

COVID-19 Antibody (IgG), Serum, Plasma, or Whole Blood (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 May 2021 the FDA released a statement that SARS-CoV-2 antibody testing should be used only for identifying individuals who have developed an adaptive immune response due to exposure to the virus. At this time antibody testing **should not be used to determine immunity or protection against the virus, including vaccine-induced antibody response** ([FDA Advises 2021](#)).

Related Information

- [COVID-19 Antibody \(IgG\), Quantitative, Serum or Plasma](#)
- [COVID-19 Antibody \(IgG\), Semi-quantitative, Serum or Plasma](#)
- [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 Antigen, Upper Respiratory Specimen](#)
- [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 situation rept 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 rept 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 molecular nucleic acid acid amplification tests (NAAT) have become the current gold standard method for diagnosis of SARS-CoV-2 infection (see [COVID-19, PCR, Respiratory Specimen](#)), there is also a need for serologic/antibody assays to assist in identifying infected patients, asymptomatic carriers, and exposed individuals, thus assuring timely treatment of patients, helping to prevent virus transmission, and determining depth of population exposure. The FDA has issued several Emergency Use Authorizations (EUA) for the qualitative detection of IgG antibodies to SARS-CoV-2. These IgG assays are intended for detecting individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The FDA recently issued an EUA for the first COVID-19 self-collected at-home serology test. It is a prescription-required ELISA assay for the qualitative detection of IgG antibodies to SAR-CoV-2 in a fingerstick dried blood spot sample. The kit is shipped directly to patient's home and the collected specimen is sent to Symbiotica, Inc. laboratory for analysis (Symbiotica 2021).

Use/Indications

Aid in the identification of individuals who have been exposed and/or recovered from SARS-CoV-2 infection by identifying an immune response. IgG assays should **not** be used to diagnose acute SARS-CoV-2 infection. It is recommended to use a viral (nucleic acid or antigen) test to diagnose acute infection ([CDC Overview of Testing 2021](#)).

- Support diagnosis of COVID-19 illness for patients who present later in infection (≥ 7 days). Serologic testing should be offered in addition to recommended molecular testing ([CDC Interim Guidelines 2021](#)). During this time period, the sensitivity of nucleic acid detection is decreasing, and the sensitivity of serologic testing is increasing.
 - A positive antibody test in a symptomatic patient (with negative viral test) at least 7 days post symptom onset. The CDC recommends proof of seroconversion (ie, two

antibody tests, a negative result on initial specimen converting to a positive result on second specimen).

- Assessment of multisystem inflammatory syndrome (in both children and adults) and other post-acute sequelae of COVID-19 illness ([CDC Interim Guidelines 2021](#); [IDSA \[Hanson 2020\]](#)).
- Serosurveillance studies to estimate prevalence of infection (or vaccination) in a community ([CDC Interim Guidelines 2021](#); [IDSA \[Hanson 2020\]](#)).

IgG and IgM antibodies rise (almost) simultaneously and are detectable 1 to 3 weeks post symptom onset. IgG antibodies persist longer than other antibodies. As the time between infection and antibody testing increases, assays that measure IgG and total antibody may have more sensitivity. The [IDSA \[Hanson 2020\]](#) recommends IgG antibody testing when repeated molecular testing is negative in symptomatic patients with high clinical suspicion (IgG testing 3 to 4 weeks post symptom onset maximizes sensitivity and specificity for detection of past infection). When laboratory confirmation is needed for clinical or epidemiological purposes, the [IDSA \[Hanson 2020\]](#) recommends IgG antibody or total antibody 3 to 4 weeks after symptom onset to detect evidence of past SARS-CoV-2 infection. In children with multisystem inflammatory syndrome, the [IDSA \[Hanson 2020\]](#) recommends both IgG antibody and NAAT to provide evidence of current or past infection.

Test Includes

Qualitative detection of IgG antibodies to SARS-CoV-2

Contraindications

Although some individuals (23% to 63%) will develop antibodies within the first week of symptom onset, the IDSA recommends **against** serologic testing during the first two weeks (14 days) following symptom onset due to variable sensitivities and specificities of available assays (IDSA [Hanson 2020]).

Assessing immunity to COVID-19 following vaccination or assessing the need for vaccination in an unvaccinated person via antibody testing in **not** currently recommend ([CDC Interim Guidelines 2021](#)).

