

June 2020 ~ Resource #360601

COVID-19 Testing FAQs

For an up-to-date list of COVID-19 tests authorized to be used during the COVID-19 pandemic, in laboratories and in patient-care areas, see <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Emergency Use Authorization (EUA) testing options for COVID-19 infections are rapidly evolving. A variety of healthcare professionals are involved in testing including nurses, prescribers, pharmacists, etc. Some tests identify active infection. Other tests look for the body's immune response to the virus, to identify people who have already been exposed. The chart below answers common questions about COVID-19 testing, including how to safely participate in testing, interpret test results, and communicate test results to patients.

Abbreviations: CLIA = Clinical Laboratory Improvement Amendments; EUA = emergency use authorization; FDA = Food and Drug Administration; NPV = negative predictive value; PPV = positive predictive value; SARS-CoV-2 = coronavirus that causes COVID-19 infections.

Question	Answer/Pertinent Information
What is emergency use authorization?	<ul style="list-style-type: none">• EUA is a process through the FDA to allow use of unapproved medical products or unapproved uses of approved products during an emergency to diagnose, treat, or prevent serious or life-threatening conditions when there are no approved alternatives available.² A regularly updated list of diagnostic and antibody tests for COVID-19 can be found at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas. This list provides helpful information including:²<ul style="list-style-type: none">○ date of EUA approval○ manufacturer○ test name○ type of test (e.g., antigen, molecular or polymerase chain reaction [PCR], serology)○ approved settings for testing (e.g., certified labs for high- or moderate-complexity, patient care settings under a CLIA waiver)^a○ product-specific labeling information including:<ul style="list-style-type: none">▪ instructions for use for laboratories and point-of-care testing sites (when applicable)▪ information for healthcare providers▪ information for patients• COVID-19 EUAs are only valid during the COVID-19 public health emergency (i.e., they are no longer valid after the public health emergency is terminated).³• The FDA suggests the following minimum specifications for EUA test approval:^{15,b}<ul style="list-style-type: none">○ molecular or PCR: 95% positive agreement, 100% negative agreement○ serology: 90% positive agreement (overall and for IgG), 70% positive agreement (for IgM), 95% negative agreement○ antigen: 80% sensitivity (specificity and/or negative percent agreement NOT specified at time of publication)

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Question	Answer/Pertinent Information
<p>What do the different COVID-19 tests detect?</p>	<ul style="list-style-type: none"> • Serology tests (uses a blood specimen) detect the body’s immune response (e.g., IgG, IgM, antibody) to SARS-CoV-2.¹ Examples of EUA-approved serology COVID-19 tests include <i>SARS-CoV-2 IgG Assay</i> and <i>Elecsys Anti-SARS-CoV-2</i>. <ul style="list-style-type: none"> ○ It can take one to three weeks after an infection to make antibodies.¹² ○ It is not yet known if antibodies from COVID-19 infections provide immunity against a future infection.⁵ • Molecular or PCR tests (uses a respiratory specimen) detect genetic material (e.g., nucleic acid) from SARS-CoV-2. Examples of EUA-approved molecular or PCR COVID-19 tests include <i>ID Now COVID-19</i> and <i>Accula SARS-CoV-2</i>. • Antigen tests (uses a respiratory specimen) detect protein antigens from SARS-CoV-2. At the time of publication, <i>Sofia 2 SARS Antigen FIA</i> is the only EUA-approved COVID-19 antigen test. • Only molecular (PCR) or antigen tests, along with exposure risk and patient symptoms, should be used to identify active COVID-19 infections.⁴ However, a negative <i>Sofia SARS-2 Antigen FIA</i> result may not rule out an active COVID-19 infection. If patients have positive exposure and/or symptoms, confirm negative <i>Sofia SARS-2 Antigen FIA</i> results with a follow-up molecular test.¹⁷ • AVOID using serology (antibody) tests to diagnose acute COVID-19 infections.⁴
<p>Who should be tested for COVID-19 infection?</p>	<ul style="list-style-type: none"> • Symptoms of COVID-19 infection may include fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.⁴ • Not everyone needs a viral test (e.g., molecular [PCR], antigen) for COVID-19. Follow state and local health department guidance on who to test.¹² <ul style="list-style-type: none"> ○ The highest priority for testing for acute COVID-19 infections should be the following symptomatic people: hospitalized patients; healthcare workers; first responders; workers and residents in congregate living settings (e.g., nursing homes, long-term care facilities, prison, shelters). <ul style="list-style-type: none"> ○ Priority should be given to people with symptoms of COVID-19 infection (see first bullet above).⁴ ○ Follow local and state health department guidance for prioritizing testing for patients without symptoms.⁴ • Serology (antibody) tests are being used for COVID-19 surveillance. Follow state and local guidance for who should receive a serology test.¹⁴
<p>How do sensitivity and specificity impact test results and predictive values?</p> <p><i>Continued...</i></p>	<ul style="list-style-type: none"> • No test is 100% sensitive, specific, or predictive. All tests can give false negative and false positive results.¹ • To accurately interpret test results, it is important to know the particular test’s sensitivity (sometimes called positive percent agreement) and specificity (sometimes called negative percent agreement) often found in product information.^b <ul style="list-style-type: none"> ○ Sensitivity (%): the ability to identify what is being tested for when it is present in the sample (true positive). For example, the percentage of people who test positive for COVID-19 that actually have COVID-19. When highly Sensitive tests are Negative, they rule OUT (SnNOUT) people who don’t have what is being tested for.⁹ ○ Specificity (%): the ability to NOT identify what is being tested for when it is NOT present in the sample (true negative). For example, the percentage of people WITHOUT COVID-19 who test negative for COVID-19. When highly Specific tests are Positive, they rule IN (SpPIN) people who have what is being tested for.⁹

