

Proposed HHS ELR Submission Guidance using HL7 v2 Messages

- NOTE: HHS has published their implementation guidance table: <https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf>
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Revision Log:

- 11/3/2020: Updated the SCT code description for fever from 426000000^Fever over 104F^SCT to 426000000^Fever greater than 100.4 Fahrenheit^SCT to match HHS implementation guidance.
- 9/21/2020: Added note to NOT send Symptom Onset Date AOE, when unknown (as that creates a change in datatype).
- 9/14/2020: Updated syntax for the Device Identifier, when using the UDI definition (numeric values accessible via the FDA GUUID database)(section).

Introduction

The purpose of this page is to capture the goals and requirements to enhance ELR reporting in the context of the COVID pandemic, in light of [HHS guidance](#), and in that context provide clear guidance to all parties in the communication flow to enhance their contributions to enhance the ELR transaction to a Public Health Authority.

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Definitions

- AOE - Ask at Order Entry
- eCR - Electronic Case Report (can be reported using [CDA](#) or [FHIR](#)) - is complimentary dataflow
- eDOS - Electronic Directory of Services implementation guide or transaction according to that guide
- CLIA - Clinical Laboratory Improvement Amendments
- ELR - Electronic Lab Reporting implementation guide or transaction according to that guide - in this context the referened guide is R1 (2010 with clarification and errata)
- EUA - Emergency Use Authorization
- IICC - IVD Industry Connectivity Consortium
- LDT - Laboratory Developed Test
- LIS/LIMS - Laboratory Information System (Clinical Labs) or Laboratory Information Management System (Public Health Labs)
- LOI - Laboratory Order Interface implementation guide or transaction according to that guide
- LRI - Laboratory Results Interface implementation guide or transaction according to that guide
- O - Optional
- PD1 - Patient Demographics
- PHA - Public Health Authority
- PID - Patient Identification Segment
- PV1 - Patient Visit Segment
- RE - Required but may be Empty (Must support)
- R - Required
- UDI - [Unique Device Identifier](#)

Current Challenges

When ELRs are sent to PHA at times, they may not contain sufficient demographic, and other data as required by public health by law. This guidance aims to facilitate collection and transmission of these vital data at order entry, for transmission to the performing laboratory and on to the respective PHA. While some of the data may be part of a provider eCR report to public health, eCR is out of scope for this discussion, but ELR data would need to be aligned with eCR reporting. These data often available at order entry, and their transmission to the performing laboratory and in that lab's ELR report, may be the first notice to PHA and accelerate PHA processes.

Currently, the following are the data flows that would be impacted:

- Device manufacturer(s) provide(s) label information with UDI(s) and [insert information](#) to the laboratory to enable them to validate their test system (EUA, LDT) in accord with regulations like CLIA (i.e. §493.1253). (Same information is provided to test performers using waived testing device(s).)
 - Format: [package label\(s\) with barcode UDI\(s\)](#),
- Performing laboratory/test performer builds test orders, results, result values, reference ranges, AOE's, and associated test information in their LIS/LIMS; configures interfaces from their instruments to their LIS/LIMS and/or sets up capabilities for manual results entry in LIS/LIMS; and configures interfaces from performing laboratory LIS/LIMS to/from ordering provider EHRs, other laboratory LIS/LIMS, and PHAs to support transmission and receipt of data for orders, results, public health reporting, etc.
 - Format (in lab interfaces): IHE-LAW, ASTM
 - Format (external interfaces): HL7 v2.x orders/results, LOI (future), LRI, ELR
- Performing laboratory maps national code systems (i.e. LOINC, SNOMED CT) for test(s) performed with their device(s) into their LIS/LIMS for use in messages LRI, LRI, etc. AOE's, test orders, and results are mapped to LOINC, while SNOMED CT is used for qualitative test result values, specimen types (i.e. swab), specimen source (i.e. left nares).
 - Format: paper, LIVD-IICC spreadsheet format, LIVD-FHIR (future)
- Performing laboratory builds information required for test ordering (in accord with [§493.1241 Standard: Test request](#)) into their paper or electronic CLIA Specimen Collection Manual. AOE's for orderable tests should include their code system mappings. The performing laboratory informs the ordering provider (EHR) or referral laboratory (LIS) (who informs their ordering providers) of required data elements for test requests (orders) including relevant AOE's. For consumer/home testing, home specimen collection, or where Direct to Consumer (DTC) Testing is allowed, a system shall be in place to collect the required data elements from the consumer and/or ordering provider about the patient being tested.
 - Format: Paper, eDOS IG, FHIR order catalog (future)
- The ordering provider (via their EHR or order entry system) must include all required data available at the time of order entry on the test request (order message) directly to the performing laboratory or indirectly via a referral laboratory that forwards the required information to the performing laboratory. Both laboratories may be responsible for ELR submission depending on jurisdictional requirements and at a minimum, the performing laboratory.
 - Format: Paper, web portal (pdf or structured data), HL7 v2.3 and higher using ORM, HL7 v2.5 and higher OML, HL7 LOI IG (future)

- The performing lab using their LIS/LIMS reports results back to the ordering provider directly (to their EHR or portal system) or to the referral laboratory (to their LIS/LIMS or portal) which sends the results to the ordering provider (to their EHR or portal system). The patient may receive their results via phone, their EHR, or other online portal or application, from the performing laboratory directly, especially in jurisdictions where Direct to Consumer testing (DTC) is allowed; from the ordering provider, or PHA.
 - Format: Paper, fax, telephone, webportal (pdf or structured data), HL7 interfaces in any version using ORU, HL7 LRI IG (future)
- The performing laboratory with their LIS/LIMS has capabilities to receive and store all test request information from senders including AOE and code mappings so they can be associated with patient results, device(s) utilized in performing testing, and any other required data elements to be leveraged in reporting to the provider, referral laboratory if applicable, and PHA. The performing laboratory communicates all required information for reportable conditions in accord with all pertinent regulations/laws (i.e. CLIA, HHS, PH jurisdictions) and their timelines for reporting.
 - Format: Paper, telephone, flatfile, various HL7 v2.x formats, ELR IG,
- The Public Health Agency forwards the information as appropriate (e.g., de-identified) to HHS for sharing with and use by federal agencies (i.e. CDC, FEMA, White House, FDA)
 - Format: flatfile, HL7 v2.3.1, ELR R1, NMI formats (for cases), various other file formats

As certification to HL7 ELR R1 IG is not required for EHRs, nor LISs, and adoption of certified ELR capabilities is voluntary under CMS' Meaningful Use /Promoting Interoperability program for providers, while not addressed in other programs for Laboratory (e.g., CLIA), while states introduce further variations, and lab order transaction formats are not addressed anywhere, implementations across all data flows vary widely and production use of HL7 ELR R1 IG is limited. Additionally, the ELR reporting enhancements could almost all be addressed with the latest HL7 LRI R1 STU R3 IG, but that has not been adopted by anybody, since it was not included in MU regulation.

