

Guidance for the use and interpretation of SARS-CoV-2 antigen tests

December 22, 2020

Adapted from CDC’s Interim guidance for antigen testing for SARS-CoV-2, updated on December 5, 2020, available at: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Antigen tests can be used in a variety of testing strategies to respond to the coronavirus disease 2019 (COVID-19) pandemic. This guidance is intended for clinicians who order antigen tests, receive antigen test results, and perform point-of-care testing.

Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection.

Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens.

Antigen tests for SARS-CoV-2 are generally less sensitive than real-time reverse transcription polymerase chain reaction (RT-PCR) and other nucleic acid amplification tests (NAATs) for detecting the presence of viral nucleic acid.

Both antigen tests and NAATs perform best when the person is tested when viral load is generally highest.

Antigen tests work best in people who are symptomatic within the first 5 to 7 days from symptom onset, depending on the specific Emergency Use Authorization of the test being used. Generally, clinicians can rely upon a positive antigen test result for a symptomatic patient because the specificity of current FDA-authorized antigen tests is high.

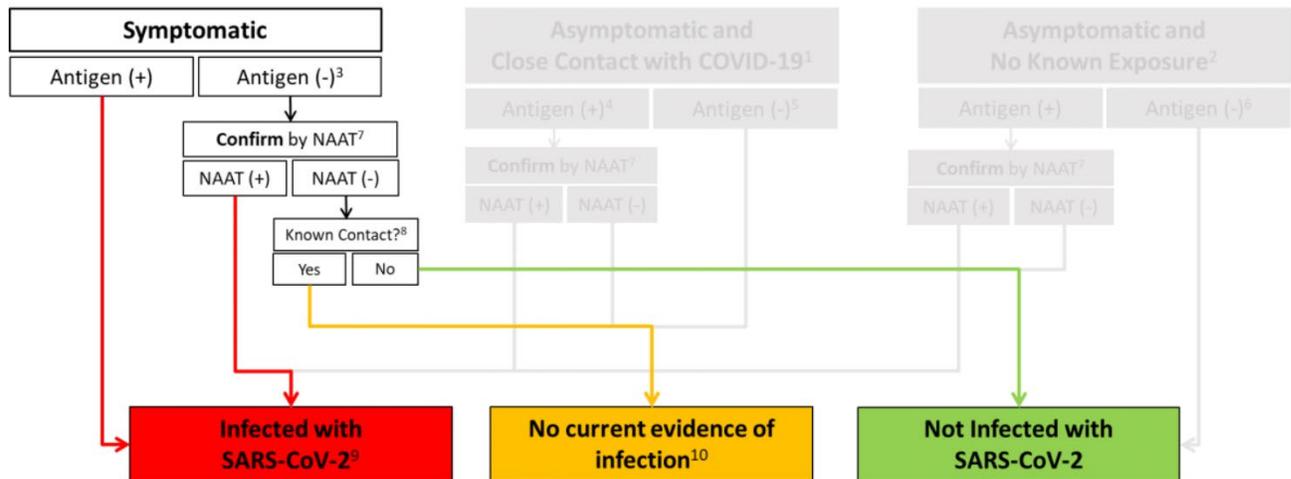
Purpose	PCR	Antigen
Regular and repeated screening of unexposed and asymptomatic people	Preferable	Acceptable
Diagnostic testing in symptomatic people	Preferable	Preferable within the first 5 to 7 days from symptom onset
Diagnostic testing in asymptomatic people	Preferable	Acceptable in people with known exposure
Diagnostic testing in previously COVID-19 positive patients with new exposure and symptomatic (potential re-infection)	X	Preferable within the first 5 to 7 days from symptom onset

It may be appropriate to confirm antigen test results with another test. CDC recommends following its antigen testing algorithm to determine when confirmatory testing is recommended.

