

INCONCLUSIVE

An inconclusive result is neither positive nor negative. This result can occur from inadequate sample collection, very early-stage infection, or for patients close to recovery. With an inconclusive result, collecting and testing another sample is recommended. Please make an appointment for another test as soon as possible.

Methods: The RT-PCR test was performed using a protocol adapted from CDC-designed assays specific to the SARS-CoV-2 virus in order to detect the virus in saliva samples. SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. The result is based on CDC guidelines, which rely on the detection of two viral genes as positive and detection of only one gene as inconclusive. The result is negative when neither gene is detected.

Limitations: There are limitations to all laboratory tests. This test is only valid for the SAR-CoV-2 virus. Several factors may affect test results. The collection and test protocols minimize the chances of false positive and false negative results. However, false positive and false negative results may still occur. Viral loads below the limits of detection may occur in the very early stages of infection or in individuals close to recovery.

This test was developed and its performance characteristics determined by the Genome Center, University of California, Davis. It has not been cleared or approved by the FDA. The laboratory is certified under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

This test will be submitted to the FDA for an EUA (emergency use authorization) for use by designated laboratories in the Genome Center, University of California, Davis, that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.