



**U.S. Food and Drug Administration (FDA) Revisions to COVID-19 Antigen Tests:
Requirements for Serial (Repeat) Testing**

Frequently Asked Questions (FAQs)

March 20, 2023

In response to new data on the performance of COVID-19 antigen tests, the FDA is revising the emergency use authorization of COVID-19 antigen tests. Manufacturers of COVID-19 antigen tests are required to modify their instructions to include serial (repeat) testing on both symptomatic and asymptomatic individuals. The goal of serial testing is to decrease the number of false negative results.

For symptomatic individuals, COVID-19 antigen tests will now be authorized for use on symptomatic individuals when tested at least twice over three (3) days with at least forty-eight (48) hours between tests.

For asymptomatic individuals, COVID-19 antigen tests will now be authorized for use on asymptomatic individuals when tested at least three (3) times over five (5) days with at least forty-eight (48) hours between tests.

These frequently asked questions (FAQs) were prepared to provide additional information and guidance on the use of COVID-19 antigen tests.

Frequently Asked Questions

1: What is serial testing?

A: Serial testing, or repeat testing, is when a test is performed more than once over a period of time.

2: What is the FDA requiring of COVID-19 antigen tests manufacturers?

A: Manufacturers of COVID-19 antigen tests will be required to modify the COVID-19 antigen test instructions to include requirements for serial (repeat) testing for both symptomatic and asymptomatic individuals. The goal of serial testing is to decrease the number of false negative results.

3: Will serial (repeat) testing be required when COVID-19 antigen tests are used on a symptomatic individual?

A: Yes. COVID-19 antigen tests will now be authorized by the FDA for use on symptomatic individuals when tested at least twice over three (3) days with at least forty-eight (48) hours between tests. If a symptomatic individual has a negative COVID-19 antigen test result, a second COVID-19 antigen test needs to be performed. The second test should be performed over three (3) days with at least forty-eight (48) hours between the first and second test. If the first COVID-19 antigen test is positive, a second test is not required.

4: Will serial (repeat) testing be required when COVID-19 antigen tests are used on an asymptomatic individual?

A: Yes. COVID-19 antigen tests will now be authorized by the FDA for use on asymptomatic individuals when tested at least three (3) times over five (5) days with at least forty-eight (48) hours between tests. If an asymptomatic individual has a negative COVID-19 antigen test result, a second COVID-19 antigen test needs to be performed with at least forty-eight (48) hours between the first and second test. If the second test is positive, a third test is not required. If the second test is negative, a third test needs to be performed with at least forty-eight (48) hours between the second and third test.

5: Is there a summary that describes how COVID-19 antigen tests should be used and interpreted when testing symptomatic and asymptomatic individuals?

A: Yes. The table below gives an overview of how serial testing needs to be done on symptomatic and asymptomatic individuals and what the results mean.

At-Home/Over the Counter COVID-19 Testing Recommendations				
Symptomatic Individuals <i>(COVID-19 symptoms present)</i>	First Result* Day 1	Second Result Day 3	Third Result Day 5	Final Result/Interpretation
	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
	<ul style="list-style-type: none"> *The first test should be taken immediately if you have symptoms of COVID-19. The second test should be taken if first test is negative with at least 48 hours between the first and second test. 			
Asymptomatic Individuals <i>(Exposed to COVID-19 but no COVID-19 symptoms present)</i>	First Result* Day 1	Second Result Day 3	Third Result Day 5	Final Result/Interpretation
	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19
<ul style="list-style-type: none"> *The first test should be taken 5 days after a known exposure (day 0 = last known exposure). The second test should be taken if the first test is negative with at least 48 hours between the first and second test. The third test should be taken if second test is negative with at least 48 hours between the second and third test. 				

For more information, please visit: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results>. The most current at home/OTC test instructions may be accessed at <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list> or on the brand/manufacture's website. Free community COVID-19 testing locations can be found at <https://testinglocator.cdc.gov/>.

6: Do the new requirements for serial (repeat) testing impact all COVID-19 tests?

A: No. The requirements for serial testing apply to point of care (POC) and at-home over the counter (OTC) COVID-19 antigen tests. The new requirements do not apply to non-antigen based COVID-19 tests such as COVID-19 molecular (also known as "PCR" or "NAAT" tests) and antibody tests.

