

Coronavirus Disease (COVID-19), PCR, Saliva (Lab Tests and Diagnostic Procedures)

Comment

The FDA has noted that unauthorized **fraudulent** COVID-19 test kits are being sold online. Currently the only way to be tested for COVID-19 is through licensed health care providers. The FDA advises consumers and health professionals to be cautious of websites and stores selling products that claim to prevent, diagnose, treat, or cure COVID-19 ([FDA 2020](#)). Any concerns regarding fraudulent products, including tests, should be sent to: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov.

Related Information

- [Coronavirus Disease \(COVID-19\) Antibody \(IgG\) Serum or Plasma](#)
- [Coronavirus Disease \(COVID-19\) Antibody Total Serum or Plasma](#)
- [Coronavirus Disease \(COVID-19\) Antibody, IgG/IgM Rapid Test, Whole Blood, Serum, or Plasma](#)
- [Coronavirus Disease \(COVID-19\) Antigen, Upper Respiratory Specimen](#)
- [Coronavirus Disease \(COVID-19\), PCR, Respiratory Specimen](#)
- [Influenza SARS-CoV-2 Multiplex Assay, CDC](#)

Overview

At the end of 2019, a novel coronavirus was identified as the cause of several cases of pneumonia in Wuhan City, Hubei Province, China. Initially linked to a large seafood and animal market suggesting animal-to-human spread, person-to-person transmission was quickly confirmed (Li Q 2020). The virus spread rapidly worldwide and in January 2020, the World Health Organization (WHO) declared the outbreak a "public health emergency of international concern." On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. Currently, more than 42 million infections have been confirmed globally in over 200 countries and territories with over 1.1 million deaths ([WHO situation report 2020](#)).

The novel virus has been named **severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)** and the disease it causes has been named **coronavirus disease 2019 (COVID-19)**. The virus is thought to spread mainly by respiratory droplets produced when an infected person coughs or sneezes. The droplets can land in the mouths, noses and eyes of nearby people, or possibly be inhaled into the lungs. Touching a contaminated surface and transferring to eyes, nose or mouth is also thought to be a mode of transmission although not as dominant as by respiratory droplets. Symptoms typically appear within 2 to 14 days (median of 5 days) of exposure and include **fever, chills, fatigue, cough, shortness of breath, myalgia, recent loss of taste or smell, vomiting or diarrhea, and/or sore throat**. Sickness ranges from a mild respiratory illness to severe disease including respiratory failure, septic shock, or other organ failure. Most fatalities have occurred in patients with underlying comorbidities, with overall global fatalities around 3 percent ([WHO situation report 2020](#)). The CDC currently estimates that about 40% of COVID-19 infections are asymptomatic, and 50% of transmission occurs prior to symptom onset ([CDC Pandemic Planning 2020](#)). Currently, there is no vaccine or specific treatment; care is supportive.

Although molecular nucleic acid polymerase chain reaction testing on respiratory specimens has become the current gold standard method for diagnosis of SARS-CoV-2 infection (see [COVID-19, PCR, Respiratory Specimen](#)), there has been a need for a more robust specimen that is easier to collect. In early May 2020, the FDA issued an Emergency Use Authorization (EUA) to Rutgers Clinical Genomics Laboratory for TaqPath SARS-CoV-2-Assay, a real time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) assay for the detection of SARS-CoV-2 nucleic acid in NP, OP, NMT, NS, BAL, and **self-collected saliva** specimens. Since the initial EUA for saliva, several other saliva tests have received FDA authorization. Saliva specimens can be collected at home or in a health care setting when determined to be appropriate by a health care provider. See [FDA EUA](#) for further information on available COVID-19 saliva testing.

Use/Indications

Aid in the diagnosis of coronavirus disease (COVID-19)

Special Instructions

With the rapid spread and newly acquired knowledge of COVID-19 along with the increased availability of tests, the CDC and IDSA testing recommendations are continuously changing, see

[Overview of Testing for SARS-CoV-2 \(COVID-19\), Considerations for COVID-19 Diagnostics \(Molecular or Antigen\) Testing](#) and

[Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19](#).

Note: Testing for other respiratory pathogens by the provider should be done as part of the initial work-up and should not delay specimen shipping to CDC or qualified laboratory. If a patient tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a person under investigation (PUI).

