

## Coronavirus Disease (COVID-19) Antibody, IgG/IgM Rapid Test, Whole Blood, Serum, or Plasma (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](#)). 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:** On June 16, 2020, the FDA revoked the EUA for Chembio Diagnostic Systems, Inc.'s DPP Covid-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2 ([FDA Revoked Chembio EUA 2020](#)).

**Note:** On August 6, 2020, the FDA revoked the EUA for Autobio Diagnostics Anti-SARS-CoV-2 Rapid Test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 ([FDA Revoked Autobio EUA 2020](#)).

### Related Information

- [Coronavirus Disease \(COVID-19\) Antibody \(IgG\) Serum or Plasma](#)
- [Coronavirus Disease \(COVID-19\) Antibody Total 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, Respiratory Specimen](#)
- [Coronavirus Disease \(COVID-19\), PCR, Saliva](#)
- [Influenza and SARS-CoV-2 Antigen, Upper Respiratory Specimen](#)
- [Influenza SARS-CoV-2 Multiplex Assay, PCR, 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 93 million infections have been confirmed globally in over 200 countries and territories with over 2 million deaths ([WHO situation report 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 (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 situation rept 2021](#)). 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](#)).

Although molecular nucleic acid polymerase chain reaction tests 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 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 Emergency Use Authorizations (EUA) for several IgG/IgM rapid assays. These tests are authorized for the qualitative detection of IgG and/or IgM antibodies against SARS-CoV-2. See FDA [EUA](#).

EUAs have also been issued for IgG only assays, IgM only assays, and total IgG and IgM antibodies. See FDA [EUA](#).

#### 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/IgM 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 2020 Overview of Testing](#)).

- Support diagnosis of acute COVID-19 illness for patients who present later in infection (9 to 14 days post symptom onset). Serologic testing should be offered in addition to recommended molecular testing ([CDC Interim Guidelines 2020](#)). During this time period, the sensitivity of nucleic acid detection is decreasing, and the sensitivity of serologic testing is increasing.
- Assessment of multisystem inflammatory syndrome in children ([CDC Interim Guidelines 2020](#); [IDSA 2020](#)).
- Serosurveillance studies ([IDSA 2020](#)).

Currently, there is no identified advantage of assays whether they test for IgG, IgM and IgG, or total antibody ([CDC 2020 Antibody Testing](#)), however, the [IDSA](#) recommends against IgM or IgG combination tests to detect evidence of past SARS-CoV-2 infection.

#### Test Includes

Qualitative detection and differentiation of IgM and/or IgG antibodies to SARS-CoV-2 virus

#### Contraindications

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

#### Specimen

Serum, plasma, venous whole blood, fingerstick dried blood spot (method dependent), fingerstick whole blood (point of care)

#### Container(s)

- Confer with testing laboratory for proper specimen container and collection.
- Red top (no additive) tube or lavender top (EDTA) tube
- Use items provided by manufacturer for fingerstick procedures.

#### Alternate Container(s)

- Confer with testing laboratory for appropriate alternate container(s).
- Green top (lithium heparin) tube
- Green top (sodium heparin) tube
- Light blue top (sodium citrate) tube

#### Volume / Minimum Volume

Tube filled to capacity or 1 mL whole blood or 0.5 mL serum or 0.5 mL plasma

#### 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. Specimen should be tested as soon as possible after collection.

#### 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.
- Refer to manufacturer instructions.
- Whole blood: Refrigerate

#### Stability

### Serum or plasma

- Room temperature: Unacceptable
- Refrigerated: 24-72 hours (manufacturer dependent)
- Frozen (-20°C): For longer storage; stability not established

### Whole blood

- Room temperature: Unacceptable
- Refrigerated: 24 hours
- Frozen: Unacceptable
- Dried blood spot specimen has been proven stable through standard shipping requirements (Vibrant 2020).
- Fingerstick whole blood point of care assay must be performed immediately upon specimen collection.

### Causes for Rejection

Gross hemolysis, gross lipemia, turbidity; fingerstick whole blood specimen

### Methodology

Lateral Flow Chromatographic Immunoassay; Chemiluminescence Immunoassay (CLIA)

### 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. A positive test indicates detection of antibodies to SARS-CoV-2 and patient has been exposed to the virus.

- IgM presence is consistent with acute or recent SARS-CoV-2 virus infection.
- IgG presence is consistent with a recent or previous infection with SARS-CoV-2 infection.
- IgM and IgG presence is consistent with current or recent SARS-CoV-2 infection.
- A positive result may not indicate previous infection with SARS-CoV-2 virus as false positives may occur due to cross-reactivity from pre-existing antibodies or other causes. It is recommended that samples with positive test results be confirmed with alternative testing method(s); clinical history and local disease prevalence should be considered when determining the need for an alternative serology test.

- A negative result does not rule out SARS-CoV-2 infection; 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

- In patients tested too early during infection, antibody levels may be below level of detection despite active infection, thus yielding false-negative results.
- Not all patients will develop detectable antibody (IgM or IgG) levels to SARS-CoV-2 infection. Immunocompromised patients may have a delayed antibody response to COVID-19 and produce levels of antibody which may be below the detection level of assay.
- Viral amino acid mutations in the epitope recognized by the antibody utilized in the test can cause false negative results (Cellex 2020).
- IgM/IgG assays have been noted as having poor specificity of IgM antibodies (IDSA 2020).
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

#### Diagnostic Role

Understanding the antibody response to SARS-CoV-2 is still in the early stages and clinical utility is not completely established. When more information is acquired, the potential of serology testing may include:

- Testing of PCR-negative cases when patient presents late and the viral load has decreased; or when lower respiratory tract sampling is not possible
- Identification of convalescent plasma donors
- Studies of community disease prevalence
- Possible verification of vaccine response (IDSA Ab Testing Primer 2020)

Note: At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

#### 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.

- Although more information is needed to determine a definite seroconversion window, in a study of 173 Chinese patients, the median seroconversion time for IgM and IgG antibodies, after symptom onset, was 12 days and 14 days respectively (Zhao 2020). In the first week after symptom onset, fewer than 40 percent had detectable antibodies; by day 15, IgM and IgG were detectable in 94 and 80 percent, respectively. **Note:** The CDC is currently reporting 1 to 3 weeks after symptoms appear for detection of SARS-CoV-2 antibodies (CDC, Serology 2020). Further information/studies are needed for a firm seroconversion window.
- Antibodies to SARS-CoV-2 are unusual in that IgM and IgG antibodies rise almost simultaneously within 2 to 3 weeks after symptom onset. The detection of IgM without IgG is uncommon ([CDC 2020 Antibody Testing](#)).
- 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).

#### 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.
2. Nucleocapsid phosphoprotein (N), an immunodominant antigen (or protein) of the CoV family that interacts with RNA.

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: [Information for Laboratories](#)

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

See: [For Healthcare Professionals](#)

See: FDA [Emergency Use Authorizations](#)

#### Index Terms

COVID Antibody Test; COVID-19 Antibody Test; COVID-19 Rapid Antibody Test; qSARS-CoV IgG/IgM Rapid Test; Rapid Antibody Test, COVID-19

Applies to

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

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