Additionally, as the PHA onboards the lab, they may accept a variety of fields, formats as long as they are receiving key information. Also it's unclear if point of care testing locations like pharmacies, drive up/drive through testing sites or state national guard collection sites for COVID-19 are 1) reporting ELR at all, 2) providing all required information and 3) those reporting on paper requisitions will not be providing LOINC or SNOMED CT codes and are often lacking demographics, specimen source and other required PHA elements.

Throughout the data collections and flows there are numerous challenges in terms of data not being able to be collected (even if it could be available), not being documented, not using standard vocabulary, not including it in the order, not forwarding certain data, dropping standard vocabulary, not retaining data, not communicating data available to the PHA.

Currently the specific challenges in that area are:

- Deployed lab order implementation guides do not include the guidance on how to convey all the relevant ask-at-order-entry questions and answers recognizably and consistently.
 - [The latest eDOS guide](#) has the commonly used set of AOE with standard LOINC codes and where applicable answer sets, but is not complete to cover the latest updates at this time.
 - [The latest LOI guide](#) addresses the ability to communicate all relevant data, including any AOE, but is not deployed in active use.
 - Upgrading to [the latest LOI guide](#) is a major lift for everybody, so although desired for the mid/long-term, it is not a good short-term recommendation.
- Deployed lab reporting implementation guides do not include the guidance on how to convey all the relevant ask-at-order-entry questions and answers recognizably and consistently, nor the relevant device information, nor sufficient clarity on minimum desired demographic data (some fields may need to be marked RE rather than O, or X).
 - [The latest LRI guide](#) (that now includes ELR in form of the PH_component) accommodates the ability to send any relevant AOE, but may need more specificity on other patient demographic data already available in PID, PV1 or PD1, and will need added guidance on how to convey the relevant device/test kit(s) used to perform the test.
 - Upgrading to [the latest LRI guide](#) is a major lift for everybody, so although desired for the mid/long-term, it is not a good short-term recommendation.
- Device identification data is not included in lab results reporting
 - While the device identification (at least manufacturer and model) is available (either by label/insert/documentation or the LIVD-IICC spreadsheet, not all device identification information of interest is available in a way that the result can include automatically all device identification information for the relevant test kit/reagent, instrument platform, manual kit, and/or emergency use authorization as needed, ideally the UDI(s), but at least the model and manufacturer.

As indicated before, there are many other challenges to ensure that data is fully, accurately, and consistently documented and communicated, including use of encoded standard vocabulary (at least along with any local coding that remains relevant), but that is not addressed here. Our goal is to provide guidance on how to address the above challenges in the necessary implementation guides that can be deployed as quickly as possible and as consistent as possible across ALL jurisdictions.

In short, the challenges this guidance is looking at is ensuring that the relevant data can be communicated from ordering provider through a potential intermediary lab to the performing lab and on to PHA as an ELR in a complete, standard, consistent format and with vocabulary, with the least amount of effort to meet the deadlines.

Existing Implementation Guides

Considering the existing implementation guides and updates to them in flight, upgrading to the latest versions would support most of the requirements and address the challenges outlined above, but still would require various updates to address all requirements. The following updates need to be made in the base implementation guides for a next version to include the short-term Implementation Guidance provided in the next section.

- LIVD-FHIR
 - Add the device identifier for the test kit in the correct resource (DeviceDefinition or ObservationDefinition?)
 - Need a product reference uid to identify the ObservationDefinition OR is it really on the DeviceDefinition?
 - If on the ObservationDefinition, need to re-include ObservationDefinition.identifier 0..*
 - identifier.type = "product-reference-identifier"
 - identifier.system = TBD (for uid)
 - If on the DeviceDefinition
 - Add the assigning authority as well. This is particularly important for OBX-18.3 if the identifier is not an official device identifier.
- eDOS
 - Add new AOE to master list, but nothing needed for the rest

- [LOI](#)
- CLIA test request requirements listed under Resources below.
- Update the value sets for race and ethnicity
- [LRI](#)
- Add LAB_PH_HHS_ELR_Guidance_Component to enable pre-adoption of latest ELR capabilities in earlier versions or HL7 ELR guidance or other HL7 v2.x based guidance:
 - Guidance on how to convey device identification information
 - Report information about the manufacturer and model in OBX-17 (can repeat to accommodate the test kit and the instrument)
 - Report instance information (i.e. the serial number / UDI) in OBX-18 (can repeat), changing usage of OBX-18 to RE
 - Use of PRT when communicating parsed UDI components and possible addition of device relationships
 - Support for test order date by changing usage of ORC-15 to RE
 - Create the MSH-21 component ID
 - Update the value sets for race and ethnicity
 - Update conformance statement around OBX-14 timing
 - Identify use of OBX-29 as part of this profile

We suggest that HHS works with the key stakeholders and HL7 to pursue these updates as quickly as possible to enable adoption. In the meantime, the following section outlines the specific short-term guidance to make substantive progress that also prepares the industry for future adoption of the guides referenced above.

Implementation Guidance for Immediate Use

As adoption of the latest guides is not an option short term, we recommend to adopt the following specific guidance to enable communication of the data in the HHS guidance.

This guidance is based on the technique of pre-adopting the relevant capabilities from more current HL7 v2 versions in context of the latest applicable implementation guides referenced in the prior section, which is an acceptable approach that is reflected in many HL7 implementation guides already. Thus this can be added to any existing HL7 v2.x based ELR specification, recognizing that certain software and integration engines may not recognize and therefore fail "mixed" content without further work.

