What you should know on FDA’s new SARS-CoV-2 antibody test rules

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What’s the news: The Food and Drug Administration (FDA) is updating its policy on SARS-CoV-2 antibody testing after a flood of serology tests came to market, some with poor performance and fraudulent labeling.

The FDA will now require all commercial test manufacturers to apply for an emergency use authorization (EUA) to offer their tests on the market. The FDA has also provided recommended performance criteria for these tests. Tests developed as laboratory-developed tests (LDTs) will still be allowed to be offered without going through the EUA process.

Under the revised policy, explained by FDA leaders Anand Shah, MD, and Jeff Shuren, MD, the agency is requiring commercial manufacturers to “submit EUA requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing.” The agency also “has provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers,” Drs. Shah and Shuren wrote.

Learn more with the AMA about the essentials on new CPT codes for SARS-CoV-2 antibody tests.

Why it’s important: The FDA has noted the many limitations serology tests currently present, including the significant risk of false-positive results in areas where there is low prevalence of COVID-19, the disease caused by SARS-CoV-2. The FDA noted that these tests should currently be used in limited circumstances, such as population-level study, to evaluate potential donors for convalescent plasma, and in other well-defined testing plans in concert with other clinical information.

The AMA recently noted rising worries “over the performance of many of these tests currently coming to market” in a letter to Adm. Brett P. Giroir, MD, the White House coronavirus task force’s point man on testing.

“We are growing increasingly concerned that, without proper guidance, physicians and members of the general public could consider results of these tests to be actionable on an individual level, potentially resulting in individuals making decisions to limit physical distancing on the basis of the results,” wrote AMA Executive Vice President and CEO James L. Madara, MD.

The AMA recommended the tests “be limited to use in epidemiological/population-level study or by physicians and laboratorians trained in interpretation of serological tests and with a strong understanding of the limitations of the results.”

Learn more: Stay up to speed on the AMA’s COVID-19 advocacy efforts and track the fast-moving pandemic with the AMA's COVID-19 resource center, which offers a library of the most up-to-date resources from JAMA Network™, the Centers for Disease Control and Prevention, and the World Health Organization.