Diagnostic Testing: Testing a symptomatic person

- When testing a person who has symptoms associated with COVID-19 the healthcare provider generally can interpret a positive antigen test to indicate that the person is infected with SARS-CoV-2.
- A negative antigen test result for a symptomatic person should be confirmed with an FDA-authorized NAAT.
 - When a symptomatic person receives a negative antigen test result followed by a negative confirmatory NAAT, the healthcare provider should take into consideration whether the person has had exposure to a person with COVID-19 within the past 14 days. If the person is a close contact of a known COVID-19 case, they should complete their quarantine period according to the [Shortened Quarantine Guidance](#).

Figure 2. Antigen Testing Algorithm – High Pretest Probability



³If a symptomatic person has a low likelihood of SARS-CoV-2 infection, clinical discretion should determine if this negative antigen test result requires confirmatory testing. Per KDHE guidance, if unsure, default to confirmation with an FDA authorized NAAT.

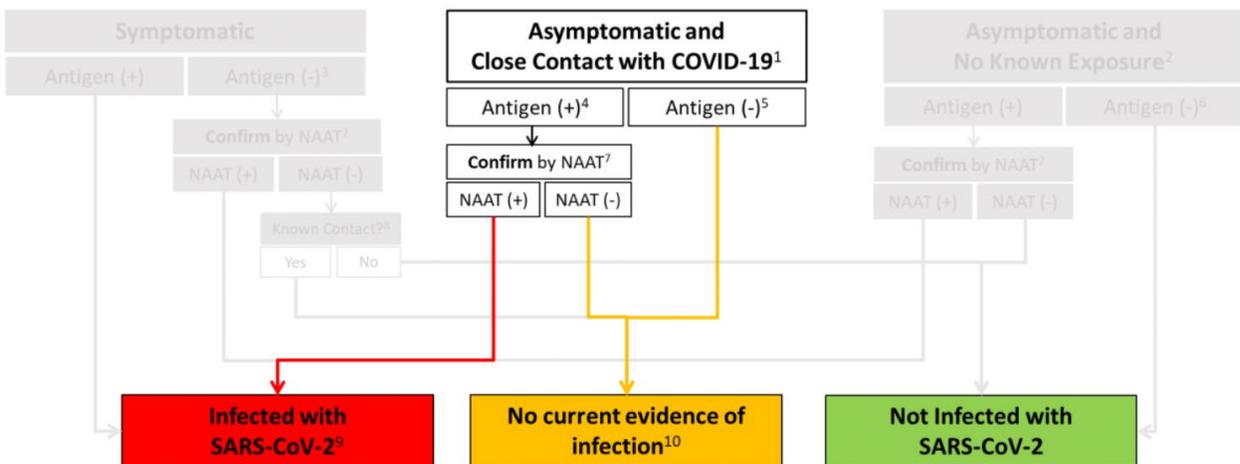
⁷Nucleic acid amplification test; confirm within 48 hours using a NAAT, such as RT-PCR, that has been evaluated against FDA’s reference panel for analytical sensitivity

⁸Known exposure to a person with COVID-19 within the last 14 days, complete quarantine period according to Shortened Quarantine Guidance. If unsure of exposure, clinical discretion should determine whether isolation is necessary.

Diagnostic Testing: Testing an asymptomatic person who has had close contact with a person with COVID-19

- When testing a person who is asymptomatic and has had exposure to a person with COVID-19 within the last 14 days the healthcare provider should confirm a positive antigen test result with an FDA-authorized NAAT.
- When there is high incidence of infection in the community, community spread, or a person with household or continuous contact to a person or people with COVID-19, clinical judgement should determine if a positive antigen result for an asymptomatic person should be followed by a confirmatory NAAT. In these circumstances, a confirmatory NAAT test may not be necessary.
- Persons who receive a positive antigen test result that should undergo confirmatory testing should isolate while awaiting results of the confirmatory testing.
 - Confirmatory testing should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAAT should be considered a separate test – not a confirmation of the earlier test. If the results are discordant between the antigen test and the confirmatory NAAT, in general the confirmatory test result (NAAT result) should be interpreted as definitive for the purpose of clinical diagnosis.

