



# Medical Coverage Policy

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## COVID-19: In Vitro Diagnostic Testing

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### Overview

This Coverage Policy addresses in vitro diagnostic testing methods to detect the presence of, or suspected exposure to the SARS-CoV-2 virus which causes COVID-19 infection. Molecular tests and antigen tests are considered diagnostic of an active infection with the SARS-CoV-2 virus. In general, antibody (serology) tests are not diagnostic; rather, they are used to identify individuals who have developed antibodies against the SARS-CoV-2 virus and may be used for public health purposes such as population prevalence estimates. The Coverage Policy applies to both individual and pooled testing methods.

### Coverage Policy

#### Medically Necessary

A molecular or antigen in vitro diagnostic test is considered medically necessary if the following criteria are met:

- ALL of the following:
  - recommended by a health care provider

- FDA approved or cleared or Emergency Use Authorization (EUA)
- performed by a CLIA-accredited high or medium-complexity or CLIA-waived laboratory (per test Instructions for Use)

**For EITHER of the following:**

- Symptomatic individual, suspected of having COVID-19 due to ANY of the following:
  - cough
  - shortness of breath or difficulty breathing
  - fever
  - chills
  - repeated shaking with chills
  - headache
  - sore throat
  - new loss of taste or smell
  - congestion or runny nose
  - fatigue
  - persistent pain or pressure in the chest
  - body aches or muscle pain
  - diarrhea
  - nausea
  - new confusion
  - inability to wake or stay awake
  - bluish lips or face
  - suspected multisymptom inflammatory syndrome in children (MIS-C)
  
- Asymptomatic individual with ANY of the following:
  - known or suspected to have been exposed to an individual with a laboratory-confirmed case of COVID-19
  - prior to elective admission to or procedure at a healthcare facility in a community with a high prevalence of COVID-19
  - prior to elective admission of an immunocompromised individual
  - prior to an immunosuppressive procedure (e.g., cytotoxic chemotherapy, solid organ or stem cell transplantation, long acting biologic therapy, cellular immunotherapy, or high-dose corticosteroids)
  - prior to a time-sensitive elective aerosol-generating procedure (e.g., bronchoscopy)

**An antibody (serology) test for SARS-CoV-2 antibodies is considered medically when ALL of the following criteria are met:**

- recommended by a health care provider
- FDA approved or cleared or Emergency Use Authorization (EUA)
- performed by a CLIA-accredited high or medium-complexity laboratory (per test Instructions for Use)
- when results of a molecular or antigen test is non diagnostic for COVID-19 and the results of the test will be used to aid in the diagnosis of a symptomatic individual (e.g., Multisystem Inflammatory Syndrome in Children [MIS-C]).

## **Not Medically Necessary**

**Molecular, antigen or antibody (serology) testing is considered not medically necessary for any indication other than the ones listed above.**

## Not Covered

**A high-throughput molecular or antigen in vitro diagnostic test for the diagnosis of COVID-19 infection will not be covered unless billed by a CLIA-accredited high-complexity laboratory.**

**Under most benefit plans, in vitro testing is not covered for population or public health screening including but not limited to, the following indications:**

- determine prevalence of COVID-19 infection in the community or congregate setting
- return-to-work
- return-to-school
- participation in sports
- routine and/or executive physicals
- travel

**Over-the-Counter (OTC) tests for the diagnosis of COVID-19 infection are not covered.**

## General Background

COVID-19 is the infectious disease caused by the coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus is highly contagious and is believed to be spread from person to person through respiratory droplets or when aerosol is produced as an infected person coughs or sneezes. Symptoms of COVID-19 infection are fever, cough and shortness of breath, persistent pain or pressure in chest, confusion, inability to wake or stay awake, cyanosis of the lips or face, fatigue, body aches or muscle pain, sore throat, new loss of taste or smell, diarrhea and nausea (Centers for Disease Control and Prevention ([CDC], 2020; Infectious Disease Society of America [IDSA], 2020). These symptoms typically appear 2–14 days after exposure. Symptoms can progress rapidly to severe respiratory distress requiring hospitalization, culminating in death.

### Prevalence

Prevalence of disease is a measure of risk and is the proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period of time. It is used to characterize the occurrence of health events in a population and as a measure of public health impact of disease (CDC, 2020). According to IDSA (2020), seroprevalence data will be important in understanding the scale of the pandemic and future vaccine utility.

