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June 2020 ~ Resource #360601

COVID-19 Testing FAQs

(Updated January 15, 2021)

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 been infected with SARS-CoV-2 in the past. 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?	• 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] o date of EUA approval and dates for any revisions to EUA o manufacturer (referred to as entity) o test name (referred to as diagnostic) o type of test (referred to as product attributes) (e.g., antigen, molecular or polymerase chain reaction [PCR], serology) o authorized settings for testing (e.g., certified labs for high- or moderate-complexity, patient care settings under a CLIA waiver, at home)[a,d] o product-specific labeling information (under authorization documents) including: ▪ 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:[15,33,b] o molecular or PCR: 95% positive agreement, 100% negative agreement o serology: 90% positive agreement (overall and for IgG), 70% positive agreement (for IgM), 95% negative agreement o antigen: 80% sensitivity (specificity and/or negative percent agreement NOT specified at time of publication)

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3120 W. March Lane, Stockton, CA 95219 ~ Phone: 209-472-2240 ~ Fax: 209-472-2249
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Question	Answer/Pertinent Information
What do the different COVID-19 tests detect?	• **Serology tests** (uses a blood specimen) detect the body's immune response (e.g., IgG [late], IgM [early], virus-specific antibody) to SARS-CoV-2.[1] Examples of EUA-approved serology COVID-19 tests include *SARS-CoV-2 IgG Assay* and *Elecsys Anti-SARS-CoV-2*. o It takes about two weeks after symptoms appear to detect antibodies. Levels peak at about three to four weeks and then drop over time.[12,35] o 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 *ID Now COVID-19* and *Accula SARS-CoV-2*. • **Antigen tests** (uses a respiratory specimen) detect protein antigens from SARS-CoV-2. • 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 *Sofia SARS-2 Antigen FIA* result may not rule out an active COVID-19 infection. If patients have positive exposure and/or symptoms, confirm negative *Sofia SARS-2 Antigen FIA* results with a follow-up molecular test.[17] • The role for serology (antibody) tests is still evolving. Antibody tests are generally not recommend to diagnose acute COVID-19 infections.[4] Possible uses for antibody tests may include evaluating patients with a high suspicion for COVID-19 when molecular testing is negative and at least two weeks have passed since symptom onset; assessment of multisystem inflammatory syndrome; and collecting surveillance data.[35]
Who should be tested for COVID-19 infection?	• Symptoms of COVID-19 infection may include fever, cough, shortness of breath, fatigue, chills, muscle pain or body aches, new loss of taste or smell, nausea or vomiting, diarrhea, congested or runny nose, and/or sore throat.[14] • Follow state and local health department guidance on testing for active COVID-19 infection (e.g., molecular, antigen). o The highest priority for testing for acute COVID-19 infections should be people with symptoms. o Next, give priority to people who have had close contact (within six feet for at least 15 minutes) with someone with confirmed COVID-19.[26] This is because of significant asymptomatic and pre-symptomatic spread, as well as for contact tracing.[4] ▪ People exposed to SARS-CoV-2 who remain asymptomatic should quarantine for ten days if no testing is done or seven days with a negative test no earlier than day five post-exposure.[34] • Some organizations may mandate testing of larger groups, regardless of exposure (e.g., employers, colleges/universities). • If patients test positive, avoid retesting to see if the virus has cleared. Patients can remain positive for weeks to months.[30,32] Patients are not considered contagious as long as they meet the criteria outlined in the "What should patients be told about how long to continue isolation procedures?" row. • Serology (antibody) tests are being used for COVID-19 surveillance.[27] In addition, some experts suggest a possible role in evaluating patients with a high suspicion for COVID-19 when molecular testing is negative and at least two weeks have passed since symptom onset, and for assessment of multisystem inflammatory syndrome.[35] Follow state/local guidance for serology testing.

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Question	Answer/Pertinent Information
When should patients be tested for active infection after suspected exposure to SARS-CoV-2?	• Exact time frames for testing are not clearly defined. Use these principles to help determine if testing is appropriate: o Testing too soon after exposure (e.g., sooner than 3 to 5 days after exposure), can lead to false negative results. Viral replication takes some time to achieve detectable levels of SARS-CoV-2 following exposure.[29,30] o False negative results are more common in asymptomatic patients or PRIOR to symptom onset.[30] o Diagnostic tests (e.g., PCR, antigen) are most likely to be positive in the first three weeks of symptoms.[30] Viral levels start to decline within about a week of symptoms starting.[28]
How do sensitivity and specificity impact test results and predictive values?	• 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] o **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 **Sen**sitive tests are **N**egative, they rule **OUT** (**SnNOUT**) people who don't have what is being tested for.[9] o **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 **Sp**ecific tests are **P**ositive, they rule **IN** (**SpPIN**) people who have what is being tested for.[9] • To accurately interpret test results, it is important to understand PPV and NPV. o **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? o **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.

