

## 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 <a href="#">harmonized LOINC codes</a>, 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: <a href="#">94558-4</a> : 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 <a href="#">harmonized LOINC codes</a>, when available</p> <p>Qualitative tests: Must use <a href="#">harmonized SNOMED-CT</a> value set codes</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column E: 'Vendor Result Description'</i></p>		<p>Example LOINC: <a href="#">94558-4</a>: 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"> <li>• <a href="#">260373001</a> Detected</li> <li>• <a href="#">260415000</a> Not detected</li> <li>• <a href="#">419984006</a> Inconclusive</li> <li>• <a href="#">455371000124106</a> Invalid Result</li> </ul>
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 <a href="#">harmonized Device Identifiers (DI)</a> , when available. The DI is contained within the unique device identifier (UDI), created by manufacturer	Manufacturer <a href="#">requests UDI issuance</a> , then provides DI, or pull from <a href="#">GUDID database</a>	Example DI: 01234567891011

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						<i>See LIVD file 'LOINC Mapping' Tab, column M: 'TestkitName ID' for assay and column O: 'Equipment UID' for instrument</i>	If DI unavailable: Use 'Trade Name_Manufacturer Name' (a unique element controlled under <a href="#">21 CFR 209.10(b)(1)</a> )	Example Trade Name: SARS-CoV-2 Test_Company
6	Patient age	Patient	✓	✓	✓	Patient age units – numeric: <ul style="list-style-type: none"> <li>• number of years for patients &gt;2</li> <li>• months for patients &lt; 2</li> <li>• [YY yr] OR [MM mo]</li> </ul> LOINC: <a href="#">35659-2</a> 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: <a href="#">21112-8</a> Birth date		Examples: 19460616
8	Patient race	Patient	✓	✓	✓	Use <a href="#">OMB race codes</a> value set, which is consistent with <a href="#">Census 2020</a>  <a href="#">LOINC: 32624-9 Race</a>	Identified by patient	OMB Values: <ul style="list-style-type: none"> <li>• 1002-5 American Indian or Alaska Native</li> <li>• 2028-9 Asian</li> <li>• 2054-5 Black or African American</li> <li>• 2076-8 Native Hawaiian or Other Pacific Islander</li> <li>• 2106-3 White</li> <li>• UNK Unknown</li> <li>• ASKU Asked, but unknown</li> </ul>
9	Patient ethnicity	Patient	✓	✓	✓	Use <a href="#">OMB ethnicity codes</a> value set, which is consistent with <a href="#">Census 2020</a>	Identified by patient	OMB Values: <ul style="list-style-type: none"> <li>• 2135-2 Hispanic or Latino</li> <li>• 2186-5 Non Hispanic or Latino</li> <li>• UNK Unknown</li> </ul>

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						LOINC: <a href="#">69490-1</a> Ethnicity OMB.1997		• ASKU Asked, but unknown
10	Patient sex	Patient	✓	✓	✓	Male Female Other  LOINC: <a href="#">72143-1</a> 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: <a href="#">45401-7</a> Postal code [Location]		Example: 20993
12	Patient residence county	Auto from zip	✓	✓	✓	Patient county name – Alpha  LOINC: <a href="#">87721-7</a> 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 <a href="#">NPPES NPI Registry</a>	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 <a href="#">specimen codes (in LIVD file, e.g., SNOMED-CT codes)</a> , when available		SNOMED-CT Values: • <a href="#">871810001</a> Mid-turbinate nasal swab • <a href="#">697989009</a> Anterior nares swab • <a href="#">429931000124105</a> Nasal aspirate • <a href="#">258529004</a> Throat swab • <a href="#">119334006</a> 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"> <li>• <a href="#">119342007</a> Saliva specimen</li> <li>• <a href="#">440500007</a> Dried blood spot specimen</li> </ul>
16	Patient name	Patient		✓	✓	LOINC: <a href="#">45392-8</a> Patient First Name  LOINC: <a href="#">52461-1</a> Patient Middle Name  LOINC: <a href="#">45394-4</a> 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: <a href="#">56799-0</a> Address	Address of location where patient resides	Example: Number Street City, State, Zip
19	Patient phone number	Patient		✓	✓	10-digit numeric (###) ###-####  LOINC: <a href="#">42077-8</a> Patient phone number	Home/cell phone (non-business)	Example: (123) 456-7890
20	Patient email address	Patient		✓	✓	LOINC: <a href="#">76458-9</a> 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: <a href="#">95417-2</a>  Value Set: <ul style="list-style-type: none"> <li>• YES</li> <li>• NO (move to 28b)</li> <li>• UNK - Unknown</li> </ul>
	(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"> <li>•Molecular (LOINC: <a href="#">94309-2</a>) <ul style="list-style-type: none"> <li>•Detected (<a href="#">260373001</a>)</li> <li>•Not Detected (<a href="#">260415000</a>)</li> <li>•UNK - Unknown (<a href="#">261665006</a>)</li> </ul> </li> <li>•Antigen (LOINC: <a href="#">94558-4</a>) <ul style="list-style-type: none"> <li>•Detected (<a href="#">260373001</a>)</li> <li>•Not Detected (<a href="#">260415000</a>)</li> <li>•UNK - Unknown (<a href="#">261665006</a>)</li> </ul> </li> <li>•Antibody (LOINC: <a href="#">94762-2</a>) <ul style="list-style-type: none"> <li>•Detected (<a href="#">260373001</a>)</li> <li>•Not Detected (<a href="#">260415000</a>)</li> <li>•UNK - Unknown (<a href="#">261665006</a>)</li> </ul> </li> <li>•<a href="#">261665006</a> Unknown</li> <li>•<a href="#">276727009</a> Null (Prior test type unknown)</li> </ul>
	(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: <a href="#">95418-0</a>
	(if YES)	Patient	✓	✓	✓			If yes: SNOMED-CT Values: <ul style="list-style-type: none"> <li>• <a href="#">223366009</a> Healthcare Professional</li> <li>• <a href="#">More Detailed Healthcare Professional List</a></li> </ul>

