Virginia Department of Health

COVID-19 Flat File Specifications
with new HHS data reporting requirements

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Data Element Specifications

The tables below outline the data elements requested for COVID-19 electronic lab report submission via flat file. It now contains the new laboratory data reporting elements that allows labs to comply with HHS guidance for COVID-19 testing. If you have the capability of adapting to LOINC and SNOMED CT, where requested, we strongly encourage it.

Field	Data Element	Length	Use	Definition
1	Sending Facility Name	100	R	Name of Reporting Lab
2	Sending Facility CLIA	40	R	CLIA of Reporting Lab
3	Message Control ID	55	RE	A unique identifier for each record. This can be alphanumeric
4	PatientID	15	R	VDH prefers that the first patient ID provided always be a laboratory assigned patient identifier or a patient medical record number. The identifier provided should allow the reporting or ordering facility to retrieve information on the patient when requested by public health.
5	SSN	9	RE	**Please leave blank.**
6	Last Name	50	R	Patient's last name
7	First Name	50	R	Patient's first name
8	Middle Initial	50	RE	Patient's middle name
9	Street Address	50	RE	Patient's address line 1
10	Street Address 2	50	RE	Patient's address line 2
11	City	50	RE	The city from the patient's address
12	County FIPS Code	5	RE	Submit the FIPS code for the county where the patient resides, if the information is available. If address is in an independent city in Virginia, submit the city FIPS code. Use the two digit VA state code ("51") followed by the three digit county/city-specific code.
13	State	2	RE	The state from the patient's address. Use the U.S. Postal Service 2-character state abbreviation (e.g., VA).
14	Zip	5	RE	The zip code from the patient's address. Use a valid 5-digit zip code.
15	Patient Phone	10	RE	Patient's phone number. Expected format is XXXXXXXXXX
16	Race	45	RE	Patient's race. Acceptable values are "American Indian or Alaska Native", "Asian", "Black or African American", "Native Hawaiian or Other Pacific Islander", "White", "Other Race", "Unknown" or "Refused to Answer".
17	Ethnic Group	25	RE	Patient's ethnicity. Acceptable values are "Hispanic or Latino", "Not Hispanic or Latino", or "Unknown".
18	DOB	8	RE	Patient's date of birth. Expected format is yyyymmdd

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Field	Data Element	Length	Use	Definition
19	Sex	15	RE	Patient's current gender text description see example column for text. Acceptable values are "Ambiguous", "Female", "Male", "Not Applicable", "Other", or "Unknown".
20	Message Date Time	14	R	The date time stamp when the record is created to send to VDH. Expected format is yyyymmddHHMMSS.
21	Specimen ID	50	R	A unique identifier for the specimen. Generally, the accession number is the specimen ID.
22	Specimen Type Description	199	R	Expecting the standardized text description. Please use SNOMED CT (specimen codes) or equivalently detailed alternative codes to populate in their respective fields. The "Vendor Specimen Description" column in the Mapping tool: LIVD SARS-CoV-2 Test Codes.xlsx contains specimen type examples. Example from "Vendor Specimen Description" column for nasopharyngeal swab is: 258500001^Nasopharyngeal swab^SCT "258500001" is the Specimen Type Identifier (See field 67) “Nasopharyngeal swab” is the Specimen Type Description "SCT" is the Specimen Type Naming System (See field 68)
23	Specimen Source Site Text	250	RE	Additional specimen information if available, (e.g. Right antecubital, etc.)
24	Result Unit ID	20	RE	Expecting the units of measure for quantitative results.
25	Provider ID	50	RE	Expecting NPI (National Provider Identifier) assigned to the physician ordering the test, but internal identifier may be provided if NPI unavailable
26	Provider Last Name	50	RE	Ordering provider Last Name
27	Provider First Name	50	RE	Ordering provider First Name
28	Ordering Provider Addr 1	50	RE	The ordering provider’s street address line 1
29	Ordering Provider Addr 2	50	RE	The ordering provider’s street address line 2
30	Ordering Provider City	50	RE	The city in which the ordering provider is located.
31	Ordering Provider State	2	RE	The state in which the ordering provider is located. Use the U.S. Postal Service 2-character state abbreviation (e.g., VA).
32	Ordering Provider Zip	5	RE	The zip code of the ordering provider’s address. Use a valid 5-digit zip code.