Positive and negative predictive values of a test are affected by prevalence. In a high-prevalence setting, the positive predictive value increases (i.e., more likely that persons who test positive are truly positive). When a test is used in a population with low-prevalence the positive predictive value is decreased (i.e., there are more false positives). Likewise, negative predictive value is also affected by prevalence. In a high-prevalence setting, the negative predictive value declines whereas in a low-prevalence setting, it increases (CDC, 2020).

At this time there is no national reference standard for the prevalence rate of COVID-19; rather, it is based on complex mathematical modeling (CDC, 2020). The Infectious Disease Society of America ([IDSA], 2020) notes that low prevalence of COVID-19 corresponds to <2% prevalence of SARS-CoV-2 antibodies within a community. High prevalence corresponds a prevalence of ≥10%. The CDC (2020) notes that prevalence of SARS-CoV-2 antibody in the US is expected to be low, ranging from <5% to 25%, so that testing might result in relatively more false-positive results and fewer false negative results.

### Testing

To control the spread of this disease, it is imperative to test for and diagnose those who have been infected with COVID-19. In vitro diagnostic devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or finger stick (US Food and Drug Administration [FDA], 2020).

Generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends (CDC, 2020).

Diagnostic testing errors can result in false positives and/or false negatives that stem from improper sample collection, testing procedural errors, and variability in assay performance (sensitivity/specificity). The performance of tests is described by their analytical and clinical sensitivity, specificity, and positive and negative predictive values. Analytical sensitivity is the assay's ability to detect the minimum concentration of a substance in a sample while clinical sensitivity measures how accurately a test identifies positive patients who are infected. Analytical specificity refers to the ability to detect only the desired analyte in a specimen without cross reacting with other substances, while clinical specificity determines how accurately a test identifies negative patients who do not have COVID-19. A test with lower sensitivity test means higher false negative results, while lower specificity means higher false positive results. A test with good analytical sensitivity and specificity does not necessarily correlate with clinical sensitivity and specificity (Chau et al., 2020). Regarding antibody (serology) testing positive predictive and negative values describe how likely it is that a person who receives a positive result from a test truly does have antibodies to SARS-CoV-2 and how likely it is that a person who receives a negative result from a test truly does not have antibodies to SARS-CoV-2 (FDA, 2020).

Multiple methods are used in formation and processing of molecular, antigen and antibody tests, including the use of different probes and reagents and interpretation and reporting standards. The FDA has established minimum validation standards for these tests, which are authorized under the Emergency Use Authorization (EUA) designation.

Two types of tests are used for the diagnosis of COVID-19 infection: molecular and antigen tests. These tests detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. Molecular tests are not useful in distinguishing between highly infective viruses versus ones that have been neutralized by the host, and it cannot assess immunity status against SARS-CoV-2 antibody. Antibody (serology) tests cannot be used to diagnose a current infection (CDC, 2020; FDA, 2020).

For the purpose of this Coverage Policy, molecular, antigen and antibody (serology) testing for the diagnosis of SARS-CoV-2 is informed by authoritative statements by the FDA, CDC and published professional society recommendations (e.g., IDSA, 2020).

### **Molecular Testing**

Molecular tests using nucleic acid amplification methodologies are most commonly used to determine the presence or absence of SARS-CoV-2 virus and to make a diagnosis of active infection. Molecular testing involves the in vitro qualitative detection of ribonucleic acid (RNA) from the SARS-CoV-2 virus. Analytical validity of the test is highly accurate in controlled laboratory conditions. It can identify and quantify the presence of infectious agents in a sample through the process of detection, amplification, and output measurement. Performance has been validated for use in symptomatic individuals; however, is unknown in asymptomatic patients (FDA, 2020).

The FDA further notes that clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information (2020).

Understanding the predictive value of molecular testing with regards to time from exposure and symptom onset is important as the assay may not have been appropriately validated against a clinically meaningful reference standard for detecting SARS-CoV-2 in the absence of symptoms, such as during earlier stages of the disease, or in asymptomatic individuals (Chau et al., 2020). Molecular tests have high analytical specificity and sensitivity to detect the presence of the virus. Nonbinding standards from the FDA for

validation of tests recommend analytical sensitivity (limit of detection [LOD]) for the virus of 95%. The LOD is defined as the lowest concentration where at least 19 of 20 viral replicates are positive. Most test developers self-report high performance statistics with their FDA submissions, with reported results ranging from 95-100%.

