Diagnostic testing

Accula SARS-CoV-2 Test technology overview

The Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test facilitates comparable lab-based reverse transcription polymerase chain reaction (RT-PCR) results for the detection of SARS-CoV-2 in a point-of-care format [1]. RT-PCR testing is streamlined from start to finish using a fully integrated, single-use microfluidic test cassette and the reusable Thermo Fisher Scientific™ Accula™ Dock.

Workflow

Following collection, an anterior nasal swab sample is eluted into a buffer-containing collection tube that is provided with the Accula SARS-CoV-2 Test kit. The Accula SARS-CoV-2 test cassette is placed into the Accula Dock, and the sample is loaded directly into the test cassette using the provided transfer pipette. The dock lid is closed to initiate (1) nucleic acid extraction, (2) reverse transcription, (3) PCR amplification, and (4) visual detection of amplicons.

Enabling technology

The Accula SARS-CoV-2 Test is enabled by proprietary Oscar™ PCR technology. After the reverse transcription step, Oscar technology enables PCR at reduced absolute temperatures and reduced temperature differentials—resulting in rapid exponential amplification with shortened thermal cycling times. Instead of relying on optical detection systems to report PCR results, the **amplicon-based** detection method of the Accula test employs two sequence-specific hybridization probes to generate a colorimetric signal on the detection strip [2]. Results are interpreted visually by the operator after the test is completed (approximately 30 minutes). All steps of sample testing are fully integrated for decentralized use at the point of care.

References

1. Accula SARS-CoV-2 Test Instructions for Use (IFU)
2. Moore SC, Penrice-Randal R, Alruwaili M et al. (2020) Amplicon-based detection and sequencing of SARS-CoV-2 in nasopharyngeal swabs from patients with COVID-19 and identification of deletions in the viral genome that encode proteins involved in interferon antagonism. *Viruses* 12:1164. doi: 10.3390/v12101164

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The Accula SARS-CoV-2 test has not been FDA cleared or approved but has been authorized for emergency use by the FDA for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of 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 declaration is terminated or authorization is revoked sooner.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.