

## ASPR TRACIE Technical Assistance

**Requestor:** Redacted

**Requestor Phone:** Redacted

**Requestor Email:** Redacted

**Request Receipt Date (by ASPR TRACIE):** March 12, 2020

**Response Date:** March 16, 2020

**Type of TTA Request:** Complex

### Request:

ASPR TRACIE received a request for information on the COVID-19 testing process.

### Response:

ASPR TRACIE compiled and synthesized information from the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and other open sources.

Please refer to the Centers for Disease Control and Prevention's [Coronavirus Disease 2019 webpage](#) for the most up-to-date clinical guidance on COVID-19 outbreak management.

### What is the test for Coronavirus?

The test is called the “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel.” Laboratories need additional supplies and equipment in addition to what is included in CDC’s laboratory test kit to conduct these tests. Source: [CDC Tests for COVID-19](#)



### What kind of test is being used?

The test is a real-time RT-PCR intended for the presumptive qualitative detection of nucleic acid from COVID-19 in upper and lower respiratory specimens.

In lay terms, this test is a polymerase chain reaction or PCR test which is looking for specific viral genetic material in samples. Those samples could include a nose or throat swab or sputum sample. Once collected and sent to a certified laboratory, the laboratorians will extract the virus’s nucleic acid, which holds the virus’ genome. Laboratorians can amplify or replicate certain regions of the genome to make a larger sample for testing. PCR tests can detect the virus only if the patient is actively sick.

Other tests used in China are serologic tests which can detect antibodies, which is helpful in that it can detect if the person was ever sick and produced antibodies to fight off an infection from

SARS-CoV-2. This serologic antibody test is not available in the US.

## How accurate is the test?

The test is accurate if conducted while the viral load is high enough to be detected – typically by the time the patient is symptomatic. Results may be negative for asymptomatic patients. A negative test after the patient has been ill and recovered should indicate the patient is no longer infectious.

There is the potential for false negatives if either test is conducted too early. The patient may not have a high enough viral load to trigger the PCR test or hasn't produced enough antibodies for the serological test.

## How long does the test take for results?

The tests can be run in a matter of hours, not including the time to transport the samples to a certified laboratory.

## How are samples collected?

The FDA provides [instructions for use](#) for the test kits.

Specimen collection is conducted in accordance with the [CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation \(PUIs\) or Coronavirus Disease 2019 \(COVID-19\)](#).

“For initial diagnostic testing for COVID-19, CDC recommends collecting and testing upper respiratory (nasopharyngeal [through the nose to the back of the throat] **AND** oropharyngeal swabs [through the mouth to the back of the throat]), and lower respiratory (sputum, if possible) for those patients with productive coughs. Induction of sputum is not recommended. Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset. Maintain [proper infection control](#) when collecting specimens.”

Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

## What is the testing process in place for persons under investigation (PUIs)?

“Health care providers should contact their local/state health department immediately to notify them of patients with fever and lower respiratory illness who live in or have recently traveled to an affected area with sustained transmission or have been in close contact with a confirmed COVID-19 patient. Local and state public health staff will determine if the patient meets the [criteria for a person under investigation \(PUI\)](#) for COVID-19. Clinical specimens should be collected from PUIs for routine testing of respiratory pathogens at either clinical or public health

labs.” Source: [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation \(PUIs\) for Coronavirus Disease 2019 \(COVID-19\)](#)

## Resources

Association of Public Health Laboratories. [Coronavirus Disease \(COVID-19\): Laboratory Risk Assessments and Lessons Learned](#). March 12, 2020.

CMS. [FAQs on Essential Health Benefit Coverage and the Coronavirus \(COVID-19\)](#). March 12, 2020

CMS. [Medicare Administrative Contractor \(MAC\) COVID-19 Test Pricing](#). March 12, 2020

Live Science. [How do the New Coronavirus Tests Work?](#) Accessed March 16, 2020