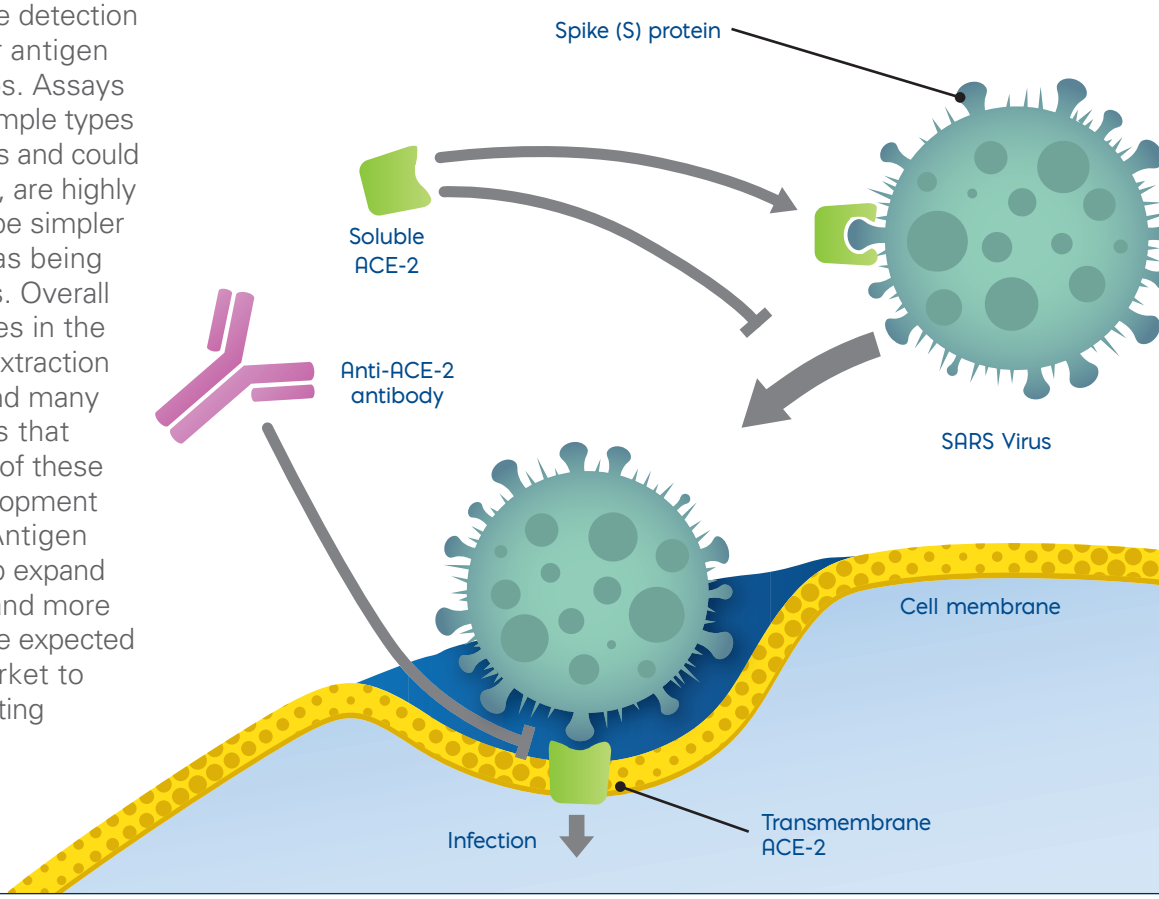
COVID-19

Reagents Solutions for Molecular and Immunology SARS-CoV-2 Diagnostic Assays

The key to fighting the COVID-19 pandemic is through diagnostic testing. By identifying infectious individuals, it is possible to trace the pathogen's spread and stop the chain of transmission. Research labs are racing to develop innovative testing methods to overcome the bottlenecks which are creating challenges to conducting widespread testing.

Viral tests for COVID-19 that diagnose an acute infection rely on the detection SARS-CoV-2 nucleic acid or antigen using nasopharyngeal swabs. Assays that could use alternative sample types such as saliva or nasal swabs and could be collected by an individual, are highly sought after as they would be simpler and quicker to use as well as being safer for healthcare workers. Overall challenges such as shortages in the reagents required for RNA extraction have created bottlenecks and many labs are searching solutions that provide flexibility in the face of these shortages such as the development of extraction-free assays. Antigen detection assays should help expand COVID-19 testing capacity and more rapid, point-of-care assays are expected to be launched into the market to help quickly scale up the testing of millions of individuals.



