

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 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, 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 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.

The Center of Disease Control and Prevention (CDC) has developed a 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 ([IDSA 2020](#)). Health care providers should contact their local laboratory for testing options including use of the state health department or reference labs that have been approved to conduct testing.

On March 21, 2020, the [FDA](#) issued emergency use authorization (EUA) for the first rapid coronavirus diagnostic test, with a detection time of approximately 45 minutes. This is the first COVID-19 test that can be used at the point of care (POC) and should quickly aid with distinguishing presumptive diagnosis from confirmed diagnosis, thus assisting in the decision-making process (isolation, treatment, risk to others, etc.) ([Cepheid 2020](#)). Although marketed as POC, most of the testing will be performed in clinical laboratories and not at health provider's office or bedside. Produced by Cepheid, this test is unique in that all steps of the testing process are integrated within one cartridge in which specimen is added. The test is run on Cepheid GeneXpert systems which are located in many health organizations in the US and throughout the world. Currently, supplies are allocated to areas most in need.

On March 27, 2020, under EUA by the FDA, Abbott Laboratories molecular point of care test for the detection of SARS-COV-2 viral RNA in nasal, nasopharyngeal, or throat swabs was approved. This test is run on Abbott's ID NOW™ platform, a small unit that can be used in a variety of locations including health care providers' offices and urgent care clinics. Positive results can be reported in as little as 5 minutes and negative results in 13 minutes (Abbott 2020). On May 14, 2020 the FDA issued an alert on the accuracy of the Abbott ID NOW™ COVID-19 assay, stating the test may return false-negative results (FDA May 14 2020). Abbott and the FDA are working together to investigate the issue. Abbott reiterated a collection requirement: This is a direct swab test method, the inoculated swab should **not** be placed in any type of transport media prior to testing as this will dilute out specimen. Testing should be performed immediately after specimen collection (Abbott May 14 2020).

Also, becoming 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).

On April 22, 2020, a [FDA EUA](#) was issued to Laboratory Corporation of America (LabCorp) for production of the first at-home COVID-19 collection kit. It is authorized only for use in the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The EUA permits nasal swab specimens to be collected at home using Pixel by LabCorp COVID-19 test home collection kit which must be recommended by a health care provider after the patient completes a COVID-19 questionnaire. This self-collection (nasal swab) kit will initially be available for health care workers and first responders who may

have been exposed to the virus or may have coronavirus symptoms, but will eventually be available for consumers.

Use/Indications

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

Nucleic acid 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). 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 (CDC [Discontinuation of Transmission](#) 2020). Note however, many recovered patients continue to shed detectable SARS-CoV-2 RNA for prolonged periods of time but are no longer infectious.

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

Specimen

Upper Respiratory Tract Specimen

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

- Nasopharyngeal (NP) specimen collected by a health care professional. **Or**
- Oropharyngeal (OP) specimen collected by a health care professional. **Or**
- Nasal Mid-turbine (NMT) specimen collected by a health care professional or by a supervised onsite self-collection (using flocked or tapered swab). Both nares should be swabbed. **Or**

- Anterior nares (nasal swab; NS) specimen collected by a health care professional or by onsite or home self-collection (using a flocked or spun polyester swab). Both nares should be swabbed. **Or**
- Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by health care professional.
- Saliva, supervised self-collection

Lower Respiratory Trace 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, saliva, 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 wash/aspirate or nasal wash/aspirate specimen: Sterile viral transport media tube
- NP or OP specimen: Use only synthetic fiber swab with plastic or wire shaft. Do not use calcium alginate swab or cotton swab with wooden shaft.
- 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

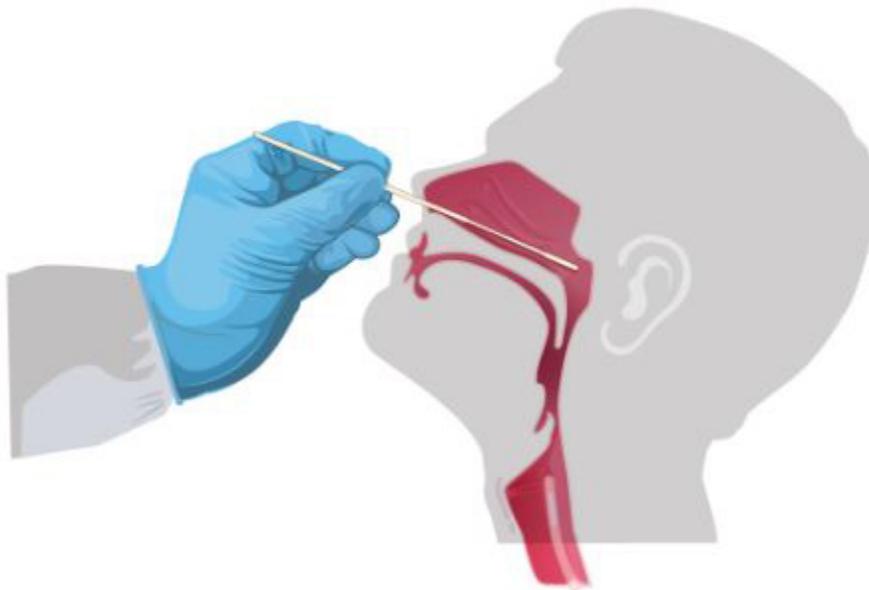
Prior to specimen collection, patient identity should be confirmed using two independent identifiers; use of a patient identification arm band or similar system is recommended. Specimen label(s) should include the two independent identifiers and the date of collection. There should be a method to identify 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 PUI as soon as possible regardless of time of symptom onset. Specimen should be collected by trained health care professional using proper infection control techniques and wearing