Figure 3. Antigen Testing Algorithm – Moderate Pretest Probability



¹Single, multiple, or continuous known exposure to a person with COVID-19 within the last 14 days; perform NAAT first if short turnaround time is available, if person cannot be effectively and safely quarantined, or if there are barriers to possible confirmatory testing

⁴In instances of higher pretest probability, such as high incidence of infection in the community, clinical discretion should determine if this positive antigen result requires confirmation. Per KDHE guidance, in these circumstances, a confirmatory NAAT test may not be necessary.

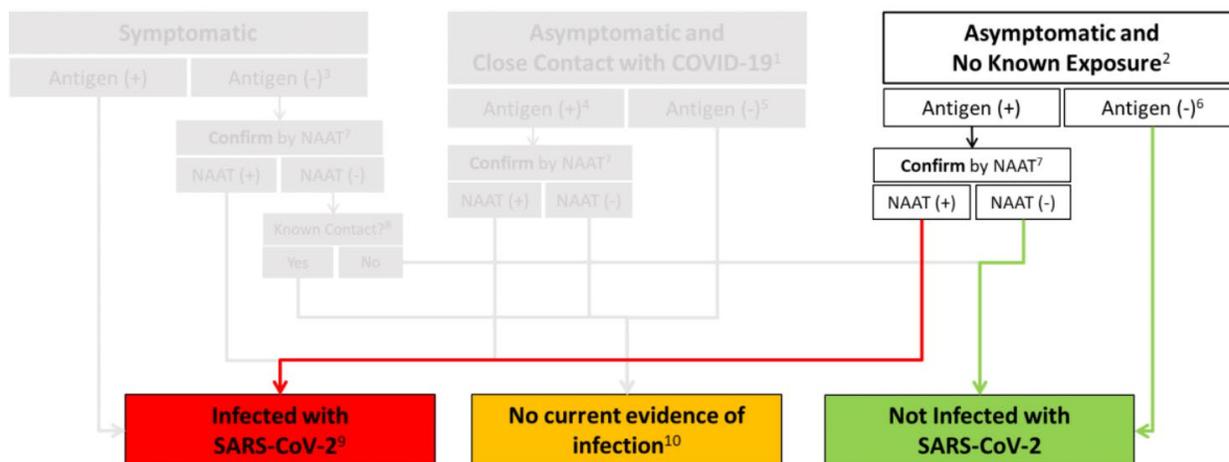
⁵In certain settings, serial antigen testing could be considered for those with a negative antigen test result; serial testing may not require confirmation of negative results

⁷Nucleic acid amplification test; confirm within 48 hours using a NAAT, such as RT-PCR, that has been evaluated against FDA’s reference panel for analytical sensitivity

Screening Testing: Testing an asymptomatic person with no known exposure to a person with COVID-19

- When testing a person who is asymptomatic and has not had known exposure to a person with COVID-19 within the last 14 days the healthcare provider generally can interpret a negative antigen test to indicate that the person is not infected with SARS-CoV-2.
- The probability for a false positive in these circumstances is higher; therefore, a positive antigen test result should be followed by a confirmatory NAAT.
 - Persons who receive a positive antigen test result that should undergo confirmatory testing should quarantine while awaiting results of the confirmatory testing.
 - Confirmatory testing should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAAT should be considered a separate test – not a confirmation of the earlier test. If the results are discordant between the antigen test and the confirmatory NAAT, in general the confirmatory test result (NAAT result) should be interpreted as definitive for the purpose of clinical diagnosis.

Figure 4. Antigen Testing Algorithm – Low Pretest Probability



²No known exposure to a person with COVID-19 within the last 14 days

⁶If prevalence of infection is not low in the community, clinical discretion should consider whether this negative antigen result requires confirmation. Per KDHE guidance, in these circumstances, a confirmatory NAAT test may not be necessary.

⁷Nucleic acid amplification test; confirm within 48 hours using a NAAT, such as RT-PCR, that has been evaluated against FDA’s reference panel for analytical sensitivity