

COVID-19 Lab Data Reporting Implementation Specifications

#	Data Element	Reporting Requirement*			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				
7	Device Identifier	Yes	Yes	Requested	<p>Must use harmonized Device Identifiers (DI), when available. The DI is contained within the unique device identifier (UDI), created by manufacturer</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column M: 'Testkit Name ID' for assay and column O: 'Equipment UID' for instrument</i></p>	<p>Manufacturer requests UDI issuance, then provides DI, or pull from GUDID database</p> <p>If DI unavailable: Use 'Trade Name_Manufacturer Name' (a unique element controlled under 21 CFR 209.10(b)(1))</p>	<p>Example DI: 01234567891011</p> <p>Example Trade Name: SARS-CoV-2 Test_Company</p>	<p>Click here for HL7 V2 Guidance</p> <p>OBX-17, OBX-18 (barcode)</p>
8	Accession # / Specimen ID	Yes	Yes	Requested	<p>Unconstrained alphanumeric string (follow HL7 specs for documentation)</p> <p>Must be unique for the lab</p>	<p>Can create by concatenating, as needed.</p> <p>Typically includes:</p> <ul style="list-style-type: none"> • Date/time entered • Collection date • Specimen type (SNOMED-CT) 	<p>Example of Accession #: 18617001</p> <p>Example of Specimen ID: QD00032000</p>	<p>OBR-3, SPM-2</p>
9	Patient age	Yes	Requested		<p>Patient age units – numeric:</p> <ul style="list-style-type: none"> • number of years for patients >2 • months for patients < 2 • [YY yr] OR [MM mo] 	<p>Patient age at the time of specimen collection, if date of birth is not known</p>	<p>May calculate from DOB</p>	<p>OBX-5</p>
10	Patient date of birth	No	Yes		<p>YYYY[MM[DD]] – numeric</p>		<p>Examples: 19460616</p>	<p>PID-7</p>
11	Patient race	Yes	Yes		<p>Use OMB race codes value set, which is consistent with Census 2020</p>	<p>Identified by patient</p>	<p>OMB Values:</p> <ul style="list-style-type: none"> • 1002-5 American Indian or Alaska Native • 2028-9 Asian 	<p>PID-10</p>

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		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				Click here for HL7 V2 Guidance
							<ul style="list-style-type: none"> • 2054-5 Black or African American • 2076-8 Native Hawaiian or Other Pacific Islander • 2106-3 White • UNK Unknown • ASKU Asked, but unknown 	
12	Patient ethnicity	Yes	Yes		Use OMB ethnicity codes value set, which is consistent with Census 2020	Identified by patient	OMB Values: <ul style="list-style-type: none"> • 2135-2 Hispanic or Latino • 2186-5 Non Hispanic or Latino • UNK Unknown • ASKU Asked, but unknown 	PID-22
13	Patient sex	Yes	Yes		Male Female Other	Biological sex at birth (XY, XX, other)	SNOMED-CT Values: <ul style="list-style-type: none"> • M (Male) • F (Female) • O (Other) 	PID-8
14	Patient residence zip code	Yes	Yes		5-digit or 9-digit numeric notation (with dash) ##### or #####-####		Example: 20993	PID-11.5
15	Patient residence county	Yes	Yes		Patient residence county name – Alpha	Patient residence county name can be auto-populated from zip code	Example: Dallas County	PID-11.9
16	Ordering provider name and NPI	Yes (as applicable)	Yes (as applicable)		Name – Alpha NPI – Numeric, 10-digit #####	Current provider name, or NPI from NPPES NPI Registry	Example Name: <ul style="list-style-type: none"> • Last, First Example NPI: <ul style="list-style-type: none"> • 1234567899 	ORC-12.1 OBR-16.1 ORC-12.2 OBR-16.2 ORC-12.3 OBR-16.3
17	Ordering provider zip code	Yes	Yes		5-digit or 9-digit numeric notation (with dash) ##### #####-####		Example: 20993	ORC-24.5

