Missouri Department of Health & Senior Services

Health Update:

Antigen Testing for COVID-19

June 3, 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 immediate action.

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SUBJECT: Antigen Testing for COVID-19

The Missouri Department of Health and Senior Services is issuing this health update notification to Missouri clinicians, physicians, and laboratories related to the use and reporting of antigen tests for SARS CoV-2, the virus that causes COVID-19. Providers and laboratories should immediately report all results from antigen tests for SARS CoV-2 to DHSS in accordance with established rules and waivers for the reporting of COVID-19 in the state of Missouri. Reporting guidance was included in a prior Health Update released on April 6, 2020, available at https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update4620.pdf.

Antigen Tests

On May 8, 2020, the U.S. Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for an antigen test for COVID-19. Antigen tests are new type of diagnostic test designed for rapid detection SARS CoV-2. Although a new diagnostic tool for COVID-19, antigen tests are routinely used for the diagnosis of other infections including influenza. Antigen tests are considered diagnostic tests and work by quickly detecting fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. Antigen tests are an important addition to the overall response against COVID-19 and the FDA expects many more antigen tests to receive EUA approval. Additional information regarding the EUA approved antigen test is available from the FDA at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes

The advantages of antigen tests generally include the lower cost to produce and the speed of the test. Antigen test results are usually available in minutes. However, it is important to note there are limitations. Antigen tests may not detect all active infections. Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

Antigen tests results are included in the national reporting case definition developed by the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL), and the Centers for Disease Control and Prevention (CDC). In accordance with the case definition, results from

antigen and antibody tests are considered presumptive laboratory evidence. Results from PCR and other approved molecular amplification detection tests are considered confirmatory laboratory evidence. Additional information on case classification and the national reporting case definition was included in the Health Update released on April 10, 2020, available at https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update41020.pdf

General questions about COVID-19 reporting should be directed to DHSS' Bureau of Reportable Disease Informatics at 573-526-5271.