Reporting SARS-CoV-2 (COVID-19) Test Results and Cases: Guidance for Laboratories, Point of Care Providers, and Others

To Meet CARES Act Section 18115 Requirements for COVID-19 Laboratory Reporting

Connecticut Department of Public Health (CT DPH)
Infectious Disease Section Informatics Program

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Purpose

This document is to assist CLIA certified laboratories and provider point of care and other locations with CLIA certificates of waiver that are testing for the COVID-19 virus (SARS-CoV-2) in reporting results to the Connecticut Department of Public Health (CT DPH). This reporting will fulfill requirements as defined in the guidance from the federal Department of Health and Human Services (HHS): *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* dated June 4, 2020[1]. Under the HHS guidance laboratories are defined as:

- Laboratories that perform clinical diagnostic testing under CLIA,
- Non-laboratory COVID-19 testing locations, and,
- Other facilities or locations offering point-of-care testing or in-home testing related to COVID-19.

This document will outline the test result reporting requirements and methods for COVID-19 testing entities to fulfill CT DPH reporting even as COVID-19 test methods and requirements are changing during the pandemic. This document will also mention the appropriate reporting that providers must make to CT DPH for persons found with a positive COVID-19 test (by PCR or antigen methods). This document will be updated as needed to incorporate new or updated information.

It should be noted that to protect patient privacy and in keeping with State of Connecticut confidentiality statutes, the data CT DPH sends to the CDC will be de-identified and will not include some patient-level information. The de-identified data shared with CDC will contribute to national understanding of COVID-19's impact, positivity trends, testing coverage, and will help identify supply chain issues for reagents and other materials.

This document has the following main sections:

This document is not intended to be the guidance for long term care facilities or assisted living facilities receiving antigen instruments from HHS. Those facilities will receive separate guidance about reporting.

[1] https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

Background

In Connecticut, SARS-CoV-2 identification and COVID-19 disease were made state reportable in February 2020[2]. For SARS-CoV-2 (COVID-19) testing, both positive and negative test results from any type of test must be reported to CT DPH. Test reports must include required information about the patient or person being tested, the test performed, and the ordering provider. To facilitate timelier reporting of COVID-19 test results, CT DPH has modified allowable result reporting methods for COVID-19 testing. These methods will be described further in this guidance.

The HHS June 4 guidance listed not only required data elements, but additional Ask at Order entry (AOE) questions that laboratories and testing locations, as defined in the prior section, must report. This requirement has changed. The CDC website[3] outlining the reporting requirements was updated on August 1, 2020 and again on August 7, 2020 to reflect the emphasis on *required* data elements. AOE questions are considered *requested* and are not required at this time. The CDC Division of Laboratory Systems (DLS) also posted updates in the 7/31/2020 Lab Advisory[4]. Laboratories and others performing COVID-19 testing should check these webpages for further updates.

Although the AOE questions are not required at this time, testing locations should make changes, as possible, to their ordering interfaces, forms, and laboratory systems to capture the required information and include it in reports to the CT DPH. This will be discussed further in this guidance.

Reportable disease test reporting is managed by CT DPH staff in the Infectious Disease (ID) Section Informatics Program.

A note about provider COVID-19 case reporting

Providers (hospital, outpatient, or other point of care locations) who have patients identified with a positive SARS-CoV-2 molecular (PCR, nucleic acid) or antigen result must send case reports to CT DPH per state provider reporting requirements for COVID-19[5]. To simplify this reporting, CT DPH has an online provider reporting portal at https://dphsubmissions.ct.gov/Covid/InitiateCovidReport.
Other methods for reporting COVID-19 cases will be described further in this document.

[2] https://portal.ct.gov/-/media/DPH/EEIP/CTEPI/Vol40_No2.pdf?la=en
[3] https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
[4] https://www.cdc.gov/csels/dls/locs/2020/update-on-covid-19-reporting-requirements.html
[5] https://portal.ct.gov/-/media/DPH/EEIP/CTEPI/Vol40_No2.pdf

Guidance for Providers Ordering COVID-19 Tests

Providers ordering COVID-19 tests must take all reasonable efforts to provide complete information on test orders as defined in the list below. These data elements are required to meet CT DPH laboratory test result reporting requirements[6].

- Patient name (last name, first name, middle Initial)
- Patient residential street address, including secondary address
- Patient city/town of residence
- Patient residence zip code
- Patient phone number with area code
- Patient date of birth
- Patient age (if date of birth is not available)
- Patient race
- Patient ethnicity
- Patient sex
- Patient residence county
- Ordering provider name
- Ordering provider address, city, state, zip code
- Ordering provider phone

If available, please include patient email.

If the person is being tested at a 'walk-in' or 'drive-through' setting, the staff collecting the specimen for testing should record or provide the person being tested with a way to record, at minimum the following: patient name, address, phone number, date of birth, race, ethnicity, and sex. This information should be provided to the testing laboratory and/or included on results reported to CT DPH.

If a laboratory has added the AOE questions to the test ordering interface, providers should attempt to include that information with the test order, particularly for persons presenting with symptoms of possible COVID-19 disease.