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Question	Answer/Pertinent Information					
Sensitivity, specificity and predictive values, continued	<ul style="list-style-type: none"> To accurately interpret test results, it is important to understand PPV and NPV. <ul style="list-style-type: none"> Positive Predictive Value (PPV):¹⁰ If a patient has a positive diagnostic test result, what is the probability that the patient really HAS the diagnosis being tested for? Negative Predictive Value (NPV):¹⁰ If a patient has a negative test result from a screening test, what is the probability that the patient really does NOT have what the test is screening for? PPV and NPV are influenced by prevalence. As the prevalence of the infection increases, PPV increases and NPV decreases. Similarly, as the prevalence of the infection decreases the PPV decreases and NPV increases.¹¹ The FDA has a calculator (https://www.fda.gov/media/137612/download) available to calculate PPV and NPV using a particular test’s sensitivity and specificity. 					
How are positive and negative predictive values calculated?			Patient’s True COVID-19 Status			
			Positive	Negative		
	COVID-19 Test Result	Positive	88	4	Total = 88 + 4 = 92	PPV ¹⁰ = 88/92 = 95.6%
		Negative	12	96	Total = 12 + 96 = 108	NPV ¹⁰ = 96/108 = 88%
			Total = 88 + 12 = 100	Total = 4 + 96 = 100	Total = 100 + 100 OR 92 + 108 = 200	
			Sensitivity ⁹ = 88/100 = 88%	Specificity ⁹ = 96/100 = 96%		
How should COVID-19 test results be interpreted?	Type of Test ⁶		Test Result ⁶		Interpretation ⁶	
	Viral testing (e.g., molecular or PCR, antigen) (looking for an active infection)		Positive		Most likely has a current infection	
			Negative		Most likely does NOT have a current infection	
	Antibody testing (e.g., serology) (looking for a previous infection)		Positive		Likely had an infection	
			Negative		Likely never had an infection	
	Viral AND antibody testing (looking for an active or previous infection)		Virus (positive) Antibody (positive)		Most likely has a current infection	
			Virus (positive) Antibody (negative)		Most likely has a current infection	
			Virus (negative) Antibody (positive)		Likely had and recovered from an infection	
			Virus (negative) Antibody (negative)		Likely never had an infection	