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18	Performing facility name and/or CLIA #	Yes (if known)	Yes (if known)		Alphanumeric; ##D#####	CLIA Laboratory Search	Example: 21D1234567	OBX-23
19	Performing facility zip code	Yes	Yes		5-digit or 9-digit numeric notation (with dash) ##### #####-####		Example: 20993	OBX-24.5
20	Specimen source	Yes	Yes		Must use appropriate harmonized specimen codes (in LIVD file, e.g., SNOMED-CT codes) , when available <i>See LIVD file 'LOINC Mapping' Tab, column D: 'Vendor Specimen Description'</i>		SNOMED-CT Values: <ul style="list-style-type: none"> • 258500001 Nasopharyngeal swab • 871810001 Mid-turbinate nasal swab • 697989009 Anterior nares swab • 258411007 Nasopharyngeal aspirate • 429931000124105 Nasal aspirate • 258529004 Throat swab • 119334006 Sputum specimen • 119342007 Saliva specimen • 258607008 Bronchoalveolar lavage fluid sample • 119364003 Serum specimen • 119361006 Plasma specimen • 440500007 Dried blood spot specimen • 258580003 Whole blood sample • 122555007 Venous blood specimen 	SPM-4
21	Patient name	No	Requested		LOINC: 45392-8 Patient First Name LOINC: 52461-1 Patient Middle Name		Example: Last, First Middle	PID-5.1 , PID-5.2 , PID-5.3

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		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				Click here for HL7 V2 Guidance
					LOINC: 45394-4 Patient Last Name			
22	Unique patient identifier	No	Requested	Requested				PID-3
23	Patient street address	No	Requested		Patient street address – Alphanumeric	Address of location where patient resides (e.g., apartment, condo, house, shelter, care facility, etc.)	Example: Number Street City, State, Zip	PID-11
24	Patient phone number	No	Requested		10-digit numeric (###)###-####	Home/cell phone (non-business)	Example: (123) 456-7890	PID-13
25	Ordering provider address	No	Requested		Alphanumeric	Ordering provider street address	Example: Number Street City, State, Zip	ORC-24
26	Ordering provider phone number	No	Requested		10-digit numeric (###)###-####		Example: (123) 456-7890	ORC-14 OBR-17
27	AOE: First test	Optional	Optional		YES NO UNK - Unknown	Is this the first test (of any kind) the patient has had for COVID-19?	LOINC: 95417-2 Value Set (HL7 0136): • YES • NO • UNK - Unknown	OBX-5
	(if NO)	Optional	Optional		Molecular Antigen Antibody/Serology UNK - Unknown	What type of test was the most recent prior test, and what was the result? To be filled out by patient or provider, or pulled from a patient's test history, if possible.	Test Type and Result: • Molecular (LOINC: 94309-2) • Detected (260373001) • Not Detected (260415000) • UNK - Unknown (261665006) • Antigen (LOINC: 94558-4) • Detected (260373001) • Not Detected (260415000) • UNK - Unknown (261665006) • Antibody (LOINC: 94762-2) • Detected (260373001) • Not Detected (260415000)	OBX-5

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		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				
							<ul style="list-style-type: none"> • UNK - Unknown (261665006) • 261665006 Unknown • 276727009 Null (Prior test type unknown) 	Click here for HL7 V2 Guidance
	(if NO)	Optional	Optional		YYYY[MM[DD]] – numeric	Date of most recent prior test (date when test was performed), if known.	Example: 20200716	OBX-5
28	AOE: Employed in healthcare	Requested	Requested		YES NO UNK - Unknown	Is the patient employed in healthcare <i>with direct patient contact</i> ?	LOINC: 95418-0	OBX-5
	(if YES)	Optional	Optional				If yes: SNOMED-CT Values: <ul style="list-style-type: none"> • 223366009 Healthcare Professional More Detailed Healthcare Professional List	
29	AOE: Symptomatic per CDC	Requested	Requested		YES NO UNK - Unknown	Per CDC list of symptoms	LOINC: 95419-8 Value Set (HL7 0136): • YES • NO • UNK - Unknown	OBX-5
	(if YES)	Requested	Requested		If yes, date symptom onset, if known YYYY[MM[DD]] – numeric		LOINC: 65222-2 (date) Example: 20200716	OBX-5
	(if YES)	Optional	Optional		Use LOINC and SNOMED-CT codes when possible	Per CDC list of symptoms	LOINC: 75325-1 Symptom SNOMED-CT Values: <ul style="list-style-type: none"> • 426000000 Fever over 100.4F • 103001002 Feeling feverish • 43724002 Chills • 49727002 Cough • 267036007 Shortness of breath 	OBX-5