[6] https://portal.ct.gov/DPH/Epidemiology-and-Emerging-Infections/Laboratory-Reporting

Methods for Reporting COVID-19 Test Results to CT DPH

Reporting of COVID-19 test results may be outside of the usual reporting experience for some testing locations, such as point of care (POC) providers, schools, pharmacies, or others that have obtained a CLIA certificate of waiver to obtain test instruments and conduct testing. It should be noted that any location looking to set up either COVID-19 specimen collection and/or testing must contact the CT DPH Facility Licensing and Inspections Section (FLIS) to obtain required documentation and approval for these activities. FLIS can be reached at DPH.FLISLab@ct.gov.

What to include in laboratory test order interfaces

Laboratories are requested to set up order interfaces and update laboratory systems to capture the *required* data elements as described in the prior section and as indicated in Table 1. If possible, laboratories should consider adding the *requested* AOE questions to their ordering interfaces. These are defined in the Ask at Order Entry section of this document.

How to report test results to CT DPH

Under the Centers for Medicare and Medicaid (CMS) Promoting Interoperability[7] requirements, CT DPH has already been working with eligible hospitals, critical access hospitals, and dual-eligible hospitals looking to attest to CMS for public health reporting requirements to set up reporting using HL7 v2.5.1 ELR ORU. To expedite COVID-19 result reporting from the greatly expanded set of laboratories and test locations performing these tests, CT DPH is now accepting COVID-19 results by one of three methods:

- HL7 version 2.5.1 or 2.3.1 ORU for electronic laboratory reporting (ELR),
- Flat files in comma separate value or MS Excel formats (E-File reporting),
- Faxed paper reports.

CT DPH has made every effort to work with laboratories and testing locations to transition to one of the two electronic formats. For ease of reference, laboratory reporting by either HL7 version 2 ORU message type will be noted as **ELR**; flat files will be noted as **E-Files**. The required data elements for COVID-19 reporting are the same for any test result reporting method.

For eligible hospitals reporting COVID-19 results in a non-HL7 2.5.1 format, the promoting interoperability engagement status will remain as registration for attestation until CT DPH is able to continue work to put all reportable diseases into HL7 2.5.1 reporting for that hospital.

[7] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2020ProgramRequirementsMedicare

HL7 v. 2.5.1/2.3.1 ELR reporting

This document assumes the laboratory that is reporting results is following the *Electronic Laboratory Reporting to Public Health (US Realm), Release 1, HL7 version 2.5.1: ORU^R01 Informative Document* (ELR HL7 v 2.5.1 IG) or HL7 version 2.3.1 based on the *Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using Version 2.3.1 of the Health Level 7 (HL7) Standard Protocol.*

Complete reporting requirements for HL7 ELR messaging to CT DPH can be found on the CT DPH website Electronic Laboratory Reporting (ELR) page[8]. A CT DPH specific local implementation guide for ELR HL7 v2.5.1 is posted[9]. The CT DPH ELR webpage also includes information on the onboarding process for ELR via HL7 v2.5.1. Laboratories using the older HL7 v 2.3.1 ELR standard follow a similar process. HL7 files can be sent using the CDC provided PHINMS system as defined on the ELR webpage or posted using the DPH IT secure file transport protocol (sFTP).

High Level process for HL7 ELR reporting

1. Registration – if an eligible laboratory is seeking Promoting Interoperability credit, they must register using the form on the CT DPH ELR webpage, even if they are reporting COVID-19 results in a non-HL7 format. Laboratories will be transitioned to HL7 ELR once resources are available post-pandemic. Registration forms are sent to DPH.ELR@ct.gov.
2. Initial touch base call – CT DPH will arrange to have a call with the laboratory to review the HL7 ELR requirements, determine the secure file transport method, and set up ongoing meetings or emails.
3. Validation – HL7 ELR message validation occurs in two steps.
    a. HL7 structure and content validation based on the v2.5.1 ELR requirements. This will be a report back to the laboratory on any items that need to be adjusted so that the HL7 ELR message will not fail this validation.
    b. Content validation. This is an assessment of the information about the patient tested, the COVID-19 results, and other data to see if the message meets CT DPH reporting requirements.
4. Production ELR. Once all of the validation requirements have been met, the laboratory will send the HL7 ELR messages as a batch file to CT DPH on a schedule to be determined with the reporting laboratory, but no less than once a day.

[8] https://portal.ct.gov/DPH/Epidemiology-and-Emerging-Infections/Electronic-Laboratory-Reporting

[9] https://portal.ct.gov/-/media/DPH/EEIP/CT_ELR_Local_Guide.pdf

E-File (flat file) reporting

To accommodate laboratories or testing locations that are unable to build and generate an HL7 ELR message, CT DPH has defined content and the data variable order for the use of flat files. The preferred format is a comma separated value (csv) file, but a Microsoft Excel file spreadsheet can also be accepted if necessary. Secure message transport options are secure file transport protocol (sFTP; preferred method) or secure email or other secure file pick-up. Use of a csv file posted by sFTP is strongly encouraged as this will allow CT DPH to use a semi-automated process to process files.

