

COVID-19

Molecular Diagnosis

Adapted solutions to meet
your laboratory needs

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 and saliva 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.
- **Lyophilized master mix and positive control** to ensure stability and reduce transportation costs.
- **Different kit presentations** for greater user convenience: vials, dispensed plates.
- **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



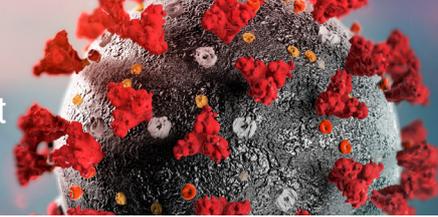
Ref. RTPCR002-LPD



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.

Kit formats:

Ref. RTPCR002-LPD contains caps and 96 x 0.1ml Tear Off 8-Tube Strip Mat with pre-dispensed lyophilized master mix.

Ref. RTPCR002-LPP contains optical sealing film and a 96-well plate with pre-dispensed master mix.

Ref. RTPCR002 does not include reaction tubes and can therefore be used with any FAM/Cy5/HEX (VIC) qPCR cycler.

COMPATIBILITY



Extraction systems:

Qiagen (Viral RNA Mini Kit & MinElute Virus Spin Kit), bioMérieux (NucliSENS® easyMag®), Roche (MagNA Pure System) and TANBead (Maelstorm 4800 and 9600) among others.

RealTime PCR thermocyclers:

Ref. RTPCR002-LPD: Bio-Rad (CFX96), Roche (LightCycler® 480 and COBAS® z480), Agilent (Aria Mx) and Applied Biosystems (7500 Fast).

Ref. RTPCR002-LPP: Bio-Rad (CFX96) and Roche (Lightcycler® 480, COBAS® z480).

Ref. RTPCR002: 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) and Applied Biosystems (7500, Quantstudio 5) among others.

INFORMATION AND RELATED PRODUCTS

Description	Reference	Content
DIRECT SARS-COV-2 REALTIME PCR KIT	RTPCR002/-LPD/-LPP	96 tests
SARS-COV-2 PLUS UK REALTIME PCR KIT	RTPCR009/-LPD	96 tests
SARS-CoV-2/FLU/RSV REALTIME PCR KIT	RTPCR003/-LPD	96 tests
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)	MBTC030	10 vials
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)	MBTC031	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	MC110	10 vials

APPLICATIONS



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

PERFORMANCE



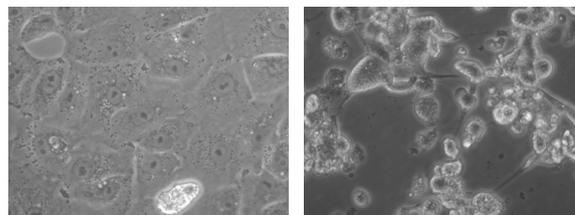
Sensitivity	Specificity	No. of samples	Sample type
90%	100%	691	Swab*
100%	100%	600	Saliva

*Nasopharyngeal/oropharyngeal swab.

Analytical sensitivity - Limit of detection:

Nasopharyngeal smear	copies/ml	copies/reaction	IU/copies
SARS-CoV-2 (N gene)	800	4	0.8
SARS-CoV-2 (E gene)	800	4	0.8

Saliva	copies/ml	copies/reaction	IU/copies
SARS-CoV-2 (N gene)	1000	5	1
SARS-CoV-2 (E gene)	1000	5	1



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

Vircell S.L.

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