sub-ID)	R [1..1]	RE [0..1]	This may be present only when a single message contains multiple OBX segments with the same OBX-3 value.
OBX-5 (value)	R [1..1]	R [1..1]	OBX-5 may be empty, and for IIS purposes this is meaningful on an update to clear a previous value.
OBX-6 (units of measure)	RE [0..1]	RE [0..1]	This should be populated only for quantitative results where OBX-2 is NM or SN.
OBX-7 (reference range)	O [0..1]	RE [0..1]	This indicates the "normal" range of test results. This is more common for quantitative tests.
OBX-8 (abnormal flag)	O [0..1]	RE [0..*]	This indicates the "normalcy" of the result. Typically only "abnormal" results are flagged using OBX-8.
OBX-11 (result status)	R [1..1]	R [1..1]	E.g., final, preliminary
OBX-14 (observation date/time)	RE [0..1]	RE [0..1]	This is typically the time the specimen was collected. This field can be used to help distinguish an "updated" result from a "new" result for a given patient. An "updated" result should always have the same OBX-14 value as a previous result.
OBX-17 (observation method)	O [0..1]	RE [0..1]	Some tests in OBX-3 can be performed via different methods.

OBX Data Element	VXU Profile Usage	ORU Profile Usage	Lab Results Comments
OBX-19 (analysis date/time)	O [0..1]	RE [0..1]	Time the testing was performed.
OBX-23 (performing organization)	O [0..1]	R [1..1]	Who performed the test (note that the lab's address and medical director are also provided in OBX-24 and OBX-25).

Processing and storing data

Currently, IIS receive, process, and store data observations for contraindications, precautions, indications, and immunity that impact the patient immunization recommendations. The general immunity scenarios, based on laboratory evidence of immunity, are supported with the following two codes from the NIP003 CDC-defined code table for observation identifiers:

- 59784-9: Disease with presumed immunity
- 75505-8: Serologic evidence of immunity

The current identifiers provide only for the sending and storing of a positive result. In order to store additional detail about the result, including the type of test and either a qualitative or quantitative result, the IIS will need the following:

- Data model to store this information
    - IIS should store the test result and the test date as received.
        - The IIS can infer a meaning from a quantitative result but should store the original values, as the implications for immunity on a quantitative result may change as more is learned.
    - The IIS should be able to store multiple test results, on different dates, for the same test type and patient.
        - As not all immunity results confer lifetime immunity, the patient's immunity may change over time.
        - The IIS should support updates to a test and differentiate an update from a new test for the same patient. This can be done by storing the order number as a unique identifier for the test or by comparing the specimen collection date/time.
    - Lack of immunity information should not be treated as a negative result, so the IIS should support differentiating between a negative result and "test not given" in the business logic.
    - The HL7 specification provides for two dates: the date of sample collection and the date the analysis was performed. If the IIS chooses to record only one date, the date of sample collection should be used.

- Business logic to incorporate patient immunity into the immunization recommendations
    - This will be based on the ACIP guidance for COVID-19 (and any additional vaccine where the patient's immunity status is significant, such as dengue fever).

Code sets

NIP003 (values supported in the HL7 2.5.1 specification)

Table 6 - LOINC codes

LOINC Code	Description	Corresponding Data Type (OBX-2)	Corresponding Observation Value (OBX-5)
59784-9	Disease with presumed immunity	(CE)	Value Set OID - 2.16.840.1.114222.4.11.3293 Value Set Code: PHVS_EvidenceOfImmunity_IIS For COVID-19, use 840535000 (Antibody to SARS-CoV-2).
75505-8	Serologic evidence of immunity	(CE)	Value Set OID - 2.16.840.1.114222.4.11.7245 Value Set Code: PHVS_SerologicalEvidenceOfImmunity_IIS For COVID-19, use 840535000 (Antibody to SARS-CoV-2).

New codes

COVID-19 tests are currently authorized under Emergency Use Authorizations (EUA) by the FDA. This list is still actively updated and is available here: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

Additionally, guidance for COVID-19 LOINC codes has been created and is available here: https://loinc.org/sars-coronavirus-2/.

While both sources contain both diagnostic and antibody tests, it is expected that IIS would support receiving antibody tests only for the purposes of representing immunity.

This table is for example purposes only and is not a comprehensive list of possible codes.

