

Coronavirus Disease (COVID-19), PCR, Respiratory Specimen (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 2020a](#)). Consumers and health care professionals can help by reporting suspected fraud to the [FDA's Health Fraud Program](#) or the [Office of Criminal Investigations](#).

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 \(COVID-19\) Neutralization Antibody, Serum or Plasma](#)
- [Coronavirus Disease \(COVID-19\), PCR, Saliva](#)
- [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 83 million infections have been confirmed globally in over 200 countries and territories with over 1.8 million deaths ([WHO 2021a](#)).

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 larger respiratory droplets (and less commonly, small aerosol droplets) produced when an infected person exhales (eg, breathes, speaks, coughs, sneezes, or sings). 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 efficient 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 2 to 3 percent ([WHO 2021a](#)). The CDC currently estimates that about 40% of COVID-19

infections are asymptomatic, and 50% of transmission occurs prior to symptom onset ([CDC 2020d](#)). Currently, there is no vaccine or specific treatment; care is supportive.

The Center of Disease Control and Prevention (CDC) developed a nucleic acid amplification/real time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) assay to diagnose SARS-CoV-2 in respiratory specimens. In the early stages of disease dissemination, the CDC was the only lab conducting the SARS-CoV-2 testing; however, with the rapid spread of the viral infection, in February 2020 the FDA issued an Emergency Use Authorization (EUA) allowing qualified laboratories (as designated by CDC) to perform testing. Those facilities included US state and local public health laboratories, Department of Defense (DOD) laboratories, and select reference and international laboratories. Currently, under FDA guidance, there has been local, hospital-based SARS-CoV-2 test development. The developed tests may be based on the CDC, WHO, or manufacturer assays, or created de novo. The laboratories must perform an assay validation and pursue an FDA Emergency Use Authorization. See [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#).

As the pandemic has progressed many FDA EUA nucleic acid tests have entered the market, including batch testing platforms with various turnaround times (useful for large facilities or reference laboratories that have bigger sample volumes); rapid testing, with results available in 45 minutes ([FDA, Cepheid 2020b](#)) or as little as 5 to 13 minutes (Abbott 2020a) (useful in point-of-care situations); nucleic acid testing on pooled specimens (can save time and money); saliva testing; at home self-collection devices to be sent into specific testing facilities; and recently a prescription-only test that can be self-collected and performed at home or at point-of care ([FDA, Lucira 2020f](#)).

Also, available (via EUA) are molecular respiratory panels that include SARS-CoV-2 and several other well-known respiratory pathogens. These panels are intended for qualitative differentiation of nucleic acid from multiple organisms and can assist health care providers in differentiating various infectious agents that produce similar symptoms to COVID-19. Panel testing can also assist in diagnosing coinfections which have been noted in some COVID-19 patients (Ding 2020; Kim 2020).

As each of these assays has unique specificities regarding specimen, collection, transport and processing, it is important that health care providers understand testing options available and follow manufacturer instructions for proper specimen collection, processing, and transport. The information below covers the specimens and collection procedures required by the CDC.

Use/Indications

Aid in the diagnosis of coronavirus disease (COVID-19); detect current infection

Nucleic acid amplification testing was also originally recommended for determining resolution of infection, a test-based strategy which required serial tests and improvement of symptoms to determine when an individual with SARS-CoV-2 infection was no longer infectious and transmission-based precautions could be discontinued. However, the CDC has changed to a symptom-based strategy with recommendations based on severity of illness (eg, 10 days from onset of symptoms for mild to moderate illness **and** 24 hours fever free without fever-reducing medications **and** symptoms have improved). It was found in the majority of cases, the test-based strategy actually prolonged the isolation of patients who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious (virus is no longer replication-competent).

A test-based strategy is still considered useful in some instances when transmission-based precautions could be discontinued earlier than if the symptom-based strategy was used, or for some patients who are severely immunocompromised (chemotherapy, transplant, untreated HIV infection, combined primary immunodeficiency disorder, prednisone treatments, advanced age, diabetes mellitus, end-stage renal disease) ([CDC 2020e](#)).

Criteria for test-based strategy:

Symptomatic patients:

- Fever has resolved without use of fever-reducing medications **and**
- Improvement of symptoms (cough, shortness of breath) **and**
- FDA-authorized SARS-CoV-2 molecular test results are negative from at least two consecutive respiratory specimens collected ≥ 24 hours apart.