High level process for reporting using E-Files

1. Contact the CT DPH Infectious Disease Section Informatics Program at DPH.ELR@ct.gov. Because Connecticut based testing locations must register with CT DPH FLIS, emails will also be passed to the Informatics Program Lead by FLIS staff.
2. Initial touch base email or call – with CT DPH to review the laboratory data requirements, determine secure file transport, and set up ongoing meetings or emails.
3. Validation – CT DPH will review a test message or actual message for order of headers, content, missing data elements and send feedback to the testing location.
4. Set up of sFTP or other secure transfer – so files can be sent or posted for use.
5. Production E-File. As with HL7 reporting, CT DPH requires a file of results posted at least once a day.

Reporting by fax

CT DPH prefers that testing locations report by HL7 or E-File, however, recognizes that some testing locations may need to fax reports. CT DPH has a laboratory reporting right fax number **860-920-3131.** Right fax is a secure fax method that delivers reports to a secure email box. This allows CT DPH staff to retrieve the results remotely if needed, and reduces the burden of paper.

Please be sure and consult with CT DPH Informatics staff before sending results, by email DPH.ELR@ct.gov or by phone during work hours 860-509-7994. If you have other contact information you can use those routes also.

Test Reporting Data Elements and Requirements

Table 1 defines the *required* data elements for reporting to CT DPH for COVID-19 results determined by any approved method. These required elements align with CT DPH state reportable laboratory testing requirements.

The only new element for COVID-19 reporting is the Device Identifier. This identifier is defined by the CDC in the so-called LIVD table. A link to the table can be found here https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html. The LIVD table defines the LOINC codes used to define the test method, the SNOMED CT codes used to define results, and the device identifiers to be included in the results. These are arranged by manufacturer and test method and are updated periodically. CT DPH Informatics Program staff will assist testing laboratories and locations as to which identifiers to use and how to report them.

Example of Device Identifier

The easiest way to report the Device Identifier is from the LIVD codes table. Both the Testkit Name ID and the Equipment UID can be reported but at least one of these must be included. The way to report this in an HL7 message is to put in OBX-17 as follows:

TestKit Name ID (EUA) Equipment UID

xMAP SARS-CoV-2 Multi-Antigen IgG Assay_Lumine_EUA^^99ELR~MAGPIX System_Luminex Corp_MNI^^99ELR

If a reporting laboratory has a limitation on the length of the name that can be put into OBX-17, the TestKit Name IDs have been shortened to fit a 50 character maximum length.

For laboratories or testing locations using a csv (flat file), you have the following options:

1. Use the TestKit Name or Model information.
2. Use another abbreviation or nickname for the test method/instrument defined with CT DPH so it can be translated to the proper Device Identifier.

See Appendix A for an example.

Note: this identifier is not the same as the test method.

Table 1. Required COVID-19 Data Elements by Method of Report

For any reporting format, please use coded value sets as much as possible.

Data element/header	HL7 Data Element	Flat file (non-HL7) content requirements	Notes/comments
Testing Laboratory	OBX-23 (v2.5.1) OBX-15 (v2.3)	CLIA number	CLIA number of the testing laboratory.
Patient Last Name	PID-5.1	character	Submit first, last, middle in separate fields.
Patient First Name	PID-5.2	character	
Patient Middle Initial	PID-5.3	character	
Patient Address	PID-11.1	Residential address	This is the residence at the time of testing, even if a congregate setting, college, etc.
Address 2	PID-11.2	Secondary address	Apt, Bldg, Unit, etc. Put in a separate field from residential address.
Patient City	PID-11.3	character	
Patient State	PID-11.4	two letter abbreviation	e.g., CT
Patient Zip Code	PID-11.5	five or nine digit format allowed	
Patient County	PID-11.9	Full county name	Include County if possible. E.g., Tolland County
Patient Phone	PID-13	10 digit format (with area code)	Required for persons with positive test results.
Patient Email	PID-13.4		If available, especially if result positive.
Date of Birth	PID-7 yyyymmdd at minimum	mm/dd/yyyy	
Patient Gender	PID-8	Male, Female, Other, Unknown	Usually assumed as sex at birth.
Patient Race	PID-19 See Table 2	See Table 2	Multiple race selections allowed; please avoid using “other” race.

Data element/header	HL7 Data Element	Flat file (non-HL7) content requirements	Notes/comments
Patient Ethnicity	PID-22 See Table 3	See Table 3	Should be asked separately from race.
Patient Occupation	NTE for OBX discuss with DPH	character	Occupation can be used as a place to capture student, staff, resident.
Patient Medical Record Number	PID-3	character	Unique person identifier.
Ordering Lab	OBR-3/ORC-3	CLIA or character	If the specimen was referred to another lab for testing, enter the CLIA or name here.
Ordering Facility	ORC-21	Character	This is the facility of the provider who ordered the test.
Ordering Provider Last Name	OBR-16.2/ORC-12.2	Character	
Ordering Provider First Name	OBR-16.3/ORC-12.3	Character	
Ordering Provider NPI (optional)	OBR-16.1 (also populate ORC-12.9 and OBR-16.9)	Character	National Provider Identifier; provide if available.
Ordering Provider Phone number	ORC-14/OBR-17 or ORC-13	10 digit format (with area code)	Callback number for the provider ordering the test.
Ordering Provider Address	ORC-24.1 Street	Character	
Ordering Provider City	ORC-24.3 City	Character	
Ordering Provider State	ORC-24.5 State	two letter abbreviation	
Ordering Provider Zipcode	ORC-24.6 ZipCode	five or nine digit format allowed	
Specimen ID	SPM-2.2 (v2.5.1) OBR-3 (v2.3.1)	character	This is the unique ID that is assigned to the specimen in the laboratory system.

