# Accula SARS-CoV-2 Test technology overview

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

## Workflow

Following collection, a swab sample is eluted into a buffer-containing collection tube that is provided with the Accula SARS-CoV-2 Test kit. The 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 amplicon detection. Reduced sample handling provides an efficient workflow and helps reduce the potential for sample contamination by eliminating multiple manipulation steps.

## 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 thermocycling times. Instead of relying on optical detection systems to report PCR results, the amplicon detection method of the Accula Test employs two sequence-specific hybridization probes to generate a colorimetric signal on the detection strip. 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.

This test has not been FDA cleared or approved but has been authorized for emergency use by 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.

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