

## 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](#)). Any concerns regarding fraudulent products, including tests, should be sent to: [FDA-COVID-19-Fraudulent-Products@fda.hhs.gov](mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov).

**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 \(COVID-19\), 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, 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 rept 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.

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).
- Fingertick whole blood point of care assay must be performed immediately upon specimen collection.

#### Causes for Rejection

Gross hemolysis, gross lipemia, turbidity; fingertick 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: [COVID-19 Testing and Reporting by Laboratories: Q & A](#)

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

#### References

Anti-SARS-CoV-2 Rapid Test, by Autobio [product information]. Santa Maria, CA; Hardy Diagnostics: 2020.

Assure COVID-19 IgG/IgM Rapid Test Device, by Assure Tech [product information]. Houston, TX: 2020.

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. [\[PubMed 32673296\]](#)

Cellex qSARS-CoV-2 IgG/IgM Rapid Test [product information]. Research Triangle Park, NC: Cellex, Inc; March 2020.

Centers for Disease Control and Prevention (CDC). 2020 Novel Coronavirus. Evaluating and reporting persons under investigation (PUI). <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>. Updated May 5, 2020. Accessed May 6, 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 June 13, 2020. Accessed June 15, 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). 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). 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 February 11, 2020.

Centers for Disease Control and Prevention (CDC). Interim Guidelines for COVID-19 Antibody Testing. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>. Updated August, 2020. Accessed August 24, 2020.

Centers for Disease Control and Prevention (CDC). Serology Testing for COVID-19. <https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html>. Accessed May 4, 2020.

DPP COVID-19 IgM/IgG System [product information]. Medford, NY: Chembio Diagnostic Systems, Inc; April 2, 2020.

Infectious Diseases Society of America (IDSA). COVID-19 Prioritization of Diagnostic Testing. <https://www.idsociety.org/globalassets/idsa/public-health/covid-19-prioritization-of-dx-testing.pdf>. Updated March 17, 2020. Accessed March 24, 2020.

Infectious Diseases Society of America (IDSA). IDSA COVID-19 Antibody Testing Primer. <https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf>. Updated May 4, 2020. Accessed May 6, 2020.

Infectious Diseases Society of America (IDSA). IDSA Guidelines on the Diagnosis of COVID-19: Serologic Testing. <https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/>. Published August 18, 2020. Accessed September 14, 2020.

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*. [\[PubMed 31995857\]](#)

Li Z, Yi Y, Luo X, et al. Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis [published online February 27, 2020]. *J Med Virol*. [\[PubMed 32104917\]](#)

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. [\[PubMed 32027631\]](#)

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

Sienna™-Clarity COVIBLOCK™. COVID-19 IgG/IgM Rapid Test Cassette [product information]. Boca Raton, Florida: Clarity Diagnostics; July 13, 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](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). Chembio Diagnostic Systems [EUA revocation letter]. <https://www.fda.gov/media/139109/download>. Published June 16, 2020. Accessed June 23, 2020.

US Food & Drug Administration (FDA). EUA Revocation for Autobio Diagnostics Co. Ltd.'s Anti-SARS-CoV-2 Rapid Test (EUA200349). <https://www.fda.gov/media/140908/download>. Published August 6, 2020. Accessed August 11, 2020.

US Food & Drug Administration (FDA). qSARS-CoV-2 IgG/IgM Rapid Test [Letter of Authorization]. <https://www.fda.gov/media/136622/download>. Published April 1, 2020. Accessed April 1, 2020.

US Food & Drug Administration (FDA). Vibrant COVID-19 Antibody Assay [EUA Summary]. <https://www.fda.gov/media/138626/download>. Published June 4, 2020. Accessed June 8 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* January 29, 2020]. *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.

Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019 [published online ahead of print, 2020 Mar 28]. *Clin Infect Dis*. 2020;[[PubMed 32221519](#)]

Last Updated 10/26/20



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