QUIDEL

Solana® SARS-CoV-2 ASSAY

AVAILABLE FOR SALE IN THE USA AS EUA

Results you can trust when accuracy is critical, on a platform built for your lab.

Solana is a molecular testing solution for COVID-19 without the tradeoffs between throughput, lengthy turnaround times, highly complex workflows, and unsustainable costs. Quidel's Solana instrument and robust respiratory testing menu now features the Solana SARS-CoV-2 Assay. With Solana, we offer a scalable and flexible molecular solution that delivers highly accurate molecular results in an actionable timeframe.

Prompt initiation of patient management and antimicrobial therapy

- Results in just 25 minutes
- High volume throughput capabilities
  Batch up to 12 tests per run

True, Molecular Accuracy

- Gold standard sensitivity
- Confidence in pandemic response and management

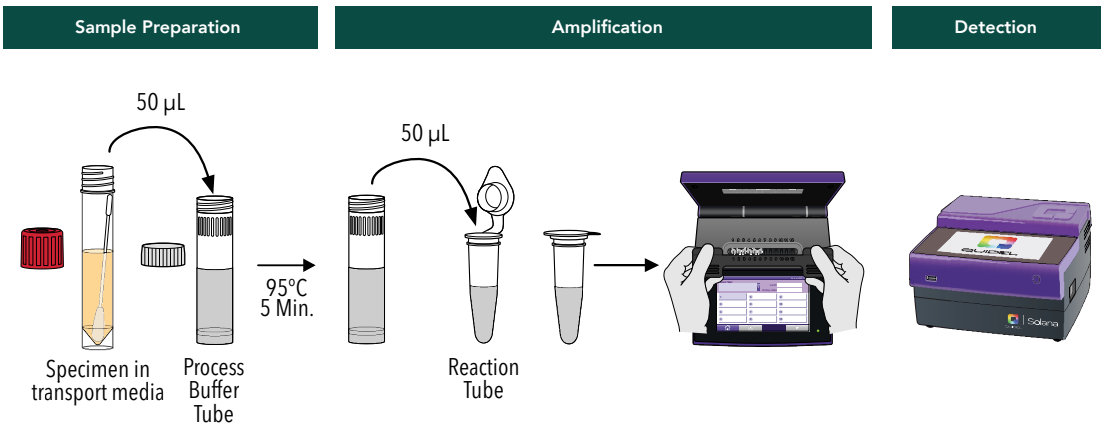
Ease and Affordability

- Orderable with swabs and media
- Simple procedure
- Sustainable reagent pricing

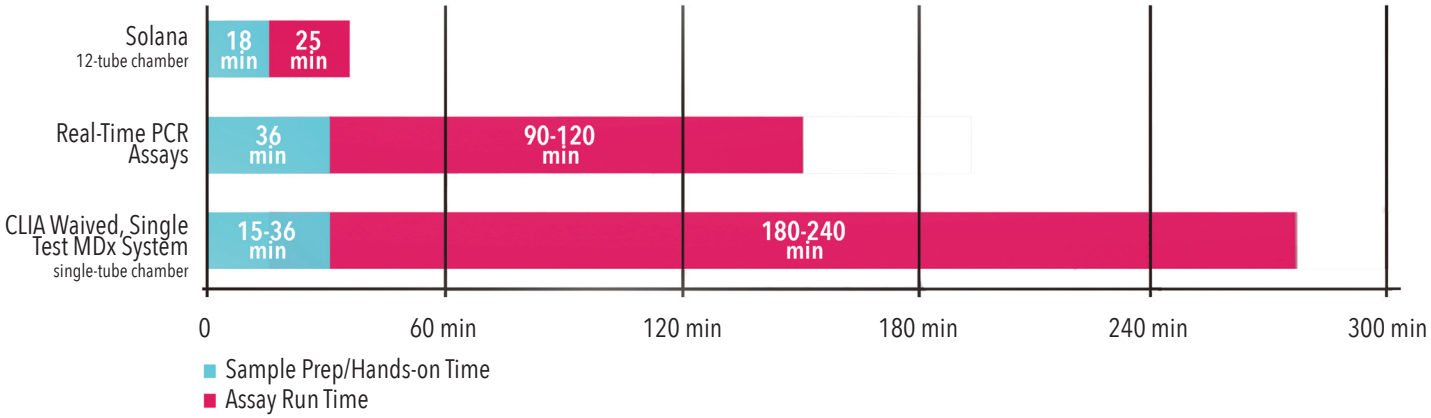
The Accurate. Sustainable. Molecular **COVID-19** Solution.

Solana SARS-CoV-2 Assay run with the Solana bench top instrument a mere 9.4" x 9.4" x 5.9"

Procedure



Time to 12 results



Clinical Performance

Comparison of Solana SARS-CoV-2 Assay and FDA-cleared molecular comparator assay

Specimen Type	# Tested	True POS	False POS	True NEG	False NEG	PPA	NPA	PPA 95% CI	NPA 95% CI
Nasal	157	83	0	73	1	98.8%	100%	93.6% to 99.8%	95.0% to 100%

A study was performed comparing the Solana SARS-CoV-2 Assay to an FDA cleared molecular assay. One hundred fifty-seven (157) nasal swab samples in viral transport media were tested with both devices according to the respective Package Inserts.

The Solana SARS-CoV-2 Assay has not been FDA cleared or approved, but has been authorized by the FDA under Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of nucleic acids from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration 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 terminated or revoked sooner.

SL3207 | SSM312000EN00 (05/22)

Solana SARS-CoV-2 Assay (includes controls) – 48 Test Kit: Cat. #M312

Solana Instrument – Cat. #20278

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