



Increase your COVID-19 testing efficiencies with the OPTI SARS-CoV-2 RT-PCR Test

The **OPTI* SARS-CoV-2 RT-PCR Test** is based on real-time reverse transcription polymerase chain reaction (RT-PCR). It is designed for the detection of SARS-CoV-2 RNA extracted from nasopharyngeal swabs, oropharyngeal swabs and other upper respiratory sample types. The test is based on the United States Centers for Disease Control and Prevention (CDC) test design¹ and has been validated on common PCR instruments.

- Get more accurate results with high sensitivity (limit of detection of 0.36 copies/ μ L).
- Optimize workflow from start to finish using an internal sample control that targets human RNase P.
- Minimize impact of viral mutation with multiplexed detection of N1 and N2 regions of the virus.
- Increase testing efficiencies by **pooling up to 5 samples²**.
- Limit the need for validation with included validation report.

For more information on the OPTI SARS-CoV-2 RT-PCR Test, please contact your area manager or distributor, or visit **optimedical.com**.

covid19@optimedical.com

IDEXX USA

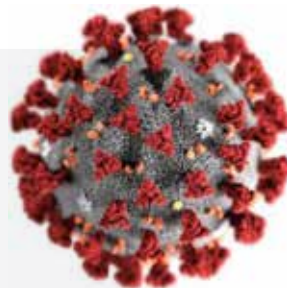
+1 800 548 9997

IDEXX Europe

+800 727 43399

Combining this test with the OPTI* Rapid Lysis Buffer or the OPTI* DNA/RNA Magnetic Bead Kit provides a complete SARS-CoV-2 testing solution

| OPTI* Rapid Lysis Buffer | OPTI* DNA/RNA Magnetic Bead Kit |
|--|---|
| Extraction-free sample preparation protocol | Automated or manual protocol |
| Simple and efficient workflow: No need for extraction instrumentation and reagents | Minimum hands-on-time when used on automated magnetic separator |
| Reduced cost | Validated on KingFisher* Flex and KingFisher* Duo Prime |



Efficient PCR testing

The OPTI* SARS-CoV-2 RT-PCR Test includes all components needed for RT-PCR testing, including the RNA master mix, SARS-CoV-2 target mix, a positive control, and water to be used to reconstitute lyophilized reagents and as a negative control. The reagents do not require shipment on dry ice, and product inserts are electronically available at optimedical.com.

Product name: OPTI* SARS-CoV-2 RT-PCR Test

| Kit components | Size |
|----------------|---------------|
| 99-57004 | 500 reactions |

Product name: OPTI* SARS-CoV-2 PCR and Lysis

| Kit components | Size |
|----------------|-------------|
| 99-58020 | 500 samples |

Product name: OPTI* DNA/RNA Magnetic Bead Kit

| Kit components | Size |
|----------------|-------------|
| 99-58015 | 384 samples |



OPTI Medical Systems, Inc.

235 Hembree Park Drive
Roswell, Georgia 30076
USA

Tel: +1 770 510 4444
Fax: +1 770 510 4445

Product disclosure

The OPTI* SARS-CoV-2 RT-PCR Test has been authorized by the United States Food & Drug Administration (FDA) under an Emergency Use Authorization issued by the FDA on May 6, 2020. This test has not been FDA cleared or approved, and the FDA has not determined that the test is safe or effective for the detection of SARS-CoV-2. The test has been authorized only for the detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens. The 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 U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Use in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (CLIA) to perform high-complexity tests. The test is not intended for home use.

This CE mark certification represents OPTI Medical Systems' assurance that its test complies with the European Union's In Vitro Diagnostic Directive, which applies to products that are manufactured in or designed to be sold in the European Economic Area[†] and Switzerland.

[†]The European Economic Area includes the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden) and the following countries: Iceland, Liechtenstein, Norway, and United Kingdom.

Reference

1. Centers for Disease Control and Prevention. 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR primers and probes [research use only]. www.cdc.gov/coronavirus/2019-nCoV/lab/rt-pcr-panel-primer-probes.html. Updated June 6, 2020. Accessed February 19, 2021.

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†The detection of an individual positive nasopharyngeal swab sample in a pool of 5 samples has been validated with the OPTI* DNA/RNA Magnetic Bead Kit and the OPTI* SARS-CoV-2 RT-PCR Test.

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