Testing in asymptomatic individuals or in real-world community samples has not been clinically validated. Results may not be as robust as accuracy will be dependent on when in the course of illness the sample is collected, test performance, collection technique and quality, storage and transport conditions. As an example, if the test has a 95% accuracy in its performance in the lab in detecting the virus, 50,000 individuals would be incorrectly identified as having a negative result in a sample of 1,000,000 test results. The test cannot distinguish between active virus and dead viral fragments, which may result in an incorrect diagnostic interpretation of a positive result.

Sensitivity, specificity, and positive and negative predictive values for each test for which an FDA EUA has been granted are reported in the individual test EUA summary or Instructions for Use and can be accessed on the FDA website at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

Recommendations regarding SARS-CoV-2 testing have been published by the CDC:

- Testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider.
- Viral tests are recommended to diagnose acute infection.
- Testing the same individual more than once in a 24-hour period is not recommended.
- Testing for SARS-CoV-2 is appropriate for individuals with signs or symptoms consistent with COVID-19 and asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2, to control transmission.
- Testing of asymptomatic individuals without known or suspected exposure to SARS-CoV-2 may also be appropriate in special settings for early identification of infection
- Note that except for rare situations, a test-based strategy is no longer recommended to determine when an individual with SARS-CoV-2 infection is no longer infectious (e.g., to discontinue transmission-based precautions or home isolation). Evidence supports a symptom-based strategy (CDC, 2020).

The CDC (2020) also published five populations for which SARS-CoV-2 testing with viral tests (i.e., nucleic acid or antigen tests) is appropriate:

- individuals with signs or symptoms consistent with COVID-19
- asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission
- asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings
- individuals being tested to determine resolution of infection (i.e., test-based strategy to discontinue transmission-based precautions, health care provider return to work and discontinuation of home isolation)
- individuals being tested for purposes of public health surveillance for SARS-CoV-2

The CDC further notes that generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends.

The ISDA (2020) published guidelines regarding testing for COVID-19 infection, including the following:

- SARS-CoV-2 nucleic acid amplification test (NAAT) is recommended in symptomatic individuals in the community suspected of having COVID-19, even when the clinical suspicion for COVID-19 is low.
- SARS-CoV-2 RNA testing is recommended in asymptomatic individuals who are either known or suspected to have been exposed to COVID-19. Known exposure is defined as direct contact with a laboratory confirmed case of COVID-19.
- SARS-CoV-2 RNA testing is recommended in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a low prevalence of COVID-19 in the community. Asymptomatic individuals are defined as those with no symptoms or signs of COVID-19. A low prevalence of COVID-19 in the community is defined by the IDSA as a prevalence of <2%.
- SARS-CoV-2 RNA testing is recommended in asymptomatic individuals with no known contact with COVID-19, who are being hospitalized in areas with a high prevalence of COVID-19 in the community (i.e., hotspots). High prevalence of COVID-19 is defined by the IDSA as a prevalence of ≥10%.

### **Pooled Sample Diagnostic Testing**

Pooled sample testing for the qualitative detection of nucleic acid from the SARS-CoV-2 virus has been proposed as a laboratory method to conserve testing resources. The technique allows upper or lower respiratory samples from several individuals (e.g., 4-5 test samples) to be combined and tested together in a batch. This method may be useful for diagnostic testing in a population where low-prevalence of infection is present. Use in a population with high-prevalence of COVID-19 infection would likely result in the need to perform individual testing to identify the positive sample(s) and result in the consumption of additional testing resources.

There are limitations to pooled testing. In a pooling procedure, the laboratory cannot ensure the diagnostic integrity of an individual specimen because it is combined with other specimens before testing. Specimen integrity can also be affected by the quality of swab specimen collection, which can result in some swabs having limited amounts of viral genetic material for detection. Inadequate individual specimens might not be eliminated from the pooled specimen before testing (CDC, 2020). A decrease in performance is also likely with pooling strategies due to dilution of the primary clinical sample and a decrease in sensitivity may result.

The FDA notes that because samples are diluted there is a greater likelihood of false negative results, particularly if the test is not properly validated (2020). In general, the larger the pool of specimens, the higher the likelihood of generating false negative results (CDC, 2020). These limitations mean that monitoring the prevalence of disease and properly validating the assay for the real world population in which the test is being used is important to limit the potential for false negative results. Negative results from pooled samples should be considered to be presumptive negatives (FDA, 2020).