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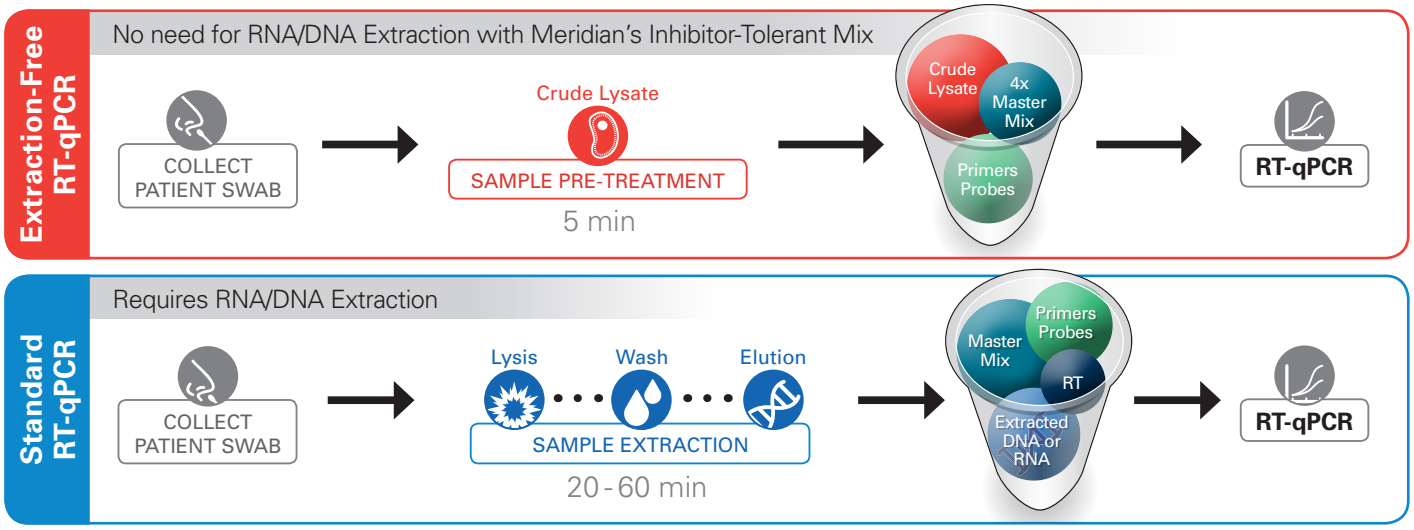
Molecular Reagents

Optimized RT-qPCR Mixes

Meridian's portfolio of RT-qPCR master mixes have been designed to simplify the development of SARS-CoV-2 molecular assays and enable new features such as extraction-free amplification. Each master mix contains a hot-start polymerase, dNTPs, buffer and other components optimized for each particular application (e.g. lyophilization). Only primers and probes are required to complete the assay formula.

SARS-CoV-2 requires an RNA extraction step which is time limiting step and can result in RNA being lost during the extraction process reducing the performance of the assay. However, extraction is typically required to remove inhibitors which would otherwise impact an assay's sensitivity and accuracy. In order to address this challenge, Meridian has developed an Inhibitor-Tolerant RT-qPCR Mix capable of delivering sensitive multiplex detection, even in the presence of difficult inhibitors found in sputum, saliva and stool specimens. This new mix offers a novel alternative to nucleic acids extraction, saving both time and labor which are vitally important in viral screening assays that require rapid detection for infection control.

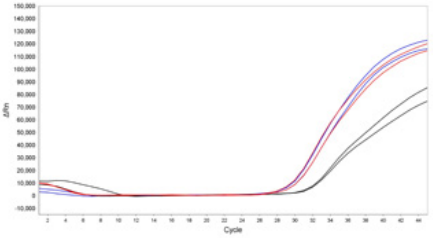


Product Data

Inhibitor-Tolerant RT-qPCR Mix exhibits a high tolerance to PCR inhibitors from clinical samples

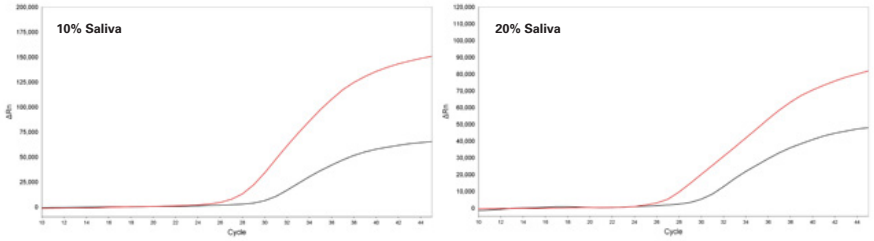
SPUTUM SPECIMENS

Amplification profile of inactivated influenza virus spiked into samples containing 5% sputum or no sputum. The data illustrates that the performance of Inhibitor-Tolerant RT-qPCR Mix (MDX016) in the presence of 5% artificial sputum (red) is the same Fast One-Step RT-qPCR Mix (MDX032) with no sputum (blue). In contrast, the sensitivity and performance of Fast One-Step RT-qPCR Mix (MDX032) significantly decreases in the presence of 5% artificial sputum (**black**) compared to no sputum or compared to Inhibitor-Tolerant RT-qPCR Mix (MDX016) with sputum.



