



Test Name: SARS-CoV-2 Molecular

CPT Code: 87635 - 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

Synonyms: COVID-19, SARS-CoV-2

Test Description: The laboratory will determine the most appropriate testing algorithm for your sample based on current reagent availability, specimen type, specimen container, specimen volume, specimen storage, and specimen transport.

At this time, our laboratory has two methods available.

1. *TaqPath™ COVID-19 Combo Kit*

The TaqPath™ COVID-19 Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens. Results are for the identification of SARS-CoV-2 RNA. The TaqPath™ RT-PCR COVID-19 Kit is a COVID-19 Real Time PCR multiplexed assay containing three primer/probe sets specific to different SARS-CoV-2 genomic regions and primers/probes for bacteriophage MS2. In addition, the TaqPath™ COVID-19 control is used. This is an RNA control that contains targets specific to the SARS-CoV-2 genomic regions targeted by the assays.

2. *Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit*

The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and anterior nasal swab specimens from individuals suspected of COVID-19. Results are for the identification of SARS-CoV-2 RNA. The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit is a COVID-19 Real Time PCR multiplexed assay containing three primer/probe sets specific to different SARS-CoV-2 genomic regions and primers/probes for bacteriophage MS2. In addition, the TaqPath™ COVID-19 control is used. This is an RNA control that contains targets specific to the SARS-CoV-2 genomic regions targeted by the assays.

Possible Results:

• ***TaqPath™ COVID-19 Combo Kit***

SARS-CoV-2 Positive
SARS-CoV-2 Not Detected
SARS-CoV-2 Inconclusive
Invalid

- *Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit*

SARS-CoV-2 Positive
SARS-CoV-2 Not Detected
SARS-CoV-2 Inconclusive
Invalid

Reference Range:

- *TaqPath™ COVID-19 Combo Kit*

SARS-CoV-2 Not Detected

- *Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit*

SARS-CoV-2 Not Detected

Specimen Type:

Nasopharyngeal (NP) swab is the preferred choice for swab-based SARS-CoV-2 testing. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- Nasal swabs (NS)
- Nasal mid-turbinate (NMT) swab □ Anterior nares specimen

Specimen Container(s):

Viral Transport Media (VTM), Universal Transport Media (UTM), Phosphate Buffered Saline, or Liquid Amies. Please be aware that the CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Polyester, Rayon, or Nylon tipped swabs with plastic shafts are acceptable.

We are continuing to evaluate other options for specimen collection supplies, and we will update this list accordingly as this information becomes available.

Specimen Volume:

Request 1-3 mL specimen in viral transport media (VTM), universal transport media (UTM), phosphate buffered saline, or Liquid Amies.

Collection Instructions:

If

Nasopharyngeal swabs (NP)
Nasal swabs (NS)
Nasal mid-turbinate (NMT) swab
Anterior nares specimen

Then

- Swab should be placed and mixed well in a VTM, UTM, PBS, or Liquid Amies immediately after collection. Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron) and an aluminum or plastic shaft.
- Swabs may need to be broken in such a way to ensure the caps can be tightly secured to prevent leakage and specimen rejection.
- NP swab collection from **either** the right **or** left nares is acceptable.
- For NS, a single polyester swab with a plastic shaft should be used to sample **both** nares

Test Requisition:

Complete Omega MDX-ID Laboratory Requisition. This must accompany the sample. Requisition must include patient's first and last name, 2nd unique identifier, gender, date of birth, date and time of collection, specimen source, test requested, submitter's name and address, fax and contact number.

Storage and Transport Instructions:

- Store specimens at **2-8°C** and should be received in the laboratory within **72 hours** of collection.
- Transport specimens at **2-8°C** to laboratory as soon as possible after collection. Alternately, if shipping is delayed, specimens should be frozen at **-70°C or lower** and shipped overnight on dry ice. If samples are frozen, freeze date and time is required on the test request form.

General Storage and Transport Instructions:

- Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.
- Label outermost bag with appropriate transport temperature (2-8°C, 2-25°C or ≤-70°C). Refer to the *Additional Information* section below for more information on acceptable specimen criteria.

Rejection Criteria:

- Specimens that were not stored within the appropriate time after collection.
- Specimens that are delivered outside acceptable temperature.
- Specimens from unacceptable sources.
- Specimens collected in unacceptable media types.
- Dry swabs or wooden swabs.
- Specimen not labeled with 2 unique identifiers.
- Specimens that are leaking upon receipt by the laboratory.

Limitations of the Procedure:

- These assays are approved via Emergency Use Authorizations.
- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Due to the importance of specimen quality, training in specimen collection is highly recommended. CLSI MM13-A may be referenced as an appropriate resource.

Interfering Substances:

Calcium alginate swabs are unacceptable. Cotton swabs with wooden shafts are not recommended.