

FAQ on the MDH Supplemental Notice for Reporting SARS-CoV-2 Test Results

Background

On April 20, 2023, the Commissioner of Health (“Commissioner”) issued a Supplemental Notice of Test Result Reporting for SARS-CoV-2. The supplemental notice was issued under 4605.7080 of the Minnesota Communicable Disease Reporting Rule. It addresses the state law requirements for reporting test results for SARS-CoV-2.

This supplemental notice updates the Commissioner’s prior December 5, 2022, notice, which addresses reporting requirements for COVID-19 cases, hospitalizations, deaths, and submission of both clinical materials and sequencing data. The updates in the supplemental notice only address test result reporting; all other reporting requirements in the December notice remain in effect 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 \(state.mn.us\)](https://www.state.mn.us/health/cdr/4605.7080.html)

A summary of the updated reporting requirements for test results under state law, effective May 12, 2023, is in the table at the end of this document.

What reporters are covered by the supplemental notice?

The supplemental notice covers two categories of reporters: (1) all CLIA-certified laboratories and (2) entities operating under a CLIA Certificate of Waiver that conduct tests to detect SARS-CoV-2. Some common examples of entities that have performed CLIA Certificate of Waiver testing during the COVID-19 pandemic include long-term care facilities, corrections facilities, and shelters.

What type of reporting is addressed by the supplemental

notice?

The supplemental notice addresses test result reporting requirements for the above-referenced CLIA-certified and CLIA-waived entities.

When do the test result reporting requirements in the supplemental notice take effect?

The effective date is May 12, 2023. Until then, CLIA-certified and CLIA-waived entities must continue to follow federal requirements for test result reporting for SARS-CoV-2.

Will test result reporting requirements change when the supplemental notice takes effect?

Yes. The supplemental notice **only requires reporting of positive results** from tests for SARS-CoV-2. The federal requirements that govern test result reporting through May 11, 2023, require many reporters to report non-positive results.

What other reporting does Minnesota require for SARS-CoV-2/COVID-19 beyond tests results and where can I find these requirements?

The Commissioner of Health issued a prior notice on December 5, 2022, requiring reporting of COVID-19 cases, hospitalizations, and deaths by health care providers, schools, child care, long-term care, corrections facilities, shelters, and others. It also required laboratories to submit clinical materials and sequencing data for SARS-CoV-2. These requirements remain in effect and can be found at [Reporting of COVID-19/SARS-CoV-2 under the Minnesota Communicable Disease Rules, Chapter 4605.7080 - MN Dept. of Health \(state.mn.us\)](https://www.health.state.mn.us/diseases/communicable/4605.7080.html)

Why did MDH issue the supplemental notice?

Since March 2020, federal law has required CLIA-certified and CLIA-waived entities to report

FAQ ON THE MDH SUPPLEMENTAL NOTICE FOR REPORTING SARS-COV-2 TEST RESULTS

results of tests to detect SARS-CoV-2. The federal authority to require these reports will expire when the federal public health emergency (PHE) ends, which is expected to occur at the end of the day on May 11, 2023. MDH is issuing this supplemental notice to establish state law requirements for reporting the results of SARS-CoV-2 tests.

MDH cautions that the supplemental notice addresses SARS-CoV-2 test reporting requirements under Minnesota law. MDH cannot rule out the possibility of the federal government taking action to require additional test result reporting before or after the expiration of the federal PHE, so laboratories are encouraged to monitor [Diagnostic Data & Reporting \(https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html\)](https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html) for up-to-date federal information.

Under the supplemental notice, what are CLIA-certified laboratories required to report for SARS-CoV-2?

The reporting requirements for CLIA-certified laboratories under the supplemental notice are:

- Report positive results to MDH from tests to detect SARS-CoV-2. Tests include NAAT and non-NAAT tests. Laboratories should not report non-positive results from these tests. These results must be reported within one working day of completion.
- Laboratories can select among multiple methods to submit test results for SARS-CoV-2 to MDH. The options for submission are specified at: [COVID-19 Test Reporting Requirements \(www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html\)](http://www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html).
- Upon request of the Commissioner, submit clinical materials for reported cases of SARS-CoV-2/COVID-19 to the MDH Public Health Laboratory (PHL). (Note: This is a continuing requirement from the December 5, 2022, notice.)
- As applicable, submit the results of genomic testing on SARS-CoV-2 specimens to the MDH Public Health Laboratory (PHL). The details for this requirement are in the supplemental notice. (Note: This is a continuing requirement from the prior December 5, 2022, notice.)
- For all reports, entities must include as much disease report information as is known for the fields identified in Minn. Rules 4605.7090.

Under the supplemental notice, what are entities with CLIA Certificates of Waiver required to report?

The reporting requirements under the supplemental notice for entities operating under a CLIA Certificate of Waiver are:

- Report positive results to MDH from tests to detect SARS-CoV-2. These results must be reported within one working day of completion. Entities should not report non-positive results from these tests.
- Entities must submit test results through the methods specified at [COVID-19 Test Reporting Requirements \(www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html\)](http://www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html).
- For all reports, entities must include as much disease report information as is known for the fields identified in Minn. Rules 4605.7090.

Is there a summary of new state law requirements for test result reporting effective May 12, 2023?

Yes, please refer to the table 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

FAQ ON THE MDH SUPPLEMENTAL NOTICE FOR REPORTING SARS-COV-2 TEST RESULTS

* 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.

Who do I contact with 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 submission, contact Sarah Boneske, Operations, Minnesota Electronic Disease Surveillance System, phone: 651-201-5914 or email: health.ElectronicDiseaseReporting@state.mn.us.

Minnesota Department of Health
Infectious Disease Epidemiology, Prevention and Control Division
www.health.state.mn.us

04/20/2023

To obtain this information in a different format, call: 651-201-5414.