Oregon Public Health Division
Electronic Laboratory Reporting
Local Implementation Guide
Alternative Format

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Version 1.9

Oregon Electronic Laboratory Reporting

Contents

Electronic Laboratory Reporting in Oregon

Thank you for your interest in electronic data exchange with the Oregon Electronic Laboratory Reporting (ELR) project. **In Oregon, licensed laboratories are required to report all test results indicative of and specific for the diseases, infections, microorganisms, and conditions specified by statute for Oregon residents**. Getting timely and accurate information on reportable conditions is critical for Public Health disease surveillance and improving population health. Oregon ELR encourages the least burdensome method for laboratories to submit data, and mandates ELR for laboratories sending an average of more than 30 records per month to the Oregon Public Health Division (OPHD).

Laboratories that are performing **COVID-19 Genetic Sequencing** from a human specimen must report the results to the Oregon Health Authority in accordance with the Electronic Laboratory Reporting Manual's direction: **(6) Any laboratory that performs genetic sequencing of SARS-CoV-2 from a human specimen shall, within 24 hours of completion of the genetic sequence analysis, report to OHA electronically in accordance with the Authority's Electronic Laboratory Reporting (ELR) Manual, the following:**

(a) Required elements in the electronic reports;

(b) The identity of any SARS-CoV-2 sequence designated by the federal Centers for Disease Control and Prevention as a Variant of Concern or a Variant of High Consequence; and

(c) The GISAID Accession ID, if known.

Participating in ELR allows incoming laboratory data to be translated, processed, and routed to appropriate public health recipients (Local Health Departments and State Programs) for swift public health action. Standardized HL7 messaging is the preferred format for ELR in Oregon, and to meet Federal Meaningful Use requirements, HL7 version 2.5.1 is the only acceptable message format for ELR. Even though HL7 is the preferred method of data submission, we understand that not every facility has the capability to submit data structured in this way. Therefore, we are providing an alternate method for data submission for certain facilities.

For details on which conditions are reportable, please review Oregon Administrative Rules (OARs), Divisions 18 (Disease Reporting) and 26 (Enforcement of Public Health Rules).

Scope of This Document

The purpose of this document is to provide guidance on *how to construct and send laboratory data in a standardized message format*. Unfortunately, messages that do not conform to the specification outlined below will not be approved for electronic submission.

This guide is designed for use by analysts and developers who are unable to send HL7 messages but would like to switch to an electronic data exchange method in lieu of faxing reportable conditions. Sending data in the method outlined in this document is not appropriate for large volume laboratories and is not acceptable to meet federal Promoting Interoperability (formerly, Meaningful Use) requirements. Further, information on message transport is not included in this document. Currently, Oregon ELR accepts messages via secure file transfer protocol (SFTP) only.

File Format – Comma Separated Values (CSV)

Message standardization is essential because it allows for a wide variety of submitters to participate in electronic laboratory reporting, ensuring timely, accurate, and complete data are received and processed by the Public Health Division. The table below describes the data elements expected for sending laboratory reports as a comma separated (CSV). The first column in the table (seq) refers to the sequence of the field order, the second (use) describes whether the field is required (R), conditional and may be empty (CE) or optional (O); we strongly encourage reporters to provide optional elements as many of them allow us to better describe the population being served and target interventions appropriately. The third column (name) describes the name of the field, and the last column (guidance) provides instructions for how to populate that field.

Your CSV file must abide by the following formatting conditions:

- Every column must be represented in the order listed below, regardless of whether it is populated with data. Maintain header row to assure all columns are included.
- No column shall exceed 255 characters in length, and none shall have extraneous commas or carriage returns.
- Dates must be formatted as YYYYMMDD.
- Files will be named as follows: YYYYMMDD_SiteName

If you are unable to meet any of these requirements, please notify the ELR Coordinator prior to submitting a test file.

