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FDA: SARS-CoV-2 mutations may cause false negative test results

by Melissa Jenco, News Content Editor

Editor's note:*For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Mutations in the SARS-CoV-2 virus may cause false negatives on molecular diagnostic tests, the Food and Drug Administration (FDA) warned Friday.

The FDA is monitoring mutations including one found in the United Kingdom that is associated with an increased risk of transmission, but officials said they believe the impact on authorized tests and vaccines is low.

"The FDA will continue to monitor SARS-CoV-2 genetic viral variants to ensure authorized tests continue to provide accurate results for patients," FDA Commissioner Stephen M. Hahn, M.D., said in a press release. "While these efforts continue, we are working with authorized test developers and reviewing incoming data to ensure that health care providers and clinical staff can quickly and accurately diagnose patients infected with SARS-CoV-2, including those with emerging genetic variants. At this time, we believe the data suggests that the currently authorized COVID-19 vaccines may still be effective against this strain."

The FDA noted false negatives can happen with any test. In the case of molecular tests, those that use a single genetic target may be more impacted than those using multiple targets.

The agency called out three tests that could be impacted - Mesa Biotech Accula, TaqPath COVID-19 Combo Kit and Linea COVID-19 Assay Kit, but said "the impact does not appear to be significant." More information about these tests is available in an FDA letter to clinicians.

Clinicians with a patient who tests negative should consider the person's history, symptoms and local epidemiology, according to the FDA. If they still suspect the person is infected with SARS-CoV-2, they should consider re-testing using a test with different genetic targets.

Adverse events including performance issues with molecular tests can be reported through the FDA's MedWatch reporting program. Clinicians with questions about COVID-19 testing can contact the FDA at COVID19DX@fda.hhs.gov.

Resources

- AAP interim guidance on COVID-19 testing
- Information from the FDA on the basics of COVID-19 testing