Marshfield Labs™

Laboratory News

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Introduction of In-house SARS-CoV-2, 2019 Novel Coronavirus (COVID-19) Testing by Nucleic Acid Amplification

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Beginning March 27, 2020, Marshfield Labs will begin in-house testing for SARS-CoV-2, 2019 Novel Coronavirus (2019-nCoV) the causative agent of COVID-19. We are using the FDA EUA approved DiaSorin Molecular Simplexa™ COVID-19 Direct real-time RT-PCR assay which is intended for the in vitro qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in nasopharyngeal swabs (NPS) from individuals suspected of COVID-19 by their healthcare provider.

Principle of the Test: The assay targets two different regions of the SARS-CoV-2 genome, ORF1ab and S gene. The S gene encodes the spike glycoprotein of the SARS-CoV-2. The ORF1ab region encodes well-conserved non-structural proteins and therefore is less susceptible to recombination. An RNA internal control is used to detect RT-PCR failure and/or inhibition.

Indications: COVID-19 testing needs to be reserved for those patients requiring an Urgent Care or ED visit and judged to be acutely ill, with pending or realized hospitalization, or a symptomatic employee with fever. This process will markedly preserve PPE, and conserve test swabs and transport media. Please see: **MCHS COVID-19 Testing Algorithm** posted on the Marshfield Labs' online TRM.

At this time **ABNAT (influenza) testing has been suspended**. Ordering of ABRNAT (influenza/RSV) alone is strongly discouraged to conserve test swabs and media unless ordered simultaneously with COV19 or may be added later as a U-Have. Providers may choose to treat cases suspicious for influenza empirically and self-quarantine.

Patients not meeting Wisconsin Department of Health Services Tier 1 or Tier 2 criteria DO NOT need to be tested for COV19, and may be discharged with instruction for home isolation and follow up if symptoms worsen.

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Ordering Details: This test is designed for detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider.

A completed Wisconsin 2019 Novel Coronavirus (COVID-19) **Patient Information Form** must accompany specimens and must also be sent to the patient's local health department. This form will be linked on the Marshfield Labs' online TRM. Confirmed and suspected COVID-19 disease is a Category 1 reportable condition in Wisconsin.

HOW TO ORDER THIS TEST

- **Test Name: COVID19, SARS-CoV-2**
- **Test Code: COV19**
- **Specimen:** Preferred: Nasopharyngeal (NP) swab in M6 multi-microbe transport medium
  Acceptable specimens for **COV19 testing only**: NP swab in 1-3 mL of Universal Transport Media (UTM, Copan) or, Universal Viral Transport (UVT, BD) or equivalent.
- **Specimen Volume:** 1 NP swab
- **Storage:** 2°- 8°C or freeze if >72 hours
- **Test Availability:** Monday through Sunday
- **Qualitative interpretation**
  Reported as Negative, Positive, or Indeterminate
  Indeterminate results are inconclusive. Repeat testing with a new specimen is recommended
- **CPT Codes:** 87635

Questions:

Test information is available in: Marshfield Labs' Test Reference Manual.

- Clinical and technical information: Mary Stemper, Technical Specialist III, Microbiology Laboratory or Timothy S. Uphoff, PhD, Molecular Pathology Laboratory.
- Phone number: 1-800-222-5835.

References

1. Simplexa™ COVID-19 Direct, For Emergency Use Authorization Only, For in vitro diagnostic use Rx Only: https://www.fda.gov/media/136286/download