Although proposed as a method that consumes fewer testing resources, a unique sample collection kit, swab and reagents must be used for each specimen collection regardless of pooling technique used. If the sample is collected by someone other than the individual being tested, personal protective equipment is also required. If the pooled sample is negative, it can be deduced that all individuals tested within the pool have a negative test result and the pooled test result is sufficient. However, if the pooled sample is inconclusive or positive, each sample must be tested individually to determine which sample or samples are positive, resulting in the use of additional testing resources.

### **Antigen Testing**

Antigen testing is subject to the same analytic and clinical performance limitations, such as those described for molecular tests. An antigen test may yield false negatives if the viral protein production is low or if there is not enough virus replication in the sampled area. FDA EUA designated antigen assays report a clinical sensitivity of 80% when compared to an EUA-designated molecular device; a test specificity of 100% is reported. Negative results do not rule out COVID-19.

The FDA (2020) also notes that antigen tests should not be used as the sole basis for treatment or for patient management decisions and should be treated as presumptive and confirmed with a molecular assay if

necessary, for patient management (FDA, 2020). The analytic sensitivity, specificity and positive and negative predictive values of individual tests that have received an FDA EUA designation can also be accessed on the FDA website at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

An antigen test detects fragments of proteins found on or within the SARS-CoV-2 virus (e.g., nucleocapsid protein antigen). The antigen is generally detectable during the acute phase of infection; however, an antigen test may not detect all active infections. Positive results indicate the presence of viral antigens. Samples are collected from areas such as the nasal passage.

Indications for the use of an antigen test to detect SARS-CoV-2 infection in a symptomatic or asymptomatic individual are the same as those described for molecular testing. An advantage of antigen testing is that the methodology lends itself to adaptation in the point of care testing environment and results can be delivered fairly rapidly, often within minutes. While the main advantage of these antigen tests is the speed of the test, they are often plagued with inaccurate results and have lower sensitivity and specificity than nucleic acid assays (Chau et al., 2020). Clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Antigen tests that have received an FDA EUA designation are limited in number.

### **Antibody (Serology) Testing**

Antibody tests detect the body's immune response to the infection caused by the virus rather than detecting the virus itself. The primary role for antibody testing is to inform on exposure to a specific pathogen by detection of the presence of antibodies to a specific virus. Clinical utility for diagnosis has not been established; the relationship between the presence of antibodies and re-infection and or re-activation of the virus is unknown. It is also unclear to what degree the immunologic response persists and continues to be a relevant indicator of the body's immunity. Antibody testing may be used as an aid in diagnosis but is of limited value when COVID-19 infection is suspected because such testing cannot be used to rule in or rule out an active infection. Likewise, a positive test does not necessarily assure immunity.

In humans, three types of antibodies or immunoglobulins have been the target of COVID-19 serological tests: IgM, IgG, and IgA. Although the dynamics of the immune response in COVID-19 are not fully understood, typically IgM antibodies are produced by host immune cells during the early stages of a viral infection. IgG is often the most abundant antibody in the blood and plays a more prominent role in the later stages of infection and in establishing long-term immune memory. Recent studies show that IgA, predominately present in the mucosal tissue, may also play a critical role in immune response and disease progression (CDC, 2020; Ghafferi et al., 2020). Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time that antibodies are present post-infection is not well characterized (FDA, 2020). Asymptomatic patients may seroconvert later in the course of infection or may not at all (Chau et al. 2020).

The FDA notes that a positive antibody test result is difficult to interpret for a number of reasons. For some assays both sensitivity and specificity are poor or undefined in a real-world population. Accuracy of an antibody test depends in part on the prevalence of the infection in the population. The prevalence of SARS-CoV-2 antibody positive individuals in the U.S. population is currently unknown. Prevalence may vary based on the duration of the virus, the effectiveness of mitigations and between locations and different groups of people, due to different rates of infection. In low prevalence populations, such as much of the asymptomatic general population, the result of a single antibody test is not likely to be sufficiently accurate to make an informed decision regarding whether or not an individual has had a prior infection or truly has antibodies to the virus.