Test Includes

Qualitative detection of nucleic acid from SARS-CoV-2

Turnaround Time

24-72 hours from receipt of specimen in testing laboratory

Patient Preparation

Patient should not eat, drink, chew gum, brush teeth, or smoke for at least 30 minutes prior to saliva collection.

Specimen

Saliva

Container(s)

- Collection device provided in kit
- Sterile, leakproof, plastic container

- Swab collection system provided in kit

Volume / Minimum Volume

1-5 mL; collection system dependent

Collection

Patient collected either in the presence of health care provider or at-home collection. Manufacturer instructions must be followed. Package and ship specimen on the same day as collected.

Methodology

Real time Reverse Transcriptase-Polymerase Chain Reaction (rRT-PCR)

Normal Values/Findings

Not detected

Note: If a negative result is obtained from a patient with a high index of suspicion, the World Health Organization (WHO) recommends collection of additional specimens, including the lower respiratory tract if possible, for further testing (WHO March 2020).

All positives must be reported to local/state health departments.

Interpretative Information

- A positive result indicates the presence SARS-CoV-2 RNA; results must be correlated with patient history and clinical symptoms. Positive results do not rule out infection with other pathogens (bacteria or coinfection with other viruses).
- A Not Detected test result means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection, thus a negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated (FDA Rutgers 2020).

Limitations

Factors that can lead to a false-negative result include:

- Poor specimen quality; small amount of patient specimen
- Dilution of viscous specimen can cause loss of sensitivity
- Specimen collected very early or very late in the infection process
- Inadequate processing, storage, or shipping of specimen
- Technical reasons inherent in the test (eg, virus mutation, PCR inhibition) (WHO March 2020)

False positive results can occur due to technical error or reagent contamination

Laboratory/Diagnostic Pearls

- PUI: Any person who is under investigation for having SARS-CoV-2 that causes COVID-19 or who was under investigation but tested negative.
- Severe Acute Respiratory Syndrome (SARS) was identified in 2003 and Middle East Respiratory Syndrome (MERS) was identified in 2012. As these syndromes are also caused by viruses in the coronavirus family, researchers are incorporating information learned from these previous infections to aid in understanding SARS-CoV-2.
- For biosafety reasons it is not recommended to perform viral isolation in cell culture for SARS-CoV-2 or perform initial characterization of viral agents recovered in cultures of specimens from PUI.
- Studies indicate SARS-CoV-2 may persist on surfaces for a few hours up to several days dependent on conditions (eg, type of surface, temperature or humidity of the environment) (WHO Q&A 2020).
- High SARS-CoV-2 viral loads (more in nose than throat) can be detected soon after symptom onset (within first week) and can also be found in the asymptomatic patient (Zou 2020). Viral shedding may continue for days after symptom relief and recovery (Lan 2020). Median range of viral shedding among hospitalized patients has been documented as 12 to 20 days (Zhou 2020; Young 2020).
- Current data indicate that low levels of SARS-CoV-2 may persist for up to 3 months in the respiratory tracts of persons recovered from COVID-19 infection, although it has not been found to be replication competent. If tested within 3 months of initial infection, the individuals may continue to have a positive test result, however; there is no evidence that they are contagious (CDC Duration of Isolation 2020).

Additional Information

For more information, interim guidance has been issued by the United States [CDC](#) and the [World Health Organization](#).

See: [Information for Laboratories](#)

See: [COVID-19 Testing and Reporting by Laboratories: Q & A](#)

See: [For Healthcare Professionals](#)

See: FDA [Emergency Use Authorizations](#)

The CDC has developed a serologic test for detection of antibodies to SARS-CoV-2. This will assist in determining how much of the US population has been exposed to the virus. This test is not designed for testing individuals who want to know if they have been previously infected with SARS-CoV-2; however, commercially manufactured serologic tests for COVID-19 antibodies are becoming increasingly available.

Index Terms

2019 Novel Coronavirus; 2019-nCoV; COVID-19 PCR; COVID-19 Saliva Test; COVID-19, Qualitative, PCR; Covid19; nCoV, 2019; Novel Coronavirus, 2019; Qualitative COVID-19; SARS-CoV-2; Severe Acute Respiratory Syndrome Coronavirus 2; Wuhan

Applies to

Pandemic; Person Under Investigation (PUI); Pneumonia of Unknown Etiology

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