

COVID-19 Data Reporting for Non-Lab-Based Testing

#	Data Element	Source	Reporting			Technical Specifications	Notes	Example
			Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record			
1	Test ordered	Device (Auto)	✓	✓	✓	<p>Must use harmonized LOINC codes, when available</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column H: 'LOINC Order Code'</i></p>	Use LOINC panel codes and general LOINC codes for individual tests for orders	Example LOINC: 94558-4 : SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay
2	Test result (performed) Test result (values)	Device (Auto)	✓	✓	✓	<p>Must use harmonized LOINC codes, when available</p> <p>Qualitative tests: Must use harmonized SNOMED-CT value set codes</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column E: 'Vendor Result Description'</i></p>		<p>Example LOINC: 94558-4: SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay</p> <p>Example SNOMED-CT Qualitative Values:</p> <ul style="list-style-type: none"> • 260373001 Detected • 260415000 Not detected • 419984006 Inconclusive • 455371000124106 Invalid Result
3	Test result date	Device (Auto)	✓	✓	✓	YYYY[MM[DD]] – numeric	Date the test result was obtained	Example: 20200716
4	Test report date	Device (Auto)	✓	✓	✓	YYYY[MM[DD]] – numeric	Date the test result was reported to the state public health authority*	<p>Example: 20200716</p> <p><i>*Note: this data element definition differs from the lab-based test report date.</i></p>
5	Device Identifier	Device (Auto)	✓	✓	✓	Must use harmonized Device Identifiers (DI) , when available. The DI is contained within the unique device identifier (UDI), created by manufacturer	Manufacturer requests UDI issuance , then provides DI, or pull from GUDID database	Example DI: 01234567891011

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						<i>See LIVD file 'LOINC Mapping' Tab, column M: 'Testkit Name ID' for assay and column O: 'Equipment UID' for instrument</i>	If DI unavailable: Use 'Trade Name_Manufacturer Name' (a unique element controlled under 21 CFR 209.10(b)(1))	Example Trade Name: SARS-CoV-2 Test_Company
6	Patient age	Patient	✓	✓	✓	Patient age units – numeric: <ul style="list-style-type: none"> • number of years for patients >2 • months for patients < 2 • [YY yr] OR [MM mo] LOINC: 35659-2 Age at specimen collection	Patient age at the time of specimen collection	May calculate from DOB, if known
7	Patient date of birth	Patient		✓	✓	YYYY[MM[DD]] – numeric LOINC: 21112-8 Birth date		Examples: 19460616
8	Patient race	Patient	✓	✓	✓	Use OMB race codes value set, which is consistent with Census 2020 LOINC: 32624-9 Race	Identified by patient	OMB Values: <ul style="list-style-type: none"> • 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 • UNK Unknown • ASKU Asked, but unknown
9	Patient ethnicity	Patient	✓	✓	✓	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

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						LOINC: 69490-1 Ethnicity OMB.1997		• ASKU Asked, but unknown
10	Patient sex	Patient	✓	✓	✓	Male Female Other LOINC: 72143-1 Sex	Biological sex at birth (XY, XX, other)	SNOMED-CT Values: • M (Male) • F (Female) • O (Other)
11	Patient residence zip code	Patient	✓	✓	✓	5-digit or 9-digit numeric notation (with dash) ##### #####-#### LOINC: 45401-7 Postal code [Location]		Example: 20993
12	Patient residence county	Auto from zip	✓	✓	✓	Patient county name – Alpha LOINC: 87721-7 County of residence [Location]	Patient county name can be auto-populated from zip code	Example: Dallas County
13	Ordering provider name; NPI	Patient/ Auto	✓	✓	✓	Name – Alpha NPI – Numeric, 10-digit #####	Current ordering provider name, and/or NPI from NPPES NPI Registry	Example Name: Last, First Example NPI: 1234567899 <i>Not applicable for non-prescription tests</i>
14	Ordering provider zip code	Patient/ Auto	✓	✓	✓	5-digit or 9-digit numeric notation (with dash) ##### #####-####		Example: 20993 <i>Not applicable for non-prescription tests</i>
15	Specimen source	Patient/ Device	✓	✓	✓	Must use appropriate harmonized specimen codes (in LIVD file, e.g., SNOMED-CT codes) , when available		SNOMED-CT Values: • 871810001 Mid-turbinate nasal swab • 697989009 Anterior nares swab • 429931000124105 Nasal aspirate • 258529004 Throat swab • 119334006 Sputum specimen

