



revogene®

SARS-CoV-2

This Product is only for use under FDA's  
Emergency Use Authorization (EUA)

## Improve your laboratory's COVID-19 testing capacity for an uncompromised standard of care

CDC recommends that anyone with any signs or symptoms of COVID-19 get tested, regardless of vaccination status or prior infection<sup>1</sup>

**The Revogene® platform provides healthcare systems with a reliable solution that delivers near-patient testing.**

- Deliver actionable results quickly with Revogene®
- Revogene® enables physicians to make informed decisions about appropriate therapeutic and infection control strategies
- Offer on-demand or batch testing that can easily be integrated into your laboratory

**The Revogene® SARS-CoV-2 assay detects the nucleic acid of SARS-CoV-2 virus, the causative agent of COVID-19.**

- What are your biggest challenges with COVID-19 testing?
- What impact would a 2-step molecular test to detect the nucleic acid of the SARS-CoV-2 virus have on your lab's ability to fulfill COVID-19 testing needs?

# revogene®

SARS-CoV-2

## Revogene® Can Optimize Testing Capacity

- The Revogene® platform enables you to provide molecular testing throughout the health system
- Meet your increased testing demand with batch or STAT testing with Revogene®

## Improve Efficiency, Deliver Standardization

- Near patient testing with Revogene® provides a rapid turnaround time which optimizes patient management by providing an earlier diagnosis for improved patient outcomes
- Revogene® can help infections from being transmitted to others through rapid execution of infection prevention strategies
- Revogene® provides clinicians with actionable results for faster treatment decisions

## Trusted Partner

- Revogene® is a flexible molecular platform that can help standardize testing throughout your health system

## Revogene® SARS-CoV-2 Assay Procedure Steps

Sample to Result in 2 Steps

Less than 1 minute hands on time



Specimen



**1** Load sample into the PIE



**2** Place PIE into instrument and start

## Product Specifications

### Intended Use

The Revogene® SARS-CoV-2 assay is a real-time RT-PCR test intended for the qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high or moderate complexity tests.

### Turnaround Time

85 minutes, with as early as 47 minutes for positive specimens with EPro - early call feature

### Sample Type

Nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens in transport media or saline

### Kit Storage

2-8 C

### Performance

**97.7%** PPA

**97.7%** NPA

### Catalog Number

Revogene® SARS-CoV-2 — 410700

### Test Kit Size

24 assays per kit

### References

1. <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product 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 product 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.

**Ready to improve your COVID-19 testing capacity? Let's talk.**

Contact a specialist at 1-888-763-6769.

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