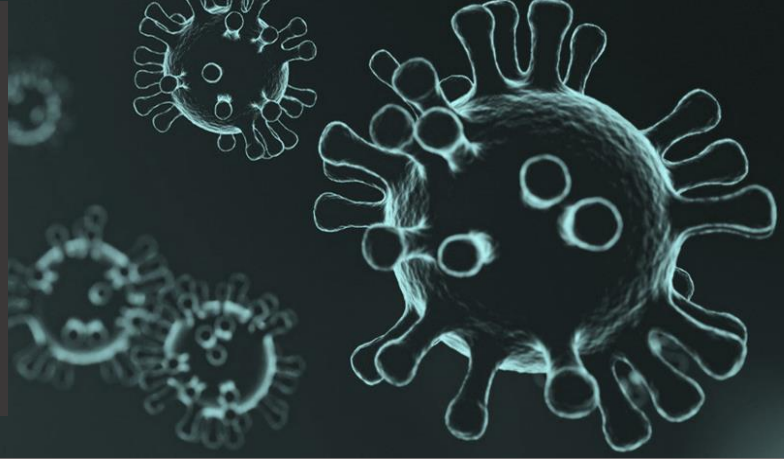


cellbae

TEPAT 1.0

SARS-CoV-2

Multiplex RT-PCR



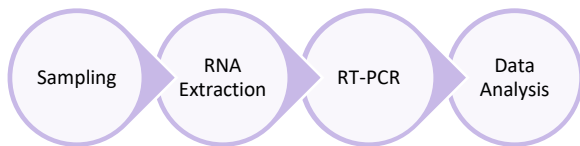
Intended Use

The Cellbae Multiplex RT-PCR kit provides for high-throughput, sensitive and specific detection of SARS-CoV-2 RNA extracted from nasopharyngeal swabs*. It can detect 6 copies of viral RNA per reaction with > 95% confidence. Clinical validation shows 100% sensitivity, with no cross-reaction with non-SARS-CoV-2 species.

Key Highlights

- ✓ 1.5 hours from RNA to results
- ✓ Multiplex RdRp and M viral genes detection enhances sensitivity and specificity
- ✓ 100% coverage of all SARS-CoV-2 genomes in the world
- ✓ Detects 6 copies of viral RNA
- ✓ Whole process control: human RNase P

Workflow



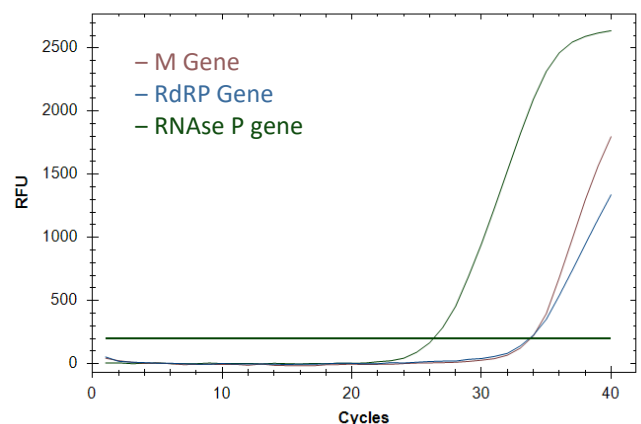
Kit Components

100 Tests/Kit

Component	Volume (100 Tests)
Master Mix A	1250 µL
Master Mix B	150 µL
Positive Control	100 µL
Internal Control	100 µL

Specimen type	• Nasopharyngeal swabs
Targets	RdRp, M and RNase P genes
Inclusivity	100% coverage of all SARS-CoV-2 genomes (as of Aug. 10, 2020)
Turnaround time	1.5 hours
Limit of detection	6 copies/reaction
Storage / Shelf life	-25 to -15°C / 6 months
Validated machines	Bio-Rad CFX96, LightCycler 480 II
Sensitivity / Specificity	100% / 100% (CV: < 4%)
Certification	Singapore Health Sciences Authority (HSA) MDPA2020-127 received Sept. 15, 2020

Multiplexed Detection



*A positive result from the test may indicate the presence of SARS-CoV-2-specific RNA in the test sample. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.