Data element/header	HL7 Data Element	Flat file (non-HL7) content requirements	Notes/comments
Specimen Source[10]	SPM-4 (Specimen type)	SNOMED codes or standard description	This is the type of source material tested. SNOMED preferred. See LIVD List[11]
Test Method[10]	OBX-3	LOINC codes	LOINC code for the test method - DPH can assist with identifying the proper LOINC. The test description can be included but must be in another column. See LIVD List.
Result[10]	OBX-5.1	SNOMED codes if qualitative See Table 4	For HL7, must be congruent with OBX-2 data type.
Result value[10]	OBX-5.2	Description if SNOMED used Number or structured numeric (e.g. <1.0) if numeric result	SNOMED description. Use interpretations if possible for numeric results.
Result units	OBX-6	units of measure for quantitative if provided	UCUM standards
Specimen Collection Date	OBX-17/OBR-7/OBX-14 (v2.5.1) OBR-7.1 (v2.3.1) yyyymmdd minimum	mm/dd/yyyy	This is a critical required date. Time if useful if it can be provided.
Specimen Received Date	OBX-18 yyyymmdd minimum	mm/dd/yyyy	Date specimen received at the testing lab.
Tested Date/Result Date	OBX-19.1 yyyymmdd minimum	mm/dd/yyyy	Date the specimen was tested or date result was occurred at the lab.
Date Reported	OBR-22 yyyymmdd minimum	mm/dd/yyyy	Date result was reported to the provider/patient.
Device Identifier	OBX-17	Work with DPH to define what to use based on the LIVD list.	See examples in prior section. The list can also be found here

[10] Although specimen source site can be reporting in SPM-8, most of the COVID-19 collections can be handled in SPM-4. CT DPH can handle both.
[11] https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

Table 2. Race

Coded Value	Description[ǂ]
1002-5	American Indian or Alaska Native
2028-9	Asian
2054-5	Black or African American
2076-8	Native Hawaiian or Other Pacific Islander
2106-3	White
2131-1	Other Race[ŧ]
UNKNOWN	Unknown
PHC1175	Refused to Answer

[ŧ]Multi-race selection is preferred over use of Other Race.

[ǂ]If cannot use coded values, the descriptions as written should be used.

Table 3. Ethnicity

CTEDSS Value	Description[ǂ]
Yes	Hispanic or Latino
No	Not Hispanic or not Latino
UNKNOWN	Unknown
PHC1367	Refused to Answer

[ǂ]If cannot use coded values, the descriptions as written should be used.

Table 4. Test Results

SNOMED	Description
260373001	Detected
260415000	Not detected/Presumptive Negative
10828004	Positive
720735008	Presumptive Positive
260385009	Negative
82334004	Indeterminate
419984006	Inconclusive

COVID-19 Result Reporting by Point of Care Providers or Other Testing Locations

Point of Care (POC) providers or others who acquire a COVID-19 testing instrument or machine to do in-office or on-site testing of patients are a unique category of reporters as they are required to report both the results of the COVID-19 tests and case information on patients who have a positive PCR or antigen test result (whether from external or on-site testing).

If possible, CT DPH suggests reporting test results as described in the prior section. If an electronic format for reporting test results is not possible or feasible, results for COVID-19 tests can be reported using the OL15C Reportable Laboratory Findings form[12] (one form for each person's result) and faxed to **860-920-3131**. Use of the PD-23 form is not sufficient to report COVID-19 results from in-office or on-site testing.

As mentioned before, providers with a patient found positive for COVID-19 can use the CT DPH COVID-19 Provider Case Report Portal[13]. However, this portal is not sufficient for test result reporting and only allows reporting of one positive COVID-19 patient at a time. To maximize efficiency for providers, this section outlines the flat file format and contents a POC or other location can use to report both patient case and lab test result information in the same file. Required data variables for this case-lab reporting are listed in Table 5.

Before reporting COVID-19 test results or using the combined patient case and lab test result files, please contact DPH.ELR@ct.gov or the ID Informatics Program Lead to review this information and process. An Excel template can be sent for use, or you can create your own, or generate the files directly from your EMR system.

Instructions

1. Obtain certificate and other items needed to be approved for testing from CT DPH FLIS.
2. Contact CT DPH Informatics to review reporting template.
3. Complete reporting template.
4. Save as a csv file if possible.
5. Post to a secure FTP folder (ask CT DPH to set up connection) or attach to a secure email (see E-File Reporting section)

[12] https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/infectious_diseases/pdf_forms_/OL15C_Form.pdf

[13] https://dphsubmissions.ct.gov/Covid/InitiateCovidReport

Table 5. Required Data Variables for POC or Other Location Reporting of Case and Lab Test Results (on-site testing locations only)