The positive and negative predictive values describe how likely it is that a person who receives a positive result from a test truly does have antibodies to SARS-CoV-2 and how likely it is that a person who receives a negative result from a test truly does not have antibodies to SARS-CoV-2 (FDA, 2020). Different serological tests have varying levels of specificity and sensitivity. Sensitivity of antibody tests for SARS-CoV-2 are typically reported to be between 88-100%, specificity 94-100% and positive and negative predictive value at 5% prevalence: 50.4-100% and 99.4-100%, respectively. This means that a positive result may result in an incorrect finding in as much as 50% of the time if the prevalence of the disease in the general population is 5%. False positives can result from cross-reactivity with pre-existing antibodies from previous infections such as other coronaviruses that

cause the common cold; SARS-CoV or MERS-CoV. Negative results may result because antibodies have not yet formed during the early stages of infections (Chau et al., 2020)

Efforts are underway to conduct large-scale validation studies on the performance of these assays, which is critical before they can be used in seroprevalence studies for disease surveillance. A collaborative effort by the FDA, National Institutes of Health, CDC and Biomedical Advanced Research and Development Authority (BARDA) is currently underway to conduct performance assessments and establish the validity of serological tests against a well-characterized set of clinical samples collected before and during the pandemic and correlate them with neutralization assays (Chau et al., 2020).

A second test, typically one assessing for the presence of antibodies to a different viral protein, generally would be needed to increase the accuracy of the overall testing results (FDA, 2020). As a result, the clinical utility of serology testing is uncertain.

Antibody tests that have received an FDA EUA designation are designed to detect IgA, IgM or IgG antibodies alone or a combination of some or all antibodies reported as a total result. Antibody (serology) tests that have received an FDA EUA designation can be found at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#sarscov2antibody>

Such testing is not recommended as a tool to establish or diagnose SARS-CoV-2 infection (FDA, 2020; CDC, 2020; National Institutes of Health [NIH], 2020). At this time, no antibody (serology) test has been validated to establish or diagnose SARS-CoV-2 infection or authorized by the FDA for diagnostic purposes (FDA, 2020). The results of ongoing research are needed before it is known whether antibodies are associated with protection from future infection. Results can help inform who may qualify to donate blood that can be used to manufacture convalescent plasma, an investigational product for use with those who are seriously ill from COVID-19. When used for surveillance, the results can help determine how widely the virus has spread in communities. Results from tests used for surveillance only are generally not shared with individual patients. Regarding antibody (serology) testing, the CDC (2020) notes:

- Antibody (serology) testing should not be used to establish the presence or absence of SARS-CoV-2 infection or reinfection.
- Antibody test results should not be used to diagnose someone with an active infection or reinfection. Antibodies may not be present among those tested early in illness before antibodies develop or among those who never develop detectable antibodies following infection. In addition, the presence of antibodies may reflect previous infection and may be unrelated to the current illness.
- Antibody tests are not recommended as the sole basis for diagnosis of acute infection; however, serologic assays may be used if an individual is suspected to have post-infectious syndrome (e.g., Multisystem Inflammatory Syndrome in Children [MIS-C]) caused by SARS-CoV-2 infection.
- From a public health perspective, serologic assays for SARS-CoV-2 can have a role in understanding the transmission dynamic of the virus in the general population and identifying groups at higher risk for infection.
- In certain situations, serologic assays may be used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests
- Antibody tests should not be used to determine a person's immune status until evidence confirms that antibodies provide protection; how much antibody is protective; and how long protection lasts.

### **Multisystem Inflammatory Syndrome in Children (MIS-C)**

Most children are asymptomatic or exhibit mild symptoms from COVID-19 infection; however, a small number of children develop a significant systemic inflammatory response. This rare syndrome shares common features with other inflammatory conditions such as Kawasaki disease, staphylococcal and streptococcal toxic shock syndromes, bacterial sepsis and macrophage activation syndromes. It can also present with unusual abdominal symptoms with excessive inflammatory markers (Royal College of Paediatrics and Child Health [RCPCH], 2020). An individual with MIS-C is defined by the CDC (2020) as  $\leq 21$  years presenting with fever (i.e. fever  $>38.0^{\circ}\text{C}$  for  $\geq 24$  hours, or report of subjective fever  $\geq 24$  hours). There is laboratory evidence of inflammation (e.g., an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and



low albumin) and evidence of clinically severe illness requiring hospitalization. Other symptoms include involvement of >2 organs (e.g., cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological) and no alternative plausible diagnoses; and positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test and/or COVID-19 exposure within the 4 weeks prior to the onset of symptoms (CDC, 2020).

In an individual with suspected MIS-C a molecular test may be positive or negative for the SARS-CoV-2 virus. While not diagnostic of infection with SARS-CoV-2 infection, an antibody (serology) test may be considered appropriate in a symptomatic individual to aid in the diagnosis of MIS-C when results of molecular or antigen tests are non-diagnostic for COVID-19 infection. As a result of the variable performance of serology tests described in the above antibody testing section, the clinical utility of the antibody result must be interpreted in the context of the individual's treatment history and presenting symptom complex.

