

Response to Point-of-Care (POC) Antigen Test Results

Although POC antigen tests for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus causing coronavirus disease 2019 (COVID-19), have emergency use authorization (EUA) for evaluation of symptomatic individuals, these testing platforms are also being used for testing of those who are asymptomatic and have no known specific exposure to COVID-19. These testing platforms are reported to have high sensitivity and specificity, so false negative and false positive results should be relatively unusual. However, there have been a number of anecdotal reports of positive results in asymptomatic individuals followed by negative results obtained from molecular (PCR) testing.

Interpretation of results from antigen testing should be considered in the context of pre-test probabilities.

- A **positive** result in an individual with symptoms consistent with COVID-19 or with history of specific exposure to COVID-19 provides presumptive laboratory evidence and the individual would be classified as a probable COVID-19 case.
- A **positive** result in an individual with no symptoms and no history of specific exposure to COVID-19 is recommended to be immediately followed by a PCR test to verify the positive result.*
- A **negative** result in an individual with no symptoms and no history of exposure to COVID-19 would be taken at face value and would not require additional follow-up.
- A **negative** result in an individual with symptoms consistent with COVID-19 would be only presumptively negative. This individual would continue as a person under investigation pending verification of that negative antigen test with a negative PCR test. A negative result in an individual with history of specific exposure to COVID-19 would not eliminate the need for quarantine.
- Per current case definition, a positive antigen test provides presumptive laboratory evidence for SARS-CoV-2 infection and is alone sufficient for identification as a probable case of COVID-19. Consequently, any individual with a positive antigen test (including those who are asymptomatic and have no known COVID-19 exposure history) should be considered presumptively positive and placed in isolation pending results of follow-up PCR testing. However, as this classification has substantial impact upon the individual, potential contacts, and public health response, a determination of the validity of the test result, as outlined below, is critical. If follow-up or confirmatory testing is not performed in this situation then the individual will be considered a probable case and release from isolation will follow current Kentucky Department for Public Health guidance. Additionally, contact investigation will be performed and exposed contacts placed in quarantine as indicated.

*It is recommended that any positive antigen result in an asymptomatic, unexposed individual be immediately followed by a PCR test to verify the positive result. This follow-up specimen should be collected within 24 hours of the original test, if possible; specimens collected greater than 48 hours after the initial specimen may lead to discordant results related to a change in viral dynamics over the course of the infection. If the PCR is negative on an appropriate specimen collected in the proper timeframe and the individual has remained asymptomatic, then the antigen test would be considered a false positive and the individual not counted as a COVID-19 case. If additional verification is felt to be necessary, a second PCR test could be performed on a specimen collected >24 hours after the initial PCR specimen.

Criteria to Determine that a Case Tested by Antigen has a False Positive Result

Cases may be determined to be false positives if they meet the following criteria:

Positive by antigen **AND**
asymptomatic **AND**
have no known contact to a COVID-19 case/setting with transmission **AND**
test negative by PCR within 24-48 hours after the collect date for the antigen test

This means you can release them from isolation, release their contacts from quarantine, and remove them from your case count list.

However, because of the volume of negative tests received by DPH every day, the local health department will be responsible for associating the negative test with the investigation in NEDSS, changing case status to not a case, and informing DPH staff so that we can adjust our case count accordingly. In order to be removed as a case, DPH must be notified. Please email the COVID19DR Inbox at COVID19DR@ky.gov.

Cases who fall outside the above scope (test positive by another mechanism; are either symptomatic and/or have a known exposure; and/or fail to get a PCR test within the 24-48 hours) will be counted as cases, will remain in isolation, and their contacts will remain quarantined. Cases that test positive by antigen, but receive two negative PCR tests at least 24 hours apart, but outside of the 48-hour window after the initial antigen positive test, will count as a probable case, but can be released from isolation (following the test-based release strategy). Their contacts will remain in quarantine based on the positive antigen result. We do not recommend that you wait for any of the following: to investigate the case; enter it into NEDSS; or conduct contact tracing pending the results of the PCR test.