



# Lucira Health, Inc.

## Healthcare Provider Guide to COVID-19 Data Reporting for Non-Lab-Based Testing

### Public Health Reporting

All prescribing healthcare providers will report Lucira COVID-19 All-In-One Test Kit results to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the [Laboratory In Vitro Diagnostics \(LIVD\) Test Code Mapping for SARS-CoV-2 Tests](#) provided by the Centers for Disease Control (CDC).

**The LOINC Code for the Lucira COVID-19 All-In-One Test Kit is 95409-9**

#### How to report Lucira COVID-19 All-In-Test Kit results from your patients:

- Please ask patients to report their Lucira COVID-19 test results to their prescribing physician. For healthcare networks that have secure MyHealth eportals, Lucira has provided a photo guide on the bottom panel of its outer packaging to facilitate healthcare provider reporting. Patients can take a picture of their test results alongside their test's unique test kit number and upload it to their secure My Health eportal.
- Lucira is also developing an online HIPPA compliant test verification and reporting system that will be available in February 2021. This document will be updated with the reporting url as soon as this service becomes available.
- Please use the below guide for 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)	✓	✓	✓	<b>Use LOINC code 95409-9 for the Lucira COVID-19 All-In-One Test Kit</b>		Lucira LOINC code: 95409-9
2	Test result (performed)  Test result (values)	Device (Auto)	✓	✓	✓	Must use <a href="#">harmonized LOINC codes</a> , when available  Qualitative tests: Must use <a href="#">harmonized SNOMED-CT</a> value set codes		<b>Lucira LOINC code: 95409-9 SARS-CoV-2 (COVID-19)</b>  Select one SNOMED-CT Qualitative Values: <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: 20201116
4	Test report date	Device (Auto)	✓	✓	✓	YYYY[MM[DD]] – numeric	Date the test result was reported to the state public health authority*	Example: 20201116 <i>*Note: this data element definition differs from the lab-based test report date.</i>
5	Device Identifier	Device (Auto)	✓	✓	✓	<b>Lucira's Device Identifier: 00810055970001</b>		<b>Lucira's DI: 00810055970001</b>

6	Patient age	Patient	✓	✓	✓	<p>Patient age units-numeric:</p> <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> <p>LOINC: <a href="#">35659-2</a> Age at specimen collection</p>	Patient age at the time of specimen collection	May calculate from DOB, if known
7	Patient date of birth	Patient		✓	✓	<p>YYYY[MM[DD]] – numeric</p> <p>LOINC: <a href="#">21112-8</a> Birth date</p>		Examples: 19460616
8	Patient race	Patient	✓	✓	✓	<p>Use <a href="#">OMB race codes</a> value set, which is consistent with <a href="#">Census 2020</a></p> <p><a href="#">LOINC: 32624-9 Race</a></p>	Identified by patient	<p>OMB Values:</p> <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	✓	✓	✓	<p>Use <a href="#">OMB ethnicity codes</a> value set, which is consistent with <a href="#">Census 2020</a></p>	Identified by patient	<p>OMB Values:</p> <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>
10	Patient sex	Patient	✓	✓	✓	<p>Male Female Other</p> <p>LOINC: <a href="#">72143-1</a> Sex</p>	Biological sex at birth (XY, XX, other)	<p>SNOMED-CT Values:</p> <ul style="list-style-type: none"> <li>• M (Male)</li> <li>• F (Female)</li> <li>• O (Other)</li> </ul>
11	Patient residence zip code	Patient	✓	✓	✓	<p>5-digit or 9digit numeric notation (with dash) ##### #####</p> <p>LOINC: <a href="#">45401-7</a> Postal code [Location]</p>		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 autopopulated from zip code	Example: Dallas County
13	Ordering provider name; NPI	Patient/ Auto	✓	✓	✓	Name– Alpha  NPI – Numeric, 10digit #####	Current ordering provider name, and/or  NPI from <a href="#">NPPES NPI Registry</a>	Example Name: Last, First  Example NPI: 1234567899  Not applicable for non-prescription tests
14	Ordering provider zip code	Patient/ Auto	✓	✓	✓	5-digit or 9 - digit numeric notation (with dash) ##### #####		Example: 20993  Not applicable for non-prescription tests
15	Specimen source	Patient/ Device	✓	✓	✓	Must use appropriate harmonized <a href="#">specimen codes</a> (in <a href="#">LIVD file</a> , e.g., <a href="#">SNOMED-CT codes</a> ), when available		SNOMED-CT Values: <ul style="list-style-type: none"> <li>• <a href="#">871810001</a> Mid-turbinate nasal swab</li> <li>• <a href="#">697989009</a> Anterior nares swab</li> <li>• <a href="#">42993100012410</a> Nasal aspirate</li> <li>• <a href="#">258529004</a> Throat swab</li> <li>• <a href="#">119334006</a> Sputum specimen</li> </ul>
						See LIVD file 'LOINC Mapping' Tab, column D: 'Vendor Specimen Description'		<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  Not applicable for nonprescription tests
22	Ordering provider phone number	Patient/Auto		✓	✓	10-digit numeric (###)#####		Example: (123) 456-7890  Not applicable for non-prescription tests
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: • 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: • Molecular (LOINC : <a href="#">94309-2</a> ) • Detected( <a href="#">260373001</a> ) • Not Detected ( <a href="#">260415000</a> ) • UNK - Unknown ( <a href="#">261665006</a> ) • Antigen (LOINC : <a href="#">94558-4</a> ) • Detected( <a href="#">260373001</a> ) • Not Detected ( <a href="#">260415000</a> ) • UNK - Unknown ( <a href="#">261665006</a> ) • Antibody (LOINC : <a href="#">94762-2</a> ) • Detected( <a href="#">260373001</a> ) • Not Detected ( <a href="#">260415000</a> ) • UNK - Unknown ( <a href="#">261665006</a> ) • <a href="#">261665006</a> Unknown • <a href="#">276727009</a> Null (Prior test type unknown)

24	<b>AOE:</b> 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>
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="#">426000000</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>
<b>26</b>	<b>AOE:</b> Resident in congregate care/living setting	Patient	✓	✓	✓	YES NO UNK – Unknown		LOINC: <a href="#">95421-4</a>  Value Set: <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	If yes: LOINC: <a href="#">75617-1</a> Residence Type  SNOMED-CT Values: <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>
<b>27</b>	<b>AOE:</b> Pregnant	Patient	✓	✓	✓	Pregnant/ Not Pregnant/ Unknown		LOINC: <a href="#">82810-3</a>  SNOMED-CT Pregnancy Status: <ul style="list-style-type: none"> <li>• <a href="#">77386006</a> Pregnant</li> <li>• <a href="#">60001007</a> Not Pregnant</li> </ul>