Table 7 – COVID-19 LOINC codes

LOINC Code	Description	Corresponding Observation Value (OBX-5)
94507-1	SARS-CoV-2 IgG rapid immunoassay	(qualitative)

94762-2	SARS-CoV-2 antibody (non-specific) immunoassay	(qualitative)
94769-7	SARS-CoV-2 antibody (non-specific) immunoassay	(quantitative)
94563-4	SARS-CoV-2 IgG immunoassay	(qualitative)
94505-5	SARS-CoV-2 IgG immunoassay	(quantitative) Units: ml
94547-7	SARS-CoV-2 IgG + IgM (does not distinguish between the two) immunoassay	(qualitative) https://covid-19-ig.logicahealth.org/ValueSet-covid19-det-not-det-inconclusive-vs.html 260415000Not detected (qualifier value) 419984006Inconclusive (qualifier value) 260373001Detected (qualifier value)
94661-6	SARS-CoV-2 antibody interpretation	(qualitative)

Appendix A: Examples and Test Cases

Warning: The HL7 examples shown in this appendix are preliminary and not yet tested or verified.

Use Case 1: Serological Evidence of Immunity Test Case 1: Send VXU Z22 Evidence of Immunity

This use case covers the existing functionality within the Release 1.5 IG for sending immunity. The example shows how COVID-19 immunity would be sent.

```
MSH|^~\&|NISTEHRAPP|NISTEHRFAC|NISTIISAPP|NISTIISFAC|20191120142514-
0500||VXU^V04^VXU_V04|NIST-IZ-
1.1_EI_Send_VXU_V04_Z22|P|2.5.1|||ER|AL|||||Z22^CDCPHINVS|NISTEHRFAC^C
DCPHINVS|NISTIISFAC|NISTIISFAC

PID|1||14445^^^NIST-MPI-
1^MR||Jackson^Hazel^^^^^L|Willis^^^^^^M|19900312|F||2131-1^Other
race^CDCREC|2501 Duval
Street^^Austin^TX^78704^USA^P||^PRN^PH^^^512^5559812|||||||||2186-
5^Not Hispanic or Latino^CDCREC||N|1|||||N

PD1||||||||||||07^Recall only - no
calls^HL70215|N|20091120|||A|20091120|20091120

ORC|RE|3598^NIST-AA-IZ-2|9999^NIST-AA-IZ-
2|||||||9914^Hill^Spencer^Tyler^^^^^wcEHR^L^^^PRN||724^Jordan^Vivian^S
arah^^^^^wcEHR^L^^^MD|||||wcEHR^West Clinic^HL70362

RXA|0|1|20091120|20091120|998^No vaccine
administered^CVX|999|||||||||||||NA

OBX|1|CWE|75505-8^Disease with serological evidence of
immunity^LN|1|840535000^Antibody to SARS-CoV-2^SCT|||||||F|||20091120
```

Use Case 1: Serological Evidence of Immunity Test Case 2: Send VXU/ELR-OBX Z22-covid-lab Evidence of Immunity - Quantitative Positive

This use case shows both a quantitative result and a qualitative result (interpretation of the quantitative result).

```
MSH|^~\&|NISTEHRAPP|NISTEHRFAC|NISTIISAPP|NISTIISFAC|20191120142514-
0500||VXU^V04^VXU_V04|NIST-IZ-
1.1_EI_Send_VXU_V04_Z22|P|2.5.1|||ER|AL|||||Z22-covid-
lab^CDCPHINVS|NISTEHRFAC^CDCPHINVS|NISTIISFAC|NISTIISFAC

PID|1||14445^^^NIST-MPI-
1^MR||Jackson^Hazel^^^^^L|Willis^^^^^^M|19900312|F||2131-1^Other
race^CDCREC|2501 Duval
Street^^Austin^TX^78704^USA^P||^PRN^PH^^^512^5559812|||||||||2186-
5^Not Hispanic or Latino^CDCREC||N|1|||||N

PD1||||||||||||07^Recall only - no
calls^HL70215|N|20091120|||A|20091120|20091120
```

```
ORC|RE|3598^NIST-AA-IZ-2|9999^NIST-AA-IZ-
2||||||||9914^Hill^Spencer^Tyler^^^^^wcEHR^L^^^PRN||724^Jordan^Vivian^S
arah^^^^^wcEHR^L^^^MD|||||wcEHR^West Clinic^HL70362

RXA|0|1|20091120|20091120|998^No vaccine
administered^CVX|999|||||||||||||||NA

OBX|1|SN|94505-5^SARS-CoV-2 IgG SerPl IA-aCnc^LN^^^^2.44^^Novel 2019
Coronavirus IgG
Ratio|1|^1.3|^^^^^^^^[arb'U]|||||F|||20200428103000|||^^^^^^^^EuroImmu
n Anti-SARS-CoV-2 ELISA (IgG)||20200429173600||||STATE HYGIENIC
LABORATORY AT THE UNIVERSITY
OFIOWA^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^FI^^^16D0648109|2490
Crosspark Road^University of Iowa Research Park^Coralville^IA^52241-
4721^USA^B^^19103|^Pentella^Michael^^^^^^L

OBX|2|CWE|94563-4^SARS-CoV-2 IgG SerPl Ql
IA^LN^^^^2.44^^Interpretation|1|10828004^Positive^SCT^^^^^^Elevated|||
||||F|||20200428103000|||^^^^^^^^EuroImmunAnti-SARS-CoV-2 ELISA
(IgG)||20200429173600||||STATE HYGIENIC LABORATORY AT THE UNIVERSITY
OF IOWA^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^FI^^^16D0648109|2490
Crosspark Road^University of Iowa Research Park^Coralville^IA^52241-
4721^USA^B^^19103|^Pentella^Michael^^^^^^L
```

