Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2#5fc7c1f1492e4

Select the following question:
Q: Commercial Manufacturer Diagnostic Test Notification List - What commercial manufacturers are distributing SARS-CoV-2 diagnostic tests during FDA review as described in a policy in the Policy for Coronavirus Disease-2019 Tests? (8/31/2023)

Enter Tetracore into the search bar:

Commercial Manufacturer Diagnostic Test Notification List:

Search: Tetracore

Manufacturer and Test	Authorization Status	Settings for Use[1]
Tetracore, Inc., EZ-SARS-CoV-2 Real-Time RT-PCR	Not FDA Authorized	H

Showing 1 to 1 of 1 entries (filtered from 2 total entries)

[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

Below is the complete answer with the Tetracore Test highlighted:

A: As discussed in the November 2021 version of the FDA's *Policy for Coronavirus Disease-2019 Tests*, and maintained in the September 2022 version, the FDA generally expects COVID-19 tests to have been issued an Emergency Use Authorization (EUA) or marketing authorization [PMA, De Novo, 510(k)] prior to the tests being distributed or offered.

Previous versions of this guidance described policies regarding the distribution and offering of certain tests for clinical use prior to or without an EUA, often referred to as the notification policies. In the November 2021 version of the guidance and maintained in the September 2022 version, the FDA described policies for the review of EUA requests for COVID-19 tests offered prior to November 15, 2021, as described in the notification policies, and the policies regarding distribution and offering of such tests during FDA review. The details of these policies can be found in Section IV.C of the *Policy for Coronavirus Disease-2019 Tests*. Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under the Clinical Laboratory Improvement Amendments (CLIA), section 353 of the Public Health Service Act (42 USC 263a), use of that test is limited to laboratories that are certified under CLIA, and meet the requirements to perform tests of high-complexity, and at the point-of-care (POC) when covered by such a laboratory's CLIA certificate.

The policies regarding offering a COVID-19 tests prior to an EUA have never applied to at-home tests or tests with home specimen collection, or any testing outside of a high-complexity CLIA-certified laboratory. The commercial manufacturers listed below notified FDA prior to November 15, 2021, that they had validated and intended to distribute diagnostic tests as described in Section IV.C of the ***previous*** versions of FDA's *Policy for Coronavirus Disease-2019 Tests*.

- All tests included on the notification list are "Not FDA Authorized," indicating that the FDA has not yet reviewed the manufacturer's validation and issued an EUA for the test, and the test is included in this list to provide transparency regarding the notification submitted to FDA.
- The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing.

As discussed in the FDA's *Policy for Coronavirus Disease-2019 Tests*, reissued on September 27, 2022,

- The FDA is maintaining the policy announced in the November 15, 2021 version of the guidance and the FDA no longer intends to add tests to the notification lists.
- For tests already on the notification lists, the FDA intends to remove tests for which FDA has either issued an EUA or has notified the test developer by email that FDA declines to review, declines to issue, or otherwise decides not to authorize the test for any reason.
    - If so notified, the FDA generally expects developers to cease distributing, marketing, and offering their tests within 15 calendar days.
    - If FDA identifies a significant problem or concern with a test, based either on the provided information or external reports, the FDA generally would expect the developer to take appropriate steps to address such problems, which could include conducting a recall of the test and/or notification concerning corrected test reports indicating prior test results may not be accurate.

Tests that have been issued an EUA can be found on the EUA page.

Commercial Manufacturer Diagnostic Test Notification List:

Search:

Manufacturer and Test	Authorization Status	Settings for Use[1]
LMSI, LLC d/b/a Lighthouse Lab Services, SalivaNow SARS-CoV-2 Assay Kit	Not FDA Authorized	H
Tetracore, Inc., EZ-SARS-CoV-2 Real-Time RT-PCR	Not FDA Authorized	H

Showing 1 to 2 of 2 entries

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- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
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