

MiRXES CoVClear Mutation Panel Reagent Pack

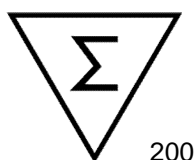
Mutation Detection Panel Reagent Pack

Instructions for Use

Instructions for Use

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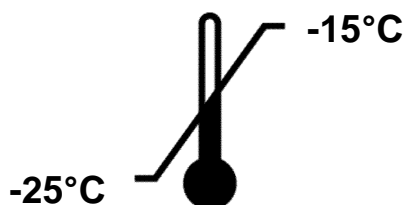
REF FGS0032R



Important!

The instructions for use must be read carefully prior to use and followed strictly to achieve reliable results. Any deviations from the instructions will have a significant impact on the end result.

Storage and Transportation Conditions



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Protect from light during transportation and storage.

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1 Introduction

Purpose

This document describes the use of the MiRXES CoVClear Mutation Panel Reagent Pack, a kit that contains reaction reagents to be used in conjunction with MiRXES CoVClear Mutation Panel Kits, N501Y, E484K and L452R. The reagent pack must be used together with one of the MiRXES CoVClear Mutation Panel Kits for a real-time Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) assay, for the qualitative detection of mutation in the receptor-binding domain (RBD) of the spike protein of the SARS-CoV-2 virus, from nasal specimens confirmed to be positive for SARS-CoV-2 by RT-PCR.

Intended Use

The MiRXES CoVClear Mutation Panel Reagent Pack is the reagent pack for qualitative in-vitro nucleic acid amplification assay for identifying the mutations (N501Y, E484K, and L542R) in the receptor-binding domain (RBD) of the spike protein, of the SARS-CoV-2 virus, from nasal specimens confirmed to be positive for SARS-CoV-2 by RT-PCR.

The MiRXES CoVClear Mutation Panel Reagent Pack is strictly for research use only.

Read the Instructions for Use carefully before using this product.

2 Principle of the Procedure

Nucleic acids from specimen(s) found to be positive for the presence of the SARS-CoV-2 virus are reverse transcribed using the Reaction Master Mix and Enzyme Mix, into cDNA which is then subsequently amplified, and, its fluorescence intensity monitored in a Real-Time PCR System.

3 Product Description

- MiRXES CoVClear Mutation Panel Reagent Pack contains CoVClear Mutation Panel Positive Control (WT), Enzyme Mix, Reaction Master Mix, and Negative Control, as the common reagents for the detection reaction of any of the three mutations in the MiRXES CoVClear Mutation Panel N501Y, E484K and L452R.
- The MiRXES CoVClear Mutation Panel Reagent Pack contains the following components:

Table 1. Components of MiRXES CoVClear Mutation Panel Reagent Pack (FGS0032R)

Part Number	Component	Number of Vials	Volume [μ L/Vial]
INT0156	CvC Mutation Panel Positive Control (WT)	1	20
INT0157	CvC Mutation Panel Enzyme Mix	1	50
INT0158	CvC Mutation Panel Reaction Master Mix	3	930
INT0159	CvC Mutation Panel Negative Control	1	1000

NOTE



The MiRXES CoVClear Mutation Panel Reagent Pack is to be used in conjunction with the MiRXES CoVClear Mutation Panel(s).

4 Storage and Transportation

- The MiRXES CoVClear Mutation Panel Reagent Pack is shipped in a cold chain environment. The components of the kit should arrive cold. If the kit components are not cold upon receipt, or if vials have been compromised during shipment, contact Technical Support (refer to section 10) for assistance.
- All components are to be stored between -25°C and -15°C upon arrival.
- Always check the expiration date prior to use. Do not use reagents beyond the specified expiration date.
- Protect fluorogenic probes from light.
- Primers, probes (including aliquots), positive control (stock and/or diluted) and enzyme master mix must be thawed and kept on ice at all times during preparation and use.

5 Material and Devices Required But Not Provided

NOTE: The names of vendors or manufacturers are provided as examples of suitable product sources. Users have to conduct verification whether using product sources provided or other product sources.

Type	Material/Devices
Reagents	<ul style="list-style-type: none"> • MiRXES CoVClear Mutation Panel N501Y (FGS0033R). • MiRXES CoVClear Mutation Panel E484K (FGS0035R). • MiRXES CoVClear Mutation Panel L452R (FGS0036R). • Molecular-grade nuclease-free water. • Surface decontaminant such as 10 % Bleach, 70 % Ethanol, RNase Away or equivalent.
Extraction equipment and consumbles	<ul style="list-style-type: none"> • MiRXES MAGec 96 Nucleic Acid Purification System (Cat No.: FGS0004) • MiRXES MAGec 96 Viral RNA Extraction Kit RUO v2 (Cat No.: FGS0029R) • QIAamp Viral RNA Mini Kit (Cat No.: 52904 / 52906).
RT-PCR Machine and consumbles	<ul style="list-style-type: none"> • Appropriate real-time PCR instrument: <ul style="list-style-type: none"> ○ Applied Biosystems® ViiA™ 7 Real-Time PCR System with 96-Well Block (Cat No.: 445534) ○ Bio-Rad CFX96 Real-Time PCR System (Cat. No.: 1841000 for C1000™ Thermal Cycler Chassis and Cat. No.: 1845096 for CFX96™ Optical Reaction Module) ○ QuantStudio™ 5 Real-Time PCR Instrument (Cat No.: A28134) • Bio-Rad Multiplate 96-well PCR Plates, low profile, unskirted, clear (Cat No.: MLL9601) for Bio-Rad CFX96 Real-Time PCR System. • BIOplastics Low Profile, SEMI skirted, 96 well plate (0.1 mL) (Ref No.: B17489) for Bio-Rad CFX96 Real-Time PCR System. • BIOplastics 96 x 0.2ml Plate, Laser Marked, White, 0.2ml (Ref No.: AB17509L) for QuantStudio™ 5 Real-Time PCR Instrument and ViiA 7 Real-Time PCR System. • Labcon PCR Plate 96-well - 0.2 mL non skirted flexible – natural (Ref No.: 3977-520-000-9) for QuantStudio™ 5 Real-Time PCR Instrument. • Bio-Rad Microseal 'B' PCR Plate Sealing Film, adhesive, optical (Cat No.: MSB1001).
Other consumbles	<ul style="list-style-type: none"> • 1.5 mL polypropylene microcentrifuge tubes (DNase/RNase free), 2 mL polypropylene microcentrifuge tubes (DNase/RNase free) and/or 5 mL polypropylene microcentrifuge tubes (DNase/RNase free). • Racks for 1.5 mL/2 mL/5 mL microcentrifuge tubes. • 96-well cold blocks . • Multi-channel or single channel Micropipettors (range