SALIVA SPECIMENS

MDX016 (red) and MDX032 (**black**) amplification traces of Influenza A spike in presence of saliva swabs (COPAN ESwab 359C) at 10% (left) and 20% (right) final concentration. With earlier Ct (approx. 4 Ct) and higher fluorescence (approx. +50%), the results demonstrate the superiority of Inhibitor-Tolerant RT-qPCR Mix (MDX016) against a standard RT-qPCR Mix (MDX032) for the detection of viral RNA in presence of saliva swab resuspension in UTM.



Product Selection Chart

Features	Inhibitor-Tolerant RT-qPCR Mix	Fast 1-Step RT-qPCR Mix	Low LOD 1-Step RT-qPCR	Lyo-Ready 1-Step RT-qPCR Mix
	Optimized for extraction-free assays from crude clinical specimens (sputum, saliva and stool)	Ideal for multiplex assays on fast, automated high-throughput systems	Designed for multiplex detection of viruses for applications such as blood bank testing	Pre-formulated with lyo-excipients for lyophilization into beads or cakes
Cat#	**MDX016**	**MDX032**	**MDX025**	**MDX024**
Concentration	4x	2x	2x	2x
Presentation	Single-tube mix	3 tubes *(Polymerase, Reverse Transcriptase, RNase Inhibitor)*	Single tube mix	3 tubes *(Polymerase, Reverse Transcriptase, RNase Inhibitor)*
Master Mix	✓	✓	✓	✓
Hot-Start	Antibody	Antibody	Antibody	Antibody
Ambient-Temperature Assays	-	-	-	★
Multiplex Reactions	★	★	★	★
RNA/DNA Extraction-free protocols	★	-	-	-
Contains dUTP	-	-	★	-
RT-qPCR Control	**RT-qPCR Extraction Control** • Monitors assay inhibition • Suitable for use with inhibitor-rich samples	**VLP RNA Extraction Control** • Closely mimics the test sample • Undergoes the same processing from lysis and extraction to detection		**VLP RNA Extraction Control** • Compatible with lyophilization for creating freeze-dried mixes
	MDX028 (Red, Quasar 670) **MDX028** (Orange, Cal Fluor Orange)	**MDX068** (Red, Cy5) **MDX069** (Orange, HEX) **MDX071** (Custom)		**MDX068** (Red, Cy5) **MDX069** (Orange, HEX) **MDX071** (Custom)

★ **Recommended**

SARS-CoV-2 Nucleoprotein Antibody Pair

For Rapid Antigen Detection Assays

Rapid antigen tests can provide a result in minutes and can be produced at a lower cost in large scales. Antigen tests are very specific for the virus but not as sensitive as PCR. A positive result by an antigen test is highly accurate, but a negative result does not rule out an infection.

The performance of a rapid antigen test is limited by the sensitivity of the antibodies used. Meridian's new pair of monoclonal antibodies are highly sensitive for the detection of SARS-CoV-2 Nucleoprotein and they do not cross-react with seasonal coronavirus strains. They are ideal for developing reliable and sensitive rapid lateral flow antigen assays for the detection of active COVID-19 infections.

- ✔ >95% purity (Protein G)
- ✔ Validated for Lateral Flow & ELISA
- ✔ This antibody pair does not cross-react with other coronaviruses, except SARS (2003)
- ✔ Proven to react with live virus
- ✔ Currently used in a commercial kit that has a detection limit of $2.8x10^3$ $TCID_{50}$/mL

Capture Antibody:

Cat# 9548	MAb to SARS-CoV-2 NP

Detection Antibody:

Cat# 9547	MAb to SARS-CoV-2 NP

SARS-CoV-2 Recombinant Antigens

For Serology Antibody Assays

Serologic tests are an important tool for monitoring the evolution of an outbreak. Specifically, IgG/IgM antibody tests are essential for identifying previously undiagnosed infections in the asymptomatic population.

Meridian has just released new high-performing SAR-CoV-2 antigens for the development of COVID-19 IgG/IgM serology assays. The recombinant antigens are expressed in human mammalian cells and insect cells using proprietary expression and purification technologies. Expression in either human or insect cells provides for post-translational modifications such as glycosylation and phosphorylation which can offer significant performance advantages over *E. coli* expressed formats.

Insect-Cell Expressed:

Cat# 9556	Spike Protein, S1 Subunit, His-tag
Cat# 9557	Spike Protein, N-terminal Domain (NTD) S1 Subunit, His-tag
Cat# 9558	Spike Protein, Receptor Binding Domain (RBD) S1 Subunit, His-tag
Cat# 9560	Nucleocapsid Protein, His-tag

HEK293 Expressed:

Cat# 9552	Spike Protein, Receptor Binding Domain (RBD) S1 Subunit, His-tag
Cat# 9553	Spike Protein, S1 Subunit, His-tag
Cat# 9554	Nucleocapsid Protein, DYKDDDDK tag
Cat# 9555	Human ACE2 Protein, Fc1 tag

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