Ordered Data Elements Required in Message Construction

Seq	Use	Name	Guidance
1	O	Sending Application	Name of the application used to generate the record. If not provided in the file, this must be provided to the ELR Coordinator prior to testing.
2	**R**	Facility Name	Name of the sending facility. If not provided in the file, this must be provided to the ELR Coordinator prior to testing.
3	**R**	Facility ID	CLIA number for the sending facility is preferred. If the facility is not CLIA certified, a unique ID will be assigned OHA.
4	**R**	Facility Street Address	Number, direction, and street name. If not provided in the file, this must be provided to the ELR Coordinator prior to testing. (Reminder: no commas or carriage returns)

Ordered Data Elements Required in Message Construction

Seq	Use	Name	Guidance
5	**R**	Facility City	If not provided in the file, this must be provided to the ELR Coordinator prior to testing.
6	**R**	Facility State	If not provided in the file, this must be provided to the ELR Coordinator prior to testing.
7	**R**	Facility Zip	If not provided in the file, this must be provided to the ELR Coordinator prior to testing. Five digits
8	**R**	Facility Phone	If not provided in the file, this must be provided to the ELR Coordinator prior to testing. Ten digits (###-###-####)
9	**R**	Date of Message	Date of message creation formatted as YYYYMMDD
10	**R**	Patient Identifier	Patient identifiers may include medical record number, social security, account number, etc.
11	**R**	Patient First Name	
12	**R**	Patient Last Name	
13	**R**	Patient Date of Birth	Formatted as YYYYMMDD
14	**R**	Patient Sex	Female (**F**), Male (**M**), Other (**O**), or Unknown (**U**)
15	O	Race	American Indian/Alaska Native (**AI**), Asian (**A**), Black (**B**), Hawaiian/Pacific Islander (**PI**), White (**W**), Other (**O**), or Unknown (**U**)
16	O	Ethnicity	Hispanic (**H**), not-Hispanic (**N**), or Unknown (**U**)
17	O	Language	Preferred language
18	**R**	Patient Street Address	Include house number, direction, and street name of residence (Reminder: no commas or carriage returns)
19	**R**	Patient City	
20	**R**	Patient State	*Only Oregon residents should be included in this file
21	**R**	Patient Zip	Five digits
22	**R**	Patient County	
23	O	Patient Phone Number	Ten digits (###-###-####)
24	O	OK to Contact Patient	Yes (**Y**) or No (**N**)

Ordered Data Elements Required in Message Construction

Seq	Use	Name	Guidance
25	O	Insurance	Name of insurer
26	O	Expedited Partner Therapy Received	Did the patient receive EPT? Yes (**Y**) or No (**N**)
27	**R**	Provider First Name	
28	**R**	Provider Last Name	
29	**R**	Provider Phone Number	Ten digits (###-###-####)
30	**R**	Specimen ID	Unique identifier for the specimen
31	**R**	Collection Date	Specimen collection date formatted as YYYYMMDD
32	**R**	Specimen Type	E.g., blood, tissue, body fluid
33	O	Specimen Site	E.g., capillary, lung, knee
34	**R**	Test Name	For SARS-CoV2, please use Local Code provided by ELR Coordinator.
35	**R**	Result	E.g., Positive, Negative, >10 ug/dL, 1:128, Variant of Concern, Variant of Interest
36	O	Notes	E.g., reason for testing (i.e., outbreak location), you can include PANGO Lineage and GIS AID ID in the notes section. **See additional detail below
37	O	First Test	Yes (**Y**), No (**N**), or Unknown (**U**) To determine if this is the individual's first COVID-19 test.
38	O	Employed In Health Care	Yes (**Y**), No (**N**), or Unknown (**U**) Determine if the individual works with patients in a high-risk role (e.g., is a first responder, front-line clinician, nursing home staff, environmental staff, or therapist in direct contact with patients).
39	O	Symptomatic As defined by CDC	Yes (**Y**), No (**N**), or Unknown (**U**) Determine if the individual is symptomatic based on current CDC guidance. Visit the CDC website for current symptom list.
40	**CE**	Symptom Onset	YYYYMMDD Only if the individual is symptomatic to determine the onset of any COVID-19 symptom the individual experienced.