### **In Vitro Testing for Population or Public Health Screening**

Molecular, antigen and antibody (serology) testing has been proposed to determine prevalence of COVID-19 infection in a population. Testing strategies include screening and surveillance. Similar analytic and clinical performance limitations as described above apply to testing for population and public health screening; these tests have not been validated for use in the asymptomatic population.

Screening for COVID-19 is looking for occurrence at the individual level even if there is no individual reason to suspect infection, such as a known exposure. Screening includes broad screening of individuals prior to development of symptoms to prevent those individuals from infecting others. Examples of screening include testing plans developed by a workplace to test all employees returning to the workplace, plans developed by a school to test all students and faculty returning to the school, testing requirements before participation in sports, pre-employment physicals and testing of residents and employees in congregate setting such as nursing homes, assisted living and dormitory residences. Testing is performed regardless of exposure or signs and symptoms, with the intent of using those results to determine who may return or what protective measures to take on an individual basis. (CDC, 2020; FDA, 2020).

Surveillance for COVID-19 is not regulated by the FDA, rather is generally a testing plan developed by a State Public Health Department. It is generally used to monitor for an occurrence, such as an infectious disease outbreak in a population or community, or to characterize the occurrence once detected, such as looking at the incidence and prevalence of the occurrence. Surveillance testing is primarily used to gain information at a population level, rather than an individual level. Surveillance testing may be random sampling of a certain percentage of a specific population to monitor for increasing or decreasing prevalence and determining the population effect from community interventions such as social distancing (CDC, 2020; FDA, 2020).

In vitro testing for the purpose of population or public health screening, including to determine prevalence of COVID-19 infection in the community or congregate setting, for return-to-work, return-to-school, participation in sports, admission to residential institution or for routine and/or executive physicals is not a covered benefit under most Cigna standard benefit plans.

### **U.S. Food and Drug Administration (FDA)**

At present there are no FDA approved tests to detect the SARS-CoV-2 virus or to determine the presence of antibodies to the virus. The FDA has issued Emergency Use Authorization (EUA) status to a number of molecular, antigen and antibody tests which allows their marketing and use during the declared Public Health Emergency period for COVID-19 infection. Detailed information for all COVID-19 EUAs, including authorizations and fact sheets is available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

### **Professional Societies/Organizations**

**American Academy of Family Physicians ([AAFP], 2020):** The AAFP notes that family physicians should use their best clinical judgement to determine who should be tested.

**Centers for Disease Control and Prevention (CDC, 2020):** The CDC published an overview of testing for healthcare professionals, including the following:

- Authorized assays for viral testing include those that detect SARS-CoV-2 nucleic acid or antigen.
- CDC does not currently recommend using antibody testing as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes. In certain situations, serologic assays may be used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests. In addition, if a person is suspected to have post-infectious syndrome (e.g., Multisystem Inflammatory Syndrome in Children) caused by SARS-CoV-2 infection, serologic assays may be used.
- Describes five populations for which testing may be appropriate:
  - Individuals with signs or symptoms consistent with COVID-19
  - Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission
  - Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings
  - Individuals being tested to determine resolution of infection (i.e., test-based strategy for Discontinuation of Transmission-based Precautions, HCP Return to Work, and Discontinuation of Home Isolation)
  - Individuals being tested for purposes of public health surveillance for SARS-CoV-2
- Recommends the use of authorized nucleic acid or antigen detection assays that have received an FDA EUA to test persons with symptoms when there is a concern of potential COVID-19. Tests should be used in accordance with the authorized labeling; providers should be familiar with the tests' performance characteristics and limitations.
- Describes strategies to determine when a person with SARS-CoV-2 infection no longer requires isolation or work exclusion and for public health surveillance
- Notes serologic assays can play role in understanding transmission of the virus in the general population and identify groups of higher risk of infection. Antibody tests help determine whether the individual being tested was previously infected—even if that person never showed symptoms.

