

Accula System

Reliable, rapid PCR test for the detection of SARS-CoV-2 in ~30 minutes

The Accula™ System from Thermo Fisher Scientific is a rapid diagnostic platform that combines the accuracy of RT-PCR with the simplicity, convenience, and procedural familiarity of traditional rapid immunoassays. The Accula™ SARS-CoV-2 Test has received an Emergency Use Authorization (EUA) from the FDA for the detection of SARS-CoV-2 in Clinical Laboratory Improvement Amendments (CLIA)–waived environments. Designed for use with the palm-sized Accula™ Dock, the Accula SARS-CoV-2 Test provides reliable, qualitative results in approximately 30 minutes.

The Accula SARS-CoV-2 Test and Accula Dock Feature:

- **Gold-standard PCR technology**—100% positive agreement (PPA) and negative agreement (NPA) with an EUA-authorized RT-PCR SARS-CoV-2 test comparator
- **Simple sample collection**—prepare and load nasal swab samples in seconds
- **Fast results**—qualitative, rapid PCR-based test provides visual results in approximately 30 minutes
- **Easy storage**—reagents stored at room temperature (15°C–30°C, 59°F–86°F); eluted samples in Accula™ buffer may be kept at room temperature for up to 2 hours or refrigerated at 2°C–8°C and tested within 24 hours from the time of elution
- **Compact design**—dock fits in the palm of your hand; ideal fit for satellite locations and clinical settings



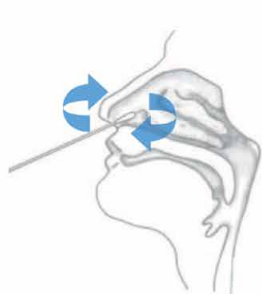
~30 minutes for accurate, accessible, and actionable results

Collect sample

Elute sample

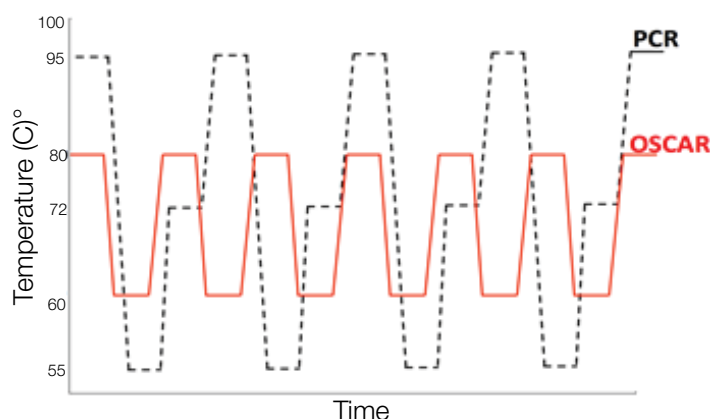
Load

Read



Technology

OSCillating Amplification Reaction (Oscar™), proprietary PCR technology, enables rapid exponential amplification while reducing overall thermocycling times.



Performance

Prospective clinical study

Accula SARS-CoV-2 Test	Comparator's assay		
	Positive	Negative	Total
Positive	4	0	4
Negative	0	48	48
Total	4	48	52
PPA	100% (95% CI: 39.76%–100%)		
NPA	100% (95% CI: 92.60%–100%)		
Overall percent agreement (OPA)	100% (95% CI: 93.15%–100%)		

Nasal swab samples were collected from 52 pediatric patients at a drive-through collection site. Testing was performed with the Accula SARS-CoV-2 Test and the comparator method, an EUA-authorized RT-PCR SARS-CoV-2 test.

Summary of limit of detection (LoD) confirmation result using the FDA SARS-CoV-2 reference panel

Reference materials provided by FDA	Specimen type	Product LoD	Cross-reactivity
SARS-CoV-2	Nasal swab	475 NDU/mL	N/A
MERS-CoV		N/A	N/D

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material, blinded samples, and a standard protocol provided by the FDA. The study included a range finding study and a confirmation study for LoD. Blinded sample testing was used to establish specificity and to corroborate the LoD. Testing was performed using the Accula SARS-CoV-2 Test with the Accula Dock.

NDU/mL = RNA NAAT detectable units/mL

N/A: not applicable

N/D: not detected

Ordering information

Product	Quantity	Cat. No.
RT-PCR Accula SARS-CoV-2 Test	1 kit	COV41000
Accula Dock	1 dock	D2000
Accula SARS-CoV-2 Control Kit	9 controls	COV4100-1

Questions? Email us at info@mesabiotech.com or go to thermofisher.com/mesa

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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.

For Emergency Use Authorization (EUA) Only. For Prescription Use Only. For In Vitro Diagnostic Use.

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