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](https://www.fda.gov/media/136286/download)