Medical Coverage Policy

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COVID-19: In Vitro Diagnostic Testing

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health

benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy discusses certain tests used to find the SARS-CoV-2 virus in the body. This virus causes COVID-19. Two types of tests help to diagnose COVID-19: molecular tests and antigen tests. Molecular tests look for the genetic material in the SARS-Co-V-2 virus while antigen tests look for the presence of small pieces of protein from the virus.

An antibody test, also called a serology test, is used to identify antibodies against the SARS-CoV-2 virus. Antibodies are proteins that work to fight infection in the body. An antibody test does not help diagnose COVID-19, but may be used for public health reasons, like to estimate how much of a virus is in a community and how quickly it may spread. It may also be used to plan where to offer testing.

This Policy applies to a test where results for one person are identified. It also discusses pooled sample testing, where test results for many people are reported together.

Nucleic acid pathogen testing by panels is outside the scope of this Coverage Policy. For information related to that type of testing, please review CP 0530 Nucleic Acid Pathogen Testing.

For the purpose of this Coverage Policy, molecular, antigen and antibody (serology) testing for SARS-CoV-2 (COVID-19) is informed by authoritative guidance from the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and evidence-based recommendations issued by relevant professional societies and organizations, such as the Infectious Diseases Society of America (IDSA).

Coverage Policy

Note: For information related to nucleic acid pathogen testing panels please review CP 0530 Nucleic Acid Pathogen Testing.

Medically Necessary

A molecular or antigen in vitro diagnostic test for SARS-CoV-2 (COVID-19) infection is considered medically necessary when ALL of the following criteria are met:

- clinical concern for a symptomatic COVID-19 infection
- individual with known or suspected exposure
- ordered and administered by a licensed or authorized healthcare provider

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

- 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 condition related to COVID-19 infection (e.g., multisystem inflammatory syndrome [MIS], post-acute sequelae)

- results of serology will be used to inform therapy for immunocompromised individuals with known or clinically suspected COVID-19 infection

Not Covered or Reimbursable

Surrogate neutralization testing to determine the presence of SARS-CoV-2 antibodies is not covered or reimbursable.

An in vitro test to determine COVID-19 variants is not covered or reimbursable.

In vitro diagnostic testing (molecular, antigen, antibody) for COVID-19 infection is not covered or reimbursable for screening, including but not limited to BOTH of the following:

- asymptomatic individual, without exposure
- general population screening

An antibody (serology) test for SARS-CoV-2 antibodies is not covered or reimbursable for any other indication, not limited to the following:

- diagnose current or active infection
- determine need for COVID-19 vaccination
- assess immunity after COVID-19 vaccination

In vitro testing (i.e., molecular, antigen, antibody) is not covered or reimbursable for ANY of the following indications:

- purposes not primarily intended for individualized diagnosis or treatment of COVID-19
- testing done for employment purposes including testing conducted to screen for general workplace health and safety (such as employee "return to work" programs)
- determine prevalence of COVID-19 infection in the community
- public health surveillance for SARS-CoV-2
- public health screening
- screening assessment in a congregate setting (e.g., nursing home, correctional facility, school, residential dormitory)

A high-throughput molecular or antigen in vitro diagnostic test for the diagnosis of SARS-CoV-2 (COVID-19) infection is not covered or reimbursable unless billed by a CLIA-certified high-complexity laboratory.

If the above criteria are not met, in vitro testing (i.e., molecular, antigen, antibody) is not covered or reimbursable, including but not limited to the following indications listed below:

(Where applicable and appropriate, ICD-10 diagnosis codes that may be used to reflect population or public health screening scenarios have been included. This list is not all inclusive and may not represent an exact indication match.)

- testing conducted to screen for general workplace health and safety (e.g., return-to-work) (Z02.79)
- return-to-school (Z02.0)
- participation in sports (Z02.5)
- pre-employment (Z02.1)

- routine and/or executive physicals (Z02.89)
- travel
- recruitment to armed forces (Z02.3)
- insurance purposes (Z02.6)
- disability evaluation (Z02.71)
- encounter for administrative exam, unspecified (Z02.9)

***Please see Coding Table section for specific not covered or reimbursable ICD-10 code descriptions.**

An Over the Counter (OTC) test for SARS-CoV-2 (COVID-19) infection is not covered or reimbursable.