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Field	Data Element	Length	Use	Definition
33	Ordering Provider County FIPS code	5	RE	Submit the FIPS code for the ordering provider address. If address is in an independent city in Virginia, submit the city FIPS code. Use the two digit VA state code (“51”) followed by the three digit county/city-specific code.
34	Ordering Provider Phone	10	RE	The ordering provider phone number. Expected format is XXXXXXXXXX
35	Ordering Facility Name	60	R	This field identifies the name of the facility where the provider originally placed the order. The ordering facility is defined as the facility in which the patient was examined and the order was initiated.
36	Ordering Facility Address 1	50	R	Ordering facility street address line 1
37	Ordering Facility Address 2	50	RE	Ordering facility street address line 2
38	Ordering Facility City	50	R	The city in which the ordering facility is located.
39	Ordering Facility State	2	R	The state in which the ordering facility is located. Use the U.S. Postal Service 2-character state abbreviation (e.g., VA).
40	Ordering Facility Zip	5	R	The zip code of the ordering facility’s address. Use a valid 5-digit zip code.
41	Ordering Facility County FIPS Code	5	RE	Submit the FIPS code for the county of the ordering facility address, if the information is available. If address is in an independent city in Virginia, submit the city FIPS code. Use the two digit VA state code (“51”) followed by the three digit county/city-specific code.
42	Ordering Facility Phone	10	R	The ordering facility phone number. Expected format is XXXXXXXXXX
43	Observation Date Time	19	R	For specimen-based observations, the start date/time of specimen collection. Expected format is yyyymmddHHMMSS-0000
44	Result Status	1	R	This field contains the coded status of the results for the order. Expecting literal value of "C" for corrected results, "F" for final results, or "P" for preliminary results.
45	Specimen Received Date	19	R	Identifies the date and time when the specimen was received at the diagnostic service. Expected format is yyyymmddHHMMSS-0000

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Field	Data Element	Length	Use	Definition
46	Order Code	20	R	Expecting a LOINC code for the test ordered. Use the appropriate LOINC code as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC Example: For the Abbott ID Now test, the suggested LOINC code is "94534-5" and LOINC long name is "SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection". • "94534-5" is the Order Code • "SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection" is the Order Code Text Description (See field 47) • "LN" is the Order Code Naming system (See field 48) If a LOINC code is not available, a Local (your internal) code may be used.
47	Order Code Text Description	199	R	Description of the test ordered that is associated with the order code. Expecting the standardized text description associated with field 46.
48	Order Code Naming system	2	R	Expecting literal value of "LN" or "Local". "LN" refers to LOINC coding system
49	Result Value Type	2	R	This field identifies the data type used in the "Observation Value" fields. Expecting literal value of "CE" for (Coded Exception), "ST" for string, "NM" for numeric, or "SN" for structured numeric. Use literal value of "CE" if adopting SNOMED CT.
50	Result Test code	20	R	LOINC code for the test performed (may be the same as Ordered Test Code). Use the appropriate LOINC code as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC Example: For the Abbott ID Now test, the suggested LOINC code is "94534-5" and LOINC long name is "SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection". • "94534-5" is the Result Test Code • "SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection" is the Result Test Text Description (See field 51) • "LN" is the Result Test Naming System (See field 52) If a LOINC code is not available, a Local (your internal) code may be used.

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Field	Data Element	Length	Use	Definition
51	Result Test Text Description	199	R	Description of the result test that is associated with the Result Test code. Expecting the standardized text description associated with the LOINC code from the Result Test Code field as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC. If a Local code is used as the Result Test code, the Local code description is expected.
52	Result Test Naming system	2	R	Expecting literal value of "LN" or “Local”. "LN" refers to LOINC coding system
53	Observation Value	20	R	If Result Value Type is 'CE', expecting a SNOMED CT for the observation value. Please refer to the ‘Vendor Result Description’ column for examples. Use SNOMED CT codes as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC. Example from "Vendor Result Description" column for Positive is: 10828004^Positive^SCT "10828004" is the Observation Value • "10828004" is the Observation Value • "Positive" is the Observation Value/Result Text (See field 54) • "SCT" is the Observation Value/Result Naming system (See field 55) If a SNOMED CT code is not available, a Local (your internal) code may be used.
54	Observation Value/Result Text	199	R	Text description associated with the Observation Value. Expecting the standardized text description associated with the SNOMED CT from the Observation Value field.
55	Observation Value/ Result Naming system	3	R	Expecting literal value of "SCT" or “Local”. "SCT" refers to the SNOMED CT coding system. Please populate field only when the Result Value Type is 'CE'
56	Test Result Status	1	R	This field contains the coded status of the result for the observation. Expecting literal value of "C" for corrected results, "F" for final results, or "P" for preliminary results.
57	Performing Lab ID/ Producer ID	40	RE	The performing laboratory identifier. The CLIA number is expected.
58	Performing Lab ID/Producer Text	50	R	The name of the laboratory that produced the test result. Please discuss format of name and any abbreviations with VDH.
59	Performing Lab ID/ Producer Naming System	4	RE	“CLIA” is expected.
60	Date Reported	19	R	Date test was resulted. Expected format is yyyymmddHHMMSS-0000
61	Performing Lab Street Address line 1	50	R	Performing lab street address line 1
62	Performing Lab Street Address line 2	50	RE	Performing lab street address line 2