Use Case 2: Presumed Immunity Test Case 1: Send VXU Z22 Evidence of Immunity

This use case covers the existing functionality within the Release 1.5 IG for sending immunity. The example shows how COVID-19 immunity would be sent.

```
MSH|^~\&|NISTEHRAPP|NISTEHRFAC|NISTIISAPP|NISTIISFAC|20191120142514-
0500|||VXU^V04^VXU_V04|NIST-IZ-
1.1_EI_Send_VXU_V04_Z22|P|2.5.1|||ER|AL|||||Z22^CDCPHINVS|NISTEHRFAC^C
DCPHINVS|NISTIISFAC|NISTIISFAC

PID|1||14445^^^NIST-MPI-
1^MR||Jackson^Hazel^^^^^L|Willis^^^^^^M|19900312|F||2131-1^Other
race^CDCREC|2501 Duval
Street^^Austin^TX^78704^USA^P||^PRN^PH^^^512^5559812|||||||||||2186-
5^Not Hispanic or Latino^CDCREC||N|1|||||N

PD1|||||||||||07^Recall only - no
calls^HL70215|N|20091120|||A|20091120|20091120

ORC|RE|3598^NIST-AA-IZ-2|9999^NIST-AA-IZ-
2||||||||9914^Hill^Spencer^Tyler^^^^^wcEHR^L^^^PRN||724^Jordan^Vivian^S
arah^^^^^wcEHR^L^^^MD|||||wcEHR^West Clinic^HL70362

RXA|0|1|20091120|20091120|998^No vaccine
administered^CVX|999|||||||||||||||NA

OBX|1|CWE|59784-9^Disease with presumed immunity
^LN^LN|1|840535000^Antibody to SARS-CoV-2^SCT|||||||F|||20091120
```

Appendix B: Items for Future Discussion

This section identifies additional considerations that are not in scope for this guidance document but may be good to consider for future guidance.

Queries

- What system or entity would perform the query (IIS, HIE, EHR, etc.)?
- Should immunity be returned as part of the RSP?
- Can immunity be sent as part of the QBP for purposes of providing an observation that will be considered in the forecast?
- Would a registry store information sent in an OBX from a query (QBP)?

Appendix C: Vocabulary and Acronyms

Vocabulary

Antibody test: An antibody test determines the presence of antibodies against a specific microorganism.

Diagnostic test: A diagnostic test is used to gather information for purposes of making a clinical decision. For COVID-19, diagnostic tests determine a current infection.

Serology: Examination of blood serum, especially with regard to the response of the immune system.

IgG: Antibody that is mostly responsible for long-term immunity after an infection or vaccination.

IgM: First response to a microbial infection/antigen invasion. May indicate active disease.

Clinical Laboratory Improvement Amendment: A high or medium complexity test will be done at a CLIA lab. A low-complexity test (point of care test) may be CLIA-waived.

Acronyms

Acronym	Definition
CLIA	Clinical Laboratory Improvement Amendment
ELR	Electronic laboratory reporting
IIS	Immunization information system

Appendix D: References and Technical Resources

- HL7 Version 2.5.1 Implementation Guide for Immunization Messaging. https://repository.immregistries.org/files/resources/5bef530428317/hl7_2_5_1_release_1_5__2018_update.pdf
- Centers for Disease Control and Prevention Testing for COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
- Centers for Disease Control and Prevention Immunization Information System Code Sets. https://www.cdc.gov/vaccines/programs/iis/code-sets.html
- Guidance for mapping to SARS-CoV-2 LOINC terms. https://loinc.org/sars-coronavirus-2/
- Logica Implementation Guide for Covid-19. https://covid-19-ig.logicahealth.org/
- HL7 2.5.1 Electronic Laboratory Reporting Documentation. https://www.cdc.gov/elr/technicalstandards.html

Appendix E: Acknowledgements

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