General

- Data Elements
 - Use proper segments per Mapping Tables below for PID, ORC, OBR, and if applicable to your version of HL7 SPM fields.
 - If the guide indicates they are optional or not supported, apply the usage as listed in the Optionality column below.
 - If not possible, then use OBX segments using LOINC codes as identified above or in Appendix A of [eDOS R2 STU 3](#).
 - For socio-demographic relevant data for population level analytics, use the fields in PID and consider them RE. These include:
 - race
 - sex
 - ethnicity
 - Although not a specific requirement for HHS, if you need to convey the clinical relevant values for for interpretation of lab result for the following data, use AOE OBX as provided by the lab:
 - race
 - ethnicity
 - sex
- Orders - Any HL7 v2 ORM or OML message in place between Ordering Provider and Laboratory as well as Laboratory and Reference Laboratory where the tests are outsourced.
 - Use [LOI R1 STU 3](#) Section 1.4.10 and 6.15 for specification on how to add AOE using pre-adopted OBX capabilities.
 - Include Profile LAB_PH_HHS_ELR_Guidance_Component in MSH-21 (LAB_PH_HHS_ELR_Guidance_Component^2.16.840.1.113883.9.259^ISO): so receiving system recognizes it may contain OBX segments that are based on HL7 v2.8.2.
 - Use [eDOS R2 STU 3](#) Appendix A for an initial list of AOE in addition to any listed above
 - AOE are sent as OBX segments after the OBR it applies to, but before the SPM.
 - AOE OBX segments include OBX-29 as pre-adopted element (from v2.8.2) that is valued "QST" (from HL70936_USL in the [Lab Value Set Companion Guide](#))
 - It is expected that the AOE description in the message is drawn from LOINC.
- Results - Any ELR to PHA
 - Use [LRI R1 STU 3](#) Section 8.11 and 13.3.3 for specification on how to add/forward AOE with the result using OBX segments that are based on HL7 v2.8.2.
 - Include Profile LAB_PH_HHS_ELR_Guidance_Component in MSH-21 (LAB_PH_HHS_ELR_Guidance_Component^2.16.840.1.113883.9.259^ISO):
 - so receiving system recognize it may contain OBX segments that are based on HL7 v2.8.2.
 - can apply additional conformance testing based on OBX-29 values to modify the usage of
 - OBX-14
 - OBX-23, OBX-24 and OBX-25 in ELR R1
 - Adjust usage of ORC-15 and OBX-18 from O to RE and declare the respective datatypes for those fields
 - Use Device Identification guidance below.
 - AOE are sent as OBX segments after the OBR it applies to, but before the SPM.

The following identifies for each of the data elements called out by the HHS guidance where in a v2 message it should be communicated.

Mapping Tables

The embedded spreadsheet includes tabs for each of the tables below as an alternative format.



HHS ELR Guidance...ping Tables.xlsx

Optionality Legend: O-Optional, R-Required (cannot be blank), RE-Required but can be empty if not available, ND-Not Desired by HHS, NF-Not Forwarded to HHS, C-Conditional

Demographic Data

Seq	Name	Optionality	Definition	HL7 Mapping	Implementation guidance	Comments / Open questions
1	Patient date of birth	RE-PHA, O-HHS	This is the preferred field to populate.	PID-7		
2	Patient race	RE-PHA, RE-HHS	Used for socio-demographic analytics, and as permitted by jurisdiction. This may be different than the race used for clinical interpretation (e.g., reference range). If a race is needed for clinical interpretation as well, that must be communicated with an AOE in addition to this field.	PID-10	Code using the expanded value set of HL70005 with these additional values: PHC1175^Refused to answer^CDCPHINVS UNK^Inknown^NULLFL We can use this existing value set in use in case notification (PHVS_RaceCategory_CDC_Ref) UPDATED: instead of using PHC1175 will support ASKU^Asked but unknown^NULLFL, so need a different value set	We will need to define this value set for the LAB_PH_HHS_ELR_Guidance_C component; listing the new values as permitted .
3	Patient ethnicity	RE-PHA, RE-HHS	Used for socio-demographic analytics, and as permitted by jurisdiction.	PID-22	If there is a desire to include refused to answer we will have to expand the traditional ELR R1 value set of HL70189 (PHVS_EthnicGroup_HL7_2x) to include: PHC1175^Refused to answer^CDCPHINVS UPDATED: instead of using PHC1175 will support ASKU^Asked but unknown^NULLFL, so need a different value set	We will need to define this value set for the LAB_PH_HHS_ELR_Guidance_C component; listing the additional value as permitted.
4	Patient sex	RE-PHA, RE-HHS	Used for socio-demographic analytics, and as permitted by jurisdiction. This may be different than the sex used for clinical interpretation (e.g.,	PID-8	Send only the codes from HL70001 table (PHVS_AdministrativeSex_HL7_2x)	

			reference range). If a sex is needed for clinical interpretation as well, that must be communicated with an AOE in addition to this field.			
5	Patient residence zip code	RE-PHA, RE-HHS		PID-11.5		Some jurisdictions consider a combination of age, sex and zipcode PII, because of the population density - need to accommodate that by allowing creation of regions (and that may be better done in the county field)
6	Patient residence county	RE-PHA, RE-HHS		PID-11.9	ELR R1 requires use of numeric FIPS 6-4 codes (PHVS_County_FIPS_6-4)	Some jurisdictions consider a combination of age, sex and county PII, because of the population density - need to accommodate that by allowing creation of regions
7	Patient name (Last name, First name, Middle Initial)	R-PHA, NF-HHS		PID-5		
8	Patient street address	RE-PHA, NF-HHS		PID-11.1		
9	Patient phone number with area code	RE PHA, NF HHS		PID-13	This assumes it is the patient's home phone	

Order Data

Seq	Name	Optionality	Definition	HL7 Mapping	Implementation guidance	Comments
1	Ordering provider address	RE-PHA, NF-HHS		ORC-24.1		The street information is not forwarded and sometimes the city (based on PHA request); state is forwarded (and zip is its own element further down)
2	Ordering provider phone number	RE-PHA, NF-HHS		ORC-14 /OBR-17		
3	Ordering provider name and NPI (as applicable)	RE-PHA, RE-HHS	If the ordering provider is not known, then the ordering facility should be included.	ORC-12 / OBR-16	Ordering Provider Name is in ORC-12.2 / OBR-16.2 and ORC12.3 / OBR-16.3; NPI would be ORC-12.1 / OBR-16.1; when populating ORC-12.1 / OBR-16.1 also populate ORC-12.9 /OBR-16.9 as: "NPI&2.16.840.1.113883.4.6&ISO" and ORC-12.13/OBR-12.13 as "NPI"	For some testing there may not be a specific ordering provider (e.g. employment related testing, mass screening) - it is a CLIA requirement so need to ensure that this is provided. What about ordering provider for home test (is covered through doctor office or on-line doctor who ordered). For drive-thru it is possibly the Surgeon General or appropriate Medical officer
4	Ordering provider zip	RE-PHA, C-HHS	The zip code of the location where the ordering provider is located at the time of ordering. Condition: If patient is in a low density area this should not be forwarded to HHS.	ORC-24.5		
5	Date test ordered (date format)	RE-PHA, RE-HHS		ORC-15		For the PH_HHS_ELR_Guidance_component this element will be RE
6	Test ordered – use harmonized LOINC codes provided by CDC	R-PHA, R-HHS	The test currently being reported to PHA as the test ordered	OBR-4	LOINC is strongly recommended in ELR R1 Use the code from column "LOINC Order Code" and optionally description from column "LOINC Order Code Long Name" in the CDC LIVD mapping file	The LIVD document in the link currently does not cover order LOINC – that needs to be clarified by HHS

Ask at Order Entry

Valueset for Y/N/U - Use PHINVADS valueset (Y/N from HL70136 and UNK from V3 Nullflavor) that is used for Case notifications: <https://phinvas.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.888>. U is replaced with UNK below, except as noted in the implementation guidance.

