TX TECHNOLOGY™

ThermoFisher SCIENTIFIC

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

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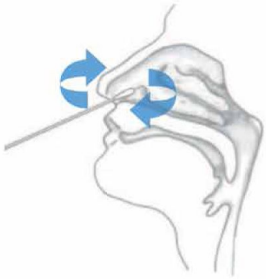
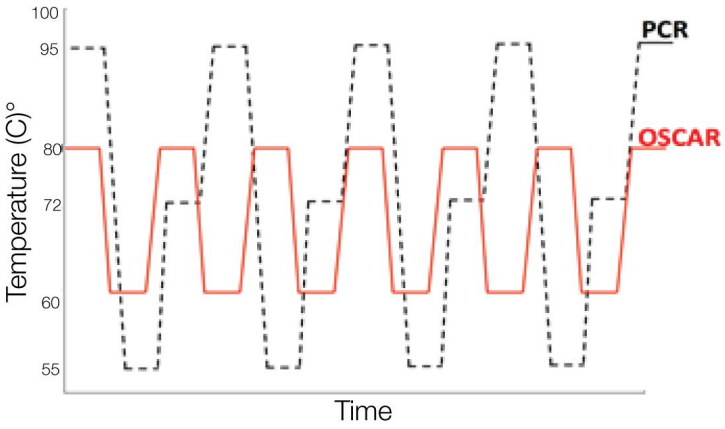
~30 minutes for accurate, accessible, and actionable results

Collect sample → **Elute sample** → **Load** → **Read**



Technology

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



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

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

Questions? Email us at support.covidebb@txtechnology.co.in

Office No. – +91-11-41097183 Mobile No. – +91-93110-77895

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