



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 96986-5

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 May 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)	✓	✓	✓	Use LOINC code 96986-5 for the Lucira COVID-19 All-In-One Test Kit		Lucira LOINC code: 96986-5
2	Test result (performed) Test result (values)	Device (Auto)	✓	✓	✓	Must use harmonized LOINC codes , when available Qualitative tests: Must use harmonized SNOMED-CT value set codes		Lucira LOINC code: 96986-5 SARS-CoV-2 (COVID-19) Select one SNOMED-CT Qualitative Values: <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: 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)	✓	✓	✓	Lucira's Device Identifier: 00810055970001		Lucira's DI: 00810055970001

6	Patient age	Patient	✓	✓	✓	<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>LOINC: 35659-2 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: 21112-8 Birth date</p>		Examples: 19460616
8	Patient race	Patient	✓	✓	✓	<p>Use OMB race codes value set, which is consistent with Census 2020</p> <p>LOINC: 32624-9 Race</p>	Identified by patient	<p>OMB Values:</p> <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	✓	✓	✓	<p>Use OMB ethnicity codes value set, which is consistent with Census2020</p>	Identified by patient	<p>OMB Values:</p> <ul style="list-style-type: none"> • 2135-2 Hispanic or Latino • 2186-5 Non Hispanic or Latino • UNK Unknown
10	Patient sex	Patient	✓	✓	✓	<p>Male Female Other</p> <p>LOINC: 72143-1 Sex</p>	Biological sex at birth (XY, XX, other)	<p>SNOMED-CT Values:</p> <ul style="list-style-type: none"> • M (Male) • F (Female) • O (Other)
11	Patient residence zip code	Patient	✓	✓	✓	<p>5-digit or 9digit numeric notation (with dash) ##### #####</p> <p>LOINC: 45401-7 Postal code [Location]</p>		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 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 NPPES NPI Registry	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 specimen codes (in LIVD file , e.g., SNOMED-CT codes), when available		SNOMED-CT Values: <ul style="list-style-type: none"> • 871810001 Mid-turbinate nasal swab • 697989009 Anterior nares swab • 42993100012410 Nasal aspirate • 258529004 Throat swab • 119334006 Sputum specimen
						See LIVD file 'LOINC Mapping' Tab, column D: 'Vendor Specimen Description'		<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 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: 95417-2 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 : 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) • UNK - Unknown (261665006) • 261665006 Unknown • 276727009 Null (Prior test type unknown)

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
25	AOE: Symptomatic per CDC	Patient	✓	✓	✓	YES NO UNK - Unknown	Per CDC list of symptoms	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"> • 426000000 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 care/living setting	Patient	✓	✓	✓	YES NO UNK – Unknown		LOINC: 95421-4 Value Set: <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	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 • 285113009 Religious institutional residence • 285141008 Work (environment)
27	AOE: Pregnant	Patient	✓	✓	✓	Pregnant/ Not Pregnant/ Unknown		LOINC: 82810-3 SNOMED-CT Pregnancy Status: <ul style="list-style-type: none"> • 77386006 Pregnant • 60001007 Not Pregnant