Omicron Variant Covered

Detection Kit

for 6 Mutations in S Gene of SARS-CoV-2 (ARMS-PCR)

For Research Use Only. Not for use in diagnostic procedures.

Product Description

The kit is a qualitative in vitro nucleic acid amplification assay to detect the mutations of N501Y, A570D, HV69-70del, K417N, K417T, and E484K in S gene of SARS-CoV-2 in B.1.1.7 lineage, B.1.1.28 lineage, B.1.351 lineage and **B.1.1.529 lineage (Omicron Variant)** of SARS-CoV-2 in throat swab or sputum specimen confirmed as SARS-CoV-2 positive by RT-PCR. B.1.1.7 lineage (UK), B.1.1.28 lineage (Brazil) as well as B.1.351 and B.1.1.529 lineages (South Africa) variants have been detected in numerous countries worldwide. They both have mutation in the receptor binding domain (RBD) of the spike protein at position 501, where the amino acid asparagine (N) has been replaced with tyrosine (Y), N501Y, leading to a tight interaction of RBD with human receptor ACE2. Other mutations include A570D and HV69-70del, both probably associated with increased transmissibility, and K417N, K417T, E484K, also a RBD mutation, which also increased the affinity of virus with human receptor.

Features

- Bundle with BGI EUA RT-PCR kit for detecting SARS-CoV-2, B.1.1.7, B.1.351, B.1.1.28 and B.1.1.529 lineage mutations
- Allele refractory mutation system (ARMS)-based quantitative PCR
- Identify spike protein mutations: N501Y, A570D, K417N, K417T, HV69-70del, E484K
- Human β–actin as an internal control
- Two reactions for each specimen in a single run to identify six spike protein mutations
- Stringent QC with positive and blank controls

Benefits

- Highly compatible - Bundled kits require very similar lab settings and procedure
- Highly sensitive –Superior limit of detection for oropharyngeal swabs or sputum
- Fast TAT – Sample to result in 2.8 hours with automated sample preparation system (1 hour for detecting mutations by RT-PCR)
- High-throughput – Ramp up labs for large-scale, community-based testing
- Ease of use – All-inclusive with pre-mixed reaction reagents
- Easy interpretation – Analysis of each allele with well-defined controls

Specifications

No. of tests per kit	50
Acceptable samples	Oropharyngeal swabs and sputum
Acceptable real-time PCR machines	– Applied Biosystems™ QuantStudio 5 Real-Time PCR System – Roche LightCycler® 480 Real time PCR System
Acceptable viral RNA extraction kits	– MGIEasy Nucleic Acid Extraction Kit, 96 or 1728 preps – QIAamp Viral RNA Mini Kit, 50 or 250 preps
Automation (Optional)	– MGISP-960RS Automated Sample Preparation System – MGISP-100 Automated Preparation System
Reagent stability	Under dark for 9 months at -15°C or below

Key Components

Contents (50 tests/kit)	Volume	Quantity	Description
Reaction Mix A	1 mL/vial	1 vial	Reagent with primers and probe for amplification of ORF1ab, internal reference, N501Y and K417N
Reaction Mix B	1 mL/vial	1 vial	Reagent with primers and probe for amplification of A570D, HV69-70del, K417T, and E484K
Enzyme Mix	240 µL/vial	1 vial	Taq polymerase, reverse transcriptase, and UDG
Positive Control	750 µL/vial	1 vial	Mixed solution of recombinant pseudo-viruses with target genes of mutant strain, ORF1ab, and internal reference
Blank Control	750 µL/vial	1 vial	DNase/RNase free water

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https://www.bgi.com/us/sars-cov-2-variant-detection/

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