



Rapid Identification Kit for B.1.1.7 lineage (N501Y and P681H) 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 identify B.1.1.7 lineage (N501Y and P681H) of SARS-CoV-2 from oropharyngeal swab specimen or sputum that is confirmed positive for SARS-CoV-2. This lineage strain of SARS-CoV-2 (known as 20B/501Y.V1, VOC 202012/01, or B.1.1.7 lineage) emerged with multiple spike protein mutations (deletion 69-70, deletion 144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H) present as well as mutations in other genomic regions. Our assay identifies two of the mutations, N501Y which is located within the receptor binding domain (RBD) of the spike protein, where amino acid asparagine (N) has been replaced with tyrosine (Y) and P681H, near the S1/S2 furin cleavage site, a site with high variability in coronaviruses.

Features

- Bundle with BGI EUA RT-PCR kit for detecting SARS-CoV-2 and B.1.1.7 lineage mutations
- Allele refractory mutation system (ARMS) - based quantitative PCR
- Identify spike protein mutations, N501Y, P681H
- Human β -actin as an internal control
- Two reactions for each specimen in a single run to identify two 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 reactions per kit	50
Acceptable samples	Oropharyngeal swabs, 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
Reagent stability	Under dark for 9 months at -15°C or below



Key Components

Contents (50 tests/kit)	Volume	Quantity	Description
Reaction Mix for Wild Strain	1 mL/vial	1 vial	Reagent with primers and probe for amplification of wild strain and internal reference
Reaction Mix for Mutant Strain	1 mL/vial	1 vial	Reagent with primers and probe for amplification of mutant strain and internal reference
Enzyme Mix	160 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 wild strain, mutant strain and internal reference
Blank Control	750 µL/vial	1 vial	DNase/RNase free water

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