Note that the following OBX fields are not usually expected for AOE's:

- OBX-6 Units, except for Patient Age (and any other AOE's that might require units of measure)
- OBX-7 Reference Range
- OBX-8 Interpretation code
- OBX-17 and -18 Method/Device
- OBX-19 Analysis date/time
- When populating OBX-23 Performing organization name, OBX-24 Performing organization address and OBX-25 Performing organization medical director should be valued with the applicable information for the provider organization that collected the data.

Note that various AOE's do not have published LOINC codes yet. These have been created in the 2.69 pre-release and are marked with "2.69-pre". Once published they should be communicated with the published release number, likely "2.69".

Note that HHS and CDC are working on finalizing wording of the AOE's and associated LOINC coding. That may result in a different LOINC code and/or a change in questions. We will update this section as soon as HHS and CDC finalize the wording and associated LOINC coding.

NOTE: July 28th Updates are captured in red font below

Seq	Name	Optionality	Definition	Allowable Answers	Implementation Guidance	Comments
1	First test Suggest to HHS to change to: Whether this is the patient's first test for the condition of interest	RE-HHS - changed to optional	Patient's first test for the condition of interest that is being ordered.	Y/N/UNK	OBX-2 = CWE OBX-3 = 95417-2*First test for condition of interest*LN OBX-5 OBX-5 can be one of: Y*Yes*HL70136 N*No*HL70136 UNK*Unknown*NULLFL OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	LOINC: 95417-2*Whether this is the patient's first test for the condition of interest*LN***2.69-pre Questions for HHS: <ul style="list-style-type: none"> • What is the intent of its use and does the patient have to answer it? • Is this for the exact test code ordered, or the type of order? If the latter, what types do we need to consider like or different? E.g. if a provider is ordering a COVID-19 serology test, but the patient has had a PCR test done in the past, would we say Y or N? • Is this only for tests ordered within that organization, or ordered anywhere anytime? E.g., since it's possible that the patient has had other tests through other means (e.g. walk-up clinics, or at a separate ED, etc.)? • Is it relevant for previous test for diagnostic, screening, or research. • Is there clarification between first diagnostic test and first screening test?
1a	Type of most recent test	Optional	Condition: If First Test is N		Molecular Antigen Antibody Unknown	Questions to resolve: How is this expected to be reported? How are patients going to know what type of test was performed? How are providers going to know if the test results are not in their system?
1b	Result of most recent test	Optional			Detected Not detected Unknown	Depending on how this will be reported, how is this result going to be differentiated from the current result, so it is not counted again? Hasn't this result already been reported?
1c	Test performed date	Optional			YYYY[MM][DD]]	Why do labs have to report this, when this is clinical data?
2	Employed in healthcare? Suggest to HHS to change to: Whether patient is employed in a healthcare setting	RE- HHS	The main focus is on patients who work in a high-risk setting with patients who could be a super spreader. (first responders, front line clinicians, environmental staff, therapists, in direct contact with patients or in their location).	Y/N/UNK	OBX-2 = CWE OBX-3 = 95418-0*Employed in a healthcare setting*LN OBX-5 OBX-5 can be one of: Y*Yes*HL70136 N*No*HL70136 UNK*Unknown*NULLFL OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	LOINC: 95418-0*Whether patient is employed in a healthcare setting*LN***2.69-pre
2a	If Yes - What is your occupation?	Optional for Aug 1, 2020	Condition: If Employed in Healthcare is Y		OBX-2 = CWE OBX-3 = 85658-3*Occupation [Type]*LN OBX-5 = SNOMED CT codes from this list: 223366009 Healthcare Professional More Detailed Healthcare Professional List OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	Suggested LOINC: 85658-3*Occupation [Type]*LN***2.68 Comments/Questions: Has NIOSH weighed in on the use of SNOMED CT codes? APHL suggests to allow use of OTH*Other*NULLFL, so that other settings can be reported in OBX-5.9 This is really not lab related data and should be available in the case report / case notification.

