CITY OF MILWAUKEE
HEALTH DEPARTMENT

Effective March 1, 2020

The Milwaukee Health Department Laboratory (MHDL) is offering the "CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR Diagnostic Panel under a Food and Drug Administration's (FDA) Emergency Use Authorization (EUA)[1] only. The Wisconsin State Laboratory of Hygiene (WSLH) is also now offering this testing.

The test is intended for the presumptive qualitative detection of nucleic acid from 2019-nCoV in upper and lower respiratory specimens collected from individuals who meet CDC criteria[2] for 2019-nCoV viral RNA testing to help in the aid of COVID-19 diagnosis.

The CDC 2019-nCOV real-time RT-PCR Dx Panel is a molecular *in vitro* diagnostic (IVD) test that aids in the detection and diagnosis of COVID-19 and is based on nucleic acid amplification (NAAT) technology.

Testing Criteria and Approval

This test should not be ordered unless a Patient under Investigation (PUI) and nCoV identification number has been assigned by the CDC through Wisconsin Department of Health Services (WI DHS). Please check the CDC website routinely for updates to the PUI criteria[2].

Requests for testing must have:

1. For testing at MHDL approval must be obtained by contacting a Communicable Disease Epidemiologist at the City of Milwaukee Health Department (MHD) or Wisconsin Department of Public Health (WDPH).
    - MHD (Survnet) call 414-286-3624
    - WDPH during normal business hours, call 608-267-9003 or after hours call 608-258-0099 emergency pager and ask for the epidemiologist on call
2. A PUI/2019-nCoV number issued.

NOTE: Specimens that are submitted without approval from public health and a PUI number will be rejected for testing.

Specimens

Current recommendations[3] for initial diagnosis are to submit the following specimens:

- Nasopharyngeal (NP) swab in viral transport media (VTM) - (*swabs not in VTM will be rejected*; NP wash or aspirate are also acceptable), **AND**
- Oropharyngeal (OP) or throat swab in VTM – (*swabs not in VTM will be rejected*)
- Sputum, if possible - (induction of sputum is not indicated; lower respiratory tract aspirate, bronchial wash and bronchoalveolar lavage-BAL are also acceptable)

Note: Currently lower respiratory specimens are not tested at MHDL. Additional specimens such as serum, urine and/or stool may be requested for follow-up on patients who test positive.

Submit your specimen(s) along with:

- A copy of the completed PUI form
- A completed MHDL specimen requisition form (Please write COVID-19 in the "Other" section for the desired testing)

Packaging and Shipping to MHDL:

If you have questions about how to submit specimens from approved patients for testing, contact MHDL laboratory @ 414-286-3526 during normal business hours (Monday – Friday 8:00 AM – 4:45 PM). If the specimen will be transported and received within 72 hours of collection, store specimens at 2-8º C and ship on cold packs.

- If unable to transport the specimen for receipt within 72 hours of collection, freeze the specimen and ship on dry ice.
- Package as a UN3373 Biological Substance 'Category B'.
- Monday – Friday specimens can be delivered to:

  Zeidler Municipal Building
  841 N Broadway St, 2nd Floor
  Milwaukee, WI 53202
- **Please use your agency's courier for transporting any COVID-19 specimens to the MHD lab**.
- If you *do not* have your own courier or to coordinate deliveries outside of business hours please call MHDL at 414-286-3526.

Test Results

Test results will be available within 24 hours of receipt of NP and OP by MHDL. Positive results will be called to the submitter. All results will be reported to the submitters electronically.

Test results will be reported as one of the following:

- **Presumptive Positive** – In compliance with the EUA instructions for this assay, this specimen will be sent to the CDC for confirmatory testing. (Note that this is an actionable result.)
- **Negative** – Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions.
- **Inconclusive** – This test result is inconclusive. It did not meet the full criteria established by the CDC for the presence of 2019-nCoV. This specimen will be sent to the CDC for additional testing. Their report will follow.
- **Invalid** – This specimen exhibited inhibition in the PCR assay or the specimen contained an inadequate amount of clinical material. If clinically warranted, repeat testing is suggested.

[1]The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Letter of Authorization (FDA EUA) Fact Sheet for Healthcare Providers, and Fact Sheet for Patients can be found at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

[2]Check CDC website for 2019-nCoV testing criteria

[3]Check the CDC website for the most up-to-date specimen collection guidance