

Missouri Department of Health & Senior Services

Health Update:

Recommended Measures to Limit False Positive Results with COVID-19 Antigen Tests

November 9, 2020

This document will be updated as new information becomes available. The current version can always be viewed at <http://www.health.mo.gov>.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require

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Health Update
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SUBJECT: Update: Recommended Measures to Limit False Positive Results with COVID-19 Antigen Tests

The Missouri Department of Health and Senior Services (DHSS) is issuing this health update notification to Missouri clinicians, physicians, laboratories, congregate care facilities, and k-12 schools regarding the importance of following the manufacturer's instructions when using antigen tests for COVID-19. The U.S. Food and Drug Administration (FDA) issued a [letter of concern](#) regarding the potential for **false positive** results with antigen tests for the rapid detection of SARS-CoV-2, the virus that causes COVID-19. Failure to strictly adhere to the manufacturer's instructions and the following guidance provided by the FDA may lead to an increase in false positive test results, which can have a substantial negative impact on the community.

There are risks of false positive results with all laboratory tests. Laboratories should expect some false positive results to occur even when very accurate tests are used for screening large populations with a low prevalence of infection. Health care providers and clinical laboratory staff can help ensure accurate reporting of test results by following the authorized instructions for use of a test and key steps in the testing process as recommended by the Centers for Disease Control and Prevention (CDC), including routine follow-up testing (reflex testing) with a molecular assay when appropriate, and by considering the expected occurrence of false positive results when interpreting test results in their patient populations.

DHSS recommends clinical laboratory staff and health care providers who use antigen tests for the rapid detection of SARS-CoV-2 consider the following recommendations from the FDA, including, but not limited to:

- Follow the manufacturer's instructions for use, typically found in the package insert, when performing the test and reading test results. If you no longer have the package insert the authorized instructions for use for each test can also be found on the FDA's [COVID-19 IVD EUA webpage](#).
 - For example, the package insert for tests include instructions for handling of the test cartridge/card, such as ensuring it is not stored open prior to use. If the test components are not stored properly, this can affect the performance of the test.

The package insert for tests also includes instructions about reading the test results, including the appropriate time to read the results. **Reading the test *before or after* the specified time could result in false positive or false negative results.**

- Be aware that processing multiple specimens in batch mode may make it more challenging to ensure the correct incubation time for each specimen. Refer to the package insert and ensure proper timing for each specimen when processing the specimen in the test device and reading the results.
- Be careful to minimize the risks of cross-contamination when testing patient specimens, which can cause false positive results. Insufficient cleaning of the workspace, insufficient disinfection of the instrument, or inappropriate use of protective equipment (for example, failing to change gloves between patients) can increase the risk of cross-contamination between specimens with subsequent false positive results. Consider the [CDC guidance](#) for changing gloves and cleaning work area between specimen handling and processing.
- Consider the [CDC's recommendations](#) when using antigen testing in nursing homes and other settings. For positive results, especially in low incidence counties, consider performing confirmatory RT-PCR test within 48 hours.
- Remember that positive predictive value (PPV) varies with disease prevalence when interpreting results from diagnostic tests.
- Consider positive results in combination with clinical observations, patient history, and epidemiological information.

The FDA will continue to monitor the use of rapid antigen test platforms and will keep clinical laboratory staff, health care providers, manufacturers, and the public informed of new or additional information. DHSS will promptly inform all Missouri users of these testing platforms as developments occur.

Missouri healthcare providers, public health practitioners and users of rapid antigen testing platforms, please contact your local public health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this Guidance. Technical questions regarding the use of rapid antigen test platforms should be directed to Russ Drury, Missouri State Public Health Laboratory at Russ.Drury@health.mo.gov