

Antigen Control Frequently Asked Questions

What controls do you have for detecting COVID?

We have developed a variety of controls for COVID-19, including synthetic RNA and inactivated whole virus controls. While synthetic RNA and inactivated whole virus controls can be used for molecular testing methods that help detect an active infection of COVID-19, item #HE0068AG SARS-CoV-2 Whole Virus Antigen Control (Swab), can be used with both molecular and antigen tests in the point-of-care (POC) setting.

Check out our complete list of COVID-19 products [here](#).

What is antigen testing?

Antigen tests detect the presence of specific viral antigens that imply current viral infection.

Antigen tests can help reduce delays in diagnosis with their rapid results by filling gaps in access to testing and alleviating pressure on laboratories performing nucleic acid tests (NAATs).

Molecular vs Antigen testing?¹

| | Molecular Test | Antigen Test |
|------------------------------------|---|--|
| Detects | Viral nucleic acids using reverse transcriptase polymerase chain reaction (RT-PCR) | Protein(s) from a virus particle (eg. nucleocapsid and/or spike proteins) |
| Intended Use | Detect current infection | Detect current infection |
| Sample Type | Nasal swab, nasopharyngeal swab, mid-turbinate swab, respiratory aspirate/lavage, or saliva sample, depending on the test | Nasal swab or nasopharyngeal swab, depending on the test |
| Laboratory or POC | Most tests are authorized for use in laboratories, with certain laboratory tests authorized for a patient's sample to be collected at home and then mailed to the laboratory for analysis. A few tests are authorized for use at the point of care. | While a few antigen tests are laboratory based, most of the currently authorized tests are for use at the point of care. |
| Cost/Test | Moderate | Low |
| Results Reporting Window | Several hours to days for laboratory test results to be reported to patients; less than an hour for point-of-care tests | Ranges from 15 minutes to 30 minutes |
| Sensitivity and Specificity | Highly sensitive and specific | Highly specific, but generally less sensitive than molecular tests |

Advantages and Disadvantages of Molecular and Antigen Testing¹

| | Molecular Test | Antigen Test |
|----------------------|--|---|
| Advantages | <ul style="list-style-type: none"> • Most sensitive test method available • Short turnaround for reporting results to patients with POC NAAT tests, but few are available • Usually does not need to be repeated to confirm results | <ul style="list-style-type: none"> • Short turnaround for reporting results to patients (approximately 15 minutes) • When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission in the community, workplace, etc. • Comparable performance to NAATs in symptomatic persons and persons with culturable virus present, who are presumed to be infectious |
| Disadvantages | <ul style="list-style-type: none"> • Longer turnaround for reporting results to patients with lab-based tests (1–3 days) • Higher cost per test • A positive NAAT diagnostic test should not be repeated within 90 days, since people may continue to have detectable RNA after risk of transmission has passed | <ul style="list-style-type: none"> • May need confirmatory testing • Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people |

Regulatory Guidance on Point-of-Care Testing (POCT)

- ISO 15189:2012
 - 5.6.2.2 Quality control materials
 - “Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.”
 - “NOTE 2 Use of independent third-party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.”
- ISO 22870:2016
 - “5.6.4 Where available, participation in an external quality assessment (EQA) shall be required (see ISO/IEC 17043). In the absence of an EQA scheme, the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of the test within the laboratory.”

- AACC Guidance Document on Management of Point-of-Care Testing
 - “Multiple studies document improved performance and quality of POCT when laboratories participate in PT/EQA programs, incorporate the PT results into a total quality improvement program, and act on the trends to identify and correct their mistakes. We recommend that all laboratories performing POCT participate in a PT/EQA program for each test that they perform.”
 - “Beyond operator technique, PT/EQA also verifies that the test kits have been stored appropriately, reagents are viable for testing, POCT devices are functioning, and staff are appropriately timing and interpreting test results.”
 - “Participation in PT/EQA is therefore recommended for all tests and locations where POCT is conducted, even for CLIA waived tests.”

Is SARS-CoV-2 Antigen Confirmatory Testing Needed?¹

The CDC states that confirmatory testing with a laboratory-based nucleic acid test (NAAT) may be required for individuals with higher risk factors or increased probability of transmission, based on the person’s health, exposure history, vaccination status, place of residency, and other considerations. For more information, refer to confirmatory testing guidelines from the CDC or other appropriate organizations.

Sources

1. CDC. Interim Guidance for Antigen Testing for SARS-CoV-2. (2021, June 14). <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
2. International Organization for Standardization. (2014). Medical laboratories — Requirements for quality and competence (ISO Standard No. 15189:2014). <https://www.iso.org/standard/56115.html>
3. International Organization for Standardization. (2016). Point-of-care testing (POCT) — Requirements for quality and competence (ISO Standard No. 22870:2016). <https://www.iso.org/standard/56115.html>
4. Nichols JH, Alter D, Chen Y, Isbell TS, Jacobs E, Moore N, Shajani-Yia Z. AACC guidance document on management of point-of-care testing. [Epub] J Appl Lab Med June 4, 2020, as doi:10.1093/jalm/jfaa059.