



## rTEST COVID-19 B.1.1.7 qPCR diagnostic kit

**A room temperature stable, multiplexed kit for the specific detection of lineage B.1.1.7, a new variant of SARS-CoV-2 first reported in the United Kingdom**

The rTEST COVID-19 B.1.1.7 qPCR kit is a qualitative in vitro confirmatory test designed for specific detection of the B.1.1.7 variant of SARS-CoV-2 first described by the United Kingdom. This coronavirus lineage is associated with increased transmissibility. The kit contains two sets of primers and hydrolysis probes (TaqMan®) targeting either the consensus (C95) sequence of the SARS-CoV-2 Spike (S) gene or select mutations in the S gene of the B.1.1.7 variant. Both sets allow the detection of the human RNase P gene. The TaqMan® probes for the S gene of both the consensus SARS-CoV-2 and B.1.1.7 variant are conjugated to FAM, while the TaqMan® probe for RNase P is conjugated to Cy5 or Yakima Yellow®. This enables multiplexed detection of either the consensus SARS-CoV-2 S gene or B.1.1.7 variant, and human RNase P,

which serves as an internal control to validate proper sample collection, RNA extraction, and performance of the test. The 5X One-step Probe CoV Mix (ROX) reagent from Solis BioDyne includes a ROX passive reference dye with a unique molecular structure allowing our RT-qPCR test to be compatible with all ROX-dependent and ROX-independent real-time PCR cyclers.

One package of the kit is sufficient for 400 testing reactions and is intended to determine the B.1.1.7 variant in patient samples that tested SARS-CoV-2 positive in the primary test. It is recommended to run two parallel reactions to detect the presence of consensus SARS-CoV-2 S gene in one reaction and the B.1.1.7 variant in another one.

### MAIN FEATURES:

- **Duplex configuration:** Innovative dual TaqMan® probes for consensus (C95) and B.1.1.7 Spike (S) genes are conjugated to FAM and the TaqMan® probe for RNase P is conjugated to Cy5 or Yakima Yellow®
- At least one-month **room temperature stability**
- Improved sensitivity of C95 and B.1.1.7 assays multiplexed with RNase P assay as an internal control
- **SARS-CoV-2 B.1.1.7 full genomic RNA** spiked with human RNA used as a positive control
- **100% clinical accuracy and specificity** for both the consensus SARS-CoV-2 and B.1.1.7 variant
- **100% analytical sensitivity** with 2 copies/rxn for consensus SARS-CoV-2 S gene and 10 RNA copies/rxn for B.1.1.7 variant
- Validated on real lineage B.1.1.7 clinical samples confirmed by sequencing
- No cold chain shipping needed