Data element	Flat file content requirements	Notes/comments
Testing Location	CLIA number	Locations performing testing under a CLIA certificate of waiver must still have a CLIA code.
Patient Medical Record Number	Free text	ID that identifies uniquely identifies the person at the provider office. Use this to uniquely identify the results.
Patient Last Name	Free text	Name components should be submitted in separate data fields.
Patient First Name	Free text	
Patient Middle Initial	Free text	
Patient Address	Residential address of the person being tested	This is the residence at the time of testing, even if a congregate setting, college, etc. Include County if possible.
Address 2	Secondary address, e.g., Apt, Bldg, Floor, etc.	Put in separate field from residential address.
Patient City	Free text	
Patient State	2 letter abbreviation	
Patient Zip Code	five or nine digit format allowed	
Patient County	Full county name, e.g., Hartford County, Tolland County, etc.	Include County if possible. If unknown, leave blank.
Patient Phone	10 digit format including area code	A must for COVID-19 contact tracing for persons with positive results.
Patient Email		If available.
Date of Birth	mm/dd/yyyy	
Patient Gender	Male, Female, Other, Unknown	Usually assumed as sex at birth.
Patient Race	See Table 2	Multiple race selections allowed.
Patient Ethnicity	See Table 3	Should be asked separately from race.
Test Method	See list in Table 6 for antigen tests. Table 7 for some PCR tests.	Method, instrument, or machine. **Meets AOE requirement.**

Data element	Flat file content requirements	Notes/comments
Result	See list in Table 6 or Table 4	Use the result descriptions recommended for the test method used. Or SNOMED code.
Specimen Source	See list in Table 6 and Table 7	Use the result descriptions recommended for the specimen source.
Specimen Collection Date	mm/dd/yyyy	It will be assumed that specimen collection date is the same as the date tested.
Date Reported	mm/dd/yyyy	Date result was reported to CT DPH.
Is this the first test (of any kind) the patient has had for COVID-19?	Yes, No	**Meets AOE requirement.**
If patient also tested for influenza at the office by influenza rapid antigen test, what was the result?	Influenza A Influenza B Influenza A or B Negative	If a patient is being tested for COVID-19 and influenza at the same visit, AND, if results are sent in an E-File, please include the influenza test result.
Patient Occupation	Free text	Occupation can be used as a place to capture student, staff, resident, etc.
Is patient pregnant? (if female)	Yes, No, Unknown	**Meets AOE requirement.**
If an adult, does the patient work or volunteer in any of the following high risk settings:		
Healthcare Facility	Yes, No, Unknown	**Meets AOE requirement.**
Veterinary Facility	Yes, No, Unknown	
First Responder?	Yes, No, Unknown	
Childcare facility?	Yes, No, Unknown	
Retail with direct contact with public (e.g. grocery store, bar, etc.)	Yes, No, Unknown	Include older teens who may work at a retail location.
If a child, does the patient attend a childcare facility?	Yes, No, Unknown	
Did the patient reside in a congregate setting?	Yes, No, Unknown	**Meets AOE requirement.**
If yes, please specify the congregate setting type:	Long term care facility (skilled nursing home) Assisted Living Homeless Shelter	

Data element	Flat file content requirements	Notes/comments
	Correctional Facility School/Dorm (residential school or campus residence) Other	
If yes to any of the above, please provide:		
Employer/Facility Name	Free text	
Employer/Facility Town	Free text	
Employer/Facility State	2 letter abbreviation	
Did the patient show any signs or symptoms associated with this illness or event?	Yes, No, Unknown	**Meets AOE requirement.**
Date of onset of symptoms/illness	mm/dd/yyyy	**Meets AOE requirement.**
Chills	Yes, No	
Fever >100.4	Yes, No	
Headache	Yes, No	
Myalgia	Yes, No	
Rigors/Shivers	Yes, No	
Sore throat	Yes, No	
New Olfactory or taste disorder	Yes, No	
Cough	Yes, No	
Difficulty Breathing or Shortness of Breath	Yes, No	
Pneumonia	Yes, No	
Acute Respiratory Disease Syndrome (ARDS)	Yes, No	
Other symptoms or diagnosis, specify	Free Text	If alternate diagnosis, please indicate
Was the patient hospitalized?	Yes, No, Unknown	**Meets AOE requirement**.
If yes, Hospital Name	Free Text	
Hospital Medical Record Number	Free Text	
Admission Date	mm/dd/yyyy	

Data element	Flat file content requirements	Notes/comments
Discharge Date	mm/dd/yyyy	
Admitted to ICU?	Yes, No, Unknown	**Meets AOE requirement.**
Did the patient die?	Yes, No	
Date of death	mm/dd/yyyy	
Does the patient have any pre-existing conditions?	Yes, No, Unknown	Please specify below
Chronic Lung Disease	Yes, No, Unknown	
Diabetes	Yes, No, Unknown	
Cardiovascular Disease	Yes, No, Unknown	
Chronic Renal Disease	Yes, No, Unknown	
Chronic Liver Disease	Yes, No, Unknown	
Immunocompromised	Yes, No, Unknown	
Neurological/Neuorodevelopmental/Id	Yes, No, Unknown	
Current Smoker	Yes, No, Unknown	
Former Smoker	Yes, No, Unknown	
Ordering Facility	Character	This is the facility of the provider who ordered the test.
Ordering Provider Last Name	Character	
Ordering Provider First Name	Character	
Ordering Provider NPI (optional)	Character	National Provider Identifier; provide if available
Ordering Provider Phone number	10 digit phone number	Include area code. Callback number for the provider ordering the test.
Ordering Provider Address	Character	
Ordering Provider City	Character	
Ordering Provider State	2 letter abbreviation	
Ordering Provider Zipcode	5 or 9 digit zipcode	
Ordering Provider fax number	10 digit number	
Ordering Provider email		

Table 6. COVID-19 antigen test information

Test Method	Test Results to be reported*	Test Specimen Types
BD Veritor	Positive Presumptive Negative	Nasal swabs
Quidel Sofia 2	Positive Negative	Nasopharyngeal swab Or Nasal swabs
LumiraDx Ag Test	Positive Negative	Nasal swabs
BinaxNOW COVID-19 Ag card	Positive Negative	Nasal swabs

*Do not report invalid or unsatisfactory test results. If these occur, follow manufacturer recommendations.