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<table>
<tr><th>Question</th><th colspan="6">Answer/Pertinent Information</th></tr>
<tr><td rowspan="4">How are positive and negative predictive values calculated?</td><td colspan="2" rowspan="2"></td><td colspan="2">Patient’s True COVID-19 Status</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>Positive</td><td>Negative</td></tr>
<tr><td rowspan="2">COVID-19 Test Result</td><td>Positive</td><td>88</td><td>4</td><td>Total = 88 + 4 = 92</td><td>PPV[10] = 88/92 = 95.6%</td></tr>
<tr><td>Negative</td><td>12</td><td>96</td><td>Total = 12 + 96 = 108</td><td>NPV[10] = 96/108 = 88%</td></tr>
<tr><td colspan="2"></td><td>Total = 88 + 12 = 100</td><td>Total = 4 + 96 = 100</td><td>Total = 100 + 100 OR 92 + 108 = 200</td><td></td></tr>
<tr><td colspan="2"></td><td>Sensitivity[9] = 88/100 = 88%</td><td>Specificity[9] = 96/100 = 96%</td><td colspan="2"></td></tr>
<tr><td rowspan="6">How should COVID-19 test results be interpreted?</td><td colspan="2">Type of Test[6]</td><td colspan="2">Test Result[6]</td><td colspan="2">Interpretation[6]</td></tr>
<tr><td colspan="2" rowspan="2">Viral testing (e.g., molecular or PCR, antigen)
(looking for an active infection)</td><td colspan="2">Positive</td><td colspan="2">Most likely has a current infection</td></tr>
<tr><td colspan="2">Negative</td><td colspan="2">Most likely does NOT have a current infection</td></tr>
<tr><td colspan="2" rowspan="2">Antibody testing (e.g., serology)
(looking for a previous infection)</td><td colspan="2">Positive</td><td colspan="2">Possibly had a recent infection</td></tr>
<tr><td colspan="2">Negative</td><td colspan="2">Likely has not had a recent infection</td></tr>
<tr><td colspan="2" rowspan="4">Viral AND antibody testing
(looking for an active or previous infection)</td><td colspan="2">Virus (positive)
Antibody (positive)</td><td colspan="2">Most likely has a current infection</td></tr>
<tr><td colspan="2">Virus (positive)
Antibody (negative)</td><td colspan="2">Most likely has a current infection</td></tr>
<tr><td colspan="2">Virus (negative)
Antibody (positive)</td><td colspan="2">Possibly had and recovered from an infection</td></tr>
<tr><td colspan="2">Virus (negative)
Antibody (negative)</td><td colspan="2">Likely has not had a recent infection</td></tr>
</table>

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Question	**Answer/Pertinent Information**
What to consider after a negative COVID-19 viral test?	• 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. o People exposed to SARS-CoV-2 who remain asymptomatic should quarantine for seven days with a negative test no earlier than day five post-exposure.[34]
How should COVID-19 test results be reported and communicated?	• 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.[23,24] • Regardless of results and the type of test, advise patients to use preventive measures to protect themselves and others.[26] • 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: o keep track of their symptoms.[13] o 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] o follow isolation procures (e.g., stay home, separate themselves from others). (See below for how long to continue isolation procedure.) o wear a cloth face covering over their mouth and nose if around other people or pets. o cover coughs or sneezes. o clean hands frequently with soap and water or hand sanitizer. o avoid sharing personal household items (e.g., dishes, cups, eating utensils, towels, bedding). o 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**: o If symptoms are present, advise patients to keep monitoring symptoms and contact their prescriber about staying home and if retesting is appropriate.[6] o If symptoms are not present, advise patients to continue to take steps to protect themselves and others.[6] • For patients whose tests indicates they **possibly had a previous infection**, but most likely do NOT have an acute infection: o It is not yet known if antibodies from COVID-19 infections provide immunity against a future infection.[5] o Advise patients to continue to take steps to protect themselves and others.[6] • For patients whose tests indicates they **likely NEVER had an infection**: o 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?	• For patients with a positive test for acute infection and **who experienced COVID-19 symptoms**, isolation procedures can be stopped after:[4,13] o no fever for at least 24 hours (without using any medicine to reduce fever) AND o improved symptoms (e.g., cough, shortness of breath) AND o at least ten days have passed since onset of symptoms • For patients with a positive test for acute infection **who did NOT experience any COVID-19 symptoms prior to testing**, isolation procedures can be stopped after:[13] o ten days have passed since the positive test AND o WITHOUT any COVID-19 symptoms since the test was performed
What should be done to protect staff administering COVID-19 tests?	• 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: o specimen collection and storage (i.e., if not able to run test immediately or specimens are transported for testing) o performing the test o 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] o **mask** (N95 or higher-level respirator [can use a facemask if a respirator is not available]) ▪ 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. o **eye protection** (goggles or disposable face shield that covers the front and sides of the face) ▪ Personal eyeglasses or contact lens do NOT provide adequate protection. ▪ Put eye protection on before or upon entering the patient-care area. Remove AFTER leaving the patient-care area. o **gloves** (non-sterile) ▪ Put gloves on upon entering the patient-care area. Remove BEFORE leaving the patient-care area. ▪ Perform hand hygiene (e.g., wash hands, use alcohol-based hand sanitizer) IMMEDIATELY AFTER removing gloves. o **gown** (non-sterile) ▪ 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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<table>
<tr><th>Question</th><th colspan="4">Answer/Pertinent Information</th></tr>
<tr><td rowspan="7">What respiratory collection methods can be used for COVID-19 viral testing?