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						<i>See LIVD file 'LOINC Mapping' Tab, column D: 'Vendor Specimen Description'</i>		<ul style="list-style-type: none"> • 119342007 Saliva specimen • 440500007 Dried blood spot specimen
16	Patient name	Patient		✓	✓	LOINC: 45392-8 Patient First Name LOINC: 52461-1 Patient Middle Name LOINC: 45394-4 Patient Last Name		Example: Last, First Middle
17	Unique patient identifier			✓	✓	Multifactor authentication system		Example: Multifactor authentication system, using cloud-based registration, with time-dependent serial pings, geographic location, and biometrics (e.g., voice print, facial recognition, etc.)
18	Patient street address	Patient		✓	✓	Patient street address – Alphanumeric LOINC: 56799-0 Address	Address of location where patient resides	Example: Number Street City, State, Zip
19	Patient phone number	Patient		✓	✓	10-digit numeric (###) ###-#### LOINC: 42077-8 Patient phone number	Home/cell phone (non-business)	Example: (123) 456-7890
20	Patient email address	Patient		✓	✓	LOINC: 76458-9 Patient Email address		
21	Ordering provider address	Patient/ Auto		✓	✓	Alphanumeric	Ordering provider street address	Example: Number Street, City, State, Zip <i>Not applicable for non-prescription tests</i>
22	Ordering provider phone number	Patient/ Auto		✓	✓	10-digit numeric (###) ###-####		Example: (123) 456-7890 <i>Not applicable for non-prescription tests</i>

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23	AOE: First test	Patient	✓	✓	✓	YES NO UNK - Unknown	Is this the first test (of any kind) the patient has had for COVID-19?	LOINC: 95417-2 Value Set: <ul style="list-style-type: none"> • YES • NO (move to 28b) • UNK - Unknown
	(if NO)	Patient	✓	✓	✓	Molecular Antigen Antibody/Serology Unknown	What type of test was the most recent prior test, and what was the result?	Test Type and Result: <ul style="list-style-type: none"> •Molecular (LOINC: 94309-2) <ul style="list-style-type: none"> •Detected (260373001) •Not Detected (260415000) •UNK - Unknown (261665006) •Antigen (LOINC: 94558-4) <ul style="list-style-type: none"> •Detected (260373001) •Not Detected (260415000) •UNK - Unknown (261665006) •Antibody (LOINC: 94762-2) <ul style="list-style-type: none"> •Detected (260373001) •Not Detected (260415000) •UNK - Unknown (261665006) •261665006 Unknown •276727009 Null (Prior test type unknown)
	(if NO)	Patient	✓	✓	✓	YYYY[MM[DD]]	Date of most recent prior test (date when test was performed), if known	
24	AOE: Employed in healthcare	Patient	✓	✓	✓	YES NO UNK - Unknown	Is the patient employed in healthcare <i>with direct patient contact</i> ?	LOINC: 95418-0
	(if YES)	Patient	✓	✓	✓			If yes: SNOMED-CT Values: <ul style="list-style-type: none"> • 223366009 Healthcare Professional • More Detailed Healthcare Professional List

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25	AOE: Symptomatic per CDC	Patient	✓	✓	✓	YES NO UNK - Unknown	Per CDC list of <hr/>	LOINC: 95419-8 Value Set: <ul style="list-style-type: none"> • YES • NO • UNK - Unknown
	(if YES)	Patient	✓	✓	✓	If yes, date symptom onset, if known YYYY[MM[DD]] – numeric		LOINC: 65222-2 (date) Example: 20200716
	(if YES)	Patient	✓	✓	✓	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"> • 42600000 Fever over 100.4F • 103001002 Feeling feverish • 43724002 Chills • 49727002 Cough • 267036007 Shortness of breath • 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
	(if YES)	Patient	✓	✓	✓			If Yes, SNOMED-CT Value: <ul style="list-style-type: none"> • 309904001 Intensive care unit (environment)
26	AOE: Resident in congregate	Patient	✓	✓	✓	YES NO UNK - Unknown		LOINC: 95421-4 Value Set:

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	care/living setting							<ul style="list-style-type: none"> • YES • NO • UNK - Unknown
	(if YES)	Patient	✓	✓	✓		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	<p>If yes: LOINC: 75617-1 Residence Type</p> <p>SNOMED-CT Values:</p> <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 • 285113009 Religious institutional residence • 285141008 Work (environment)
27	AOE: Pregnant	Patient	✓	✓	✓	Pregnant/ Not Pregnant/ Unknown		<p>LOINC: 82810-3</p> <p>SNOMED-CT Pregnancy Status:</p> <ul style="list-style-type: none"> • 77386006 Pregnant • 60001007 Not Pregnant • 261665006 Unknown • 276727009 Null