



Product Announcement

Introducing...

LightMix® Modular SARS-CoV Assays

This Product Announcement was changed to include the updated names of the LightMix Modular assays used to detect SARS-CoV viruses. Changes are indicated by black bars in the margin.

Roche continues to monitor the virus, SARS-CoV-2, that causes coronavirus disease 2019 (COVID-19) and is pleased to announce the availability of the LightMix Modular Assays used to detect this virus. These assays are for Research Use Only (RUO*) on the LightCycler® 480 and/or **cobas z 480** instruments, and Roche is the exclusive distributor for these assays. The MagNA Pure 96 instrument or High Pure Viral Nucleic acid kit can be used for extraction. The three LightMix Modular assays are used to detect the SARS and CoV genes outlined in the table below in human tracheal aspirates or bronchoalveolar lavage samples from individual human donors.



These assays are not intended for use as an aid in the diagnosis of coronavirus infection.

Test Features

The test features of the LightMix Modular assays for SARS-CoV-2 (COVID-19) include:

- Typical samples are tracheal aspirates or bronchoalveolar lavage. SARS-CoV-2 (COVID-19) affects the lower respiratory system; nasopharyngeal swabs/aspirate are not optimal.
- The MagNA Pure 96 instrument and High pure Viral Nucleic acid kits are available for extraction.
- Individual target-specific primers/probes and positive controls
- Detection of the 2019-nCoV and SARs-related viruses as follows:

Assay	Detects
LightMix Modular SARS-CoV (COVID19) E-gene	SARS and SARS-CoV-2 pneumonia virus as well as other bat-associated SARS-related viruses (Sarbecovirus)
LightMix Modular SARS-CoV (COVID19) N-gene	SARS and SARS-CoV-2 pneumonia virus as well as other bat-associated SARS-related viruses (Sarbecovirus)
LightMix Modular SARS-CoV-2 (COVID19) RdRP	SARS-CoV-2 pneumonia virus but not all SARS-like viruses

*For research use only. Not for use in diagnostic procedures.

over...

cobas z 480 LightCycler 480 MagNA Pure 96

**Roche Diagnostics
Corporation**

9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457
USA

Phone +1-800-428-5074

Ordering Information

Please use the following information when placing your order for the LightMix® Modular assays with Roche Diagnostics Customer Service at 1-800-428-5076.

Assay	Catalog Number	Tests per Kit
LightMix Modular SARS-CoV (COVID19) E-gene	09155368001	96 tests
LightMix Modular SARS-CoV (COVID19) N-gene	09155350001	96 tests
LightMix Modular SARS-CoV-2 (COVID19) RdRP	09155376001	96 tests

Please use the following information when placing your order for the associated Roche products to be used with the LightMix Modular assays with Roche Diagnostics Customer Service at 1-800-428-5076.

Product Type	Description	Catalog Number
Extraction	MagNA Pure 96 DNA & Viral NA SV Kit	06543588001
	MagNA Pure 96 DNA & Viral NA LV Kit	06374891001
Manual Extraction	High Pure Viral Nucleic Acid Kit	11858874001
Extraction Control	Modular EAV RNA Extraction Control	07374330001
Amplification & Detection	LightCycler® Multiplex RNA Virus Master	06754155001
Other	Universal Color Compensation Hexaplex	06296971001

Purchasing Department Information

Please forward this information to your purchasing department to eliminate ordering delays. Purchasing department, please update your purchasing system with the new catalog numbers listed above.

Documentation

The following Instructions for Use are available on the [diagnostics.roche.com](https://www.diagnostics.roche.com) website. Please file for future reference.

- LightMix Modular SARS-CoV (COVID19) E-gene, MDx 53-0776-96, V200408
- LightMix Modular SARS-CoV (COVID19) N-gene, MDx 53-0775-96, V200408
- LightMix Modular SARS-CoV-2 (COVID19) RdRP, MDx 53-0777-96, V200408

Questions

If you have questions regarding the sale or distribution of products referenced in this Product Announcement, please contact your Roche Diagnostics Sales Representative.

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