**Alabama Department of Public Health (ADPH)**
**Alabama Emergency Response Technology (ALERT)**
**Health Alert Network (HAN)**
**December 20, 2021**

**COVID-19 Testing for Omicron Variant and J&J Vaccine Update**

**COVID-19 omicron variant may negatively affect the test results of currently used COVID-19 tests**

On December 16, 2021, the first verified case of the SARS-CoV-2 omicron variant (B.1.1.529, BA.1) was identified in Alabama. Mutations present in this virus strain might lead to false negative PCR/molecular test results in a test that your office or laboratory provider may be using.

The United States Food and Drug Administration (FDA) has developed specific guidelines for manufacturers that outline each company's responsibility to test its product's reliability in the face of novel variants. These guidelines are publicly available on the FDA's website. Neither ADPH nor the Centers for Disease Control and Prevention (CDC) has jurisdiction or authority over these processes.

Using data submitted by manufacturers and based on the specific mechanism of the test, the FDA can release preliminary guidance on tests that may fail to detect a novel SARS-CoV-2 variant. These tests are listed on the FDA's website and are subject to change based on further investigation or with the development of future variants.

ADPH recommends that all facilities offering testing regularly check the FDA's website to determine if the test applicable to you may be subject to further review or may be likely to fail. If this is discovered, it is recommended that you contact the manufacturer and consider using a different testing option until further review has been accomplished. This verification is the responsibility of the manufacturer, not the FDA, the CDC, or ADPH.

Additional information can be found at the website listed below.

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests#omicron-reduced

**ACIP recommends mRNA COVID vaccines over the Johnson & Johnson vaccine due to rare risk of blood clots**

Also, on December 16, CDC's Advisory Committee on Immunization Practices (ACIP) met to discuss the latest evidence on the safety and efficacy of the currently available COVID-19 vaccines in the United States. After careful review, the committee unanimously recommended that individuals preferentially receive an mRNA COVID-19 vaccine over Johnson & Johnson's COVID-19 vaccine due to the rare risk of Thrombosis with Thrombocytopenia Syndrome (TTS). This aligns with recommendations from other countries such as Canada and the United Kingdom.

Currently, there is a plentiful supply of mRNA vaccines in the U.S. The committee did reaffirm that receiving any vaccine is better than being unvaccinated and that individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to Johnson & Johnson's COVID-19 vaccine after a thorough discussion of the risks and benefits with their providers.

https://www.cdc.gov/media/releases/2021/s1216-covid-19-vaccines.html

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html