7: Why has the FDA updated the requirement for serial (repeat) testing when using COVID-19 antigen tests?

A: The FDA, in collaboration with the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School, performed a study that showed that repeat testing over a longer timeframe improves test performance and increases the likelihood that a COVID-19 antigen test will detect an infection. Based on these results, the FDA determined that repeat testing after a negative result reduces the risk of a false negative result. COVID-19 antigen tests are less accurate than molecular tests such as polymerase chain reaction (PCR) tests. COVID-19 antigen tests may not detect the SARS-CoV-2 virus early in an infection, meaning testing soon after exposure to someone with COVID-19 could lead to a false negative result, especially if an individual does not have symptoms. If an individual tests shortly after an exposure, they might not yet have enough virus in their system for the COVID-19 antigen test to detect it. However, they may test positive later, which is why COVID-19 antigen tests are meant to be used repeatedly. Additional information can be found on the FDA's web site at: <https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety>.

8: I am using a COVID-19 antigen test and the instructions do not require serial (repeat) testing on symptomatic and asymptomatic individuals as described above. Are there some COVID-19 antigen tests that do not require serial testing on symptomatic and asymptomatic individuals?

A: The COVID-19 test kits you have may contain an older version of the test instructions. Manufacturers of COVID-19 antigen tests were required to submit updated instructions reflecting requirements for serial testing to the FDA by November 11, 2022. Once approved by the FDA, manufacturers will have twenty (20) business days to update electronic and mobile applications and thirty (30) business days to update paper instructions. Manufacturers will also notify their customers when changes are made to the instructions. You can also go to the FDA's website to look at any updates to the instructions at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>. This website lists all the COVID-19 antigen tests and provides links to each test's instructions for use (IFU).

9: If our facility is registered as a Limited Service Laboratory (LSL) and we are performing COVID-19 antigen testing, is our LSL required to perform serial testing as described in the instructions provided with a COVID-19 antigen test?

A: New York State Public Health Law requires an LSL to ensure that tests are performed in accordance with the manufacturers' instructions. If an LSL performs a COVID-19 antigen test on a symptomatic or asymptomatic patient and the result is negative, a follow-up test is required. The LSL should inform the patient that repeat testing is needed to determine if an individual is positive or negative for COVID-19 and that serial testing improves test accuracy.

10: Can a K-12 school exclude symptomatic students/staff/faculty until a second negative COVID-19 antigen test result is obtained?

A: Students and staff with symptoms of respiratory or gastrointestinal infections, such as cough, fever, sore throat, vomiting or diarrhea should be sent home or directed to stay home. If at school, the individual should wear a well-fitted mask while arrangements are

made to go home even if they have not yet had a test. Testing is recommended for people with symptoms of COVID-19 as soon as possible after symptoms begin. If a student, staff, or faculty member uses a COVID-19 antigen test and they test negative, serial (repeat) testing should be performed as recommended by the FDA. Additional information can be found on the FDA's web site at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results>.

11: Can a K-12 school exclude asymptomatic students/faculty/staff who were recently exposed to COVID-19 until a third negative COVID-19 antigen result is obtained?

A: Exposed or potentially exposed individuals do not need to be excluded from school but are strongly encouraged to wear a well-fitting mask and test as [recommended by the Centers for Disease Control and Prevention \(CDC\)](#). The CDC notes that accommodations may be necessary for exposed people who cannot or have difficulty wearing a mask. Schools can also consider recommending masking and/or testing for a classroom in which a student was recently exposed who is unable to wear a mask or respirator consistently and correctly. Schools may need to consider other prevention strategies—such as improving ventilation and avoiding crowding—when the [COVID-19 Community Level](#) is medium or high or in response to an outbreak. School administrators should confer with local health departments as applicable to determine how to manage exposures based on the local context and benefits of preserving access to in-person learning.

12: Are all K-12 schools that perform testing under an LSL required to follow the serial/repeat testing requirements for COVID-19 antigen tests?