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:** 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, 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 (ID NOW COVID-19) do **not** require media as test is run immediately; use swabs provided and follow manufacturers instructions for swab storage and processing.



CDC 2020

- **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, 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 (ID NOW COVID-19) do **not** require media as test is run immediately; 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, or sterile saline. **Note:** Some point of care assays (ID NOW COVID-19) do **not** require media as test is run immediately; use swabs provided and follow manufacturers instructions for swab storage and processing.
- **NS (anterior nares):** Using a flocked or spun polyester swab, insert the swab at least 0.5 inch (1 cm) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nares with same swab. Place swab immediately into sterile tubes containing 2 to 3 mL of viral transport media (VTM), Amies transport medium, or sterile saline. **Note:** Some point of care assays (ID NOW COVID-19) do **not** require media as test is run immediately; use swabs provided and follow manufacturers instructions for swab storage and processing.
- **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. Note, collection of lower respiratory specimen other than sputum may be limited to patients presenting with more severe disease (admitted to hospital and/or fatal cases).
- **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. **Note:** Sputum induction is **not** recommended.

For more information see: [CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 \(COVID-19\)](#).

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 labs, follow specific shipping guidelines.

Stability

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

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.

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

See: [Information for Laboratories](#)

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

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

References

Abbott Diagnostics. ID NOW COVID-19 [product information]. Scarborough, Maine; April 2020.

Abbott Laboratories. Abbott Provides Update on ID NOW™. <https://abbott.mediaroom.com/2020-05-14-Abbott-Provides-Update-on-ID-NOW-TM>. Published May 14, 2020. Accessed May 18, 2020.

Abbott Laboratories. Detect COVID-19 in as little as 5 minutes. Abbott Laboratories website. <https://www.abbott.com/corpnewsroom/product-and-innovation/detect-covid-19-in-as-little-as-5-minutes.html>. Updated March 27, 2020. Accessed March 30, 2020.

Bai Y, Yao L, Wei T, et al. Presumed Asymptomatic Carrier Transmission of COVID-19 [published online February 21, 2020]. *JAMA*. 2020;10.1001/jama.2020.2565. [\[PubMed 32083643\]](#)

Burke RM, Killerby ME, Newton S, et al. Symptom Profiles of a Convenience Sample of Patients with COVID-19 - United States, January-April 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(28):904-908. Published 2020 Jul 17. [\[PubMed 32673296\]](#)

Centers for Disease Control and Prevention (CDC). CDC Tests for 2019-nCoV. <https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html>. Updated February 5, 2020. Accessed February 13, 2020.

Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Duration of Isolation and Precautions for Adults with COVID-19. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>. Updated August 16, 2020. Accessed August 18, 2020.

Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Overview of Testing for SARS-CoV-2. <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>. Updated August 24, 2020. Accessed August 24, 2020.

Centers for Disease Control and Prevention (CDC). COVID-19 Pandemic Planning Scenarios. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>. Updated July 10, 2020. Accessed July 13, 2020.

Centers for Disease Control and Prevention (CDC). Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>. Updated July 17, 2020. Accessed July 28, 2020.

Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV). <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>. Accessed May 1, 2020.

Ding Q, Lu P, Fan Y, Xia Y, Liu M. The clinical characteristics of pneumonia patients coinfecting with 2019 novel coronavirus and influenza virus in Wuhan, China [published online March 20, 2020]. *J Med Virol*.[\[PubMed 32196707\]](#)

Infectious Diseases Society of America (IDSA). Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19. <https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/>. Published May 6th, 2020. Accessed May 13, 2020.