MiRXES CoVClear Mutation Panel Reagent Pack

	<p>between 1-10 μL, 10-200 μL and 100-1000 μL).</p> <ul style="list-style-type: none">• Disposable pipette tips with filters and aerosol barriers.• Disposable powder-free gloves.• Micropipettors (0.1-2.5 μL, 1-10 μL, 10-200 μL).• Benchtop centrifuge with a rotor for 2 mL reaction tubes.• Centrifuge capable of 1000 x <i>g/rcf</i> with a rotor for microtiter plates, if using 96-well reaction plates.• Vortex mixer.• Biohazard bags and bins.
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NOTE



Please ensure that all instruments used have been installed, calibrated, checked and maintained according to the manufacturer's instructions and recommendations.

6 Limitations, Warnings and Precautions

The MiRXES CoVClear Mutation Panel Reagent Pack described here has not been systematically verified for platforms or chemicals other than those mentioned in these instructions.

Read the Instructions for Use carefully before using the product.

6.1 Acceptable Specimens

Extracted RNA from SARS-CoV-2 positive nasopharyngeal swab specimens.

6.2 Specimen Collection, Transport and Storage

a) Specimen Collection

- Specimen collection should be performed by a qualified healthcare professional.

b) Transport and Storage

- For transport, the swab specimens collected in UTM or VTM can generally be stored at 2-8 °C up to 72 hours.
- For long-term storage, store at -70°C or below.

6.3 Handling

- Before initial use, check the product and its components for:
 - Cold state upon arrival
 - Integrity
 - Completeness with respect to number, type and filling
 - Correct labelling
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time RT-PCR.
- Avoid microbial and nuclease (DNase/RNase) contamination of the specimens and the components of the Kit.
- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling kit components.
- The workflow in the laboratory should proceed in a unidirectional manner. Use separated and segregated working areas for:
 - (i) sample preparation,
 - (ii) reaction setup and
 - (iii) amplification/detection activities.
- Always wear disposable powder-free gloves in each area and change them before entering a different area.

MiRXES CoVClear Mutation Panel Reagent Pack

- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Store positive and/or potentially positive material separately from all other components of the Kit.
- Do not open the reaction tubes/plates post amplification, to avoid contamination with amplicons.
- Do not autoclave reaction tubes in the same facility after the RT-PCR, since this may not completely degrade the amplified nucleic acid and risks contaminating the laboratory area.
- Do not use expired components, refer to the label for expiration date.

7 Procedure

Please refer to individual mutation panel kit (N501Y or E484K or L452R) for reaction set up and data analysis instructions, as well as individual performance evaluation.

8 Assay Limitations

- This product is intended for research use only for research involving the development of mutations of SARS-CoV-2 nasal swab specimen. These instructions should not be used to obtain clinical diagnostic results.
- Strict compliance with the instructions for use is required for optimal results.
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR, including testing procedures and interpretation of results prior to performing the assay.
- Good laboratory practice is essential for proper performance of this assay. Extreme care should be taken to preserve the purity of the components of the Kit and reaction setups. All reagents should be closely monitored for impurity and contamination. Any suspicious reagents should be discarded.
- Appropriate specimen collection, transport, storage and processing procedures are required for the optimal performance of this test.
- This assay must not be used on the specimen directly. Appropriate nucleic acid extraction methods have to be conducted prior to using this assay.
- The presence of RT-PCR inhibitors (e.g. heparin) may cause false negative or invalid results.
- As with any test, results of the MiRXES CoVClear Mutation Panel Reagent Pack and any of the mutation panels need to be interpreted in consideration of all clinical and laboratory findings.
- A false negative result can be caused by improper operations in sample collection, transportation or processing, very low concentrations of target virus in the specimens, mutations within the viral genome not covered by the kit's primers and/or probe.

9 Quality Control

- To ensure consistent product quality, each lot of the MiRXES CoVClear Mutation Panel Reagent Pack is tested against predetermined specifications.
- Users are strongly discouraged to combine components from assay kits of different lot numbers.

10 Technical Assistance

For technical advice, please contact Technical Support:

techsupport@mirxes.com

11 Disclaimers

MiRXES CoVClear Mutation Panel Reagent Pack should only be used for the intended purpose and in accordance with the Instructions for Use.

MiRXES Pte Ltd is not liable for any damage or loss that may result from your use of the test.

12 Explanation of Symbols and Abbreviations



Catalogue number



Manufacturer



Caution



Batch Code



Consult instructions for use



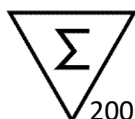
Temperature Limit



Research Use Only



Use-by date



Maximum 200 reactions



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