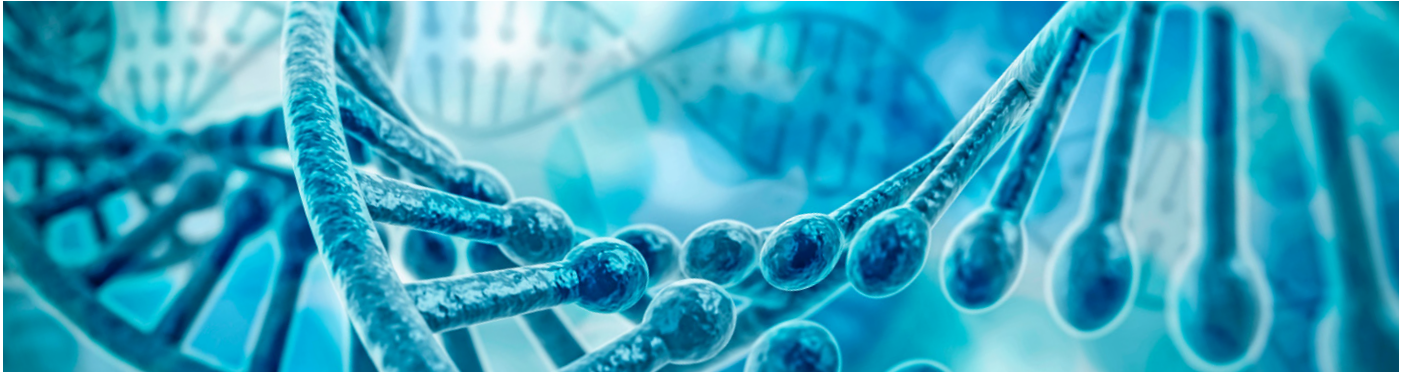




FILTER TECHNOLOGY

Flame CoViD -19 VARIANTS qPCR Master Kit - CE-IVD



Experiment Process V2.0

The kit is able to simultaneously detect the presence of COVID infection of both the “common” strain and the English, South African and Brazilian P2 variants with RT-PCR method in a single “well”. This kit is designed with specific primers and Taqman probes for the New Coronavirus ORF1ab and the conservative region of the N gene sequence encoding the nucleocapsid protein of the new coronavirus to diagnose or differentially diagnose whether the tested patient is infected with the new coronavirus, the British B.1.1.7 strain-specific N501Y mutation site and the South African B.1.351 and Brazilian P2 B.1.1.28.P2 strain-specific E484K mutation sites

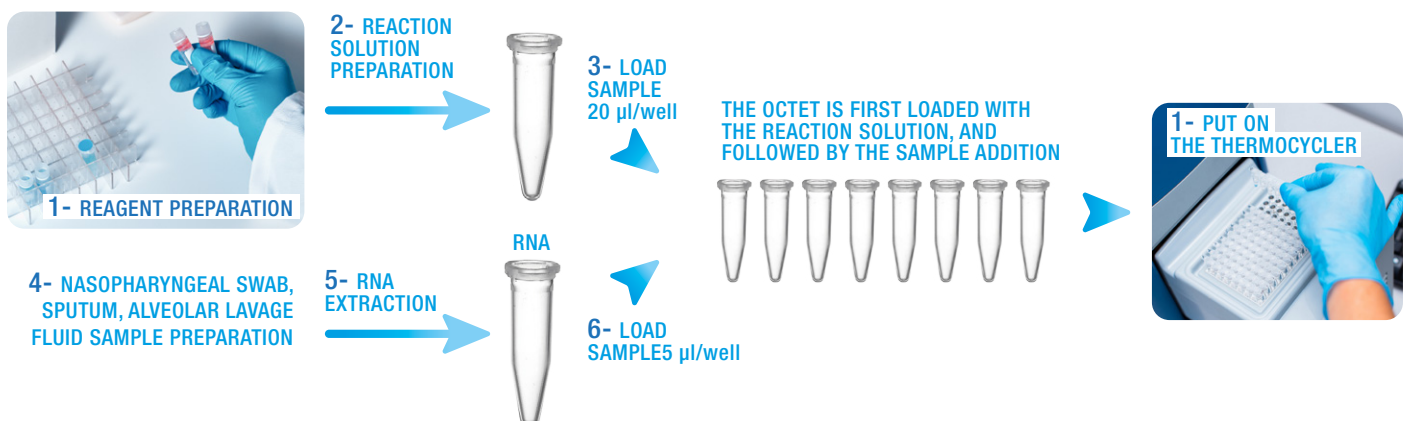
The mix contains:

- ◆ 2 specific genes: Orf 1ab and N
- ◆ Genomic Internal control
- ◆ Specific sequences for the English variant
- ◆ Specific sequences for the South African variant
- ◆ Specific sequences for the Brazilian variant P2

4 channels:

4 (FAM, Cy5, VIC, ROX), for optimal compatibility with PCR instruments. Ability to view data simultaneously and in real time. “One Step” Workflow.