Kim D, Quinn J, Pinsky B, Shah NH, Brown I. Rates of Co-infection Between SARS-CoV-2 and Other Respiratory Pathogens [published online April 15, 2020]. *JAMA*[\[PubMed 32293646\]](#)

Kucirka LM, Lauer SA, Laeyendecker O, Boon D, Lessler J. Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction-Based SARS-CoV-2 Tests by Time Since Exposure. *Ann Intern Med*. Published online May 13, 2020. doi:10.7326/M20-1495.[\[PubMed 32422057\]](#)

Lan L, Xu D, Ye G, et al. Positive RT-PCR Test Results in Patients Recovered From COVID-19 [published online February 27, 2020]. *JAMA*. 2020.[\[PubMed 32105304\]](#)

Lippi G, Simundic AM, Plebani M. Potential preanalytical and analytical vulnerabilities in the laboratory diagnosis of coronavirus disease 2019 (COVID-19) [published online March 16, 2020]. *Clin Chem Lab Med*.[\[PubMed 32172228\]](#)

Li D, Jin M, Bao P, Zhao W, Zhang S. Clinical Characteristics and Results of Semen Tests Among Men With Coronavirus Disease 2019. *JAMA Netw Open*. 2020;3(5):e208292. Published 2020 May 1.[\[PubMed 32379329\]](#)

Li Q, Guan X, Wu P, et al. Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia [published online January 29, 2020]. *N Engl J Med*.[\[PubMed 31995857\]](#)

Patel A, Jernigan DB; 2019-nCoV CDC Response Team. Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak - United States, December 31, 2019-February 4, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(5):140–146. Published February 7, 2020.[\[PubMed 32027631\]](#)

Pixel by Lab Corp. Introducing Self-Collection Kits for COVID-19 Testing. <https://www.pixel.labcorp.com/blog/introducing-self-collection-kits-covid-19-testing>. Published April 2020. Accessed April 22, 2020.

QIAstat-Dx Respiratory SARS-CoV2 Panel Instructions for Use (Handbook). Germantown, MD: QIAGEN; March 2020.

Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2 [published online ahead of print, 2020 May 6]. *JAMA*. 2020;10.1001/jama.2020.8259.[\[PubMed 32374370\]](#)

Shen S, Woo R. Coronavirus incubation could be as long as 27 days, Chinese provincial government say. [Reuters \[online\]](#) [online]. Published February 22, 2020. Accessed February 27, 2020.

US Food & Drug Administration (FDA). Beware of Fraudulent Coronavirus Tests, vaccines and Treatments. https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments?utm_campaign=FDA%20MedWatch%20-

[%20Fraudulent%20Coronavirus%20Tests%2C%20Vaccines%20and%20Treatments&utm_medium=email&utm_source=Eloqua](#). Published March 24, 2020. Accessed March 26, 2020.

US Food & Drug Administration (FDA). Coronavirus (COVID-19) Update: Daily Roundup [News Release]. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-21-2020>. Published April 21, 2020. Accessed April 22, 2020.

US Food & Drug Administration (FDA). Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point>. Published May 14, 2020. Accessed May 18, 2020.

US Food & Drug Administration (FDA). Rutgers Clinical Genomics Laboratory SARS-CoV-2 ASSAY [EUA Summary]. <https://www.fda.gov/media/137776/download>. Accessed May 13, 2020.

Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern [published online January 24, 2020] [published correction appears in *Lancet*. 2020 Feb 15;395(10223):470-473. [\[PubMed 31986257\]](#)

World Health Organization (WHO). Coronavirus disease 2019 (COVID-19). Situation reports. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/>. Updated October 25, 2020. Accessed October 26, 2020.

World Health Organization (WHO). Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>. Updated February 7, 2020. Accessed February 13, 2020.

World Health Organization (WHO). Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases. <https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>. Published March 2, 2020. Accessed March 9, 2020.

World Health Organization (WHO). Q&A on coronavirus (COVID-19). WHO Newsroom. <https://www.who.int/news-room/q-a-detail/q-a-coronaviruses>. Published February 23, 2020. Accessed March 4, 2020.

Xpert[®] Xpress SARS-CoV-2 Test. Cepheid website. <https://www.cephheid.com/coronavirus>. Update March 21, 2020. Accessed April 1, 2020.

Young BE, Ong SWX, Kalimuddin S, et al. Epidemiologic Features and Clinical Course of Patients Infected With SARS-CoV-2 in Singapore [published online ahead of print, 2020 Mar 3]. *JAMA*. [\[PubMed 32125362\]](#)

Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study [published correction appears in *Lancet*. 2020;395(10229):1038]. *Lancet*. 2020;395(10229):1054–1062. [\[PubMed 32171076\]](#)

Zou L, Ruan F, Huang M, et al. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. *N Engl J Med*. 2020;382(12):1177-1179. [\[PubMed 32074444\]](#)

Last Updated 10/26/20



© 2020 UpToDate, Inc. and its affiliates and/or licensors. All rights reserved.