Test should **not** be used for screening of donated blood for the purpose of preventing COVID-19 transmission.

Specimen

Serum, plasma, whole blood (venous or fingerstick), dried blood spot (DBS) (manufacturer dependent)

Container(s)

- Confer with testing laboratory for proper specimen container and collection.
- Dried blood spot card
- Green top (sodium or lithium) heparin tube
- Lavender top (EDTA) tube
- Serum separator tube or red top (no additive) tube

- Use items provided by manufacturer for fingerstick procedures.

Alternate Container(s)

- Confer with testing laboratory for appropriate alternate container(s).
- Light blue top (sodium citrate) tube
- Yellow top (ACD) tube

Volume / Minimum Volume

Tube filled to capacity or 1 mL blood (0.5 mL serum or plasma); follow manufacturer's instructions for fingerstick volume

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.

Routine venipuncture, using appropriate personal protective equipment; transport to laboratory immediately. Although SARS-CoV-2 antibodies can be detected in some individuals within the first week of illness, both IgM and IgG antibodies most commonly rise (almost) simultaneously within 2 to 3 weeks post symptom onset. The IDSA [Hanson 2020] recommends against testing prior to 14 days of symptoms, however; different assays have different recommended collection windows. Refer to manufacturer instructions for collection timing.

Processing and Storage

- Allow red top (no additive) tube to clot completely at room temperature. Centrifuge clotted or anticoagulated specimen within 1 hour of collection and transfer serum or plasma into clean, plastic vial and refrigerate or freeze.
- Refer to testing laboratory.

Stability

Fingerstick whole blood specimen should be tested immediately.

Venous whole blood is stable refrigerated; see manufacturers recommendations.

Serum or plasma:

- Room temperature: 4-48 hours (manufacturer dependent)
- Refrigerated: 2-7 days (manufacturer dependent)
- Frozen: 1-12 months (manufacturer dependent)

Causes for Rejection

Gross hemolysis, gross lipemia, gross icterus, presence of particulate matter, microbial contamination

Methodology

Lateral flow (LF); Chemiluminescent Immunoassay (CIA or CLIA); Chemiluminescent Microparticle Immunoassay (CMIA); Enzyme-Linked Immunosorbent Assay (ELISA); Fluorescent Microsphere Immunoassay (FMIA); Enzyme Linked Fluorescent Assay (ELFA)

Normal Values/Findings

Negative or nonreactive

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

Interpretative Information

Results from antibody testing should not be used as the sole basis to diagnose or rule out SARS-CoV-2 infection. Results should be used in conjunction with other data including symptoms, results of other tests, and clinical impression.

- A positive test indicates detection of IgG antibodies to SARS-CoV-2 and is consistent with a recent or previous infection with SARS-CoV-2.
 - See Additional Information (below) for interpretation of antibody test for vaccine recipients.
- A negative result suggests absence of detectable IgG antibodies to SARS-CoV-2, however, this does not preclude SARS-CoV-2 infection and should not be the sole basis for patient management decisions. A negative result can occur if antibody level is below the assay limit of detection, or if antibodies are not present during disease stage in which the sample was collected (eg, too early in the infection cycle [prior to IgG seroconversion] or due to a decline in titer over time). For patients who have been in contact with known infected individuals, have been in areas with high prevalence of active infection, or are experiencing symptoms consistent with COVID-19, a molecular diagnostic test is necessary to rule out infection.
- It is important to note, as very little is known about protective immunity of SARS-CoV-2 antibodies, serology results should **not** be used to establish immunity, make staffing decisions or decisions regarding the need for personal protective equipment.

Limitations

- Immunocompromised patients may have a delayed antibody response to COVID-19 and produce levels of antibody which may be below the detection level of IgG assay.
- In patients tested too early during infection or prior to appearance of IgG antibodies, levels may be below level of detection despite active infection, thus yielding false-negative results.
- The presence of rheumatoid factor, HIV antibodies, HSV antibodies, or heterophilic antibodies in patient specimen can interfere with immunoassay.