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		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				Click here for HL7 V2 Guidance
							<ul style="list-style-type: none"> • 230145002 Difficulty breathing • 84229001 Fatigue • 68962001 Muscle or body aches • 25064002 Headache • 36955009 New loss of taste • 44169009 New loss of smell • 162397003 Sore throat • 68235000 Nasal congestion • 64531003 Runny nose • 422587007 Nausea • 422400008 Vomiting • 62315008 Diarrhea 	
30	AOE: Hospitalized (at time of testing, for COVID)	Requested	Requested		YES NO UNK - Unknown	To determine if the individual is hospitalized for confirmed or suspected COVID-19 at time of testing	LOINC: 77974-4 Value Set (HL7 0136): • YES • NO • UNK – Unknown	OBX-5
	(if YES)	Optional	Optional				If Yes, SNOMED-CT Values: <ul style="list-style-type: none"> • 840544004 Suspected disease caused by 2019 novel coronavirus (situation) • 840539006 Disease caused by 2019 novel coronavirus (disorder) 	
31	AOE: ICU (at time of testing, for COVID)	Requested	Requested		YES NO UNK - Unknown	To determine if the individual is in the ICU for confirmed or suspected COVID-19 at time of testing	LOINC: 95420-6 Value Set (HL7 0136): • YES • NO • UNK – Unknown	OBX-5
	(if YES)	Optional	Optional				If Yes, SNOMED-CT Value: <ul style="list-style-type: none"> • 309904001 Intensive care unit (environment) 	

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32	AOE: Resident in congregate care/living setting (select the best one)	Requested	Requested		YES NO UNK - Unknown	e. g., nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care	LOINC: 95421-4 Value Set (HL7 0136): • YES • NO • UNK - Unknown	OBX-5
	(if YES)	Optional	Optional				If yes: LOINC: 75617-1 Residence Type SNOMED-CT Values: <ul style="list-style-type: none"> • 22232009 Hospital • 2081004 Hospital ship • 32074000 Long term care hospital • 224929004 Secure hospital • 42665001 Nursing home • 30629002 Retirement home • 74056004 Orphanage • 722173008 Prison-based care site • 20078004 Substance abuse treatment center • 257573002 Boarding house • 224683003 Military accommodation • 284546000 Hospice • 257628001 Hostel • 310207003 Sheltered housing • 257656006 Penal institution 	

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							<ul style="list-style-type: none"> • 285113009 Religious institutional residence • 285141008 Work (environment) 	
33	AOE: Pregnant	Requested	Requested		Pregnant Not Pregnant UNK - Unknown		LOINC: 82810-3 SNOMED-CT Pregnancy Status: <ul style="list-style-type: none"> • 77386006 Pregnant • 60001007 Not Pregnant • 261665006 Unknown • 276727009 Null 	OBX-5

*** Reporting Requirements:**

This table represents a visual, side-by-side comparison of which entities ultimately receive each of the reported data elements. For example, not all data elements reported to the State / Local PHD are reported to the Federal authorities.

- This table is not meant to indicate how data elements are reported in terms of their flow between entities. Current information on reporting requirements for laboratories and associated FAQs are available on CDC's website: "[How to Report COVID-19 Laboratory Data](#)"

Requirement/Request Level:

- Yes = Required to be reported by August 1st, 2020
- Requested = Every reasonable effort should be made to achieve reporting by August 1st, 2020
- Optional = Strongly encouraged to begin reporting by August 1st, 2020, if possible
- No = Not required to be reported

Acronyms:

AOE: Ask at Order Entry

CDC: Centers for Disease Control and Prevention

CLIA: Clinical Laboratory Improvement Amendments

DI: Device Identifier

EHR: Electronic Health Record

GUDID: Global Unique Device Identification Database

HHS: Department of Health and Human Services

HL7: Health-Level Seven

ICU: Intensive Care Unit

ID: Identifier

LIVD: LOINC In Vitro Diagnostic

LOINC: Logical Observations Identifiers Names and Codes

NPI: National Provider Identifier

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<p>NPPES: National Plan and Provider Enumeration System OBR: Observation Request Segment OBX: Observation/Result Segment OMB: Office of Management and Budget ORC: Common Order Segment PHD: Public Health Department PID: Patient Identification Segment SNOMED-CT: Systematized Nomenclature of Medicine – Clinical Terms SPM: Specimen Segment UNK: Unknown</p>								