3	<p>Symptomatic as defined by CDC?</p> <p>Suggest to HHS to change to: Whether patient has symptoms related to condition of interest</p>	RE-PHA, RE-HHS	Symptomatic per current CDC guidance at time of order for the reportable condition /illness	Y/N/UNK	<p>OBX-2 = CWE</p> <p>OBX-3 = 95419-8^Has symptoms related to condition of interest^LN</p> <p>OBX-5 can be one of: Y^Yes^HL70136 N^No^HL70136 UNK^Unknown^NULLFL</p> <p>OBX-11 = F</p> <p>OBX-14 = Date question was answered</p> <p>OBX-29 = QST</p>	<p>LOINC: 95419-8^Whether patient has symptoms related to condition of interest^LN^2.69-pre</p> <p>(Note that no LOINC is currently listed on the CDC FAQ page but it is expected to be corrected soon)</p>
3a	<p>Date of Symptom Onset</p> <p>Suggest to HHS to change to: illness or injury onset date and time HHS changed the LOINC</p>	C-PHA, C-HHS	Condition: If Symptomatic is Y.	mm/dd/yy	<p>OBX-2 = DT</p> <p>OBX-3 = UPDATED LOINC 65222-2^Date and time of symptom onset^LN</p> <p>41268-8^Illness or injury onset date and time^LN</p> <p>OBX-5 = formatted as YYYYMMDD</p> <p>OBX-11 = F</p> <p>OBX-14 = Date question was answered</p> <p>OBX-29 = QST</p> <p>NOTE: Do NOT send Symptom Onset Date AOE, when unknown (as that creates a change in datatype)</p>	<p>UPDATED LOINC 65222-2^Date and time of symptom onset^LN^2.68</p> <p>LOINC: 41268-8^Illness or injury onset date and time^LN^2.68</p>
3b	<p>If Yes - What were the symptoms experienced?</p>	Optional for Aug 1, 2020	Condition: If Symptomatic is Y.		<p>OBX-2 = CWE</p> <p>OBX-3 = 75325-1^Symptom^LN</p> <p>OBX-4 = if needed for more than one symptom (suggest to number sequentially starting with "1" for each occurrence)</p> <p>OBX-5 can be one of:</p> <p>49727002^Cough^SCT 426000000^Fever over 100.4 Fahrenheit^SCT 267036007^Shortness of Breath^SCT 84229001^Fatigue^SCT 25064002^Headache^SCT 62315008^Diarrhea^SCT 103001002^Feeling feverish^SCT 43724002^Chills^SCT 230145002^Difficulty breathing^SCT 68962001^Muscle pain^SCT 36955009^Loss of sense of taste^SCT 44169009^Loss of sense of smell^SCT 162397003^Sore throat^SCT 68235000^Nasal congestion^SCT 64531003^Nasal Discharge^SCT 422587007^Nausea^SCT 422400008^Vomiting^SCT</p> <p>OBX-11 = F</p> <p>OBX-14 = Date question was answered</p> <p>OBX-29 = QST</p> <p>When more than one symptom apply send each as a separate OBX segments using OBX-4 to differentiate individual answers - in the future it is anticipated that the LAB_PH_HHS_ELR_Guidance_Component will also support multiple repeats of OBX-5 when OBX-29 is valued 'QST'</p>	<p>Suggested LOINC: 75325-1^Symptom^LN^2.68</p> <p>Comments:</p> <p>APHL suggests to allow use of OTH^Other^NULLFL, so that other settings can be reported in OBX-5.9</p> <p>This is really not lab related data and should be available in the case report / case notification.</p>
5	<p>Hospitalized?</p> <p>Suggest to HHS to change to: Whether patient was hospitalized because of this condition</p>	RE-PHA, RE-HHS	<p>Patient has been hospitalized for the reportable illness/condition that this order has been placed for (suspected or diagnosed)</p> <p>When ordered during ER duration, the answer would be N.</p>		<p>OBX-2 = CWE</p> <p>OBX-3 = 77974-4^Patient was hospitalized because of this condition^LN</p> <p>OBX-5 can be one of: Y^Yes^HL70136 N^No^HL70136 UNK^Unknown^NULLFL</p> <p>OBX-11 = F</p> <p>OBX-14 = Date question was answered</p> <p>OBX-29 = QST</p>	<p>LOINC: 77974-4^Whether patient was hospitalized because of this condition^LN^2.68</p> <p>When interested in whether hospitalized at time of order, use PV1-2 (Patient Class).</p> <p>Comment:</p> <p>The CDC web page lists a follow up question here with these expected answers:</p> <p>840544004^Suspected disease caused by 2019 novel coronavirus (situation) 840539006^Disease caused by 2019 novel coronavirus (disorder)</p> <p>This seems to indicate the case status, which is something that is determined during case investigation, not at time of test order expect this to be removed</p>
6	<p>ICU?</p> <p>Suggest to HHS to change to: Whether patient was admitted to intensive care unit for condition of interest</p>	RE-PHA, RE-HHS	<p>Patient has been admitted/transferred to the ICU at any time during the encounter for the reportable illness/condition that the order has been placed for (suspected or diagnosed).</p>	Y/N/UNK	<p>OBX-2 = CWE</p> <p>OBX-3 = 95420-6^Admitted to intensive care unit for condition of interest^LN</p> <p>OBX-5 can be one of: Y^Yes^HL70136 N^No^HL70136 UNK^Unknown^NULLFL</p> <p>OBX-11 = F</p> <p>OBX-14 = Date question was answered</p> <p>OBX-29 = QST</p>	<p>LOINC: 95420-6^Whether patient was admitted to intensive care unit for condition of interest^LN^2.69-pre</p> <p>When interested in whether in ICU at time of order, use PV1 location/organization providing care.</p> <p>Comment:</p> <p>On the CDC page a single SNOMED CT code is listed If ICU is Yes, which is ICU - expect this to be removed, as it does not provide further information.</p>
7	<p>Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment)</p>	RE-PHA, RE-HHS	This is at time of exposure where they normally live.	Y/N/UNK	<p>OBX-2 = CWE</p> <p>OBX-3 = 95421-4^Resides in a congregate care setting^LN</p> <p>OBX-5 can be one of: Y^Yes^HL70136 N^No^HL70136 UNK^Unknown^NULLFL</p> <p>OBX-11 = F</p>	<p>LOINC: 95421-4^Whether patient resides in a congregate care setting^LN^2.69-pre</p>

	facilities, group homes, board and care homes, homeless shelter, foster care or other setting) Suggest to HHS to change to: Whether patient resides in a congregate care setting				OBX-14 = Date question was answered OBX-29 = QST	
7a	If YES, what type of residence is the congregate care setting?	Optional for August 1, 2020	Condition: If Congregate Care setting is Yes		OBX-2 = CWE OBX-3 = 75617-1^Residence type^LN OBX-5 can be one of: 22232009^Hospital^SCT 2081004^Hospital ship^SCT 32074000^Long term care hospital^SCT 224929004^Secure hospital^SCT 42665001^Nursing home^SCT 30629002^Retirement home^SCT 74056004^Orphanage^SCT 722173008^Prison-based care site^SCT 20078004^Substance abuse treatment center^SCT 257573002^Boarding house^SCT 224683003^Military accommodation^SCT 284546000^Hospice^SCT 257628001^Hostel^SCT 310207003^Sheltered housing^SCT 257656006^Penal institution^SCT 285113009^Religious institutional residence^SCT OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	Suggested LOINC: 75617-1^Residence type^LN^^^2.68 Comments: APHL suggests to allow use of OTH^Other^NULLFL, so that other settings can be reported in OBX-5.9 This is really not lab related data and should be available in the case report / case notification.
8	Pregnant?	C-PHA, C-HHS	Condition: If patient is female Current pregnancy status of the patient	Pregnant, Not pregnant, Unknown	OBX-2 = CWE OBX-3 = 82810-3^Pregnancy status^LN OBX-5 can be one of: 77386006^Patient currently pregnant^SCT 402874004^Possible pregnancy^SCT 60001007^Not pregnant^SCT UNK^Unknown^NULLFL (Note: Expect to have 261665006^Unknown^SCT on the CDC page be updated to UNK^Unknown^NULLFL) OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	LOINC: 82810-3^Pregnancy status^LN^^^2.68 LOINC from https://loinc.org/sars-cov-2-and-covid-19/
9	Patient age	C-PHA, RE-HHS	For reporting from PHA to HHS (CDC), when DOB may not be included or in ELR, when DOB is not available. Condition for PHA: If Patient Date of Birth is not available or cannot be calculated correctly to reflect the age at time of order, then include the age at time of specimen collection using the methodless LOINC (30525-0^Age^LN).		Send as AOE OBX: OBX-2 = NM (can be SN) OBX-3 = 30525-0^Age^LN^^^2.68 OBX-5 = numeric value OBX-6 = age units in UCUM as applicable - expected as years => a^year^UCUM other options: months => mo^month^UCUM days => d^day^UCUM hours => h^hour^UCUM OBX-29 = QST	Questions for HHS: Can HHS accept DoB and figure out the age so we don't need to calculate?