Asymptomatic patients:

- FDA-authorized SARS-CoV-2 molecular test results are negative from at least two consecutive respiratory specimens collected ≥ 24 hours apart ([CDC 2020e](#)).

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 (as indicated) and should not delay specimen shipping to CDC or qualified laboratory.

Test Includes

Qualitative detection of nucleic acid (RNA) from SARS-CoV-2

Specimen

Upper Respiratory Tract Specimen

For initial COVID-19 testing, the CDC recommends collecting an upper respiratory specimen. This includes ([CDC 2020g](#)):

- Nasopharyngeal (NP) specimen collected by a trained health care professional. **Or**
- Oropharyngeal (OP) specimen collected by a trained health care professional. **Or**
- Nasal mid-turbine (NMT) specimen collected by a trained health care professional or by a supervised or unsupervised onsite self-collection (using flocked tapered swab), or self-collected at home following kit instructions. Both nares should be swabbed. **Or**

- Anterior nares (nasal swab; NS) specimen collected by a trained health care professional, or by a supervised or unsupervised onsite self-collection (using a flocked or spun polyester swab), or self-collected at home following kit instructions. Both nares should be swabbed using the same swab. **Or**
- Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by health care professional. **Or**
- Saliva, self-collection at home or at testing site
- **Note:** The IDSA recommends collecting an NP swab, NMT swab, anterior nasal swab, saliva, or a combined anterior nasal/oropharyngeal swab rather than an oropharyngeal swab alone for nucleic acid testing in symptomatic patients ([IDSA 2020](#)).

Lower Respiratory Tract Specimen

- Bronchoalveolar lavage (BAL), tracheal aspirate, pleural fluid, lung biopsy
- Sputum - for patients who develop a productive cough; induction of sputum is **not** recommended.

Note: SARS-CoV-2 RNA has also been detected in stool, blood, and semen (Li D 2020).

Container(s)

- Confer with testing laboratory for proper specimen container and collection.
- Lower respiratory specimen: Sterile, screw-cap plastic container
- Nasal mid-turbinate (NMT) specimen: Flocked tapered swab
- Nasal swab or anterior nares (NS) specimen: Flocked or spun polyester swab
- Nasopharyngeal or oropharyngeal specimen: Use only synthetic fiber swab with plastic or wire shaft. Do not use calcium alginate swab or cotton swab with wooden shaft.
- Nasopharyngeal wash/aspirate or nasal wash/aspirate specimen: Sterile viral transport media tube
- Saliva: Sterile, screw-cap plastic container

Volume / Minimum Volume

- 1 NP swab or 1 OP swab or 1 NS swab or 1 NMT swab
- Saliva: 1-5 mL
- Fluids: 2-3 mL

Collection

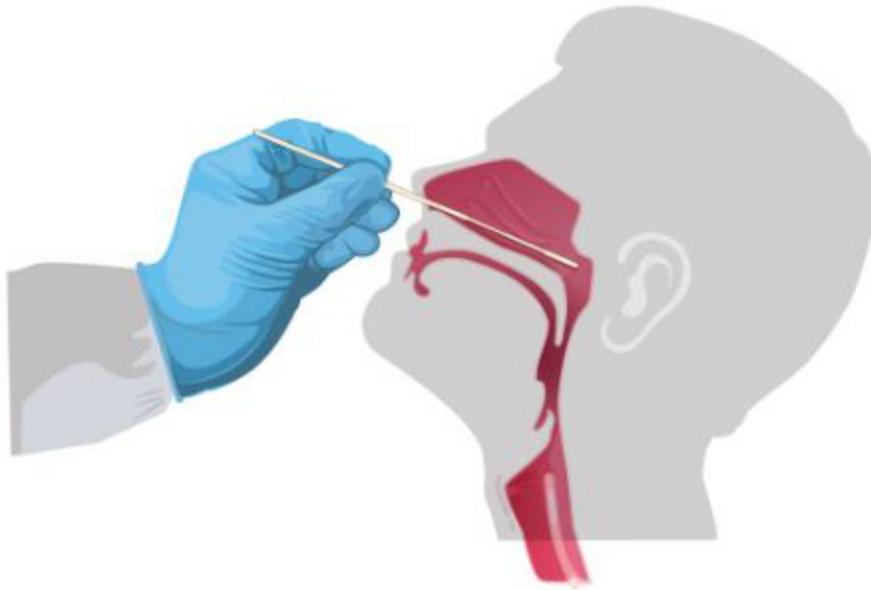
Prior to specimen collection, patient identity should be confirmed using two independent identifiers; use of a patient identification arm band or similar system is recommended. Specimen label(s) should include the two independent identifiers and the date of collection. There should be a method to identify