A test for SARS-CoV-2 (COVID-19) infection that is not diagnostic and/or does not otherwise meet the criteria above (e.g., Tiger Tech COVID Plus™) is not covered or reimbursable.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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:

CPT®* Codes	**Description**
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B
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
87811†	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])

CPT®* Codes	Description
87812†	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B

†Note: Not Covered or Reimbursable when used to report an Over-the-Counter (OTC) test for SARS-CoV-2 (COVID-19) infection.

HCPCS Codes	Description
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

Not Covered or Reimbursable when submitted with one of the CPT® or HCPCS Codes above:

ICD-10-CM Diagnosis Codes	Description
Z11.52	Encounter for screening for COVID-19
Z11.59	Encounter for screening for other viral diseases

Not Covered or Reimbursable when submitted with one of the CPT® or HCPCS Codes and one of the ICD-10 Diagnosis Codes above:

ICD-10-CM Diagnosis Codes	Description
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases

Considered Medically Necessary:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Antibody (Serology) Testing

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

CPT®* Codes	Description
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

CPT®* Codes	Description
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 (SARS-CoV-2) (coronavirus disease [COVID-19]), includes titer(s), when performed

ICD-10-CM Diagnosis Codes	Description
B20	Human immunodeficiency virus [HIV] disease
D80.0-D80.9	Immunodeficiency with predominantly antibody defects
D81.0-D81.9	Combined immunodeficiencies
D82.0-D82.9	Immunodeficiency associated with other major defects
D83.0-D83.9	Common variable immunodeficiency
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.81	Immunodeficiency due to conditions classified elsewhere
D84.821	Immunodeficiency due to drugs
D84.822	Immunodeficiency due to external causes
D84.89	Other immunodeficiencies
D84.9	Immunodeficiency, unspecified
M35.81	Multisystem inflammatory syndrome
O98.711-O98.719	Human immunodeficiency virus [HIV] disease complicating pregnancy
O98.72	Human immunodeficiency virus [HIV] disease complicating childbirth
O98.73	Human immunodeficiency virus [HIV] disease complicating the puerperium
U09.9	Post COVID-19 condition, unspecified
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z79.899	Other long term (current) drug therapy
Z83.0	Family history of human immunodeficiency virus [HIV] disease
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation
Z94.0-Z94.9	Transplanted organ and tissue status

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Not Covered or Reimbursable:

CPT®* Codes	Description
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), ELISA, plasma, serum

Not Covered or Reimbursable Under Standard Benefit Plan Language:

ICD-10-CM Diagnosis Codes	Description
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

Not Covered or Reimbursable when used to report Tests and Devices for SARS-CoV-2 (COVID-19) infection (e.g., Tiger Tech COVID Plus™) that are Not Diagnostic:

CPT®* Codes	Description
99199	Unlisted special service, procedure or report
E1399	Durable medical equipment, miscellaneous

General Background

COVID-19 is the highly contagious infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Clinical presentation ranges from mild respiratory illness to severe systemic disease and is primarily transmitted through respiratory droplets and aerosols. Common symptoms of COVID-19 infection are fever, chills, cough and shortness of breath, fatigue, body aches or muscle pain, headache, congestion or runny nose, sore throat, new loss of taste or smell, nausea, vomiting and diarrhea (Centers for Disease Control and Prevention [CDC], 2025c;

Infectious Disease Society of America [IDSA], 2023). These symptoms typically appear 2–14 days after exposure. Symptoms can progress rapidly to severe respiratory distress requiring hospitalization, culminating in death. Emergency warning signs for Covid-19 include persistent pain or pressure in chest, new confusion, inability to wake or stay awake, and pale, gray, or blue-colored skin, lips, or nail beds (CDC, 2025c)

U.S. Food and Drug Administration (FDA)

The FDA issued Emergency Use Authorization (EUA) status to a number of molecular, antigen and antibody tests which allowed for their marketing and use during the declared Public Health Emergency period for COVID-19 infection. The COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service (PHS) Act expired on May 11, 2023. Existing emergency use authorizations (EUAs) for devices relating to COVID-19 remain in effect under section 564 of the Federal Food, Drug, and Cosmetic Act. Information regarding COVID-19 in vitro diagnostic tests with EUA or traditional marketing authorization is available on the FDA's designated web pages (FDA, 2024)

Evidence Review / Literature Review

In vitro diagnostic testing for COVID-19 includes molecular, antigen, and antibody (serology) tests intended for the individualized diagnosis and treatment of COVID-19 and/or related sequelae.