Specimen Collection

Seq	Name	Optionality	Definition	HL7 Mapping	Implementation guidance	Comments
1	Date specimen collected (date format)	R-PHA, R-HHS		OBR-7 also in SPM-17 (2.5 and up)	OBR-7 is required;	ELR allows use of 0000, when date is unknown
2	Specimen Source - use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes	R-PHA, R-HHS		SPM-4 (after 2.5) OBR-15.1 SPM-8 (after 2.5) OBR-15.4	Code to SNOMED CT codes for SPM-4 as provided in the "Vendor Specimen Description" column of the "LOINC Mapping" tab in the CDC LIVD mapping file ; ELR also allows use of both SNOMED CT codes from the specimen hierarchy (PHVS_Specimen_CDC) and HL70487 codes (PHVS_SpecimenType_HL7_2x) Some labs may support the sending of source site information; ELR R1 uses SNOMED CT codes compiled in the HITSP body site value set (PHVS_BodySite_HITSP)	
3	Accession #/Specimen ID	R-PHA, R-HHS		ORC-3 /OBR-3 SPM-2 (V2.5 and up)	This is the testing lab's specimen ID or accession number - may also send the submitters specimen ID / accession number In older versions of HL7 only ORC-3/OBR-3 can be used; for the submitter's accession number use ORC-2/OBR-2.	

Test Result

Seq	Name	Optionality	Definition	HL7 Mapping	Implementation guidance	Comments
1	Performin	R-PHA, R-				

	g facility name and /or CLIA number, if known	HHS		OBX-23 (V2.5.1 and up) ORC-15	In older versions of HL7 OBX-15 (Producer's ID can be used for the Performing Lab ID) or it can be conveyed in the NTE following the result OBX, ensuring it is included on the report.	
2	Performing facility zip code	R-PHA, R-HHS		OBX-24 (V2.5.1 and up)	In older versions of HL7 this information can be conveyed in the NTE following the result OBX, ensuring it is included on the report.	
3	Device Identifier	RE-PHA, RE-HHS	The test kit/reagent(s) used to perform the test, and as necessary the instrument platform(s) when used off-label. The EUA may be used when used as authorized.	OBX-17 OBX-18 (v2.4 and up)	Use OBX-17 when describing the manufacturer and model of either test kit (reagent) or instrument used; or when referencing the EUA (see more detailed guidance below). Use OBX-18 when passing the serial number or UDI of the test kit (reagent) or instrument	The model is acceptable. It is allowed to use the Device Identifier (as defined per FDA's UDI definition) or the UDI Carrier (the full human readable form of the barcode) instead or as well if that can be obtained. For the PH_HHS_ELR_Guidance_component OBX-18 will be RE
4	Test result	R-PHA, R-HHS	This is the code of the test being resulted.	OBX-3	LOINC is required in LRI and ELR R1, when an appropriate LOINC exists - since this points to LIVD, as long as LOINC is listed there for the manufacturer test kit, MUST use.	Include the fully structured test code, name, and code system of the applicable LOINC code in accordance with the CDC guidance for the reportable illness/condition
5	Test result value	R-PHA, R-HHS	The result value.	OBX-5	For coded results use the appropriate SNOMED CT code for qualitative result values in accordance with the CDC guidance for the reportable illness/condition. For numeric results include units in OBX-6 when appropriate (code units in UCUM)	Suggest to HHS to clarify, that not all results are coded.
6	Test Result date	RE-PHA, R-HHS	The date the test result was obtained and approved for release	OBX-19 (V2.4 and later) OBR-22 (as proxy in V2.3.1 and earlier)	Must be sent for each result - may not be populated for AOE OBX segments	Note: For v2.3.1 and earlier, OBR-22 should reflect the date/time when OBR-25 was set to F. Generally, for an OBR including multiple OBX segments it would be equal to or later than the most recently finalized OBX, but without OBX-19 available OBR-22 is the closest one can get.

Device Identification

There are four components that are potentially of interest for which to include an "identifier":

- Testkit/reagent - This is the most important one to communicate. If multiple test kits/reagents are used, all need to be included.
- Instrument Platform - This is needed if the test kit/reagent is used off-label with a different instrument OR multiple instrument platforms were used as well.
- Manual kit - This is needed if the test was performed manually.
- Emergency Use Authorization - This can be used when a particular combination of testkit/reagent(s) and instrument platform(s) is used that is authorized by an EUA. In this case the individual test kit/reagent(s) and instrument platform(s) do not need to be communicated as well.

There is no need to include identification information for calibrators, controls, or collection devices.

These devices can be identified as a kind of using three different approaches:

- Model Name
 - The most likely information available for a testkit/reagent or instrument platform is a model name (unofficial or official); usually when combined with the name of the manufacturer it is unique.
- Emergency Use Authorization Identifier
 - Defines the particular combination of testkit/reagent(s) and instrument platform(s) is used that is authorized by an EUA as listed on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular>
 - The combination of the value listed in the "Manufacturer" column and the value listed in the "Diagnostic (Letter of Authorization)" - including all spaces and special characters (except (TM) or (R)) creates the official name for this EUA
 - a "+" at the end of the Diagnostic might indicate a significant update and constitutes a new entry in the table
 - The goal is to provide that string in the CDC LIVD mapping file in the "Equipment UID" column, identifying the "Equipment UID Type" as EUA. e.g for the following EUA:
 - COVID-19 Coronavirus Real Time PCR Kit Jiangsu Bioperfectus Technologies Co., Ltd.

Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search: Show entries

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s) ¹	Authorization Documents ²
06/18/2020	Jiangsu Biopertectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit	Molecular	H	HCP, Patients, IFU
06/18/2020	3R Blacklin Biotech India	TRIIPCR SARS-CoV-2 Kit	Molecular	H	HCP, Patients, IFU

- A similar identifier can be created for Lab Developed Tests (LDT) based on Appendix A table by combining "Laboratory" and "Letter Granting Inclusion under EUA", e.g. for the following

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

Search: Show entries

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
06/12/2020	Corneum Laboratory Services	Corneum SARS-CoV-2 Assay	EUA Summary
06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assav	EUA Summary

- Corneum SARS-CoV-2 Assay_Corneum Laboratory Services
- Device Identifier (AP: Question has arisen that for COVID-19, most EUA tests do NOT have UDIs. They do have GTINs as shown in data below. Thanks Riki! Do we wish to include GTIN where UDI is not available?)
 - This must then be the device identifier according to the UDI definition by the FDA
 - The manufacturer would have made this available, e.g. through their LIVD spreadsheet or otherwise and this likely would have been configured into the LIS so it need not be entered by a user at time of testing.