Table 7. COVID-19 PCR test information (selected examples)*

Test Method	Test Results to be reported*	Test Specimen Types**
Abbott ID NOW	Positive Negative	Nasal swabs Nasopharyngeal swab Throat swabs Nasal/throat swab combined
Cepheid Xpert Xpress SARS-CoV-2	Positive*** Negative	Nasopharyngeal swab Nasal swabs Mid-turbinate swab Nasal wash/aspirate
bioMérieux ARGENE SARS-COV-2 R-GENE	Positive Negative	Nasopharyngeal swab Oropharyngeal swab Sputum (among others)
Thermo Fisher TaqPath COVID-19 Combo Kit	Positive Not Detected Inconclusive	Nasopharyngeal swab Oropharyngeal swab Sputum (among others)

* A more complete list or other options to report PCR tests can be provided by CT DPH.

** May not be complete set of what specimens can be tested.

*** Also use for Presumptive positive.

Ask At Order Entry (AOE) Questions

As mentioned at the start of this guidance, HHS is only *requesting* AOE questions at this time. However, if laboratories wish to start including these questions, this section will outline which questions to add and how to add them to laboratory or other test reporting messages. Information can be obtained from providers on lab orders, or from persons being tested at walk-in or other locations.

Providers sending a case report form for patients with a positive COVID-19 PCR or Antigen test result will be providing these AOE in that case report. As outlined in Table 5, POC or other locations sending the combined case and test result files will also be providing AOE answers that meet the requirement. Table 8 describes the AOE questions and reasons the question is needed.

Laboratories or locations sending results in HL7 messages, should include this information as it is built into ordering interfaces. The HL7 data elements for AOE are in Table 9.

Table 8. AOE questions and descriptions as defined by CDC

AOE Questions and answers	Why is the question needed?
1. Do you currently work in a healthcare setting with direct patient contact? Answers: • Yes • No • Unknown Capture of specific high risk occupation is in the CT DPH COVID-19 case report form.	To determine if the individual, at the time of this COVID-19 test order, works with patients in a high-risk role, such as, but not limited to: • First responders, • Front-line clinicians (direct patient care), • Nursing home/long term care facility staff, • Environmental staff, or, • Therapists in direct contact with patients.
2. Do you/does individual currently have one or more of the following symptoms? Answers: • Yes, if yes answer Q3. • No • Unknown	To determine if the individual is symptomatic based on CDC guidance at the time of this COVID-19 test order. Consider the following list of symptoms when answering this question: • Fever or chills • Cough • Shortness of breath or difficulty breathing • Fatigue • Muscle or body aches • Headache • New loss of taste or smell • Sore throat • Congestion or runny nose • Nausea or vomiting • Diarrhea
3. [If yes to question #2] When did your symptoms start/date of symptom onset?	To determine the onset of any COVID-19 symptoms the individual is experiencing.
4. [If the individual is female] Are you/is the individual currently pregnant? Answers: • Yes • No • Unknown	To determine the current pregnancy status of the individual.

5. Do you/does the individual currently reside in a congregate (group) care setting? Answers: • Yes • No • Unknown	To determine if the individual lives in a congregate (group) care facility at the time of this COVID-19 test order. Congregate settings can include <u>but are not limited to</u>: • Nursing home/long term care facility, • Residential care locations for people with intellectual and developmental disabilities, • Psychiatric treatment facility, • Group homes, • Dormitory at a school, • Board and care home, • Homeless shelter, or • Foster care setting
6. Is this the first test you have had for COVID-19/is this the individual's first COVID-19 test? Answers: • Yes • No • Unknown	To determine if this is the individual's first COVID-19 test (e.g., molecular, antigen, antibody), or if they are being retested. Optional: Include date the question was answered or date of first test, if known.
7. Is the individual hospitalized with confirmed or suspected COVID-19? Answers: • Yes • No • Unknown **Date admitted is required by CT DPH.**	To determine if the individual is currently hospitalized for confirmed or suspected COVID-19 at the time of this COVID-19 test order.
8. [If yes to question #7] Is the individual in an intensive care unit? Answers: • Yes • No • Unknown	To determine if the individual is currently in the ICU for confirmed or suspected COVID-19 at the time of this COVID-19 test order.

