

## Performance of Antigen Tests for COVID-19 for the Detection of Current Variants

**Situation:** There is concern that rapid antigen tests for COVID-19 may be more prone to falsely-negative results with current variants. There is confusion and variability in usage of COVID-19 antigen tests.

**Background:** Evidence indicates that home antigen tests for COVID-19 may be negative, sometimes repeatedly negative, in patients who ultimately test positive for COVID-19. Over-reliance on single negative antigen tests may promote the spread of COVID-19, but positive antigen tests in the appropriate clinical scenarios can play an important role in early detection and avoiding healthcare costs and delays associated with PCR testing. Improved guidance for the use and utility of antigen tests may help alleviate these concerns. The [FDA has recently issued guidance](#) that “recommends repeat testing following a negative [antigen test] result whether or not you have COVID-19 symptoms.”

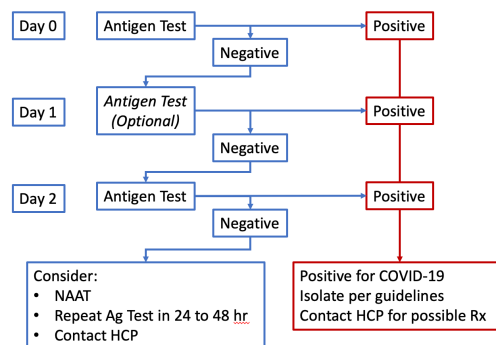
**Assessment:** COVID-19 antigen test performance depends upon multiple factors:

- 1) Test characteristics, including sensitivity may vary by test manufacturer.
- 2) Virus characteristics, including variation in amino acid sequences targeted by rapid tests, the sites of viral replication and the kinetics of viral accumulation (i.e. viral load) in the nares.
- 3) Patient characteristics, including pre-existing immunity from infection and/or vaccination.
- 4) Test utilization, including timing of testing following symptom onset.

Current literature is conflicting or lacking for the most recent circulating variants. Additionally, testing earlier after symptom onset has become more common and existing immunity may be associated with reduced viral loads *at the time of initial antigen testing*. **Thus, reports of variable antigen test performance are not unexpected and do not represent widespread failures of these tests.** However, antigen testing still can be useful if recommended principles are followed.

### Recommendations:

- Follow employer and local guidelines for masking and isolation while symptomatic
- A single, negative COVID-19 antigen test performed early after symptom onset does not exclude COVID-19. The utility of testing in this setting is when the test is positive, which is diagnostic for COVID-19. PCR/NAAT testing is not needed to confirm a positive antigen test.
- If the initial test is negative, follow the testing principles below to rule out a diagnosis of COVID-19:
  - If symptoms persist or worsen, repeat antigen testing 48 hours after the original test.
  - If symptoms persist or worsen after a *second negative* antigen test, consider a laboratory-based nucleic acid amplification test (NAAT) if isolation and daily activities would be affected. You may also consider calling your healthcare provider.
  - If NAAT is not easily obtained in the above scenario and you are concerned you could have COVID-19, perform a third antigen test 48 hours after the second.



- Further details about the FDA Guidance are here: [https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication?utm_medium=email&utm_source=govdelivery)

*This statement is based on current information, recommendations, and evidence and will be subject to revision or retraction based on continued monitoring by the YNHHS/YM Testing Stewardship Committee.*