TEST: SARS CoV-2 (COVID-19) NUCLEIC ACID DETECTION TEST

PRINCIPLE:
COVID-19 (coronavirus disease 2019) is the disease resulting from infection with coronavirus SARS-CoV-2. Testing is critical to differentiate COVID-19 from influenza or other respiratory diseases. The Clinical Immunology Laboratory SARS CoV-2 nucleic acid detection test is a molecular multi-target real time RT-PCR assay designed according to the protocols of the US Center for Disease Control and Prevention (CDC). The assay is very specific for SARS CoV-2 with a limit of detection as low as 10 viral copies per microliter. The test is intended for the qualitative detection of SARS CoV-2 virus present in nasopharyngeal swabs, mid-turbinate swabs, oropharyngeal swabs, sputum, lower respiratory tract aspirates, and bronchoalveolar lavage.

Positive results with this test indicate that RNA from SARS CoV-2 virus was detected and the individual is presumably contagious. A negative result only indicates that no adequate viral copy number was present at the Limit of Detection of this assay. In the latter case, repeating of patient sampling and testing maybe necessary if symptoms persist.

SPECIMEN REQUIREMENTS:
The preferred specimen is nasal secretion from the back of the nose and throat collected with a nasopharyngeal swab kit. Upon collection, the swab should be placed in a container with viral transport media. If not available, Clinical Immunology Laboratory will provide nasopharyngeal collection kits (container, swabs, and viral transport media) to your clinic.

It is important for the specimen to be sent to the lab as soon as it is collected. Specimen can be stored at room temperature or at 2-8°C for up to 5 days after collection. If collecting site is expecting a shipping delay then store specimens at -70°C or lower.

Please contact Clinical Immunology Laboratory if you have any questions on collection or storing criteria.

METHOD:
Real-Time Reverse Transcription Polymerase Chain Reaction (PCR).

RESULTS & INTERPRETATION:

<table>
<thead>
<tr>
<th>RESULT</th>
<th>INTERPRETATION</th>
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<tbody>
<tr>
<td>POSITIVE</td>
<td>SARS-CoV-2 virus was detected in submitted specimen.</td>
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<tr>
<td>NOT DETECTED</td>
<td>SARS-CoV-2 virus was below the limit of detection in submitted specimen. Negative results do not exclude 2019-nCoV infection.</td>
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<tr>
<td>INCONCLUSIVE</td>
<td>Indicates that not all required testing targets were detected possibly due to viral concentration near the limit of detection. An additional specimen should be considered.</td>
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TURNAROUND TIME:
1-3 business days

REFERENCES:
https://www.fda.gov/media/134922/download