Continued…</td><td colspan="4">• 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.</td></tr>
<tr><td>Collection Method[18]</td><td>Who Collects[18]</td><td>Collection Tool[18]</td><td>Comments[18]</td></tr>
<tr><td>Nasopharyngeal (NP) or oropharyngeal (OP)</td><td>Healthcare provider</td><td>Synthetic fiber swab with plastic or wire shaft</td><td>• 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.</td></tr>
<tr><td>Nasal mid-turbinate swab</td><td>Healthcare provider or supervised onsite (not at home) self-collection[c]</td><td>Flocked tapered swab</td><td></td></tr>
<tr><td>Nasal swab</td><td>Healthcare provider, home or supervised onsite self-collection[c]</td><td>Flocked or spun polyester swab</td><td></td></tr>
<tr><td>Nasal or nasopharyngeal wash/aspirate</td><td>Healthcare provider</td><td>Catheter and suction apparatus</td><td></td></tr>
<tr><td>Sputum</td><td>Supervised onsite (not at home) self-collection[c]</td><td>Sterile, leak-proof, screw-cap, cup or sterile dry container</td><td>• 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.</td></tr>
</table>

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<table>
<tr><th>Question</th><th colspan="4">Answer/Pertinent Information</th></tr>
<tr><td rowspan="3">Collection methods, continued</td><td>Collection Method[18]</td><td>Who Collects[18]</td><td>Collection Tool[18]</td><td>Comments[18]</td></tr>
<tr><td>Lower respiratory tract aspirate or bronchoalveolar lavage</td><td>Healthcare provider</td><td>Sterile, leak-proof, screw-cap sputum collection cup or sterile dry container</td><td>• Can be used for hospitalized patients receiving mechanical ventilation
• Often not obtained because of concerns about aerosolization of virus during sample collection.[25]</td></tr>
<tr><td>Saliva</td><td>Self or supervised at-home collection</td><td>Per the specific test’s instructions; including eating/drinking restrictions</td><td></td></tr>
<tr><td>When are home-collection samples permitted with COVID-19 tests?</td><td colspan="4">• Some 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.[7,19-21,31]
o Some home collection kits may:
▪ only be 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]
▪ only be approved for testing at specific laboratories.[19,21]
▪ allow for home testing (see row titled “Can COVID-19 testing be completed at home?”)
• To identify which EUA COVID-19 tests are approved to use home-collection samples for testing, look for the words “home collection” in the attribute’s column of the individual EUA tables for each type of test (i.e., molecular, antigen, serology) at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.
• At the time of publication, there are not any serology (antibody) tests with an EUA for sample collection at home.</td></tr>
<tr><td>Can COVID-19 testing be completed at home?

Continued…</td><td colspan="4">• To identify which EUA COVID-19 tests are approved to be completed at home, look for the words “home testing” in the “attributes” or “diagnostic and date EUA originally issued” columns of the individual EUA tables for each type of test (i.e., molecular, antigen, serology) at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.
• At the time of publication, there are a few EUA-approved viral COVID-19 tests that can be completed at home.[7] See our chart, COVID-19 Point-of-Care Testing, for details about these tests including how quickly results are available and other testing tips.
• Discourage use of COVID-19 tests that do not have EUA approval.
• Though it may be possible for patients to purchase other, non-EUA-approved tests for home use, warn patients of the risks:[22]</td></tr>
</table>

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Question	Answer/Pertinent Information
COVID-19 testing at home, continued	○ 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), antigen, and serology (antibody) tests have EUA approval for testing in patient care settings under a CLIA waiver or for testing at home.[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]
c. FDA issued guidance advising healthcare providers to provide clear, step-by-step instructions when patients are performing supervised self-collection in order to increase the chance that an adequate sample is obtained, thus limiting any impact on a test's sensitivity.[36]
d. Centers for Medicare & Medicaid (CMS) released a quick-start guide to streamline the CLIA-waiver certification process for labs conducting testing for COVID-19.[37] The quick-start guide can be found at https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf.

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Project Leader in preparation of this clinical resource (360601): *Beth Bryant, Pharm.D., BCPS, Assistant Editor; Last modified January 15, 2021.*

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Cite this document as follows: **Clinical Resource,** ***COVID-19 Testing FAQs. Pharmacist's Letter/Prescriber's Letter.*** **June 2020.**

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3120 West March Lane, Stockton, CA 95219 ~ TEL (209) 472-2240 ~ FAX (209) 472-2249