Ordered Data Elements Required in Message Construction

Seq	Use	Name	Guidance
41	O	Hospitalized	Yes (**Y**), No (**N**), or Unknown (**U**)
42	O	ICU	Yes (**Y**), No (**N**), or Unknown (**U**)
43	O	Resident in Congregate Care Setting	Yes (**Y**), No (**N**), or Unknown (**U**) 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.
44	O	Pregnant	Yes (**Y**), No (**N**), or Unknown (**U**)

** "Ask at Order Entry" (AOE) responses are no longer required to be reported, rows 37-44, effective April 4th, 2022. See HHS Ask on Order Entry Requirements page 7 for details.

Guidance for Coronavirus Sequencing Reporting

Please review the website listed below to ensure the appropriate LOINC Codes are being utilized to report COVID-19 Sequencing Data. LOINC COVID SEQUENCING

We would like to receive separate OBX segments for each LOINC Code utilized. For COVID Sequencing we anticipate receiving the following information if available: PANGO Lineage, GIS AID ID, and CT values if available. There are specific LOINC codes for each COVID-19 Sequencing identifier.

PANGO Lineage: PANGO LINEAGE LIST

GIS AID Accession Numbers: GISAID

****If sequencing COVID specimens, please coordinate with the Electronic Laboratory Reporting Coordinator about the details for reporting.**

Guidance for Coronavirus Test Reporting April 2022 for Sites Operating under a CLIA Certificate of Waiver

Effective April 4th, 2022, COVID-19 reporting requirements have been updated to remove the requirement to report negative results for COVID-19 tests authorized for use under a CLIA certificate of waiver. for entities reporting COVID-19 test results. This includes COVID-19 rapid PCR and antigen test.

The updated guidance continues to require laboratories certified under CLIA to perform moderate or high complexity test to report both positive and negative COVID-19 results for nucleic acid amplification tests.

Reporting of negative results, either individual test results or in aggregate, is optional. This includes rapid testing conducted in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through testing sites).

*Please see the image on the next page for details

Table 1. Reporting Requirements by Entity and Type of Testing

	Is Reporting Required Under this Guidance?		Examples
	Positive Results	**Negative & Inconclusive Results**	
NAAT-testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests	**Required**	**Required**	• Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests • See https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html for more information
All other testing (except antibody)	**Required**	**Optional***	• Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites) • Non-NAAT (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests
Antibody testing	**Optional***	**Optional***	• Tests used to determine previous infection with SARS-CoV-2 in any setting

* State, local, territorial, and Tribal jurisdictions may have additional laboratory reporting requirements applicable to testing entities subject to their jurisdiction. Refer to the applicable jurisdiction's reporting requirements.

Concluding Remarks

This document was developed as an Oregon specific non-HL7 Implementation Guide. This guide represents expectations for message construction and submission to Oregon ELR for facilities that are not able to send HL7 messages. **Again, messages that do not conform to this specification will not be approved for electronic submission.** For more information about Oregon ELR statutes, data quality assurance, and current reportable conditions visit https://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ElectronicLabReporting/Pages/index.aspx

For Information about Oregon ELR, visit us on the web at: healthoregon.org/elr or contact us at 971-673-1111.

Version History

Revision History	Issue Date	Summary of Changes
V1	April 15, 2016	First unpublished version.
V1.1	April 14, 2020	Cleaned typos; edited for COVID-19 response.
V1.2	April 28, 2020	Added language re: conformance and approval.
V1.3	May 17,2020	Added language clarifying laboratory reporting requirements; clarified scope of document limited to message construction only (please see the OARs for disease reporting requirements); field sequence 3 (Facility ID) name modified; removed option of sending via PHINMS.
V1.4	June 25, 2020	Corrected minor typos and added links to OARs. Added Appendix A
V1.6	November 25, 2020	Add Aug 2020 addition of fields 37-44 in table. Removed Appendix A
V1.7	August 27, 2021	Ask on Order Entry questions. See fields 37-44 are now “optional” and are no longer required. Added temporary rule for COVID Sequencing. Added resources and links for COVID sequencing, PANGO Lineage, GIS AID ID and reporting.
V1.8	April 15, 2022	Added new HHS/CDC guidance for COVID-19 Reporting, Effective April 4th, 2022. Added file naming requirement.
V1.9	January 4, 2023	Updated rows: Patient Phone Number and Specimen Site from Optional to Required. Clarified language for Ask on Order Entry Questions (no longer required to be submitted).