Table 9. HL7 Coding for Ask at Order Entry Questions

Question	Data Input for HL7 ORU messages
Does the patient currently work in a healthcare setting with direct patient contact?	OBX-2 = CWE OBX-3 = 95418-0^Employed in a healthcare setting^LN^^^^2.69-pre 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
Do the patient currently have one or more of the following symptoms? • Fever or chills • Cough • Shortness of breath or difficulty breathing • Fatigue • Muscle or body aches • Headache • New loss of taste or smell • Sore throat • Congestion or runny nose • Nausea or vomiting • Diarrhea	OBX-2 = CWE OBX-3 = 95419-8^Has symptoms related to condition of interest^LN^^^^2.69-pre 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
[If yes to question #2] When did symptoms start? Date is onset of symptoms or illness.	OBX-2 = DT OBX-3 = 11368-8^Illness or injury onset date and time^LN^^^^2.68 OBX-5 = formatted as YYYYMMDD OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST
[If the individual is female] Is the patient currently pregnant?	OBX-2 = CWE OBX-3 = 82810-3^Pregnancy status^LN^^^^2.86 OBX-5 = can be one of: 77386006^Patient currently pregnant^SCT 102874004^Possible pregnancy^SCT 60001007^Not pregnant^SCT UNK^Unknown^NULLFL OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST

Does the patient currently reside in a congregate setting, including but not limited to: • Nursing home or long term care facility • Residential care location for people with intellectual and developmental disabilities • Psychiatric treatment facility • Group home • Dormitory • Board and care home • Homeless shelter, or, • Foster care setting.	Use the confluence layout: OBX-2 = CWE OBX-3 = 95421-4^Resides in a congregate care setting^LN^^^^2.69-pre 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
[Optional] Is this the first test the patient reports having done for COVID-19?	OBX-2 = CWE OBX-3 = 95417-2^First test for condition of interest^LN^^^^2.69-pre 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
Is the patient hospitalized with confirmed or suspected COVID-19?	OBX-2 = CWE OBX-3 = 77974-4^Patient was hospitalized because of this condition^LN^^^^2.69-pre 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
[If yes to question #7] Is the individual in an intensive care unit?	OBX-2 = CWE OBX-3 = 95420-6^Admitted to intensive care unit for condition of interest^LN^^^^2..6.9-pre 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

Examples for HL7 messages can be found in Appendix A. Additional HL7 information is in Appendix B. CT DPH reserves the right to require additional data.

Appendix A. Examples

Reporting of other questions – add the structure for yes no unk (HL7 table 0136)

OBX|6|NM|30525-0^Age^LN||85|a^year^UCUM|||||F|||202002271957-0500|||||||||||||QST

OBX|7|CWE|95417-2^First test for condition of interest^LN||Y^Yes^HL70136||||||F|||202002271957-0500|||||||||||||QST

OBX|8|CWE|95418-0^Employed in a healthcare setting^LN||UNK^Unknown^NULLFL||||||F|||202002271957-0500|||||||||||||QST

OBX|9|CWE|95419-8^Has symptoms related to condition of interest^LN||Y^Yes^HL70136||||||F|||202002271957-0500|||||||||||||QST

OBX|10|DT|11368-8^Illness or injury onset date and time^LN||20200214||||||F|||202002271957-0500|||||||||||||QST

OBX|11|CWE|77974-4^Patient was hospitalized because of this condition^LN||Y^Yes^HL70136||||||F|||202002271957-0500|||||||||||||QST

OBX|12|CWE|95420-6^Admitted to intensive care unit for condition of interest^LN||N^No^HL70136||||||F|||202002271957-0500|||||||||||||QST

OBX|13|CWE|95421-4^Resides in a congregate care setting^LN||Y^Yes^HL70136||||||F|||202002271957-0500|||||||||||||QST

OBX|14|CWE|82810-3^Pregnancy status^LN||60001007^Not pregnant^SCT||||||F|||202002271957-0500|||||||||||||QST

Device Identifier – included with any test result OBX

OBX|1|CWE|94307-6^2020-nCoV N XXX Ql NAA N1^LN||260373001^Detected^SCT||||||F|||202002281257-0500||| **xMAP SARS-CoV-2 Multi-Antigen IgG Assay_Lumine_EUA^^99ELR~MAGPIX System_Luminex Corp_MNI^^99ELR**||202004020721-0500||||Public Health Laboratory^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^05D0897628|3434 Industrial Loop^^Little Rock^AR^72205^USA^B|||||RSLT

Appendix B. Guidance for HL7 messages

These are for certain segments in the HL7 message and do not reflect what is required in the entire HL7 message.

PID – Patient Demographics

Seq	Element Name	Optionality	HL7 mapping	Changes in HL7 guidance	Comments
1	Patient Name	R	PID-5 OUTLAND^FNAME^Z^^^^L		
2	Patient DOB	R (CT)/RE	PID-7 yyyymmdd		Minimum format
3	Patient sex	R (CT)/RE	PID-8 F		Usually assumed as sex at birth. Can use F, M, O, U or Female, Male, Other, Unknown
4	Patient race	R (CT)/RE	PID-10	Add PHC1175^Refused to answer^CDCPHINVS UNK^Unknown^NULLFL	PHVS_RaceCategory_CDC_Ref: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=2C70C8B3-F43B-E311-A464-0017A477041A
	Patient ethnicity		PID-22		• 2135-2 Hispanic or Latino • 2186-5 Non Hispanic or Latino • UNK Unknown Refused to Answer
5	Patient address	R (CT)/RE	PID-11 438 SOME ST^^SOMETOWN^CT^06000^^^^HARTFORD		Include County if possible.
6	Patient phone	R(CT)/RE	PID-13 ^PRN^PH^^1^860^9999999		Assumes patient's home phone; include area code; best phone if not home phone

The only changes to what laboratories are already sending is the additional encoding for "Refused to answer".