- Molecular tests are appropriate to detect current infection with SARS-CoV-2, guide medical care, and determine preventative measures. These tests include nucleic acid amplification tests (NAATs) and polymerase chain reaction (PCR) assays. Molecular tests work by detecting one or more viral ribonucleic acid (RNA) genes.
- Antigen tests are appropriate to detect current infection with SARS-CoV-2, guide medical care, and determine preventative measures. These tests are generally less sensitive than most molecular tests. Antigen tests work by detecting specific viral proteins.
- Antibody tests are not appropriate to detect current infection with SARS-CoV-2. These tests are primarily used for public health surveillance and epidemiologic purposes, but may have clinical utility to aid in the diagnosis of a condition related to COVID-19 infection, e.g., MIS. Serology tests work by detecting antibodies from previous infection or vaccination (CDC, 2024).

The CDC (2024) notes the following regarding molecular and antigen in vitro diagnostic testing:

- "Nucleic acid amplification tests (NAATs) are highly sensitive and highly specific tests that detect one or more viral ribonucleic acid (RNA) genes. PCR tests are the most common type of NAAT used for COVID-19 testing. Viral RNA may stay in a person's body for up to 90 days after they test positive. Therefore, NAATs should not be used to test someone who has tested positive in the last 90 days. Most NAATs need to be performed in a laboratory, although some are performed at the point-of-care. Most NAATs produce qualitative (positive/negative) results."
- "Antigen tests are immunoassays that detect the presence of specific viral proteins, called antigens. A positive test indicates current infection. Antigen tests generally have high specificity, similar to NAATs, but are less sensitive than most NAATs. Because antigen tests have lower sensitivity, FDA recommends that negative antigen tests be repeated up to three times, with each test 48 hours apart to confirm a negative result. Most antigen tests are less expensive than NAATs and can provide results in minutes. Antigen tests are available for at-home testing (self-testing), at the point of care, or in a laboratory."
- "Positive viral test results indicate current infection and the person with COVID-19 should take steps to prevent spreading COVID-19 to others."

- "Negative viral test results mean the test did not detect the virus, but this doesn't rule out that the person could have an infection. These results represent a snapshot of the time around specimen collection and could change if the same test was performed again in one or more days. Negative antigen test results should be repeated following FDA guidance."
- "Additionally, consider other illnesses with similar symptoms that may require testing. For many diseases, including flu, early diagnosis and prompt treatment can be important for preventing severe illness."

It is important to note the existence of limitations to testing. 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 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.

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. Nucleic acid amplification tests (NAAT) such as reverse transcription-polymerase chain reaction (RT-PCR) tests, remain the "gold standard" for clinical diagnostic detection of SARS-CoV-2 (CDC, 2025) 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. These tests can identify and quantify the presence of infectious agents in a sample through the process of detection, amplification, and output measurement.

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). 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%. Results may not be as robust as accuracy is 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.

Antigen Testing: An antigen test is an immunoassay test that detects the presence of a specific viral 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.

Antigen testing is subject to the same analytic and clinical performance limitations, such as those described for molecular tests. An antigen test generally has similar specificity as a molecular test but are less sensitive than NAATs and 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. Test specificity of 100% is reported. Negative results do not rule out COVID-19. Antigen tests are available for at-home (self) testing, at point of care or in the laboratory.

An advantage of antigen testing is that the methodology lends itself to 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. Clinical correlation with patient history and other diagnostic information is necessary to determine infection status (Chau et al., 2020). Rapid RT-PCR or laboratory-based NAAT remains the testing method of choice for diagnosing SARS-CoV-2 infection. However, when timely molecular testing is not readily available or is logistically infeasible, Ag testing helps identify individuals with SARS-CoV-2 infection (IDSA, 2022).

Serology (Antibody) Testing: 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. However, antibodies may not be present among those tested early in illness 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 (CDC, 2024).

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 (Ghafferi et al., 2020).

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. 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).

Per CDC (2024), SARS-CoV-2 antibody (serology) testing may be used to identify evidence of prior infection or vaccination, support diagnosis of MIS-C or MIS-A, or for population-level

surveillance, but should not be used to diagnose active infection, assess immunity, determine fitness for work or school, or guide individualized clinical or public health decisions.

Per IDSA (2024), while routine SARS-CoV-2 antibody (serology) testing is not recommended in individuals with prior infection or vaccination due to the absence of demonstrated benefit in improving clinical outcomes, evidence-based guidance recognizes a limited clinical role for serologic testing in select immunocompromised individuals. In this population, a negative spike antibody result may provide clinically relevant information to support individualized treatment decision-making, including identification of patients who may be candidates for immune-based therapies (e.g., convalescent plasma or monoclonal antibodies), when such therapies are available, or to inform prioritization of therapy during periods of limited supply. In these circumstances, serologic testing is used to inform management in the context of immunocompromise rather than to assess immunity or diagnose active infection.

