

COVID-19 Antigen, Upper Respiratory Specimen (Lab Tests and Diagnostic Procedures)

Comment

The FDA has noted that unauthorized **fraudulent** COVID-19 test kits are being sold online. 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 Fraudulent 2020](#)). Consumers and health care professionals can help by reporting suspected fraud to the [FDA's Health Fraud Program](#) or the [Office of Criminal Investigations](#).

Note: In June, 2021 the FDA issued a statement to stop the use of Lepu Medical Technology SARS-CoV-2 Antigen Rapid Test Kit due to a high risk of false results. Although not FDA-authorized for distribution in the US, these test kits were distributed to pharmacies for at-home testing by consumers, and offered for sale directly to consumers. Health care providers should consider retesting with a different SARS-CoV-2 diagnostic test if an inaccurate result is suspected (FDA Lepu 2021).

Note: In June, 2021 the FDA issued a statement to stop the use of Innova SARS-CoV-2 Antigen Rapid Qualitative Test due to the potential of false (positive or negative) results. The test has been distributed in the US without FDA authorization. It is also distributed under the following names: Innova COVID-19 Self-Test Kit (3T Configuration), Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration).

Prior receipt of a COVID-19 vaccine will **not** affect viral testing for SARS-CoV-2.

Related Information

- [COVID-19 Antibody \(IgG\), Quantitative, Serum or Plasma](#)
- [COVID-19 Antibody \(IgG\), Semi-quantitative, Serum or Plasma](#)
- [COVID-19 Antibody \(IgG\), Serum, Plasma, or Whole Blood](#)
- [COVID-19 Antibody Total, Oral Fluid](#)
- [COVID-19 Antibody Total, Serum, Plasma, or Whole Blood](#)
- [COVID-19 Antibody, IgG/IgM Rapid Test, Serum, Plasma, or Whole Blood](#)
- [COVID-19 Neutralization Antibody, Serum or Plasma](#)
- [COVID-19, PCR, Respiratory Specimen](#)
- [COVID-19, PCR, Saliva](#)
- [Influenza and SARS-CoV-2 Antigen, Upper Respiratory Specimen](#)
- [Influenza SARS-CoV-2 Multiplex Assay, PCR, CDC](#)
- [Respiratory Panel, PCR, Nasopharyngeal](#)

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 200 million infections have been confirmed globally in over 200 countries and territories with over 4 million deaths ([WHO 2021](#)).

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, or COVID-19**. The virus spreads by contact with respiratory fluids (droplets or aerosol) produced when an infected person exhales (eg, breathes, speaks, coughs, sneezes, or sings). These droplet/aerosol particles can be

- inhaled directly into lungs
- directly deposited on exposed mucous membranes (eyes, mouth, nose)
- transferred to mucous membranes by hands contaminated with virus-containing respiratory fluids or by indirectly touching surfaces with virus on them ([CDC SARS-CoV-2 Transmission 2021](#))

COVID-19 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 situation report 2021](#)). The CDC currently estimates that about 30% of COVID-19 infections are asymptomatic, and 50% of transmission occurs prior to symptom onset ([CDC Pandemic Planning 2021](#)).

Although nucleic acid amplification testing (NAAT) has become the current gold standard method for diagnosis of SARS-CoV-2 infection (see [COVID-19, Respiratory Specimen](#)), antigen testing has also been developed as a simpler and more rapid turnaround (~15 minutes) method. The FDA has issued emergency use authorizations (EUAs) for the detection of SARS-CoV-2 viral proteins in nasopharyngeal (NP) and nasal swab (NS) specimens. See [FDA EUA](#).

Initially these assays were developed and authorized for collection and performance by trained laboratory personnel in a clinical laboratory or point-of-care setting; however, newer developed tests also allow for specimen collection and testing to be performed at home either with the help of a telehealth proctor or performed by individual patient or family member.

With the need for further identification of asymptomatic individuals, the FDA has authorized specific antigen tests to be used for serial screening (testing an individual multiple times on a routine basis). This provides better testing solutions for schools, workplaces, and communities when establishing SARS-CoV-2 screening protocols. Currently several antigen assays have received EUAs for serial screening, including over-the-counter (OTC) and with/without prescription point-of-care (POC) tests (Quidel QuickVue At-Home OTC COVID-19, Abbott BinaxNOW [multiple configurations], BD Veritor System for Rapid Detection of SARS-CoV-2, Quidel Sofia SARS Antigen FIA, CareStart COVID-19 Antigen, Celltrion DiaTrust COVID-19 Ag Rapid Test, InBios SCoV-2 Ag Detect Rapid Test, OraSure InteliSwab COVID-19 Rapid Test, OraSure InteliSwab COVID-19 Rapid Test Pro). They can be used for both symptomatic and

asymptomatic persons (FDA Coronavirus update 04 2021). See [In Vitro Diagnostics EUAs- Antigen Diagnostic Tests for SARS-CoV-2](#).

Antigen tests for SARS-CoV-2 are generally less sensitive than NAAT but due to ease of use, quick turnaround, reduced cost, POC and at-home testing availability, and serial screening, this type of assay is useful for quick diagnosis of both symptomatic and asymptomatic individuals.

