<table>
<thead>
<tr>
<th><strong>Lab Dept:</strong></th>
<th>Microbiology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Name:</strong></td>
<td>SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-CoV-2) RNA DETECTION</td>
</tr>
</tbody>
</table>

### General Information

<table>
<thead>
<tr>
<th><strong>Lab Order Codes:</strong></th>
<th>SCOV2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms:</strong></td>
<td>SARS-CoV2/COVID-19; Coronavirus; Novel coronavirus</td>
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<tr>
<td><strong>CPT Codes:</strong></td>
<td>U0003: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies</td>
</tr>
<tr>
<td><strong>Test Includes:</strong></td>
<td>SARS-CoV-2 RNA detection reported as Detected or Undetected</td>
</tr>
</tbody>
</table>

### Logistics

<table>
<thead>
<tr>
<th><strong>Test Indications:</strong></th>
<th>Useful for detection of COVID-19 illness due to SARS coronavirus 2 (SARS-CoV-2). Please order according to Children’s policy and patients meeting current clinical and/or epidemiologic criteria defined by federal, state, or local public health directives.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lab Testing Sections:</strong></td>
<td>Microbiology - Sendouts</td>
</tr>
<tr>
<td><strong>Referred to:</strong></td>
<td>Mayo Clinic Laboratories (Mayo Test: SCOV2/COVOO)</td>
</tr>
</tbody>
</table>
| **Phone Numbers:** | MIN Lab: 612-813-6280  
STP Lab: 651-220-6550 |
| **Test Availability:** | Daily, 24 hours |
| **Turnaround Time:** | 1 – 2 days. |
| **Special Instructions:** | N/A |

### Specimen

| **Specimen Type:** | **Swabs:** Nasopharyngeal (NP), Oropharyngeal (OP) Swab, nares/nasal swab  
**Lower Respiratory Fluids:** Bronchoalveolar lavage (BAL), bronchial washings, endotracheal/tracheal aspirates, sputum |
Container:

Swabs:
NP Swab: Flocked Flexible Minitip NP Swab in 3 mL Universal Transport Media (UTM)
CHC # 32788 (BD Cat. No. 220531): Kit, Swab flocked Sterile 3 mL

Nasal Swab or OP: Flocked Regular Nasal Swab in 3 mL Universal Transport Media (UTM)
CHC # 32720 (BD Cat. No. 220528) , Kit, Regular Flock Swab w/UTM

Fluids: Sterile container

Draw Volume:
Swabs: Entire collection
Fluids: Minimum 1 mL

Processed Volume:
Swabs: Swab in 3 mL (Min: 1 mL) of transport media (eg, M4-RT/ M5)
Fluids: Minimum 1 mL fluid
**Collection:**  
**Swabs:** Collect specimen by swabbing back and forth over nasal or pharyngeal mucosa surface to maximize recovery of cells.

Nasopharyngeal (NP) and oropharyngeal (OP; i.e. throat) swab specimens may be combined at collection into a single vial of transport media.

**Fluids:** Collection as appropriate to specimen type

**Special Processing:**  
Lab Staff: Place aliquot in freezer in Sendouts. Store and ship at frozen (preferred) temperatures. Forward promptly.

**Patient Preparation:**  
None

**Sample Rejection:**  
Mislabeled or unlabeled specimens; calcium alginate-tipped swab; wooden shaft swab; dry swab; swab collection tubes containing gel or charcoal additive; transport media tubes containing gel or charcoal additive; glass transport tube

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**Interpretive**

**Reference Range:** Undetected

**Interpretation:** A “Detected” result indicates that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test result should be considered in the context of patient’s clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.

An “Undetected” result indicates that SARS-CoV-2 is not present in the patient’s specimen. However, this result may be influenced by the stage of the infection, quality, and type of the specimen collected for testing. Result should be correlated with the patient history and clinical presentation.

An “Indeterminate” result suggests that the patient may be infected with a variant SARS-CoV-2 or SARS-related coronavirus. Additional testing with an alternative molecular method is recommended on a newly collected specimen.

An “Inconclusive” result indicates that the presence or absence of SARS-CoV-2 RNA in the specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to RT-PCR inhibition. Submission of a new specimen for testing is recommended.

**Critical Values:**  
**Alert value:** Detected results will be reported to Infection Prevention.
Limitations: The FDA has provided emergency use authorization (EUA) of this test for testing human nasopharyngeal and oropharyngeal swab specimens. The assay is adapted to test lower respiratory tract specimens, such as bronchial washing, broncoalveolar lavage (BAL) fluid.

The sensitivity of the assay is dependent on the stage of the illness when the sample is collected, the quality of the specimen submitted, and the tests performance characteristics. SARS-CoV-2 is likely at higher viral loads in the upper respiratory tract (eg, nasopharyngeal swab) during the first 3-5 days post onset of symptoms. At later stages of the disease, the virus may be more readily detected in lower respiratory samples (eg, sputum, BAL, fluid).

The test is specific for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); therefore, the results do not exclude the possibility of infection with other respiratory viruses.

An Undetected (ie, negative) results do not preclude infection with SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions.

Methodology: Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR)

References: Mayo Clinic Laboratories (November 2020)

Updates: 4/28/2020: Added nasal swab as acceptable specimen
4/30/2020: Added additional validated specimens per Mayo
5/1/2020: Added images for swabs and updated CPT code.