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Field	Data Element	Length	Use	Definition
63	Performing Lab City	50	R	The city in which the performing lab is located.
64	Performing Lab State	2	R	The state in which the performing lab is located. Use the U.S. Postal Service 2-character state abbreviation (e.g., VA).
65	Performing Lab Zip	5	R	The zip code of the performing lab's address. Use a valid 5-digit zip code.
66	Performing Lab County FIPS Code	5	RE	Submit the FIPS code for the county of the performing lab address, if the information is available. If address is in an independent city in Virginia, submit the city FIPS code. Use the two digit VA state code ("51") followed by the three digit county/city-specific code.
67	Specimen Type Identifier	20	RE	Expecting a unique identifier code for the specimen. Please use SNOMED SCT (specimen codes) or equivalently detailed alternative codes. The "Vendor Specimen Description" column in the LIVD Mapping tool located here: contains specimen type examples with appropriate identifier and description
68	Specimen Type Naming System	5	R	Identifies the type code used for Specimen Type Identifier. Expecting literal value of "SCT" or "Local". "SCT" refers to the SNOMED CT coding system.
69	Date test ordered	19	RE	Date test was ordered. Expected format is yyyymmddHHMMSS-0000
70	EUA based test kit identification	100	RE	**Emergency Use Authorization (EUA) Identifier** Defines the particular combination of testkit/reagent(s) and instrument platform(s) used that is authorized by an EUA as listed on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular. Take the exact literal value from "Diagnostic (Letter of Authorization)" with the exception of (TM) or (R) and the literal value from "Manufacturer" with the exception of (TM) or (R). A similar identifier can be created for Lab Developed Tests (LDT) based on Appendix A table by combining "Letter Granting Inclusion under EUA" and "Laboratory". Populate the value by concatenating using '_' as follows: <value from "Diagnostic (Letter of Authorization)">_<value from "Manufacturer">_EUA <value from "Letter Granting Inclusion under EUA">_<value from "Laboratory">_EUA It may also be included in "Testkit Name Identifier" column on the "LOINC Mapping" tab of the CDC LIVD file located here . You can filter by manufacturer and model for guidance and populate the value by concatenating <value from "Testkit Name ID">_<value from "TestKit Name ID Type"> **HHS Element: Device Identifier**

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Field	Data Element	Length	Use	Definition
71	Model name based test kit identification	100	RE	This should be used when no EUA identifier is available, or when there is a desire to explicitly list the test kit. Populate this field by concatenating using '_' as follows: <test kit name used in package insert (or "Testkit Name Identifier" in LIVD file)>_<"Manufacturer" in LIVD file>_MNT Unless this is for a manual kit, there is an expectation that the instrument used will also be identified, by either model name, device identifier or UDI. For a manual kit populate this field by concatenating using '_' as follows: <Manual kit name (or "Testkit Name Identifier" in LIVD file)>_<Manufacturer>_MNM Link to the CDC LIVD file: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html **HHS Element: Device Identifier**
72	Device identifier based test kit identification	100	RE	This information will be provided in the LIVD file by the manufacturer; it is intended to be the device identifier per the definition of the Unique Device Identifier (UDI) FDA publication and represents the kind of test kit. For more on UDI see: http://www.hl7.org/documentcenter/private/standards/HL7_IG_UDI_R2_2020JUN.pdf Populate this field by concatenating using '_' as follows: < "Equipment UID" in LIVD file>_<Manufacturer>_DIT Link to the CDC LIVD file: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html **HHS Element: Device Identifier**