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Question	Answer/Pertinent Information
<p>What to consider after a negative COVID-19 test?</p>	<ul style="list-style-type: none"> • Is the patient symptomatic? Consider retesting using a molecular test, if symptoms persist or worsen. • What type of test was used? Antigen tests may lead to false negatives more often than molecular tests.¹⁷ • When was the sample taken and was the sample taken properly? Testing too early after exposure or without a properly obtained sample can lead to false negative results.
<p>How should COVID-19 test results be reported and communicated?</p> <p>*New guidance on required data to collect and report (as well as timelines) goes into effect no later than August 1, 2020.</p>	<ul style="list-style-type: none"> • Follow policies and procedures for reporting positive and negative test results to patients, prescribers, and local and state health departments. Required information to be collected and reported (along with timelines) can be found at https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.* • Regardless of results and the type of test, advise patients to use preventive measures to protect themselves and others.¹² • For all patients with symptoms OR anyone whose test result indicates they most likely have a current infection, discuss symptom management (e.g., fluids, acetaminophen or ibuprofen for fever). Advise patients to: <ul style="list-style-type: none"> ○ keep track of their symptoms.¹³ ○ seek medical attention right away if they have any emergency warning signs (e.g., trouble breathing, persistent chest pain or pressure, new onset confusion, an inability to wake up or stay awake, bluish lips or face).¹³ • Have a follow-up system to ensure referrals are complete, symptoms are improving, or assess med tolerability. • For patients whose test indicates they most likely have a current infection (see test interpretation above) they should:¹³ <ul style="list-style-type: none"> ○ follow isolation procures (e.g., stay home, separate themselves from others). (See below for how long to continue isolation procedure.) ○ wear a cloth face covering over their mouth and nose if around other people or pets. ○ cover coughs or sneezes. ○ clean hands frequently with soap and water or hand sanitizer. ○ avoid sharing personal household items (e.g., dishes, cups, eating utensils, towels, bedding). ○ clean and disinfect “high-touch” surfaces DAILY (e.g., phone, remote control, counters, doorknobs, toilets). • For patients whose tests indicate they most likely do NOT have a current infection: <ul style="list-style-type: none"> ○ If symptoms are present, advise patients to keep monitoring symptoms and contact their prescriber about staying home and if retesting is appropriate.⁶ ○ If symptoms are not present, advise patients to continue to take steps to protect themselves and others.⁶ • For patients whose tests indicates they likely had a previous infection, but most likely do NOT have an acute infection: <ul style="list-style-type: none"> ○ It is not yet known if antibodies from COVID-19 infections provide immunity against a future infection.⁵ ○ Advise patients to continue to take steps to protect themselves and others.⁶ • For patients whose tests indicates they likely NEVER had an infection: <ul style="list-style-type: none"> ○ Advise patients to continue to take steps to protect themselves and others.⁶

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Question	Answer/Pertinent Information
What should patients be told about how long to continue isolation procedures?	<ul style="list-style-type: none">• For patients with a positive test for acute infection and who experienced COVID-19 symptoms, isolation procedures can be stopped after:¹³<ul style="list-style-type: none">○ no fever for at least 72 hours (without using any medicine to reduce fever) AND○ improved symptoms (e.g., cough, shortness of breath) AND○ at least ten days have passed since onset of symptoms• For patients with a positive test for acute infection who did NOT experiencing any COVID-19 symptoms prior to testing, isolation procedures can be stopped after:¹³<ul style="list-style-type: none">○ ten days have passed since the positive test AND○ WITHOUT any COVID-19 symptoms since the test was performed
What should be done to protect staff administering COVID-19 tests?	<ul style="list-style-type: none">• Follow facility policies and procedures and ensure anyone participating in testing is properly trained on specific testing activities that they will be involved in. Examples of these activities could include:<ul style="list-style-type: none">○ specimen collection and storage (i.e., if not able to run test immediately or specimens are transported for testing)○ performing the test○ proper disposal of testing supplies and PPE• Wear proper PPE (varies based on collection method) to protect yourself and patients when testing for COVID-19.⁸• To collect respiratory specimens (e.g., nasopharyngeal) for molecular (PCR) or antigen COVID-19 testing use PPE:⁸<ul style="list-style-type: none">○ mask (N95 or higher-level respirator [can use a facemask if a respirator is not available])<ul style="list-style-type: none">▪ Put mask on BEFORE entering the patient-care area. Remove AFTER leaving the patient-care area.▪ Perform hand hygiene (e.g., wash hands, use alcohol-based hand sanitizer) after removing masks.○ eye protection (goggles or disposable face shield that covers the front and sides of the face)<ul style="list-style-type: none">▪ Personal eye glasses or contact lens do NOT provide adequate protection.▪ Put eye protection on before or upon entering the patient-care area. Remove BEFORE leaving the patient-care area.○ gloves (non-sterile)<ul style="list-style-type: none">▪ Put gloves on upon entering the patient-care area. Remove when leaving the patient-care area.▪ Perform hand hygiene (e.g., wash hands, use alcohol-based hand sanitizer) immediately after removing gloves.○ gown (non-sterile)<ul style="list-style-type: none">▪ Put gown on upon entering the patient-care area. Remove BEFORE leaving the patient-care area• Follow facility policies for when it is appropriate to reuse PPE, based on specific products being used and the status of PPE shortages. Whenever possible, reusable PPE should be cleaned and disinfected (according to manufacturer instructions) prior to reuse.⁸

