Supplemental Public Notice of Test Result Reporting for SARS-CoV-2 under the Minnesota Communicable Disease Reporting Rule, part 4605.7080

To: All CLIA-certified laboratories and entities operating under a CLIA Certificate of Waiver that conduct tests to detect SARS-CoV-2

Re: Minnesota Department of Health (MDH) SARS-CoV-2 test result reporting requirements, effective May 12, 2023

Date: April 20, 2023

Introduction

Since March 27, 2020, federal law has required "[e]very laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results. Implementation guidance issued by the U.S. Secretary of Health and Human Services (HHS) instructed laboratories conducting tests on Minnesota residents to submit these results to the Minnesota Department of Health (MDH). These federal reporting requirements are set to expire at "the end of the [HHS] Secretary's Public Health Emergency ["PHE"] declaration with respect to COVID–19 or any extension of such declaration"[1] and the Executive Office of the President has announced that the federal PHE will expire at the end of the day on May 11, 2023.[2] Unless new federal regulatory requirements are issued before May 11, 2023, HHS confirmed that it "will no longer have express authority to require" laboratories to report SARS-CoV-2 test results on and after May 12, 2023.[3]

Notwithstanding these federal developments, state law continues to require reporting of specific communicable diseases to MDH. The Minnesota Communicable Disease Reporting Rule, part 4605.7080, authorizes the Commissioner of Health to establish a surveillance mechanism for "newly recognized or emerging [infectious] diseases and syndromes." On December 5, 2022, the Commissioner issued a notice under that rule requiring reporting of SARS-CoV-2/COVID-19 cases, hospitalizations, and deaths by health care providers and specified community settings.[4] It also required laboratories to submit clinical specimens and sequencing data. Those requirements remain in effect and are available at Reporting of COVID-19/SARS-CoV-2 under

[1] Public Law 116–136, § 18115.

[2] State of Administration Policy HR 382 HJ Res 7 (www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf).

[3] HHS: Fact Sheet: COVID-19 Public Health Emergency transition Roadmap (www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html).

[4] Those specified settings are long-term care facilities, Pre-K-12 schools, child care programs, institutions of higher education, corrections facilities, and shelters.

the Minnesota Communicable Disease Rules, Chapter 4605.7080 (www.health.state.mn.us/diseases/reportable/rule/process/index.html).

The purpose of this supplemental notice is to set forth state SARS-COV-2 test result reporting requirements—effective May 12, 2023—for two groups of reporting entities: (1) CLIA-certified laboratories and (2) entities performing tests under a CLIA certificate of waiver. Separate reporting standards are detailed for these two groups below. Beginning May 12, 2023, these laboratories and entities **must report all positive results** of tests for SARS-CoV-2 to MDH according to the requirements of this supplemental notice. This supplemental notice **does not require reporting of non-positive results**.

Note: This 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 HHS: Diagnostic Data & Reporting (www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html) for up-to-date federal information.

Commissioner of Health Authority

Under part 4605.7080 of the Communicable Disease Reporting Rule, the Commissioner of Health ("commissioner") shall select new or emerging diseases/syndromes for reporting if certain criteria are met. Specifically, 4605.7080 says:

> "Subpart 1. Disease selection. The commissioner shall, by public notice, require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if:
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> A. the disease or syndrome can cause serious morbidity or mortality; and
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> B. report of the disease or syndrome is necessary to monitor, prevent, or control the disease or syndrome to protect public health.
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> Subp. 2. Surveillance mechanism. The commissioner shall describe a specific, planned mechanism for surveillance of the disease or syndrome including persons and entities required to report, a time frame for reporting, and protocols for the submission of test results and clinical materials from cases and suspected cases to the Minnesota Department of Health, Public Health Laboratory."

On December 5, 2022, the Commissioner of Health published in the State Register a Notice of Statewide Surveillance for SARS-CoV-2/COVID-19 under the Minnesota Communicable Disease Rule 4605.7080 ("reporting rule").[5] The findings in Section I of the December 5, 2022, notice

[5] The State Register Notice can be found at Reporting of COVID-19/SARS-CoV-2 under the Minnesota Communicable Disease Rules, Chapter 4605.7080 (www.health.state.mn.us/diseases/reportable/rule/process/index.html)

designating SARS-CoV-2/COVID-19 as a newly recognized or emerging disease remain relevant and are fully incorporated into this supplemental notice.

Surveillance Mechanism for Laboratories with CLIA Certification

1. **Disease or Syndrome**

   This notice describes reporting requirements for SARS-COV-2 infection/COVID-19 as evidenced by a positive viral test. Viral tests include nucleic acid amplification tests (NAATs) and non-NAATS tests. Laboratories should not report the results of antibody tests for SARS-CoV-2.

2. **Reporting Entities**

   Laboratories operating under a CLIA certification.

3. **Reporting Time Frame**

   Laboratories must submit to MDH test results within one working day of completion.

4. **Protocol for Submission**

   The reporting requirements for laboratories under the state reporting rule are as follows:

- Report positive results to MDH from tests to detect SARS-CoV-2. Tests include NAATs and non-NAATS tests. Laboratories should not report non-positive results from these tests.
- 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).
- Upon request of the Commissioner, submit clinical materials for reported cases of SARS-CoV-2/COVID-19 to the MDH Public Health Laboratory. The term “clinical materials” is defined in Minn. Rules 4605.7000, subpart 3.
- Submit to the MDH Public Health Laboratory the results of genomic testing on SARS-Cov-2 specimens if the laboratory conducts genomic testing. Laboratories with the capability to identify the lineage of SARS-CoV-2 specimens must submit all such test results (variant lineage number) to MDH through the test results submission methods specified at COVID-19 Test Reporting Requirements (www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html). If a laboratory has test results that identify the actual genomic sequence for a SARS-CoV-2 specimen, the laboratory must submit the actual sequence to the MDH Public Health Laboratory upon request. Laboratories must submit the actual sequence in an electronic format by a means that is feasible for both the submitting laboratory and the MDH Public Health Laboratory.
- For all reports, entities must include as much disease report information as is known for the fields identified in Minn. Rules 4605.7090.

Surveillance Mechanism for Entities Conducting Tests under a CLIA Certificate of Waiver

1. **Disease or Syndrome**

   This notice describes reporting requirements for SARS-COV-2 infection/COVID-19 as evidenced by a positive viral test to detect SARS-CoV-2 that the entity is authorized to perform under a CLIA certificate of waiver. Entities should not report the results of antibody tests for SARS-CoV-2.

2. **Reporting Entities**

   Entities operating under a CLIA Certificate of Waiver.

3. **Reporting Time Frame**

   Entities must submit to MDH test results within one working day of completion.

4. **Protocol for Submission**

   The requirements for reporting SARS-CoV-2 test results under the state reporting rule are as follows:

- Report positive results to MDH from viral tests to detect SARS-CoV-2. 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).
- For all reports, entities must include as much disease report information as is known for the fields identified in Minn. Rules 4605.7090.

Contact Information

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.

NOTICE ISSUED BY: /s/ Commissioner Dr. Brooke Cunningham, Minnesota Department of Health

DATE: April 20, 2023