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FDA notes limitations of COVID-19 antibody tests; OKs first at-home diagnostic test

by Trisha Korioth, Staff Writer

Health care providers should not expect serological (antibody) tests for coronavirus disease 2019 (COVID-19) to definitively diagnose or exclude SARS-CoV-2 infection, according to a letter from the Food and Drug Administration (FDA).

Antibody tests for COVID-19 received emergency use authorization (EUA) from the FDA in March. This action allows unapproved medical products or unapproved uses of approved medical products to be used in an emergency.

No antibody test has been validated by the FDA for diagnosis of SARS-CoV-2 infection, according to the FDA letter. "(T)he FDA does not expect that an antibody test can be shown to definitively diagnose or exclude SARS-CoV-2 infection."

The FDA recommends health care providers:

- Continue using serological (antibody) tests as appropriate and be aware of their limitations.
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
- Be aware that not all marketed serological tests have been evaluated by the FDA. The FDA website lists authorized tests and tests offered under FDA COVID-19 diagnostic policy guidance.

Antibodies may not be present in detectable levels in early days of an infection. This limits a test's effectiveness for diagnosing COVID-19 and is why it should not be used as the sole basis to diagnose the disease. Current authorized serological tests measure IgM and/or IgG antibodies, the FDA letter explained. "We also do not know how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after the infection has been cleared."

The FDA noted that tests can provide information about the immune response in patients and how many people may have been infected and offer a better understanding of length of immunity and reinfection after recovery.

To help ensure access to accurate tests, the FDA is working with the National Institutes of Health and Centers for Disease Control and Prevention on a validation project. The ongoing project aims to identify the most promising serological tests. For details, visit https://federallabs.org/news/nci-brings-serological-test-validation-to-covid-19-fight.

The FDA also authorized the first COVID-19 diagnostic (RT-PCR) test with a home collection option today. The test could be available within a few weeks in most states with a doctor's order, according to a news release.

Through a re-issued EUA, the FDA is permitting testing of samples self-collected by patients at home using a designated home collection kit from the Laboratory Corporation of America (LabCorp). The FDA pointed out that the EUA was not a general authorization for at-home collection of patient samples using other collection swabs, media or tests, or for tests fully conducted at home.