the individual collecting the specimen. The specimen container(s) should be labeled in the presence of the patient after specimen is collected. Container(s) should **not** be pre-labeled. Use computer-generated label(s), if available, to avoid transcription errors.

Collect specimen from patient as soon as possible, regardless of time of symptom onset. Health care professionals collecting specimens should use proper infection control techniques and wear personal protective equipment, including an N95 respirator (or facemask if respirator is not available), eye protection, gloves, and a gown.

Upper Respiratory Tract Specimen

- **NP swab:** Tilt patient's head back 70 degrees. Insert a minitip swab with flexible (wire or plastic) shaft through the nostril parallel to the palate (not upwards) until resistance is detected or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Place swab immediately into sterile tubes containing 2 to 3 mL of viral transport media (VTM), Amies transport medium, phosphate-buffered saline, or sterile saline. If both are collected, NP and OP specimens should be placed in the same vial at collection site. **Note:** Some point of care assays are designed to analyze the specimen **directly (without medium)**; use swabs provided and follow manufacturers instructions for swab storage and processing. See [CDC Nasopharyngeal Specimen Collection Steps](#).



CDC 2020g

- **OP (throat) swab:** Avoiding the tongue, teeth, and gums, insert swab into the posterior of pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx. Place swab immediately into sterile tubes containing 2 to 3 mL of viral transport media (VTM), Amies transport medium, phosphate-buffered saline, or sterile saline. If both are collected, NP and OP specimens should be placed in the same vial at collection site. **Note:** Some point of care assays are designed to analyze the specimen **directly (without medium)**; use swabs provided and follow manufacturers instructions for swab storage and processing.
- **NMT swab (deep nasal swab):** Use a flocked tapered swab. Tilt patient's head back 70 degrees. While gently rotating, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. Place swab immediately into sterile tubes containing 2 to 3 mL of viral transport media (VTM), Amies transport medium, phosphate-buffered saline, or sterile saline. **Note:** Some point of care assays are designed to analyze the specimen **directly (without medium)**; use swabs provided and follow manufacturers instructions for swab storage and processing. See [CDC Nasal Mid-turbinate Specimen Collection Steps](#).
- **NS (anterior nares):** Using a flocked or spun polyester swab, insert the tip of swab 0.5 to 0.75 inch (1 to 1.5 cm) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the sample. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with same swab. Place swab immediately into sterile tubes containing 2 to 3 mL of viral transport media (VTM), Amies transport medium, phosphate-buffered saline, or

sterile saline. **Note:** Some point of care assays are designed to analyze the specimen **directly (without medium)**; use swabs provided and follow manufacturers instructions for swab storage and processing. See [CDC How to collect Your Anterior Nasal Swab Sample for COVID-19 Testing](#).

- **NP wash/aspirate or nasal wash/aspirate (NW):** Sterile collection by health care provider. Attach catheter to suction apparatus. Have the patient sit with head tilted slightly backward. Instill 1 to 1.5 mL of non-bacteriostatic saline (pH 7.0) into one nostril. Insert the tubing into the nostril parallel to the palate (not upwards). Catheter should reach depth equal to distance from nostrils to outer opening of ear. Begin gentle suction/aspiration and remove catheter while rotating it gently. Place specimen in a sterile viral transport media tube.
- **Saliva:** Supervised, patient self-collection into sterile, leakproof container

Lower Respiratory Tract Specimen

- **BAL, tracheal aspirate, pleural fluid, lung biopsy:** Sterile collection by health care provider. Collect 2 to 3 mL into sterile, leakproof, screw-cap container. Collection of lower respiratory specimens is advised if collected later in the course of disease or in patients with a negative upper respiratory test and a strong clinical suspicion of COVID-19 infection (WHO 2020b).
- **Sputum:** Patient should be educated on difference between sputum and saliva. Patient should rinse mouth with water then expectorate deep cough sputum directly into sterile, leakproof screw-cap container. Health care personnel should apply standard precautions and wear an N95 or equivalent or higher respirator when collecting specimens. **Note:** Sputum induction is **not** recommended.