Although neutralizing antibodies (serological surrogates of immune protection) are associated with reduced risk of SARS-CoV-2 infection, neither a definitive immune correlate of protection nor a clinical role for surrogate neutralization testing has been established (IDSA, 2024).

Multisystem Inflammatory Syndrome (MIS) is a rare but serious condition associated with COVID-19, characterized by systemic inflammation involving one or more organ systems, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal tract (CDC, 2025b). This rare syndrome shares common features with other inflammatory conditions such as Kawasaki disease, acute viral infection myocarditis (e.g., influenza, enteroviruses), rickettsial disease (e.g., typhus), staphylococcal and streptococcal toxic shock syndromes, bacterial sepsis, and macrophage activation syndromes. MIS may occur in children and adolescents (MIS-C, <21 years) or adults (MIS-A ≥21 years). Signs and symptoms of MIS include an ongoing fever plus one of the following: stomach pain, bloodshot eyes, diarrhea, dizziness, or lightheadedness (signs of low blood pressure), skin rash or vomiting.

In individuals with suspected MIS, molecular testing 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 provide supportive evidence of prior infection when results of molecular or antigen tests are non-diagnostic for COVID-19 infection. Due to variable performance of serology testing, 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. Population-level screening and surveillance testing are distinct from diagnostic testing intended to guide individualized clinical-decision making.

Screening tests are intended to identify infected individuals prior to development of symptoms or those infected individuals without signs or symptoms who may be contagious, so that measures can be taken 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 (FDA, 2026).

Surveillance testing for COVID-19 is conducted at the population level and is not regulated by the FDA. An example of such testing may be a plan developed by a State Public Health Department to randomly select and sample 1% of all individuals in a city on a rolling basis to determine local infection rates and trends. 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.

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 is not necessary to diagnose the infection caused by SARS-COV-2 virus. Likewise, screening for other viral diseases does not diagnose COVID-19 infection.

Other Non-Diagnostic Tests and Devices:

Testing for variants of SARS-CoV-2 is a type of testing used for surveillance. The CDC works with public health officials to monitor and track all variants. Viral genomic sequencing is used to identify, track, and monitor COVID-19 variants to protect the public's health. The CDC's COVID Data Tracker publishes estimates of how common variants are at national and regional levels. (CDC, 2025a)

Tiger Tech COVID Plus™ is a non-invasive, non-diagnostic device, sensor-embedded armband that uses machine learning to analyze biometric signals that may indicate COVID-19 infection (FDA, 2021; Tiger Tech Solutions, Inc., 2020). There is insufficient high-quality evidence in the published, peer-reviewed scientific literature to establish the accuracy or clinical utility of this device for individualized clinical decision-making.

Professional Societies/Organizations

Centers for Disease Control and Prevention (CDC, 2024):

The CDC published the following guidance:

Testing Strategies for SARS-CoV-2

- Diagnostic testing is intended to identify current infection in individuals and should be performed on anyone that has signs and symptoms consistent with COVID-19 or is asymptomatic but has recent known or suspected exposure to someone with COVID-19.
- Viral tests, including nucleic acid amplification tests (NAATs, such as PCR tests), antigen tests and other tests (such as breath tests) are used as diagnostic tests to detect current infection with SARS-CoV-2, determine the need for prevention measures like isolation, and inform an individual's medical care.

Examples of diagnostic testing include:

- Testing individuals with signs or symptoms consistent with COVID-19
- Testing individuals who were exposed to someone with a confirmed or suspected case of COVID-19

Screening Testing

- Screening tests are intended to identify individuals with COVID-19 who are asymptomatic or do not have known, suspected, or reported exposure to someone with COVID-19.

- Screening helps to identify unknown cases so that measures can be taken to prevent further transmission.

Examples of screening include testing:
- Employees in a workplace setting
- Students, faculty, and staff in a school setting
- A person before or after travel
- Someone at home who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Public Health Surveillance Testing
- Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice.
- Public health surveillance testing is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. Surveillance testing involves testing of de-identified specimens and results are not reported back to the individual.
- Public health surveillance testing may sample a certain percentage of a specific population to monitor for increasing or decreasing prevalence, or to determine the population effect from community interventions such as social distancing. Surveillance testing cannot be used for an individual's healthcare decision-making or individual public health actions, such as isolation.