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25	<b>AOE:</b> Symptomatic per <a href="#">CDC</a>	Patient	✓	✓	✓	YES NO UNK - Unknown	Per <a href="#">CDC list of symptoms</a>	LOINC: <a href="#">95419-8</a>  Value Set: <ul style="list-style-type: none"> <li>• YES</li> <li>• NO</li> <li>• UNK - Unknown</li> </ul>
	(if YES)	Patient	✓	✓	✓	If yes, date symptom onset, if known YYYY[MM[DD]] – numeric		LOINC: <a href="#">65222-2</a> (date)  Example: 20200716
	(if YES)	Patient	✓	✓	✓	Use LOINC and SNOMED-CT codes when possible	Per <a href="#">CDC list of symptoms</a>	LOINC: <a href="#">75325-1</a> Symptom  SNOMED-CT Values: <ul style="list-style-type: none"> <li>• <a href="#">42600000</a> Fever over 100.4F</li> <li>• <a href="#">103001002</a> Feeling feverish</li> <li>• <a href="#">43724002</a> Chills</li> <li>• <a href="#">49727002</a> Cough</li> <li>• <a href="#">267036007</a> Shortness of breath</li> <li>• <a href="#">230145002</a> Difficulty breathing</li> <li>• <a href="#">84229001</a> Fatigue</li> <li>• <a href="#">68962001</a> Muscle or body aches</li> <li>• <a href="#">25064002</a> Headache</li> <li>• <a href="#">36955009</a> New loss of taste</li> <li>• <a href="#">44169009</a> New loss of smell</li> <li>• <a href="#">162397003</a> Sore throat</li> <li>• <a href="#">68235000</a> Nasal congestion</li> <li>• <a href="#">64531003</a> Runny nose</li> <li>• <a href="#">422587007</a> Nausea</li> <li>• <a href="#">422400008</a> Vomiting</li> <li>• <a href="#">62315008</a> Diarrhea</li> </ul>
	(if YES)	Patient	✓	✓	✓			If Yes, SNOMED-CT Value: <ul style="list-style-type: none"> <li>• <a href="#">309904001</a> Intensive care unit (environment)</li> </ul>
26	<b>AOE:</b> Resident in congregate	Patient	✓	✓	✓	YES NO UNK - Unknown		LOINC: <a href="#">95421-4</a>  Value Set:

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	care/living setting							<ul style="list-style-type: none"> <li>• YES</li> <li>• NO</li> <li>• UNK - Unknown</li> </ul>
	(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: <a href="#">75617-1</a> Residence Type</p> <p>SNOMED-CT Values:</p> <ul style="list-style-type: none"> <li>• <a href="#">22232009</a> Hospital</li> <li>• <a href="#">2081004</a> Hospital ship</li> <li>• <a href="#">32074000</a> Long term care hospital</li> <li>• <a href="#">224929004</a> Secure hospital</li> <li>• <a href="#">42665001</a> Nursing home</li> <li>• <a href="#">30629002</a> Retirement home</li> <li>• <a href="#">74056004</a> Orphanage</li> <li>• <a href="#">722173008</a> Prison-based care site</li> <li>• <a href="#">20078004</a> Substance abuse treatment center</li> <li>• <a href="#">257573002</a> Boarding house</li> <li>• <a href="#">224683003</a> Military accommodation</li> <li>• <a href="#">284546000</a> Hospice</li> <li>• <a href="#">257628001</a> Hostel</li> <li>• <a href="#">310207003</a> Sheltered housing</li> <li>• <a href="#">257656006</a> Penal institution</li> <li>• <a href="#">285113009</a> Religious institutional residence</li> <li>• <a href="#">285141008</a> Work (environment)</li> </ul>
27	AOE: Pregnant	Patient	✓	✓	✓	Pregnant/ Not Pregnant/ Unknown		<p>LOINC: <a href="#">82810-3</a></p> <p>SNOMED-CT Pregnancy Status:</p> <ul style="list-style-type: none"> <li>• <a href="#">77386006</a> Pregnant</li> <li>• <a href="#">60001007</a> Not Pregnant</li> <li>• <a href="#">261665006</a> Unknown</li> <li>• <a href="#">276727009</a> Null</li> </ul>