

COVID-19 Molecular Diagnosis

For easier extraction,
convenience and
higher throughput

GENERATION II

DIRECT SARS-CoV-2 RealTime PCR Kit

Real-time reverse transcription and amplification of nucleic acids in one step for detection of SARS-CoV-2 in respiratory samples.

- Double target assay: specific for COVID-19 (*N* gene) and other SARS- related coronavirus (*E* gene).
- Multiplex PCR-one single reaction tube per sample.
- Suitable for FAM/Cy5/HEX (VIC) qPCR cyclers.
- Endogenous human *RNAse P* control- for detecting improper sample collection or degradation.
- Compatible with Vircell quick extraction kit.
- Lyophilized master mix and positive control to ensure stability and reduce transportation costs.
- Different kit presentations for greater user convenience: vials, dispensed strips and plate.
- No cross reaction with common human respiratory CoV or MERS.
- Fast and reliable results in less than 2 hours.
- In compliance with international guidelines: WHO, CDC and ECDC*.

* World Health Organization, Center for Disease Control Atlanta US and European Center for Disease Control



Ref. RTPCR002



Ref. RTPCR002-LP



Ref. RTPCR002-LPP

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CONTENT



Single mix, Reconstitution solution, Positive control and Negative control. The mix includes internal control primers/probes for human specimen validation that allows detecting improper sample collection or degradation.

APPLICATIONS



Oropharyngeal and nasopharyngeal swab. Tracheal aspirates, bronchoalveolar lavage (BAL) and saliva.

COMPATIBILITY



Extraction systems:

Qiagen (Viral RNA Mini Kit & MinElute Virus Spin Kit), bioMérieux (NucliSENS[®] easyMag[®]), Roche (MagNA Pure System) and Vircell (Direct RNA Extraction Kit), among others.

RealTime PCR thermocyclers:

Abbott (Abbott m2000rt), Bio-Rad (CFX96), Cepheid (SmartCycler[®]), Qiagen (Rotor-Gene 3000, Rotor-Gene 6000, Rotor-Gene Q), Roche (LightCycler[®] 480, COBAS[®]z480), Agilent/Stratagene (Aria MX, MX3000P, MX3005P), Applied Biosystems (7500, Quantstudio 5)

Kit formats: Ref. RTPCR002-LP contains 12x8 PCR strips with pre-dispensed master mix, compatible with low profile qPCR cycles. Ref. RTPCR002-LPP contains a 96-well plate with pre-dispensed master mix, compatible with CFX96 (Bio-Rad) as well as LightCycler[®] 480 and COBAS[®]z480 (Roche). Ref. RTPCR002 does not include reaction tubes and can therefore be used with any FAM/Cy5/HEX (VIC) qPCR cycler.

PERFORMANCE



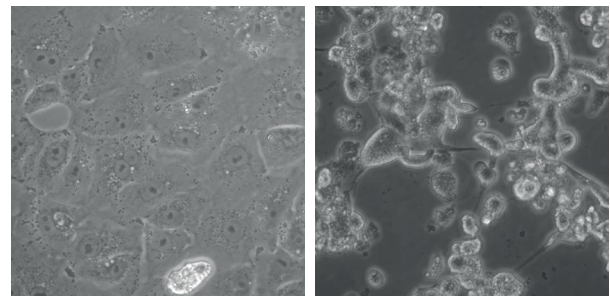
Sensitivity	Specificity	No. of samples
96%	100%	48 POS 39 NEG

Analytical Sensitivity: 700 copies/ml or 3.5 copies/reaction for both *N* and *E* targets.

Evaluated with a panel of 87 respiratory samples previously characterized by hospital reference molecular assay. Internal validation using Qiagen kit for extraction and CFX96 (Bio-Rad) for amplification/detection.

Cross Reactivity: Validated specificity with purified RNA and/or clinical samples including the following virus: HCoV-OC43, HCoV-NL63, MERS-CoV, SARS-CoV (2003), InfA nH1N1, InfA H3N2, InfB, Rhinovirus, Enterovirus, RSV A, RSV B, PIV1, PIV2, PIV3, PIV4, hMPV and AdV.

Furthermore, sensitivity with RNA of SARS-CoV-2 grown in vitro has been analyzed.



SARS-CoV-2 Vircell culture collection
Cytopathic effect in Vero cells at 24 and 48h

INFORMATION AND RELATED PRODUCTS

Description	Reference	Content
DIRECT SARS-COV-2 REALTIME PCR KIT NEW	N28-RTPCR002	96 tests
DIRECT SARS-COV-2 REALTIME PCR KIT (predispensed in strips) NEW	N28-RTPCR002-LP	96 tests
DIRECT SARS-COV-2 REALTIME PCR KIT (predispensed in plate) NEW	N28-RTPCR002-LPP	96 tests
DIRECT RNA EXTRACTION KIT NEW	N28-RTEXT001	96 tests
SARS-COV-2 REALTIME PCR KIT	N28-RTPCR001	48 tests
OPTITROL NAT SARS-COV-2 POSITIVE CONTROL	N15-NT04032	10 x 0,6 mL

Biomedical Diagnostics

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