Infectious Disease Society of America (IDSA):

The IDSA (2023) published practice guidelines related to SARS-CoV-2 molecular diagnostic testing that state:

Molecular Diagnostic Testing:
- Recommendation 1: A SARS-CoV-2 nucleic acid amplification test (NAAT) is recommended in symptomatic individuals suspected of having COVID-19 (strong recommendation, moderate certainty of evidence).
- Recommendation 2: For symptomatic individuals suspected of having COVID-19, the recommended anatomic site of specimen collection is from either the nasopharynx (NP), anterior nares (AN), oropharynx (OP), or mid-turbinate regions (MT); saliva, or mouth gargle (conditional recommendation, low certainty evidence).
- Recommendation 3: For symptomatic individuals suspected of having COVID-19, AN and MT swab specimens may be collected for SARS-CoV-2 RNA testing by either patients or healthcare providers (conditional recommendation, moderate certainty evidence).
- Recommendation 4: It is suggested to use either rapid or standard laboratory-based NAATs in symptomatic individuals suspected of having COVID-19 (conditional recommendation, moderate certainty of evidence).
- Recommendation 5: A single NAAT and not repeating testing routinely is suggested in symptomatic or asymptomatic individuals suspected of having COVID-19 whose initial NAAT result is negative with (conditional recommendation, very low certainty of evidence).
- Recommendation 6: 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, moderate certainty of evidence). Known exposure was defined as direct contact with a laboratory confirmed case of COVID-19.
- Recommendation 7: For individuals who have clinical or epidemiologic reasons that might make testing desirable, the IDSA panel suggests using either rapid or laboratory-based

NAATs in asymptomatic individuals with known exposure to SARS-CoV-2 infection (conditional recommendation, moderate certainty of evidence).

- Recommendation 8: Routine SARS-CoV-2 NAAT is not recommended in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized (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%.
- Recommendation 9: The IDSA panel suggests against routine SARS-CoV-2 NAAT of asymptomatic individuals without a known exposure to COVID-19 who are undergoing a medical or surgical procedure (conditional recommendation, very low certainty evidence).
- Recommendation 10: The IDSA panel suggests against routinely repeating NAAT before medical or surgical procedures in patients with a recent history of COVID-19 (conditional recommendation, very low certainty evidence).
- Recommendation 11: The IDSA panel suggests against routinely repeating NAAT in patients with COVID-19 to guide release from isolation (conditional recommendation, very low certainty evidence).
- Recommendation 12: The IDSA panel suggests neither for nor against home-testing for SARS-CoV-2. (evidence gap).

The IDSA (2022) published evidence-based guidelines related to SARS-CoV-2 antigen testing that state:

Antigen Testing:

- Recommendation 1: For symptomatic individuals suspected of having COVID-19, the IDSA panel recommends a single Ag test over no test (strong recommendation, moderate certainty evidence).
- Recommendation 2: For symptomatic individuals suspected of having COVID-19, the IDSA panel suggests using standard NAAT (i.e., rapid RT-PCR or laboratory-based NAAT) over a rapid Ag test (conditional recommendation, low certainty evidence).
- Recommendation 3: For symptomatic individuals suspected of having COVID-19, the IDSA panel suggests using a single standard NAAT (i.e., rapid RT-PCR or laboratory-based NAAT) rather than a strategy of two consecutive rapid Ag tests (conditional recommendation, very low certainty evidence).
- Recommendation 4: For asymptomatic individuals with known exposure to SARS-CoV-2 infection, the IDSA panel suggests using a single standard NAAT (either rapid RT-PCR or laboratory-based NAAT) over a single rapid Ag test (conditional recommendation based on moderate certainty in test accuracy of rapid Ag tests and very low certainty in comparative test accuracy of rapid RT-PCR versus rapid Ag tests).
- Recommendation 5: For asymptomatic individuals with known exposure to SARS-CoV-2 infection, the IDSA panel suggests a single (i.e., one-time) standard NAAT (either rapid RT-PCR or laboratory-based NAAT) rather than a strategy of two consecutive rapid Ag tests (conditional recommendation).
- Recommendation 6: In asymptomatic individuals with a known exposure to SARS-CoV-2, if standard NAAT testing or results are not available in a timely manner and a first Ag test is negative, the IDSA panel suggests repeat Ag testing (conditional recommendation, very low certainty evidence).
- Recommendation 7: Among students in educational settings or employees in workplaces for whom SARS-CoV-2 testing is desired, the IDSA panel suggests neither for nor against two consecutive Ag tests over no testing for the diagnosis of SARS-CoV-2 infection (evidence gap).”
- Recommendation 8: For asymptomatic individuals planning to attend a large gathering (e.g., concert, conference, party, sporting event), the IDSA panel suggests neither for nor against Ag testing over no testing (evidence gap).