Work Flow



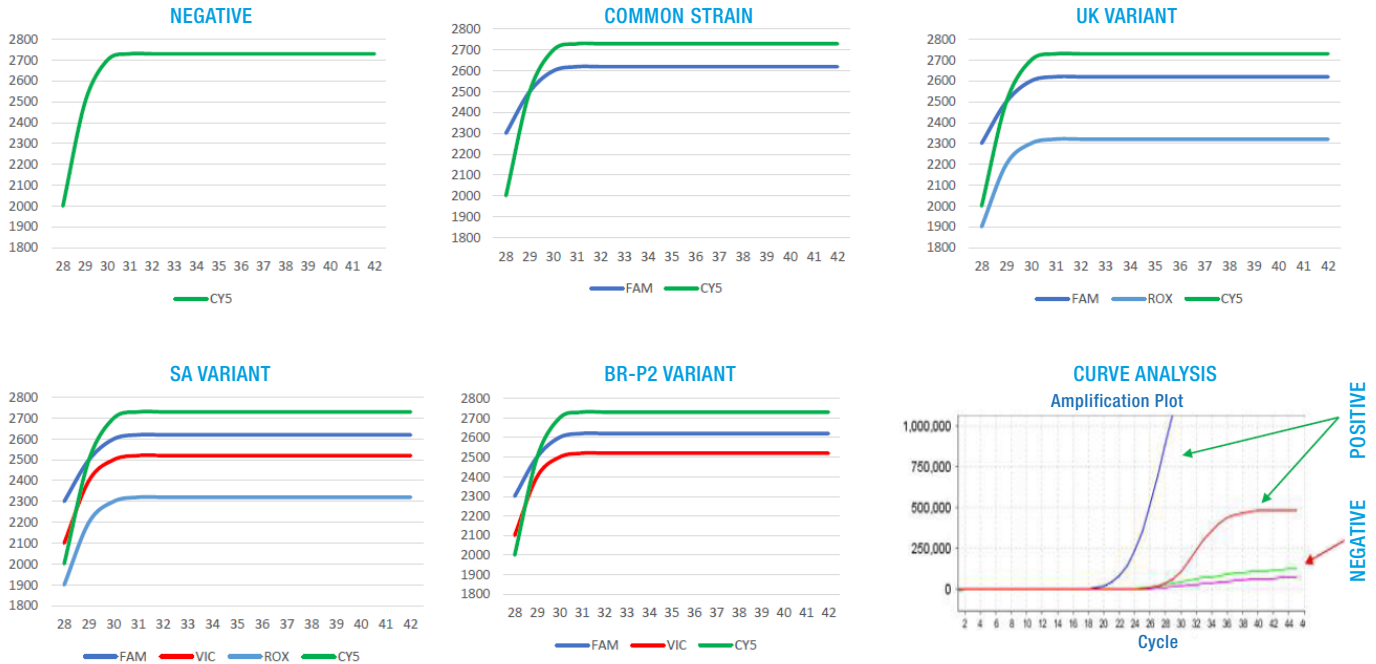
Applicable Instruments

This kit is suitable for ABI-7500. The other devices can include QuantStudio (ThermoFisher), Applied Biosystems, Bio-Rad (CFX96 Touch 1000, iQ5 iCycler), Agilent (MX-3000, Aria-Dx), MGITech, LighCycler 480II & Z480 (Roche), M2000RT Abbott, Pentabase Gentier48E, SLAN-96S, HIMEDIA INSTA Q96 LA1012, HIMEDIA INSTA Q48 LA1023, MygoPro, Rotor-Gene (6000, 3000, Q6Plex), LineGene 9600, DT-Lite, DT96, DT-Prime thermocycler series and other quantitative fluorescence PCR platforms with FAM, VIC/HEX and Cy5 channels.

RNA Extraction

- It is recommended to use the Flame Beads Viral RNA Extraction kit to extract sample RNA for PCR detection and follow the operation steps of the extraction kit instructions.
- The negative control and positive control in this kit are all involved in extraction.

RESULTS



RESULTS INTERPRETATION

- Negative control and positive control shall be tested in each experiment, and the test results can be determined only when the control meets the quality control requirements.
- When the FAM, VIC and ROX test channels are positive, the Cy5 channel result may be negative due to system competition.
- When the internal standard result is negative, if the FAM, VIC and ROX test signals of the test sample are also negative, the test result of the sample is invalid, and the cause should be found and eliminated, and the tested sample experiment repeated.

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