OBR and ORC – Ordering Information

Seq	Element Name	Optionality	HL7 mapping	Changes in HL7 guidance	Comments
1	Ordering provider name and NPI (as applicable)	R(CT)/RE	OBR-16		Report NPI Ordering Provider Name is in OBR-16.2 and OBR-16.3 NPI would be OBR-16.1; When populating 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"
2	Ordering provider phone number	R(CT)/RE	ORC-14/OBR-17		
3	Ordering provider address	R(CT)/RE	ORC-24 28 CRESCENT ST^^MIDDLETOWN^CT ^06457-3654		Include zip code ORC.24.5
4	Ordering facility	RE	ORC-21		Facility placing the order – of the ordering provider.
5	Date Test Ordered	RE	ORC-15 yyyymmdd		
6	Test Ordered	RE(CT)/R	OBR-4		LOINC code

The only change to what laboratories are currently reporting is the provider NPI. This would be for the Ordering Provider.

OBX – Observation Results

Seq	Element Name	Optionality	HL7 mapping	Changes in HL7 guidance	Comments
1	Performing facility name and/or CLIA number, if known	R(CT)/R	OBX-23 (v2.5.1) OBX-15 (v2.3)		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. CT DPH will accept CLIA or OID in OBX-23.10
2	Performing facility zip code	R(CT)/R	OBX-24 (v2.5.1) NTE (v2.3)		
3	Device Identifier	RE(CT)/RE	OBX-17 OBX-18	New requirement	Use OBX-17 when describing the manufacturer and model of either test kit (reagent) or instrument used; or when referencing the EUA. Use OBX-18 when passing the serial number or UDI of the test kit (reagent) or instrument. See examples in Appendix B.
4	Test result	R(CT)/R	OBX-3		LOINC – fully construct this component. If LOINC available, must use.
5	Test result value	R(CT)/R	OBX-5		SNOMED CT (coded/qualitative/organism) For numeric, include units in OBX-6 when appropriate – code units in UCUM
6	Test Result date	RE(CT)/RE	OBX-19 (v2.5.1.) OBR-22 (v2.3.1)		yyyymmdd 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.

The new elements are the Device Identifiers: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

OBX – Ask at Order Entry – these answers are to be encoded in OBX segments

Seq	Element Name	Optionality CT/HHS	HL7 mapping	Comments
1	First Test (for COVID-19)	RE/RE	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	Employed in health care?	RE/RE	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

Seq	Element Name	Optionality CT/HHS	HL7 mapping	Comments
3	Symptomatic as defined by CDC?		OBX-2 = CWE OBX-3 = **95419-8**^Has symptoms related to 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: 95419-8^Whether patient has symptoms related to condition of interest^LN For COVID-19 the list of symptoms is here
4	Date of Symptom Onset Condition if symptomatics is Yes	C/C	OBX-2 = DT OBX-3 = **11368-8**^Illness or injury onset date and time^LN OBX-5 = formatted as YYYYMMDD OBX-11 = F OBX-14 = Date question was answered OBX-29 = QST	LOINC: 11368-8^Illness or injury onset date and time^LN
5	Hospitalized because of COVID-19?	RE/RE	OBX-2 = CWE OBX-3 = **77974-4**^Patient was hospitalized because of this condition^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: 77974-4^Whether patient was hospitalized because of this condition^LN When interested in whether hospitalized at time of order, use PV1-2 (Patient Class). If a test were ordered during an ER/ED visit, the answer is No.

Seq	Element Name	Optionality CT/HHS	HL7 mapping	Comments
6	Admitted to ICU due to COVID-19?	RE/RE	OBX-2 = CWE OBX-3 = **95420-6**^Admitted to intensive care unit 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: 95420-6^Whether patient was admitted to intensive care unit for condition of interest^LN When interested in whether in ICU at time of order, use PV1 location/organization providing care.
7	Resident in congregate care setting (at the time of testing)	RE/RE	OBX-2 = CWE OBX-3 = **95421-4**^Resides in a congregate care 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: 95421-4^Whether patient resides in a congregate care setting^LN
8	Pregnant? Current pregnancy status at time of testing	C/C	OBX-2 = CWE OBX-3 = **82810-3**^Pregnancy status^LN OBX-5 = can be one of: 77386006^Patient currently pregnant^SCT 102874004^Possible pregnancy^SCT 60001007^Not pregnant^SCT UNK^Unknown^NULLFL OBX-11 = F	LOINC: 82810-3 Pregnancy status LOINC from https://loinc.org/sars-cov-2-and-covid-19/

Seq	Element Name	Optionality CT/HHS	HL7 mapping	Comments
			OBX-14 = Date question was answered OBX-29 = QST	
9	Patient age	C/RE	Send as AOE OBX: OBX-2 = NM (can be SN) OBX-3 = **30525-0**^Age^LN 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	For CT DPH: only if 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).