- Recommendation 9: For individuals for whom Ag testing is desired, the IDSA panel suggests for either point-of-care or laboratory-based Ag testing (conditional recommendation, low certainty evidence).
- Recommendation 10: The IDSA panel suggests either observed or unobserved self-collection of swab specimens for Ag testing if self-collection is performed (conditional recommendation, low certainty evidence).

The IDSA (2024) published evidence-based guidelines related to SARS-CoV-2 serologic testing that state:

Serologic (Antibody) Testing:

- Recommendation 1: The IDSA panel suggests against using serologic testing to diagnose SARS-CoV-2 infection during the first two weeks (14 days) following symptom onset (strong recommendation, low certainty of evidence).
- Recommendation 2: The IDSA panel recommends against using IgG antibody to provide evidence of COVID-19 infection in symptomatic patients with a high clinical suspicion and repeatedly negative NAAT testing (strong recommendation, very low certainty of evidence). There is no added benefit to assessing anti-SARS-CoV-2 antibodies over repeat NAAT for the diagnosis of acute COVID-19. No SARS-CoV-2 serologic test can differentiate between recent or remote infection.
- Recommendation 3: In pediatric patients with multisystem inflammatory syndrome (MIS-C), the IDSA panel suggests using both IgG antibody and NAAT to provide evidence of current or past COVID-19 infection (strong recommendation, very low certainty of evidence). The IDSA (2024) provides the following remarks regarding this recommendation:
    - "Differentiating MIS-C from conditions with overlapping symptomatology, such as Kawasaki disease, is important because Kawasaki disease requires treatment with specific therapies such as intravenous immunoglobulin or rituximab if diagnosed. The two diseases also differ in terms of potential complications and need for long-term medication and follow-up."
- Recommendation 4: When evidence of previous SARS-CoV-2 infection is desired, the IDSA panel suggests testing for SARS-CoV-2 IgG, IgG/IgM or total antibody three to five weeks after symptom onset (conditional recommendation, low certainty of evidence).
- Recommendation 5: When evidence of prior SARS-CoV-2 infection is desired, the IDSA panel suggests using serologic assays that target nucleocapsid protein rather than spike protein (conditional recommendation, low certainty of evidence). Sensitivity and specificity of nucleocapsid and spike antibody tests are similar and require the clinician to know and understand the antibody target of the test that is used; interpretation of results as indicative of past infection (anti-nucleocapsid) versus past infection or vaccination (anti-spike).
- Recommendation 6: In individuals with previous SARS-CoV-2 infection or vaccination, the IDSA panel suggests against routine serologic testing given no demonstrated benefit to improving patient outcomes (conditional recommendation, very low certainty of evidence). The IDSA (2024) provides the following remarks regarding this recommendation:
    - Serologic testing may be useful for diagnosing MIS-C in pediatric patients, especially when NAAT or antigen testing is negative, to provide evidence of recent COVID-19 (see Recommendation 3 above).
    - A negative spike antibody test may be a useful metric to identify immunocompromised patients who are candidates for immune therapy such as convalescent plasma or monoclonal antibodies, if such therapies were available, or to prioritize administration of monoclonal therapies when supplies are limited.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Social determinants of health, including transportation barriers, employment constraints, disability access, cost concerns, and mistrust of healthcare systems, may affect timely access to SARS-CoV-2 testing and contribute to disparities in testing utilization. Inequities in access to testing may result in delayed diagnosis, treatment, and implementation of public health measures intended to reduce transmission (CDC, 2024).

Advancing health equity includes ensuring the availability of resources, such as access to affordable, high-quality, and timely SARS-CoV-2 testing for populations that have experienced longstanding health and social inequities. Complete and accurate collection of race and ethnicity data, when available, supports understanding the impact of COVID-19 on racial and ethnic minority populations and informs efforts to identify and address disparities (CDC, 2024).

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Added criteria for serology testing for immunocompromised individuals to inform treatment decisions.	5/15/2026
Focused review	• No clinical policy statement changes.	1/15/2026
Annual review	• Added criteria for testing of asymptomatic individuals • Removed policy statements regarding FDA approval and CLIA status	4/15/2025
Annual review	• No policy statement changes.	6/15/2024