Coronavirus Disease (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. 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 2020b). 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) Neutralization Antibody, Serum or Plasma
- Coronavirus Disease (COVID-19), PCR, 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, Huber 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 Pandemic Planning 2020d). Currently, there is no vaccine or specific treatment; care is supportive.

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. These assays are authorized for use by trained laboratory personnel and individuals trained in point of care (POC) settings.

Recently FDA EUAs have been issued for at home tests including a prescription-only test that can be self-collected and performed at home (FDA, BinaxNOW Home 2020a) and an over-the-counter, nonprescription home test for individuals ≥2 years of age (nasal mid-turbinate swab collection) (FDA, Ellume 2020d).

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, this type of assay is useful for quick diagnosis of symptomatic patients. SARS-CoV-2 antigen testing has also been used in screening of select asymptomatic patients.

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.

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

For use by health care providers or individuals trained in point-of-care settings:

- Quidel Sofia® SARS Antigen FIA: Qualitative detection of the nucleocapsid protein antigen from SARS-CoV and SARS-CoV-2 in nasopharyngeal (NP) or nasal swab (NS) specimens directly, within first five days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses. Additional testing needed for differentiation of specific coronaviruses and strains (Sofia July 2020).
- BD Veritor™ System: Qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swabs (NS) directly, within first five days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV-2 (Veritor™ 2020).
- LumiraDx™ SARS-CoV-2 Ag Test: Qualitative detection of the nucleocapsid protein antigen from SARS-CoV and SARS-CoV-2 directly in nasal swab (NS) specimen within 12 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses (LumiraDx™ 2020).
- Abbott BinaxNOW™ COVID-19 Ag CARD: Qualitative detection of the nucleocapsid protein antigen from SARS-CoV and SARS-CoV-2 directly from nasal swab (NS) specimen within 7 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses. Additional testing needed for differentiation of specific coronaviruses and strains (BinaxNOW™ 2020).
- Access Bio CareStart™ COVID-19 Antigen: Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimen directly or in transport media within 5 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV-2. Additional testing needed for differentiation of specific coronaviruses and strains (CareStart 2020).
- Celltrion USA Sampinute™ COVID-19: Qualitative detection of receptor binding domains (RBDs) spike proteins from SARS-CoV-2 in nasopharyngeal (NP) swab specimen directly or in transport media within 5 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV-2. Additional testing needed for differentiation of specific coronaviruses and strains (FDA Celltrion 2020c).
- Luminostics, Inc. Clip COVID Rapid Antigen Test: Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab (NS) specimens within 5 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses. Additional testing needed for differentiation of specific coronaviruses and strains (FDA Luminostics 2020e).
- Quidel QuickVue SARS Antigen Test: Qualitative detection of SARS-CoV-2 nucleocapsid antigen directly from anterior nares nasal swab (NS) within 5 days of symptom onset. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses. Additional testing needed for differentiation of specific coronaviruses and strains (FDA Quidel QuickVue 2020f).

For at-home or POC use:

- Abbott BinaxNOW™ COVID-19 Ag Card Home Test: Qualitative detection of SARS-CoV-2 nucleocapsid antigen directly from nasal swab (NS) specimens in individuals ≥4 years of age within 7 days of symptom onset. This home test is to be performed only with the supervision of a telehealth proctor. **Note:** This assay detects both viable (live) and nonviable SARS-CoV and SARS-CoV-2. It does **not** differentiate between the two viruses (FDA Abbott BinaxNOW Home 2020a).
- Ellume COVID-19 Home Test: Qualitative detection of SARS-CoV-2 nucleocapsid antigen directly from mid-turbinate nasal swabs in individuals ≥2 years of age. Intended for use in individuals with or without symptoms (FDA Ellume 2020d).

Specimen

Nasopharyngeal swab, nasal swab, or mid-turbinate nasal swab tested directly or placed in viral transport media (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

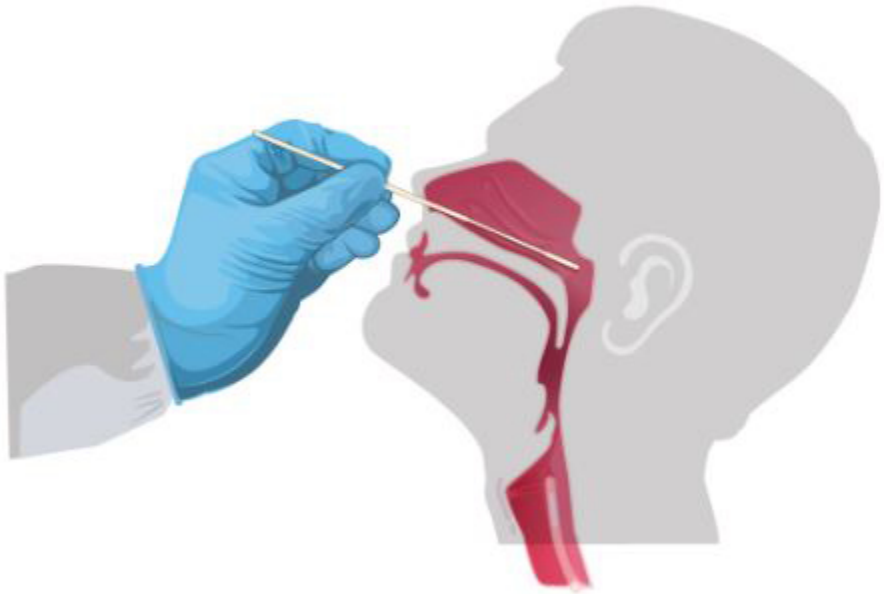
Collection

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 prelabeled. 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 2020g

- **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

Quidel Sofia and Sofia®2: Lateral Flow Immunofluorescent Assay for the detection of SARS-CoV and SARS-CoV-2. This methodology does not differentiate between the two viruses.

BD Veritor™: Chromatographic Digital Immunoassay for the detection of SARS-CoV-2

LumiraDx™ Ag: Microfluidic Immunofluorescence Assay for the detection of SARS-CoV and SARS-CoV-2. This methodology does not differentiate between the two viruses.

Abbott BinaxNOW™: Lateral flow immunoassay for detection of SARS-CoV and SARS-CoV-2.This methodology does not differentiate between the two viruses.

Access Bio CareStart™: Lateral flow immunochromatographic assay for qualitative detection of SARS-CoV-2

Celltrion USA Sampinute™ COVID-19: Magnetic electrochemical sandwich immunoassay (MESIA)

Luminostics, Inc. Clip COVID: Lateral flow luminescence immunoassay

Ellume COVID-19 Home Test: Lateral flow immunoassay

Abbott BinaxNOW™ COVID-19 Ag Card Home Test: Lateral flow immunoassay

Quidel QuickVue: Lateral flow immunoassay

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. All positives must be reported to local/state health departments.
- A negative result should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management, including infection control (Sofia® 2020; Veritor™ 2020). 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 occurs. 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).

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 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). Warmer temperatures and exposure to sunlight reduces viral survival time (CDC 2020e).
- 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 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

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; 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

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

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