

MLS Laboratory Update:

APRIL 21, 2023

Purpose of this Message:

To notify CLIA-certified and CLIA-waived entities of updated reporting requirements for SARS-CoV-2 test results under MN state law, effective May 12, 2023.

Action Item:

Review this information and forward to your associated clinics and system partners. Please update your informatics team on changes that may be needed to electronic results reporting.

Background:

Reporting of SARS-CoV-2 laboratory test results to MDH has been required since March 27, 2020, under a federal COVID-19 Public Health Emergency (PHE) Statement of Administration Policy - H.R. 382 H.J. Res. 7 (<https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>). The federal COVID-19 PHE will be ending on May 11th, 2023. The end of the PHE also ends the CARES Act authority for Health and Human Services (HHS) to require test result reporting. On April 20, 2023, the Commissioner of Health (“Commissioner”) issued a Supplemental Notice of Test Result Reporting for SARS-CoV-2 under part 4605.7080 of the Minnesota Communicable Disease Reporting Rule. The Notice establishes the reporting requirements for test results for SARS-CoV-2 under MN state law effective May 12, 2023. Under the Notice, state law will require **reporting of only positive results from tests for SARS-CoV-2**. This Notice covers CLIA-certified laboratories and entities operating under CLIA certificates of waiver. All other reporting requirements in the notice issued in December 2022 remain in effect, including the requirement to submit SARS-CoV-2 clinical materials and sequencing data, if available, and can be reviewed at: Reporting of COVID-19/SARS-CoV-2 under the Minnesota Communicable Disease Rules, Chapter 4605.7080 - MN Dept. of Health (<https://www.health.state.mn.us/diseases/reportable/rule/process/index.html>).

Specific documentation will be posted to MDH COVID-19 Test Reporting Requirements (<https://www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html>) as May 12th approaches.

Additional Information:

A summary of what to report for SARS-CoV-2 starting May 12, 2023 is below:

Test Result Reporting Requirements for SARS-CoV-2 New Under State Law Effective May 12, 2023

CLIA Certificate Type	Test platform	Reporting of SARS-CoV-2 Positive Results	Reporting of SARS-CoV-2 negative and inconclusive results
Certificate of Waiver	Molecular (NAAT)	Required	Do not report
	Antigen	Required	Do not report
	Serology (Antibody)	Do not report	Do not report
All other CLIA certified laboratories*	Molecular (NAAT)	Required	Do not report
	Antigen	Required	Do not report
	Serology (Antibody)	Do not report	Do not report

* As a reminder, if sequencing is performed, laboratories are also required to submit sequencing data to MDH regardless of whether the underlying test was a NAAT or non-NAAT test.

Electronic versions of this alert, the Supplemental Notice and a list of Frequently Asked Questions will be available on the MDH-PHL website at [Laboratory Alerts from the Minnesota Laboratory System - MN Dept. of Health](https://www.health.state.mn.us/diseases/idlab/mls/alerts.html) (<https://www.health.state.mn.us/diseases/idlab/mls/alerts.html>)

Questions:

Laboratories with questions about reporting requirements should contact Anna Strain, Manager, Infectious Disease Laboratory, MDH Public Health Laboratory, phone: 651-201-5200 or email: health.phlidops@state.mn.us

For questions about methods of results submission, including electronic laboratory reporting (ELR), contact Sarah Boneske, Operations, Minnesota Electronic Disease Surveillance System, phone: 651-201-5914 or email: health.ElectronicDiseaseReporting@state.mn.us

THIS IS AN UPDATE FROM THE MINNESOTA DEPARTMENT OF HEALTH – PUBLIC HEALTH LABORATORY (MDH-PHL) AND THE MINNESOTA LABORATORY SYSTEM (MLS). THIS MESSAGE IS BEING SENT TO MLS LABORATORY CONTACTS SERVING MINNESOTA RESIDENTS. YOU ARE NOT REQUIRED TO REPLY TO THIS MESSAGE.

****PLEASE FORWARD THIS TO ALL APPROPRIATE PERSONNEL WITHIN YOUR INSTITUTION AND HEALTH SYSTEM****

THE CONTENT OF THIS MESSAGE IS INTENDED FOR PUBLIC HEALTH AND HEALTH CARE PERSONNEL AND RESPONSE PARTNERS WHO HAVE A NEED TO KNOW THE INFORMATION TO PERFORM THEIR DUTIES. IT IS FOR OFFICIAL USE ONLY. DO NOT DISTRIBUTE BEYOND THE INTENDED RECIPIENT GROUPS AS DESCRIBED IN THIS MESSAGE.

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To obtain this information in a different format, call: 651-201-5200.