



Meridian Bioscience

Complete Respiratory Product Portfolio

Meridian Bioscience provides a robust portfolio of respiratory testing that allows healthcare professionals to collect, test and deliver same-day actionable results for improved patient care.

meridian BIOSCIENCE®
LIFE DISCOVERED. LIFE DIAGNOSED.

Catalog

Revogene® SARS-CoV-2 Assay*

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. *This product is for use under FDA's Emergency Use Authorization (EUA).*

Catalog#: 410700	Kit Size: 24 Tests
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Standard™ Q COVID-19 Ag Test 2.0** / Standard™ COVID-19 Ag Control swab

A rapid antigen test for the qualitative detection of SARS-CoV-2 from nasal swabs for suspected patients within 6 days of onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 48 hours between tests. Control swab for use as an external quality control material to monitor performance of Standard™ Q COVID-19 Ag Test 2.0. *This product is for use under FDA's Emergency Use Authorization (EUA).* CLIA waived.

Catalog#: 09COV174D	Kit Size: 25 Tests
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Control swab Catalog#: 10COVC14J	Kit Size: 5 Tests
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Revogene® Strep A / Alethia® Group A Strep

Molecular DNA amplification tests, Revogene® Strep A and Alethia® Group A Strep, allow for increased detection of positives over traditional culture in symptomatic patients with clear, objective evaluation of positive/negative test results in about one hour. Quick identification and treatment of Group A Strep pharyngitis can reduce patient/parent dissatisfaction and alleviate the need for costly follow-up visits, shorten duration of symptoms and reduce risk of spreading strep throat.

Revogene® Strep A Catalog#: 410400	Kit Size: 24 Tests
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Alethia® Group A Strep Catalog#: 480150	Kit Size: 50 Tests
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Immunocard STAT!® FLU A&B

A CLIA-waived qualitative rapid test for the detection and differentiation of influenza A and B. An easy NP swab procedure provides accurate results in as little as 10 minutes. Near patient testing can improve patient care and can positively impact overall patient outcome. ImmunoCard STAT!® Flu A&B can also be used with nasal washes, aspirates and samples in transport media.

Catalog#: 782030	Kit Size: 32 Tests
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Accessory Kit Catalog#: 781130	
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Alethia® Mycoplasma Direct

A molecular DNA amplification test, Alethia® Mycoplasma Direct allows for an accurate detection of *Mycoplasma pneumoniae* infections with improved performance and earlier detection over traditional methods. With a simple throat swab sample, you can have an objective evaluation of positive/negative test results in less than one hour, eliminating the need for repeat patient visits.

Catalog#: 480250	Kit Size: 50 Tests
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Catalog

Immunocard® Mycoplasma

A qualitative rapid test for the detection of *Mycoplasma pneumoniae* IgM antibodies. Immunocard® Mycoplasma impacts patient care by providing accurate results during the early/acute phase of illness and allows physicians to treat promptly and appropriately.

Catalog#: 709030	Kit Size: 30 Tests
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Tru® Legionella

A qualitative rapid test for the detection of Legionella SG 1 antigen in urine using a simple, three-step procedure with easy result interpretation. Tru® offers a closed system to limit pathogen exposure in the laboratory.

Catalog#: 751930	Kit Size: 32 Tests
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Alethia® Pertussis

A molecular DNA amplification test, Alethia® Pertussis allows clinicians to diagnose whooping cough with a sophisticated molecular test that can provide actionable results in about an hour. With the ability to detect infection earlier than traditional culture methods, you can collect, test and treat for same day results, providing optimal patient management.

Catalog#: 480750	Kit Size: 50 Tests
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Immunocard STAT!® Strep A

A CLIA-waived qualitative rapid test for the detection of *Streptococcus* Group A antigen from throat swabs. Reflex rapid Group A Strep negatives to Revogene® Strep A or Alethia® Group A Strep for confirmation.

Catalog#: 755250	Kit Size: 50 Tests
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Tru® RSV

A qualitative rapid test for the detection of RSV, the Tru® RSV is the only test which uses pooled monoclonal antibodies detecting two RSV proteins which may help detect more positive samples. Tru® offers the option for multiple sample types in a closed system to limit pathogen exposure in the laboratory.

Catalog#: 751330	Kit Size: 32 Tests
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*Revogene® SARS-CoV-2 Assay - 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.

**Standard™ Q COVID-19 Ag Test 2.0 - Results are for the identification of SARS-CoV-2 nucleocapsid protein antigens, which is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. All negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Testing of anterior nasal swab specimens is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This product 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 product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, 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.

To learn more about the Meridian Bioscience Respiratory Product Portfolio, visit www.meridianbioscience.com, call 1.888.763.6769, or contact your Meridian Bioscience representative.



Contact Us

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