Use/Indications

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

- Rapid detection of current infection in symptomatic patients
- Screen asymptomatic patients with known exposure to confirmed case of COVID-19
- Screen asymptomatic patients in high-risk shared housing facilities (nursing homes, student or faculty housing, shelters, penal institutions, etc.) to quickly identify infection and put infection/prevention control measures in place.
- Community expanded screening of asymptomatic groups (with and without known exposure) to prevent or reduce silent spread of virus **if** resources are available. This may include, but not exclusive to: workers in high-density worksites (restaurant, grocery store); government workers with public interactions (post office); students, faculty, staff at institutions of higher education; teachers and staff in K-12 schools; people who attended mass gatherings.

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 \(COVID-19\)](#) 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.

Test Includes

Qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal (NP) swab and/or anterior nares nasal swab (NS) specimen. Depending on manufacturer intent and FDA authorization, specimen collection and testing may be performed in a certified clinical laboratory, at point-of-care (POC), or at home. Testing is available for individual specimens and serial collections. **Note:** Most assays detect both viable (live) and nonviable SARS-CoV and SARS-CoV-2 and do **not** differentiate between the two viruses. Additional testing is needed for differentiation of specific coronaviruses and strains. For more information on current FDA EUA for SARS-CoV-2 antigen testing, see [In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2](#).

Specimen

Nasopharyngeal swab, nasal swab, or mid-turbinate nasal swab tested directly or placed in viral transport media (VMT) (follow manufacturer requirements)

Container(s)

- Confer with testing laboratory for proper specimen container and collection.
- NMT specimen: Swab provided in kit
- NP specimen: Swab provided in kit or nylon flocked nasopharyngeal swab
- NS specimen: Swab provided in kit

Volume / Minimum Volume

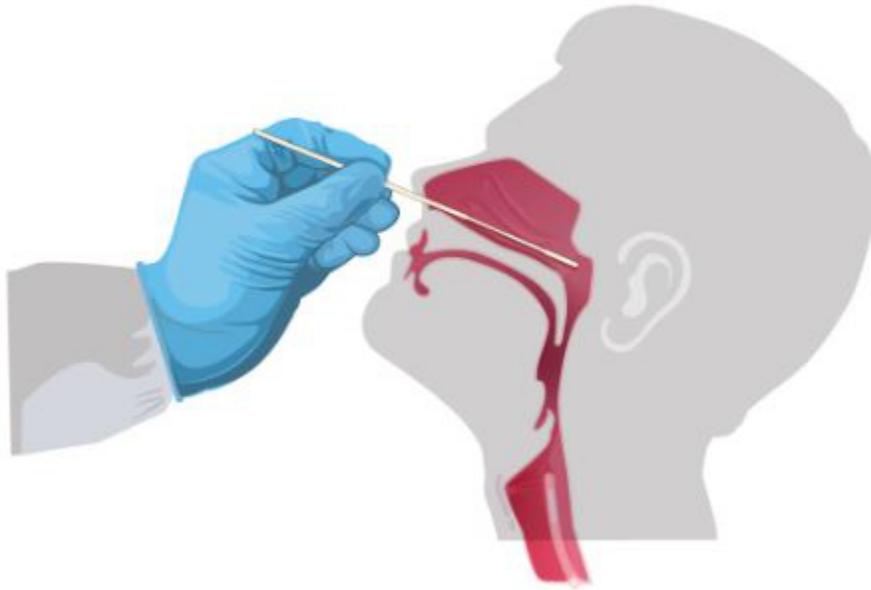
1 nasopharyngeal swab, 1 nasal swab, or 1 nasal mid-turbinate swab

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.

Rapid antigen tests perform best when individual is tested in the early stages (acute) of SARS-CoV-2 infection when viral load is typically highest. Note manufacturer specific timeframe for the best collection window. 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. For at-home collection, collector should be as cautious as possible and wear available personal protective equipment.

- **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. Use swabs provided. Refer to manufacturer instructions as most kits require direct testing only, however; viral transport media maybe be allowed for some specimens. See [CDC Nasopharyngeal Specimen Collection Steps](#).



CDC Interim Guidelines for Collecting 2020

- **NS (anterior nares):** Using swab provided in kit, 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. Follow manufacturers instructions for swab storage and processing. See [CDC How to collect Your Anterior Nasal Swab Sample for COVID-19 Testing](#).
- **NMT swab (deep nasal swab):** Using swab provided in kit, 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. Follow manufacturers instructions for swab storage and processing. See [CDC Nasal Mid-turbinate Specimen Collection Steps](#).

Processing and Storage

- Refer to manufacturer instructions.

