LUCIRA™

Lucira Health, Inc.

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

Public Health Reporting

All prescribing healthcare providers must report all test results they receive from individuals who use your product 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 (available at: https://www.cdc.gov/csels/dls/sars-cov-2- livd-codes.html). Healthcare providers will also report to Lucira Health, Inc., when requested by Lucira, how many individuals reported test results compared to how many tests they prescribed.

Test Name	LOINC Code (Test Ordered)	LOINC Code (Test Performed)
Lucira COVID-19 All-In-One Test Kit	96986-5	96986-5
Lucira CHECK-IT COVID-19 Test Kit	96986-5	96986-5
Lucira COVID-19 & Flu Test		
SARS-CoV-2 (COVID-19)	100972-9	95608-6
Influenza A	100972-9	100973-7
Influenza B	100972-9	100974-5

How to report Lucira COVID-19 test results from your patients:

- Please ask patients to report their 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.
- Please use the below guide for COVID-19 Data Reporting for Non-Lab Based Testing

Note on reporting results with multiple gene targets (ex. SARS-CoV-2 and Influenza):

- The Lucira COVID-19 & Flu Test includes the detection of multiple gene targets (for SARS-CoV-2, Influenza A and Influenza B) with reporting of individual results. For this assay, the gene-specific code should be used for the order and the result.

#	Data Element	Source	Reporting			Technical Specifications	Notes	Example
			Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record			
1	Test ordered	Device (Auto)	✓	✓	✓	The Test Ordered LOINC Order should identify the test that is being requested, not the *in vitro* diagnostic (IVD) device used to process the test. LOINC panel codes are used when there are multiple targets and the results for each target could potentially be reported indivdually For tests with a single target (analyte) the Test Order code is most likely the same as the Test Performed code		Lucira COVID-19 All-In-One Test Kit LOINC code is **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 COVID-19 All-In-One Test Kit LOINC code is **96986-5** Select one SNOMED-CT Qualitative Values: • **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 *Note: this data element definition

#	Data Element	Source	Reporting			Technical Specifications	Notes	Example
			Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record			
								differs from the lab-based test report date.
5	Device Identifier	Device (Auto)	✓	✓	✓	Lucira test kit Device Identifier (DI)		For the Lucira Health test kits, the DI number may be found on the kit box label, beneath the 3D barcode and preceded by (01). See example below (DI highlighted yellow):
6	Patient age	Patient	✓	✓	✓	Patient age units – numeric: • 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		Examples: 19460616

#	Data Element	Source	Reporting Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
						LOINC: 21112-8 Birth date		
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: • 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 Census2020	Identified by patient	OMB Values: • 2135-2 Hispanic or Latino • 2186-5 Non-Hispanic or Latino • UNK 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	Patient count name can be auto populated from zip code	Example: Dallas County

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

#	Data Element	Source	Reporting Federal / CDC / HHS	Reporting State / Local PHD	Reporting Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
						of residence [Location]		
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 See LIVD file 'LOINC Mapping' Tab, column D: 'Vendor Specimen Description'		SNOMED-CT Values: • **871810001**Mid-turbinate nasal swab • **697989009**Anterior nares swab • **445297001** Nasal swab • **258529004** Throat (oropharyngeal) swab • **119334006** Sputum specimen • **119342007** Saliva specimen • **258607008** Bronchoalveolar lavage fluid (BAL) • **119335007** Expectorated sputum • **445447003** Endotracheal aspirates • **258500001** Nasopharyngeal swab
16	Patient name	Patient		✓	✓	LOINC: **45392-8** Patient First Name LOINC: **52461-1** Patient Middle Name		Example: Last, First Middle

#	Data Element	Source	Reporting Federal / CDC / HHS	Reporting State / Local PHD	Reporting Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
						LOINC: **45394-4** Patient Last Name		
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 non-prescription 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

#	Data Element	Source	Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
				Reporting				
	(if NO)	Patient	✓	✓	✓	Molecular Antigen Antibody/Serology Unknown	What type of test was the most recent prior test, and what was the result?	• NO • UNK – Unknown 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 *with direct patient contact*?	LOINC: **95418-0**
	(if YES)	Patient	✓	✓	✓			If yes: SNOMED-CT Values: • **223366009** Healthcare Professional • More Detailed Healthcare

#	Data Element	Source	Reporting			Technical Specifications	Notes	Example
			Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record			
								Professional List
25	**AOE**: Symptomatic per CDC list of symptoms	Patient	✓	✓	✓	YES NO UNK - Unknown	Per CDC list of symptoms	LOINC: **95419-8** Value Set: • 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: • **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

#	Data Element	Source	Reporting Federal / CDC / HHS	State / Local PHD	Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
	(if YES)	Patient	✓	✓	✓			• **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, SNOMED-CT Value: • **309904001** Intensive care unit (environment)
26	AOE: Resident in congregate care/living setting	Patient	✓	✓	✓		YES NO UNK – Unknown	LOINC: **95421-4** Value Set: • **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: • **22232009** Hospital • **2081004** Hospital ship • **32074000** Long term care hospital • **224929004** Secure hospital • **42665001** Nursing home • **30629002** Retirement home

#	Data Element	Source	Reporting Federal / CDC / HHS	Reporting State / Local PHD	Reporting Provider / EHR / Personal Health Record	Technical Specifications	Notes	Example
								• **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: • **77386006** Pregnant • **60001007** Not Pregnant