
Health Law Daily Wrap Up

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The revocations are made to a named manufacturer and to multiple unnamed manufacturers of COVID-19 antibody tests.

The FDA has announced the revocation of emergency use authorizations (EUA) for manufacturers with tests for COVID-19 antibodies. The revocations were made due to EUA criteria for issuance no longer being met and other circumstances, according to the FDA. The FDA said that the revocations were appropriate to protect public health or safety (Notice, 85 FR 62739, October 5, 2020).

Background. The Food, Drug, and Cosmetic Act (FDC Act) allows the FDA to authorize the use of an unapproved medical product or and unproved use of an approved medical product in certain situations, including to strengthen public health. On April 28, 2020, the FDA issued an EUA to stakeholders for certain in vitro diagnostic SARS-CoV-2 antibody tests for use in laboratories. The virus is named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19.

Revocations. An EUA may be revoked under the FD&C if the criteria for issuance are no longer met or other circumstances make the revocation appropriate to the public health and safety. The first revocation was for a test by Autobio Diagnostices Co. Ltd, where the FDA noted that the test had poor performance regarding immunoglobulin M (IgM) sensitivity according to a National Cancer Institute (NCI) evaluation after authorization of the device. The FDA concluded that it was not reasonable to believe that the product may be effective in detecting IgM antibodies to SARS-CoV-2 or that the known or potential risks outweigh the benefits. The second revocation issued by the FDA was to manufacturers and other stakeholders for certain in vitro diagnostic SARS-CoV-2 antibody tests and did not name specific manufacturers. The letter reads: "Based on information and experience since the issuance of the umbrella EUA, FDA has determined that circumstances support the revocation of the umbrella EUA so that FDA may issue individual EUAs. Individual EUAs will allow for broader implications and scopes of authorization, individualized conditions of authorization to address any issue unique to a specific test, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA."

Companies: Autobio Diagnostices Co. Ltd

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