Stability

Swab without VTM

- Some kits state specimen must be tested within one hour of collection; storage is not appropriate.
- Room temperature: 24-120 hours (manufacturer dependent)

- Refrigerated: 24-120 hours (manufacturer dependent)

Swab in VTM (manufacturer dependent, follow instructions with kit)

Methodology

Lateral Flow Immunoassay; Lateral Flow, Fluorescence; Lateral Flow Immunoluminescent Assay; Chromatographic Digital Immunoassay; Chemiluminescence Immunoassay (CLIA); Microfluidic Immunofluorescence; Paramagnetic Microbead-based Immunoassay; Magnetic Force-assisted Electrochemical Sandwich Immunoassay (MESIA)

Normal Values/Findings

Negative

Interpretative Information

- A positive result indicates presence of viral antigens. Result should be correlated with patient history and other diagnostic information. A positive result in an asymptomatic patient should be confirmed by NAAT ([CDC expanded screening 2020](#)).
- A negative result means that SARS-CoV-2 viral antigen was not present in the specimen above the limit of detection. A negative result in a symptomatic patient should be confirmed by NAAT. A negative result when pretest probability is elevated (eg, known COVID-19 exposure) should be confirmed by NAAT.
- All positives must be reported to local/state health departments.
- See [CDC Interim Guidance for Antigen Testing for SARS-CoV-2](#) for recommended antigen testing algorithms.

Limitations

- Data is limited on the use of antigen testing of asymptomatic people to diagnose or exclude infection with SARS-CoV-2 or to determine whether a previously confirmed positive is still infectious.
- Inadequate specimen collection, improper specimen handling and/or transport can cause false testing results
- Antigen levels below the assay detection limit can yield false-negative results.
- Use of viral transport media (VTM) or universal transport media (UTM) can interfere with antigen tests designed for direct testing; false positive, false negative, or invalid results can occur. Follow test kit instructions for proper specimen collection and transport.
- Positive results do not rule out coinfections with other pathogens.
- Both viable and nonviable virus is detected
- In some test kits, positive results do not differentiate between SARS-CoV and SARS-CoV-2, consult package insert

- Monoclonal antibodies can fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- Presence of biotin can cause false negative results (CareStart™ 2020).
- Excess blood or mucus on swab specimen may yield false positive results (CareStart™ 2020).
- The presence of mupirocin may cause false negative results with BinaxNOW™ COVID-19 antigen test (BinaxNOW™ 2020)
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after the manufacturer-recommended collection timeframe be negative compared to a RT-PCR assay (Veritor™ 2020).
- The presence of fluticasone propionate may cause false positive results (Qiagen 2021).

Statistical Validity

The sensitivity of antigen testing is typically lower than most nucleic acid amplification tests (NAAT). Specificity is comparable to NAAT ([Interim Guidance for Antigen Testing for SARS-CoV-2](#) 2020). This means false-positive results are unlikely but can occur.

Laboratory/Diagnostic Pearls

- Positive and negative predictive values are highly dependent on prevalence rates. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high. When disease prevalence is low, more false positive test results are likely.
- 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 persons under investigation.
- 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 EPA 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).

- Although nucleic acid amplification testing is more sensitive and can detect a wide range of viral load levels throughout infection, the SARS-CoV-2 antigen test is useful in that it detects positive patients when they are most likely to spread disease. The recommended specimen collection window for antigen testing is 5 to 14 days (assay dependent) post symptom onset, when viral load is highest and the patient is most infectious.

Additional Information

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

See: [Guidance for Healthcare Workers about COVID-19 \(SARS-CoV-2\) Testing](#)

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

See: [Information for Laboratories](#)

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

See: FDA [Emergency Use Authorizations](#)

Index Terms

2019 Novel Coronavirus; 2019-nCoV; Antigen Test for COVID-19; COVID-19 Antigen; COVID-19 Antigen Test; COVID-19 Direct Detection; COVID-19 Rapid Antigen Testing; nCoV, 2019; Novel Coronavirus, 2019; Qualitative COVID-19; SARS-CoV-2; SARS-CoV-2 Antigen Test; Severe Acute Respiratory Syndrome Coronavirus 2; Wuhan

Applies to

BD Veritor System for Rapid Detection of SARS-CoV-2, Becton, Dickinson; BinaxNOW COVID-19 Ag 2 Card, Abbott; BinaxNOW COVID-19 Ag Card 2 Home Test, Abbott; BinaxNOW COVID-19 Ag Card Home Test, Abbott; BinaxNOW COVID-19 Ag Card, Abbott; BinaxNOW COVID-19 Antigen Self Test, Abbott; CareStart COVID-19 Antigen test, Access Bio, Inc; Clip COVID Rapid Antigen Test, Luminostics, Inc.; Ellume COVID-19 Home Test, Ellume; LIAISON SARS-CoV-2 Ag, DiaSorin, Inc; LumiraDx SARS-CoV-2 Ag Test, LumiraDx UK Ltd.; Pandemic; Pneumonia of Unknown Etiology; QuickVue At-Home COVID-19 Test, Quidel; QuickVue At-Home OTC COVID-19 Test, Quidel; QuickVue SARS Antigen Test, Quidel; Sampinute COVID-19 Antigen MIA, Celltrion; Simoa SARS-CoV-2 N Protein Antigen Test. Quanterix Corporation; Sofia SARS Antigen FIA, Quidel; VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack, Ortho

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