**Infectious Disease Society of America (IDSA, 2020):** The IDSA published practice guidelines regarding testing for COVID-19, including the following recommendations:

- A SARS-CoV-2 nucleic acid amplification test (NAAT) is recommended in symptomatic individuals in the community suspected of having COVID-19, even when the clinical suspicion for COVID-19 is low (strong recommendation, very low certainty of evidence).
- A single viral RNA test and not repeating testing is suggested in symptomatic individuals with a low clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence).
- Repeating viral RNA testing when the initial test is negative (versus performing a single test) is suggested in symptomatic individuals with an intermediate or high clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence). Intermediate/high clinical suspicion typically applies to the hospital setting and is based on the severity, numbers and timing of compatible clinical signs/symptoms.
- SARS-CoV-2 RNA testing in asymptomatic individuals who are either known or suspected to have been exposed to COVID-19 is suggested (conditional recommendation, very low certainty of evidence). Known exposure was defined as direct contact with a laboratory confirmed case of COVID-19. SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a low prevalence of COVID-19 in the community is suggested (conditional recommendation, very low certainty of evidence). Asymptomatic individuals are defined as those with no symptoms or signs of COVID-19. A low prevalence of COVID-19 in the community was considered communities with a prevalence of <2%.
- Direct SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a high prevalence of COVID-19 in the community (i.e., hotspots) is recommended (conditional recommendation, very low certainty of evidence). Asymptomatic individuals are defined as those with no symptoms or signs of COVID-19. A high prevalence of COVID-19 in the community was considered communities with a prevalence of ≥10%.

- SARS-CoV-2 RNA testing in immunocompromised asymptomatic individuals who are being admitted to the hospital regardless of exposure to COVID-19 is recommended (strong recommendation, very low certainty of evidence). Immunosuppressive procedures are defined as cytotoxic chemotherapy, solid organ or stem cell transplantation, long acting biologic therapy, cellular immunotherapy, or high-dose corticosteroids.
- SARS-CoV-2 RNA testing (versus no testing) in asymptomatic individuals before immunosuppressive procedures regardless of a known exposure to COVID-19 is recommended (strong recommendation, very low certainty of evidence). Immunosuppressive procedures are defined as cytotoxic chemotherapy, solid organ or stem cell transplantation, long acting biologic therapy, cellular immunotherapy, or high-dose corticosteroids.
- SARS-CoV-2 RNA testing in asymptomatic individuals (without known exposure to COVID-19) who are undergoing major time-sensitive surgeries is suggested (conditional recommendation, very low certainty of evidence). Time-sensitive surgery is defined as medically necessary surgeries that need to be done within three months. Testing should ideally be performed as close to the planned surgery as possible (e.g. within 48-72 hours).
- SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is available is not suggested (conditional recommendation, very low certainty of evidence). Time-sensitive procedures defined as medically necessary procedures that need to be done within three months. Procedures considered to be aerosol generating (i.e., bronchoscopy, open suctioning of airways, sputum induction, cardiopulmonary resuscitation, endotracheal intubation and extubation, non-invasive ventilation (e.g., BiPAP, CPAP), bronchoscopy, manual ventilation)
- SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is limited, and testing is available is suggested (conditional recommendation, very low certainty of evidence). Time-sensitive procedures are defined as medically necessary procedures that need to be done within three months. Testing should be performed as close to the planned procedure as possible (e.g. within 48-72 hours). Decisions about PPE will be dependent on test results because of limited availability of PPE. However, there is a risk for false negative test results, so caution should be exercised for those who will be in close contact with/exposed to the patient's airways. Procedures considered to be aerosol generating (i.e., bronchoscopy, open suctioning of airways, sputum induction, cardiopulmonary resuscitation, endotracheal intubation and extubation, non-invasive ventilation (e.g., BiPAP, CPAP), bronchoscopy, manual ventilation). The decision to test asymptomatic patients will be dependent on the availability of testing resources. This recommendation does not address the need for repeat testing if patients are required to undergo.

The IDSA also notes potential utility of antibody (serology) testing in SARS-CoV-2 includes:

- detection of PCR-negative cases, especially for patients who present late with a very low viral load below the detection limit of RT-PCR assays, or when lower respiratory tract sampling is not possible;
- identification of convalescent plasma donors;
- epidemiologic studies of disease prevalence in the community;
- verification of vaccine response once antibody correlate(s) of protection identified

**National Institutes of Health ([NIH], 2020):** The NIH published the following guidance regarding virologic and serologic testing for SARS-CoV-2 infection:

- Recommends that molecular or antigen test for SARS-CoV-2 should be used to diagnose acute SARS-CoV-2 infection (AIII).
- Recommends against the use of serologic testing as the sole basis for diagnosis of acute SARS-CoV-2 infection (AIII).