Use codes: R- Required to be sent; RE- Required to be sent but can be empty if information is not available; O- Optional; C- Conditional

Field	Data Element	Length	Use	Definition
73	Model name based instrument identification	100	RE	This should be used when no EUA identifier is available, or when there is a need to explicitly list the instrument that was used with the Test kit. Populate this field by concatenating using '_' as follows: <Instrument name>_<Manufacturer name>_MNI This information may be obtained from the "Open Instruments" tab in the CDC LIVD file: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html **HHS Element: Device Identifier**
74	Device identifier based instrument identification	100	RE	This information will be provided in the LIVD file by the manufacturer; it is intended to be the device identifier per the definition of the Unique Device Identifier (UDI) FDA publication and represents the kind of test kit used to perform the test. For more on UDI see: http://www.hl7.org/documentcenter/private/standards/HL7_IG_UDI_R2_2020JUN.pdf Populate this field by concatenating using '_' as follows: < "Equipment UID" in the LIVD file>_<Manufacturer>_IIT Link to the CDC LIVD file: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html **HHS Element: Device Identifier**
75	Instance based test kit identification	100	RE	Identifies the specific test kit instance used to perform the test by their UDI as defined by FDA - this will be the UDI Carrier (the full representation of the barcode in human readable form) and will likely only be obtained through scanning (i.e. the serial number of the instrument). For more on UDI see: http://www.hl7.org/documentcenter/private/standards/HL7_IG_UDI_R2_2020JUN.pdf UDI assigner as OID: <udi carrier>^^2.16.840.1.113883.3.3719^ISO UDI assigner URI: <udi carrier>^^http://hl7.org/fhir/NamingSystem/fda-udi^URI **HHS Element: Device Identifier**

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Field	Data Element	Length	Use	Definition
76	Instance based instrument identification	100	RE	Identifies the specific instrument instance used to perform the test by their UDI as defined by FDA - this will be the UDI Carrier (the full representation of the barcode in human readable form) and will likely only be obtained through scanning (i.e. the serial number of the instrument) For more on UDI see: http://www.hl7.org/documentcenter/private/standards/HL7_IG_UDI_R2_2020JUN.pdf UDI assigner as OID: <udi carrier>^^2.16.840.1.113883.3.3719^ISO UDI assigner URI: <udi carrier>^^http://hl7.org/fhir/NamingSystem/fda-udi^URI **HHS Element: Device Identifier**
77	Patient's Age Value	10	C	If date of birth is not known, enter numeric value of patient's current age.
78	Patient's Age Units	6	C	If age is provided, enter unit of patient's age. Acceptable values are "Years" and "Months". If patient >2, provide number of years. If patient <2, provide months for patient.
79	First Test	7	O	Is this the patient's first test for the condition of interest that is being ordered? Acceptable values are "Yes", "No" or "Unknown"
80	Employed in healthcare	7	Requested	Is the patient employed in a healthcare setting? Acceptable values are "Yes", "No" or "Unknown"
81	Symptomatic	7	Requested	Does the patient have symptoms related to condition of interest? Symptomatic per current CDC guidance at time of order for the reportable condition/illness. Acceptable values are "Yes", "No" or "Unknown"
82	Date of Symptom Onset	8	Requested	Provide if Symptomatic is "Yes". Identifies the date of symptom onset; Populate only if the patient is symptomatic. Expected format is yyyymmdd
83	Hospitalized	7	Requested	Has patient been hospitalized for the reportable illness/condition that this order has been placed for (suspected or diagnosed)? When ordered during ER duration, the answer would be "No". Acceptable values are "Yes", "No" or "Unknown"
84	ICU	7	Requested	Has patient been admitted/transferred to the ICU at any time during the encounter for the reportable illness/condition that the order has been placed for (suspected or diagnosed)? Acceptable values are "Yes", "No" or "Unknown"

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Field	Data Element	Length	Use	Definition
85	Congregate care setting	7	Requested	Is the patient a resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting)? This is at time of exposure where they normally live. Acceptable values are "Yes", "No" or "Unknown"
86	Pregnant	17	Requested, C	If the patient is female, what is their current pregnancy status? Acceptable values are "Pregnant", "Not Pregnant" or "Unknown"

Flat File Specifications

1. Must be a pipe delimited flat file
2. Must be in the exact order requested above. If the information does not exist for a particular field, do not skip field. Please leave it blank.
3. Please do not include the file header in your flat file.

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