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Question	Answer/Pertinent Information			
What respiratory collection methods can be used for COVID-19 testing?	<ul style="list-style-type: none"> Proper respiratory specimen collection is important to reduce the chance of false negative test results.¹⁸ Specific descriptions for specimen collection by collection method can be found at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html. 			
	Collection Method ¹⁸	Who Collects ¹⁸	Collection Tool ¹⁸	Comments ¹⁸
	Nasopharyngeal (NP) or oropharyngeal (OP)	Healthcare provider	Synthetic fiber swab with plastic or wire shaft	<ul style="list-style-type: none"> AVOID calcium alginate swabs or swabs with wooden shafts due to possible virus inactivation and inhibiting PCR testing. NP collection recommended over OP. If both NP and OP swabs are collected, combine into one tube for testing.
	Nasal mid-turbinate swab	Healthcare provider or supervised onsite (not at home) self-collection	Flocked tapered swab	
	Nasal swab	Healthcare provider or supervised onsite (not at home) self-collection	Flocked or spun polyester swab	
	Nasal or nasopharyngeal wash/aspirate	Healthcare provider	Catheter and suction apparatus	
	Sputum	Supervised onsite (not at home) self-collection	Sterile, leak-proof, screw-cap, cup or sterile dry container	<ul style="list-style-type: none"> Can be used for patients with a productive cough. Sputum induction not recommended. Patients should rinse mouth with water prior to collecting. Instruct patients to expectorate deep cough sputum.
	Lower respiratory tract aspirate or bronchoalveolar lavage	Healthcare provider	Sterile, leak-proof, screw-cap sputum collection cup or sterile dry container	<ul style="list-style-type: none"> Can be used for hospitalized patients receiving mechanical ventilation Often not obtained because of concerns about aerosolization of virus during sample collection.²⁵

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Question	Answer/Pertinent Information
When are home-collection samples permitted with COVID-19 tests?	<ul style="list-style-type: none"> • Some molecular (PCR) COVID-19 tests may permit home collection using specific collection kits for nasal swabs or saliva samples with subsequent testing at labs that are CLIA-certified to perform high-complexity tests.^{7,19-21} <ul style="list-style-type: none"> ○ Some home collection kits may only be: <ul style="list-style-type: none"> ▪ available to patients AFTER determined to be appropriate by a healthcare provider (e.g., based on results of a COVID-19 questionnaire, clinical evaluation).⁷ ▪ approved for testing at specific laboratories.^{19,21} • To identify which EUA COVID-19 tests are approved to use home-collection samples for testing, look for the word “home” in the authorization’s column of the EUA Test Kit Manufacturers and Commercial Laboratories Table at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.
Can COVID-19 testing be completed at home?	<ul style="list-style-type: none"> • At the time of publication, there are NOT any EUA-approved COVID-19 tests that provide immediate results at home. All EUA-approved home-collection samples are mailed to specific testing locations. Patients are informed of results in a few days.⁷ • Discourage use of COVID-19 tests that do not have EUA approval. • Though it may be possible for patients to purchase tests for home use online, warn patients of the risks with home testing:²² <ul style="list-style-type: none"> ○ If ALL test results are not reported to proper health authorities, this limits the visibility of true COVID-19 cases. ○ Patients with positive test results might not receive medical advice, know recommendations for quarantining, or be aware of which recent contacts to alert.

- a. At the time of publication only certain molecular (PCR) and antigen tests have EUA approval for testing in patient care settings under a CLIA waiver and none of the serology (antibody) tests have EUA approval for testing in non-laboratory settings under a CLIA waiver.⁷
- b. When a test is evaluated compared to a non-reference standard, true sensitivity and specificity cannot be calculated. These comparisons are called **positive percent agreement** and **negative percent agreement**, instead of sensitivity and specificity.¹⁶

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Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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