For more information see: [CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#).

See [Guidelines for submitting specimens to CDC](#) for laboratory testing for SARS-CoV-2.

Processing and Storage

- For all specimens: Refrigerate at 2°C to 8°C and ship overnight on ice pack to CDC (or qualified laboratory). Specimens are stable 72 hours.
- For longer storage, freeze specimen(s) at -70°C.
- For state, local, or reference laboratories, follow specific shipping guidelines.

Stability

- Refrigerated: 72 hours
- Frozen (-70°C): Not established

Methodology

Nucleic acid amplification testing (NAAT), with reverse-transcription polymerase chain reaction (RT-PCR) to detect SARS-CoV-2 RNA

Other types of NAAT include isothermal amplification, CRISPR-based assays, and next-generation sequencing (Brandsma 2020; Joung 2020).

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 resampling with repeat nucleic acid testing; the collection of additional specimens, including the lower respiratory tract may be necessary (WHO 2020b).

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.

Limitations

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

- Poor specimen quality; small amount of patient specimen
- Specimen collected early or late in the infection process. A study of PCR-based SARS-CoV-2 tests, funded by the National Institute of Allergy and Infectious Diseases (NIAID) and the CDC, found the median false-negative rate on the first day of symptom onset was 38%, and decreased to 20% three days after symptom onset. This percentage began to increase on day 4, and 16 days after symptom onset the false-negative rate was up to 66% (Kucirka 2020).
- Inadequate processing, storage, or shipping of specimen
- Technical reasons inherent in the test (eg, virus mutation, PCR inhibition) (WHO 2020b)

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

Diagnostic Role

Gold standard confirmation of acute SARS-CoV-2 infection is based on the detection of unique viral sequences by nucleic acid amplification tests (NAATs). These assays' targets include regions on the nucleocapsid (N), envelope (E), spike (S), and RNA-dependent RNA polymerase (RdRp) genes (WHO 2020b). Although this testing is both sensitive and specific, an accurate result is dependent on the type and quality of the specimen and the duration of illness at the time of testing.

The viral load tends to be higher in lower respiratory tract (LRT) specimens; Wang et al found RT-PCR viral loads highest in bronchoalveolar lavage (BAL) specimens (93%), followed by sputum (72%), nasal swab (63%), and pharyngeal swab (32%) (Wang 2020b). As such an LRT specimen may be recommended

when an upper respiratory tract (URT) specimen is negative for SARS-CoV-2. Some studies have shown that viral loads are higher in nasal/nasopharyngeal specimens compared to oropharyngeal specimens (Covid Investigation Team 2020; Zou 2020) while other studies do not find a difference (Wölfel 2020).

SARS-CoV-2 may be detected in the URT 1 to 3 days prior to development of symptoms (Furukawa 2020; WHO 2020b); the viral concentration is highest around the time of symptom onset and then gradually declines (He 2020; Zou 2020). Although it is important to test the suspected positive patient as soon as possible, the duration of the illness at specimen collection must be considered when interpreting results.

It is important to note that the various NAATs available have different limits of detection (LOD), thus varying sensitivities. Specimens tested on different platforms could have different results. For more information see [SARS-CoV-2 Reference Panel Comparative Data](#).

Laboratory/Diagnostic Pearls

- 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 patients.
- 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). Warmer temperatures and exposure to sunlight reduces viral survival time ([CDC 2020f](#)).
- High SARS-CoV-2 viral loads can be detected soon after symptom onset (within first week) and are also found in the asymptomatic patient (Zou 2020). At this time, it is unknown how soon viral RNA can be detectable following exposure and infection.
- 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, individuals may continue to have a positive test result, however; there is no evidence that they are contagious ([CDC 2020b](#)).

Additional Information

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

See: [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#)

See: [Information for Laboratories](#)

See: [Frequently Asked Questions about Coronavirus \(COVID-19\) for Laboratories](#)

See: [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

See: [For Healthcare Professionals](#)

See: FDA [Emergency Use Authorizations](#)

Index Terms

2019 Novel Coronavirus; 2019-nCoV; COVID-19 PCR; 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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