

Risk of False Results with the Curative SARS-Cov-2 Test for COVID-19: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is alerting patients and health care providers of the risk of false results, particularly false negative results, with the Curative SARS-Cov-2 test. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

To reduce the risk of false negative results, it is important to perform the test in accordance with its authorization and as described in the authorized labeling, e.g., the Fact Sheet for Healthcare Providers (</media/137087/download>). When the test is not performed in accordance with its authorization or as described in the authorized labeling, there is a greater risk that the results of the test may not be accurate.

Important Recommendations for Health Care Providers, Patients, and Caregivers

- Be aware of the important information regarding the use of the Curative SARS-Cov-2 test, which is described in the test's authorized labeling, including the following:
 - Collection of nasal swabs and oral fluid specimens is limited to symptomatic individuals within 14 days of COVID-19 symptom onset.
 - Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.
 - A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.
- **Health care providers:** Consider retesting your patients using a different test if you suspect an inaccurate result was given *recently* by the Curative SARS-Cov-2 test. If testing was performed more than two weeks ago, and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Patients and caregivers:** Talk to your health care provider if you think you were tested with the Curative SARS-Cov-2 test (the test name is displayed on this test's authorized

Fact Sheets and, generally, the Fact Sheets must be provided with test result reports) and you have concerns about your test results.

- Report any problems you experience with the Curative SARS-Cov-2 test to the FDA, including suspected inaccurate results.

Device Description

The Curative SARS-Cov-2 Assay is a real-time RT-PCR test used to detect SARS-CoV-2, the virus that causes COVID-19. This test is authorized for prescription-only use. The test is performed by collecting a throat swab, nasopharyngeal swab, nasal swab, or oral fluid specimen from an individual suspected of COVID-19 by their health care provider. Under the Emergency Use Authorization, the specimen is then to be processed at the KorvaLabs, Inc., laboratory, and results are returned to the patient.

Consistent with the test's authorized labeling (</media/137087/download>), collection of nasal swabs and oral fluid specimens is limited to individuals who have shown symptoms of COVID-19 within 14 days of onset of the symptoms. Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.

Consistent with the EUA summary (</media/137089/download>), negative results for SARS-CoV-2 RNA from oral fluid specimens should be confirmed by testing of another specimen type authorized for use with this test if clinically indicated.

FDA Actions

The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.



The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a Medical Device

The FDA encourages stakeholders to report adverse events or suspected adverse events, including problems with test performance or results, through MedWatch (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>), the FDA Safety Information and Adverse Event Reporting program.

Generally, as specified in a test's EUA, device manufacturers and authorized laboratories must comply with applicable Medical Device Reporting (MDR) regulations (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>).

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>) or call 800-638-2041  or 301-796-7100 .