The device identification information will be captured in either **OBX-17 when describing the kind** and **OBX-18 when describing an instance**.

In order to differentiate which of the devices is being described we propose a list of abbreviations to represent each kind (for use in OBX-17)

Element	Type of identifier	Abbreviation for the type
Emergency Use Authorization	EUA	EUA
Testkit/reagent	Model	MNT
Testkit/reagent	Device ID	DIT
Instrument Platform	Model	MNI
Instrument Platform	Device ID	DII
Manual kit	Model	MNM
Manual kit	Device ID	DIM

Sept 14, 2020 update:

In OBX-17 use OBX-17.1 for the device identification information using the format <Model name or Diagnostic (Letter of Authorization)>_<Manufacturer name>_<Abbreviation for the type> and in OBX-17.3 "99ELR". For Device ID omit "<Manufacturer name>" resulting in <Device ID>_<Abbreviation for the type> in OBX-17.1.

Best place to obtain these values is the [CDC LIVD file \(https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html\)](https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html):

<Model name or Diagnostic (Letter of Authorization)>_<Manufacturer name> is provided in the in Testkit Name ID (column M); the <Abbreviation for the type> in Testkit Name ID Type (column N) and concatenate: <Testkit Name ID>_<Testkit Name ID Type>.

<Device ID> in Equipment UID (column O); the <Abbreviation for the type> is in Equipment UID Type (column P)

Using Abbotts ID Now as example:

Using the EUA ID = ID NOW COVID-19_Abbott Diagnostics Scarborough, Inc. EUA
Using the Device ID = 10811877011269_DII^99ELR

Where OBX-17.1 length limits interfere with the full identification use the following approach:

OBX-17: ID NOW COVID-19_Abb#^99ELR

Full ID for the NTE: ID NOW COVID-19_Abbott Diagnostics Scarborough, Inc._EUA

Alternatively these devices can be identified as the specific instance used in testing by their UDI as defined by FDA (for use in OBX-18).

- UDI Carrier
 - The full representation of the barcode in human readable form.
 - Likely only obtained through scanning.

Since the OBX-17 and OBX-18 fields can repeat, multiple values can be communicated. While the newer PRT segment can improve on this somewhat, it still would require a new field to maintain these relationships. Shifting to FHIR where this already can be addressed is not realistic in the timelines needed and given most LIS/LIMS currently lack FHIR functionality. However, given the likely configurations being used, we do not believe we need to address that yet while data curation in the analytics phase can address this challenge.

Scenario	Location in message	Format to be used	Instructions	Where to find the information
Cepheid Xpert Xpress SARS-CoV-2 test used as described in EUA	OBX-17	Xpert Xpress SARS-CoV-2 test_Cepheid_EUA	OBX-17.1 = <Diagnostic (Letter of Authorization) >_<Manufacturer name>_EUA OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Testkit Name ID" column, when identified as EUA in "Testkit Name ID Type" column
Abbott ID now as described in EUA	OBX-17	ID NOW COVID-19_Abbott Diagnostics Scarborough, Inc._EUA	OBX-17.1 = <Diagnostic (Letter of Authorization) >_<Manufacturer name>_EUA OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Testkit Name ID" column, when identified as EUA in "Testkit Name ID Type" column
LDT listed in Appendix A	OBX-17	Corneum SARS-CoV-2 Assay_Corneum Laboratory Services_EUA	OBX-17.1 = <Letter Granting Inclusion under EUA>_<Laboratory>_EUA OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Testkit Name ID" column, when identified as EUA in "Testkit Name ID Type" column
CDC test run on Abbott m2000 using model names	OBX-17 for test kit	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel_CDC_MNT	OBX-17.1 = <Test kit name>_<Manufacturer name>_MNT OBX-17.3 = "99ELR"	Name used in package insert (or "Testkit Name ID" column, when identified as MNT in "Testkit Name ID Type" column in the CDC LIVD mapping file)
CDC test run on Abbott m2000 using instrument names	OBX-17 for instrument	m2000 RealTime System_Abbott_MNI	OBX-17.1 = <Instrument name>_<Manufacturer name>_MNI OBX-17.3 = "99ELR"	Name used in package insert (or "Testkit Name ID" column, when identified as MNT in "Testkit Name ID Type" column in the CDC LIVD mapping file)
bioMérieux ARGENE SARS-COV-2 R-GENE test run on ABI 7500 Fast Dx Real-Time PCR Instrument using device ID	OBX-17 for test kit	423735_bioMérieux_DIT	OBX-17.1 = <Device ID>_<Manufacturer name>_DIT OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Testkit Name ID", when identified as DIT in "Testkit Name ID Type" column
bioMérieux ARGENE SARS-COV-2 R-GENE test run on ABI 7500 Fast Dx Real-Time PCR Instrument using device ID	OBX-17 for instrument	4351106_Applied Biosystems_DII	OBX-17.1 = <Device ID>_<Manufacturer name>_DII OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Product UID" column
Manual test kit for AB testing using model name	OBX-17 for manual test kit	SARS-CoV-2 IgM/IgG Antibody Test Kit_Biohit Healthcare_MNM	OBX-17.1 = <Manual kit name>_<Manufacturer name>_MNM OBX-17.3 = "99ELR"	CDC LIVD mapping file in the "Testkit Name ID" column, when identified as MNT in "Testkit Name ID Type" column
PH Lab developed test kit on Roche Cobas 6800 using model name for both	OBX-17 for test kit	SARS-COV-2 rt-PCR_SLOPHL_MNT	OBX-17.1 = <modelname = whatever the lab calls it>_<Labname = manufacturer name>_MNT OBX-17.3 = "99ELR"	PH lab documentation
PH Lab developed test kit on Roche Cobas 6800 using model name for both	OBX-17 for instrument	cobas® 6800/8800 Systems_Roche_MNI		LIVD file from Roche in the "Model" column