- Recommends against the use of serologic testing to determine whether a person is immune to SARS-CoV-2 infection (AIII).
- Assuming the test is reliable, recommends that serologic tests to identify recent or prior SARS-CoV-2 infection may be used to:
  - Determine who may be eligible to donate blood to manufacture convalescent plasma.
  - Measure the immune response in SARS-CoV-2 vaccine studies.
  - Estimate the proportion of the population exposed to SARS-CoV-2. The NIH also notes that current serologic assays have limitations in their performance and their ability to determine whether a patient is immune to SARS-CoV-2 infection.
- Recommends serologic tests should not be used to:
  - Make decisions about the grouping of persons residing in or being admitted to congregate settings (e.g., schools, dormitories, correctional facilities), or
  - Determine whether persons should return to the workplace.

Rating of Recommendations: A = Strong, Rating of Evidence: III = Expert opinion

### Use Outside of the US

**World Health Organization ([WHO], 2020):** Regarding serological testing the WHO noted in a published Scientific Brief that:

- Laboratory tests that detect antibodies to SARS-CoV-2 in people, including rapid immunodiagnostic tests, need further validation to determine their accuracy and reliability.
- Inaccurate immunodiagnostic tests may falsely categorize people in two ways: they may falsely label people who have been infected as negative, and people who have not been infected are falsely labelled as positive. Both errors have serious consequences and will affect control efforts. These tests also need to accurately distinguish between past infections from SARS-CoV-2 and those caused by the known set of six human coronaviruses.

## Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	N/A	
LCD	Noridian Healthcare Solutions, LLC	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37301)	10/01/2019
LCD	CGS Administrators, LLC	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37348)	11/28/2019
LCD	Palmetto GBA	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37713)	11/02/2019
LCD	Wisconsin Physicians Service Insurance Corporation	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37764)	11/28/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

## Coding/Billing Information

- Note:**
- 1) This list of codes may not be all-inclusive.
  - 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Molecular (Nucleic Acid), Antigen Testing**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<b>CPT®* Codes</b>	<b>Description</b>
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARSCoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected

<b>HCPCS Codes</b>	<b>Description</b>
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
B34.2	Coronavirus infection, unspecified
J02.8	Acute pharyngitis due to other specified organisms
J02.9	Acute pharyngitis, unspecified
J34.89	Other specified disorders of nose and nasal sinuses
M79.10	Myalgia, unspecified site
M79.11	Myalgia of mastication muscle
M79.12	Myalgia of auxiliary muscles, head and neck
M79.18	Myalgia, other site
R05	Cough
R06.02	Shortness of breath
R07.89	Other chest pain
R09.81	Nasal congestion
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea

R11.2	Nausea with vomiting, unspecified
R19.7	Diarrhea, unspecified
R23.0	Cyanosis
R41.82	Altered mental status, unspecified
R43.0	Anosmia
R43.8	Other disturbances of smell and taste
R50.9	Fever, unspecified
R51	Headache (Code deleted 9/30/2020)
R51.0	Headache with orthostatic component, not elsewhere classified (Code effective 10/01/2020)
R51.9	Headache, unspecified (Code effective 10/01/2020)
R53.83	Other fatigue
R68.83	Chills (without fever)
U07.1	COVID-19
Z01.811	Encounter for preprocedural respiratory examination
Z01.812	Encounter for preprocedural laboratory examination
Z01.818	Encounter for other preprocedural examination
Z01.89	Encounter for other specified special examinations
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z79.52	Long term (current) use of systemic steroids

**Antibody (Serology) Testing**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

<b>CPT®* Codes</b>	<b>Description</b>
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
	All other codes not listed in the Not Medically Necessary section directly below

**Considered Not Medically Necessary when submitted with one of the CPT codes above:**

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
Z01.84	Encounter for antibody response examination

**Considered Not Medically Necessary:**

<b>CPT®* Codes</b>	<b>Description</b>
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum

**Not Covered**

**Considered Not Covered Under Standard Benefit Plan Language:**

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
Z02.0	Encounter for examination for admission to educational institution
Z02.1	Encounter for pre-employment examination
Z02.3	Encounter for examination for recruitment to armed forces
Z02.5	Encounter for examination for participation in sport
Z02.6	Encounter for examination for insurance purposes
Z02.71	Encounter for disability determination
Z02.79	Encounter for issue of other medical certificate
Z02.89	Encounter for other administrative examinations
Z02.9	Encounter for administrative examinations, unspecified

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