

FDA Authorizes the First Home Collection of Specimens to be Tested for COVID-19

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As an update to our prior [blog post](#), on April 20, 2020 FDA [announced](#) the authorization of the first COVID-19 test for home collection of specimens. This announcement, made via the Agency's FAQs on Diagnostic Testing for SARS-CoV-2 webpage, comes after weeks of FDA reporting that it has been working closely with manufacturers on such a test during the weekly [Virtual Town Hall Meetings](#) hosted by the Center for Devices and Radiological Health. FDA clarifies that the test is only authorized for home *collection* of specimens to be sent back to a laboratory for processing. FDA still has not authorized a COVID-19 test "to be completely used and processed at home."

According to the [Emergency Use Authorization \(EUA\) letter](#) for the test, the new home collection method involves the use of a nasal swab, as opposed to a nasopharyngeal swab. Home collection is only permitted "when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire." Instructions for self-collection must be made available to individuals online or as part of the collection kit, and the kit must include materials allowing the patient to safely mail the specimen to an authorized laboratory. The letter states that the EUA will be in effect until there is a declaration that the circumstances justifying this authorization is terminated or revoked.

The home collection authorization is specific to one test, and does not authorize other manufacturers or laboratories to begin offering their own home collection kits. In its statement, FDA reminds manufacturers that any at-home test or collection kit requires an authorized EUA, whether by amendment to an existing EUA or a new request. The Agency indicates that it continues to work actively with test manufacturers in the at-home collection and testing space.

FDA's next Virtual Town Hall Meeting on guidance related to COVID-19 diagnostic testing is scheduled for April 22, 2020 from 12:15-1:15 pm Eastern Time.

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