			OBX-17.1 = <IVD platform model name>_<Manufacturer name>_MNI OBX-17.3 = "99ELR"	
PH Lab developed test kit on Roche Cobas 6800 using model name for kit	OBX-17 for test kit	SARS-COV-2 rt-PCR_SLOPHL_MNT	OBX-17.1 = <modelname = whatever the lab calls it>_<Labname = manufacturer name>_MNT OBX-17.3 = "99ELR"	PH lab documentation
PH Lab developed test kit on Roche Cobas 6800 usingUDI for instrument	OBX-18 for instrument	[udi carrier]^2.16.840.1.113883.3.3719^ISO	OBX-18.1 = [udi carrier] OBX-18.3 = "2.16.840.1.113883.3.3719" OBX-18.4 = "ISO"	Device documentation (package insert/label)
Using Roche COBAS INTEGRA 400 plus using Device Identifier	OBX-17	4015630924592_Roc he_DII	OBX-17.1 = <Device ID>_<Manufacturer name>_DII OBX-17.3 = "99ELR"	LIVD file from Roche "Product Reference UID" provides the identifier; "Product Reference UID Type" was listed as GITN, indicating it is a device ID
UDI carrier scanned on barcode using OID	OBX-18		OBX-18.1 = [udi carrier] OBX-18.3 = "2.16.840.1.113883.3.3719" OBX-18.4 = "ISO"	Device documentation (package insert/label) on instrument, test kit (or box), or manual kit
UDI carrier scanned on barcode using URI	OBX-18		OBX-18.1 = [udi carrier] OBX-18.3 = " http://hl7.org/fhir/NamingSystem/fda-udi " OBX-18.4 = "URI"	Device documentation (package insert/label) on instrument, test kit (or box), or manual kit

Flat File

ONLY if no HL7 v2.x support then use flat file to HL7 converter excel file - first box on this page: https://preparedness.cste.org/?page_id=136. But if you have a HL7 v2 feed continue to use and upgrade as quickly as possible.

If you do not have an HL7 v2 feed, work with your PHA to determine when you can put that in place.

Issues

Open Issues

- If the ELR R1 is in use and supports PI attestation, will inclusion/adoption of this guidance invalidate that attestation.

Closed Issues

- Device ID examples that didn't make it into the table yet:
 - Is there expectation that LDTs would have a UDI and how would that be acquired? If not, what is entered when there is no UDI? N/A? Is field blank? see scenarios below.
 - May wish to distinguish LDTs using IVD reagents for a different non 510 k /EUA approved specimen type versus a LDT with totally different reagents, such as own reagents created from scratch. **RM: I DID NOT use this as the specimen type is in SPM - but assume this should be like CDC test run on Abbott m2000 - choice of either the model name or the device ID**
 - If LDT uses commercial test kit reagents with UDI on IVD platform with UDI, but with modification (i.e. specimen, reporting) that makes it LDT, expect reagent UDI and instrument UDI can be sent as specified, but should confirm with FDA whether an issue as would appear same as non LDT. **RM - did not add to table**
- Do we need multiple test kits? Ed will check if 1 or 2 UDIs
 - ROMA is a 2 step immunoassay. see <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996955/>
 - On LIVD, would those be multiple IVD Test Codes? Multiple devices/test kits?
 - If only device identifier, OBX-18 can handle multiple
 - If UDI Carrier or UDI, multiple PRTs can handle that.
 - Roche also has a ROMA Assay on the Elecsys analyzer: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153607.pdf
 - **ADDRESSED**
- Some of the AOE's may be able to be answered based on knowledge in the system (e.g. is patient hospitalized = Patient class is inpatient in encounter)

- We should do an analysis of which of these HHS questions are available in the EHR-s (and in what format) and then decide on the best way to share that data, e.g., use PID/PD1/PV1/PV2/NK1 (occupation) - I got some feedback, that UNLESS the element is already in ELR R1 (like PV1-2), OBX segments will be easiest in the short term to add to the surveillance system.
- Understanding is some drive up/drive through COVID testing sites are using paper requisitions for ordering, so data elements would be required on paper req to performing lab, who would enter them into their results reporting to PHA ELR message (if provided!).
- **ADDRESSED**
- Options for differentiating OBX for AOE vs OBX for results: (Hans Buitendijk can we delete this note since we talked about this? AP Note: The AOE question and response, would be represented as a result and result value. The LOINC is likely the same for the AOE question and result in most cases. However, they may have an order ID/identifier for the AOE, and a result ID for the result field to distinguish the two uses of the same data item. Also is this question on the ELR/LRI?)
 - NOTE: I used the OBX-29 in all of these example messages; we will need to update the OBX-14 conformance statement ELR-051 that compares OBX-14 to OBR-7 and SPM-17: based on OBX-29 is valued 'RSLT' or is not valued 'QST'?
 - LOINC code
 - OBX-29 as in LOI/LRI
 - In eDOS, AOE is represented in OMC-4, while OMC-11 defines the allowed answers and OMC-9 defines the expected datatype of the answers and OMC-6 describes the location where it can be found in the message instances.
 - In LOI, AOE is represented in OBX after the OBR it belongs to.
- **ADDRESSED**
- While communication of a .csv or flat file from performing lab to PHA, if the above guidance cannot be implemented in time, is out of scope of HL7 to define format, we could make some suggestions on what to include to match with the ELR transaction that it needs to match up with.
 - APHL is creating a flatfile format for this purpose (not csv, but rather tab delimited) - the elements in this flatfile are all mapped to the respective ELR R1 location, so that transformation could occur at the sender or receiver side (conversion tooling for the PHAs is being



- discussed) Current version of the file (still subject to change:
- Suggest to allow for Direct Messaging to convey the file. Riki: need to check with the PHA, what transport mechanism they allow, but I don't see why it shouldn't be an option
 - Why not just use ELR in xml format via Direct? Riki: Because this is for manual data entry
 - **ADDRESSED**
 - What shall we point to for LIVD latest guide? If this is for the link to the LIVD specification, I think we need to use the IICC site (since IVD on FHIR is not yet published) - if to the COVID specific LOINC listing on the CDC site - that is embedded in the HHS guidance letter and also already in Resources for Background
 - **ADDRESSED**

Resources for Background

- Link to current guidance: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>
- Link to FAQ document: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996955/> - THIS LINK IS NOT CORRECT - I ASSUME IT SHOULD GO TO THE CDC FAQs? - those are here: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#faqs>
- Information Blocking Actors: <https://www.healthit.gov/curies/sites/default/files/curies/2020-03/InformationBlockingActors.pdf> (Includes labs)
- Information Blocking Definition: <https://www.healthit.gov/topic/information-blocking>
- USCDI Data Classes, Elements and Standards: <https://www.healthit.gov/isa/sites/isa/files/2020-03/USCDI-Version1-2020-Final-Standard.pdf>
- CLIA regulations: <https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5>
 - CLIA Order/test request/requisition info as aligned to HHS requirements is below. Items I bolded apply to most of the AOE's, such as 8).
- **§493.1241 Standard: Test request.**

(a) **The laboratory must have a written or electronic request for patient testing from an authorized person.**

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

(c) The laboratory must ensure the test requisition solicits the following information:

(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

(2) The patient's name or unique patient identifier.

(3) The sex and age or date of birth of the patient.

(4) The test(s) to be performed.

(5) The source of the specimen, when appropriate.

(6) The date and, if appropriate, time of specimen collection.

(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.