- Patients who have received preparations of mouse monoclonal antibodies (for a diagnosis or a therapy) may have human anti-mouse antibodies (HAMA) which can interfere with immunoassays that employ mouse monoclonal antibodies.
- False-positive results due to cross-reactivity may occur with other coronaviruses (HKU1, NL63, OC43, or 229E).
- False-positive results due to cross-reactivity may occur with SAR-CoV-1 antibodies (EUROIMMUN 2020).
- Presence of biotin may interfere with immunoassay (LIAISON 2020).
- Individual immune response to SARS-CoV-2 can vary and different assays may provide different results. Values or results obtained cannot be used interchangeably with values obtained with different manufacturers' test methods.
- IgG antibodies to SARS-CoV-2 can persist for months. When serologic tests are used to support a diagnosis of recent COVID-19 illness, a single positive antibody test result may reflect previous SARS-CoV-2 infection rather than a recent illness.

Diagnostic Role

Current antibody testing can help identify patients who previously had SARS-CoV-2 infection as well as patients with current infection who have had symptoms for several days to weeks. However, due to variability in detectable antibody levels in early stage disease, there is limited utility for diagnosis of acute infection with antibody testing.

Thus far, serologic correlates of protective immunity are not fully understood, but current evidence indicates that production of antibodies following SARS-CoV-2 infection confers some portion of immunity to reinfection for at least three to six months ([CDC Interim Guidelines 2021](#); Lumley 2021; Hall 2020). The robustness and durability of natural-infection immunity, how it compares to vaccine-induced immunity, and the impact of emerging viral variants are currently unknown and under study.

Because SARS-CoV-2 infection can be asymptomatic or minimally symptomatic, the official tally of actual infections is probably substantially underestimated. Large-scale serologic screening with validated tests may be able to provide a better measure of disease activity.

Laboratory/Diagnostic Pearls

- Antibodies to SARS-CoV-2, typically detected 1 to 3 weeks post symptom onset, have been reported in patients with mild and severe disease. The antibody response is more robust (higher titers and longer persistence) in those with severe disease (Rijkers 2020). How long the antibodies persist after infection is unknown but they appear to persist for several months in most (Dan 2021).
- 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 Environment 2020](#)).

Additional Information

The major antigenic targets of SARS-CoV-2 virus that induce antibody response are:

1. Spike glycoprotein (S) which is responsible for receptor binding and membrane fusion for viral entry into the host cell. Spike protein includes two regions S1 and S2. S1 contains a receptor-binding domain (RBD) that binds to the receptor angiotensin-converting enzyme 2 (ACE2) on host cells, and S2 facilitates viral fusion and entry (Huang 2020).
2. Nucleocapsid phosphoprotein (N) is an abundantly-produced immunodominant antigen (or protein) that takes part in the formation of viral structure and packaging of the viral genome, regulates viral RNA synthesis in replication/transcription, and modulates infected cell metabolism. ([CDC Interim Guidelines 2021](#); Kang 2020; Chang 2020).

Different serologic assays detect antibodies specific for various antigenic targets (N, S, or RBD), single or in combination. Current vaccines are focused on initiating antibody response against the spike (S) protein. Although current EUA tests have not been authorized to assess vaccine response, indications for these tests do not preclude using these tests on persons who have been vaccinated. Interpretation is below ([CDC, Interim Guidelines 2021](#)):

- Patient never vaccinated for SARS-CoV-2:
 - A positive test for antibody against N, S, or RBD indicates prior natural infection.
- Vaccinated patient:
 - A positive test for antibody against the vaccine target antigen (S), and negative for all other antigens, suggests vaccine-induced antibody (patient was never infected with SARS-CoV-2).
 - A positive test for any antibody other than vaccine-induced antibody, such as N protein, indicates resolving or past SARS-CoV-2 infection that could have occurred before or after vaccination.

Regardless of vaccination status, the presence of N protein antibodies is indicative of natural infection; the presence of S protein antibodies indicates either natural infection or vaccination. The presence of S protein antibodies with the absence of N protein antibodies is indicative of vaccination or could also indicate natural infection where N antibodies have declined.

If a serologic test to identify prior infection is performed in an individual who has received a spike protein COVID-19 vaccine, a test that detects antibodies to antigens other than the spike protein should be used.

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

See: [Interim Guidelines for COVID-19 Antibody Testing](#)

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

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

Betacoronavirus; COVID Antibody Test; COVID-19 Antibody IgG; IgG Antibody to SARS-CoV-2; SARS-CoV-2 Antibody, IgG; SARS-CoV-2 IgG

Applies to

Pandemic; Pneumonia of Unknown Etiology

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