A: New York State Public Health Law requires an LSL to ensure that tests are performed in accordance with the manufacturers' instructions. If an LSL performs a COVID-19 antigen test on a symptomatic or asymptomatic patient and the result is negative, a follow-up test is required so the LSL should inform the patient that repeat testing is needed to improve test accuracy. In addition, schools conducting testing under an LSL must follow all applicable reporting requirements for those tests they conduct. Schools performing COVID-19 antigen testing under an LSL are required to report positive results. Reporting of negative and inconclusive results is optional.

13: In a K-12 school, how soon after exposure notification should a person take the first test?

A: The recommended timing of testing depends on whether the individual has [symptoms of COVID-19](#). A listing of various scenarios based on exposure and/or the presence of symptoms and recommended steps for testing using at-home over the counter (OTC) antigen tests can be accessed at <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results>.

- It is recommended that those who have known exposure to COVID-19 but have no symptoms (asymptomatic) wait at least five (5) full days after the exposure to test. Testing earlier without symptoms (asymptomatic) may increase the likelihood of inaccurate results.
- Those with symptoms should test immediately and follow the guidance noted above for continued serial/repeat testing if a negative test result is received.
- If an individual receives a positive test result, they should follow [isolation guidance](#) and contact their healthcare provider to discuss treatment options.

14: Is it allowable for a K-12 school operating under an LSL to do the first test for those with symptoms and for the second and third test to be conducted outside the LSL setting using an over the counter (OTC) rapid antigen test?

A: Yes; this would be allowed. We recommend providing those who will be testing using at-home tests the most current information regarding serial testing as multiple negative tests increase the confidence that someone is not infected with the virus that causes COVID-19. This information can be found at <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results>. Individuals who may need assistance accessing no-cost testing can find resources at <https://testinglocator.cdc.gov/>.

15: Are K-12 schools operating under an LSL required to test exposed and symptomatic students and staff on-site, as outlined in the new serial testing guidance from the FDA (i.e., serial testing on days 1, 3 AND 5)?

A: No. A school providing COVID-19 testing through an active LSL registration may offer those who were exposed to continue serial/repeat testing using at-home tests.

16: If individuals who are permitted to test using OTC/at-home tests on days 3 and 5 test negative, would proof of results be required for K-12 schools operating under an LSL?

A: No; this would not be a requirement for those with an LSL; however, this may be the requirement of a school district/school for return to school/work, so we recommend inquiring about any requirements for your applicable school/district.

17: The February 28, 2023, [health advisory on elective surgery pre-procedure testing for SARS-CoV-2](#) states that facilities that choose to implement a pre-procedure testing program can use a COVID-19 antigen test authorized by the FDA when testing asymptomatic patients. If a COVID-19 antigen test is used for this purpose, is serial testing required?

A: To provide the greatest assurance that someone does not have SARS-CoV-2 infection, if using an antigen test instead of a nucleic acid amplification test (NAAT), facilities should perform three (3) tests over five (5) days, with at least forty-eight (48) hours between tests, in line with [U.S. Food & Drug Administration \(FDA\) recommendations](#). This includes point of care and home test use. Additional information for serial (repeat testing) when using antigen tests can be found on the [CDC website](#).

18: Currently, nursing homes are required to test residents and staff based on parameters and a frequency set forth by the U.S. Health and Human Services (HHS) Secretary as described in [QSO-20-38-NH Revised 9/23/2022](#). If a COVID-19 antigen test is used to meet these testing requirements, is serial testing required?

A: Yes. As described on the [CDC website](#), that is referenced in QSO-20-38-NH Revised 9/23/2022, anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test for SARS-CoV-2 as soon as possible. If the first test is negative, a second test is required to be performed over three (3) days with at least forty-eight (48) hours between tests. For asymptomatic individuals with close contact with someone with SARS-CoV-2 infection, the [CDC website](#) states that the individual should have a series of three (3) viral tests for SARS-CoV-2 infection. Testing is recommended immediately (but not earlier than twenty-four (24) hours after the exposure) and, if negative, again forty-eight (48) hours after the first negative test and, if

negative, again forty-eight (48) hours after the second negative test. This testing cadence is consistent with how COVID-19 antigen tests need to be used on asymptomatic individuals.