SARS-CoV-2/FLU/RSV
Molecular Diagnosis

Efficient triage for winter respiratory infections

SARS-CoV-2/FLU/RSV REALTIME PCR KIT

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

- **4 virus Multiplex PCR detection-** one single reaction **tube** per sample.

- **Endogenous human *RNAse P* control-** for detecting unsuitable sample collection or degradation.

- Suitable for **5-channel qPCR cyclers**: FAM, Quasar 705 (Cy5.5), Cy5, HEX (VIC), Texas Red (ROX).

- Fast and reliable **results in under 2 hours**.

- **Lyophilized** master mix and positive control to ensure stability and reduce transportation costs.

- **Different kit presentations** for greater user convenience: vials and pre-dispensed divisible plates.

- Two SARS-CoV-2 targets 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. RTPCR003

Ref. RTPCR003-LPD

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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 detect improper sample collection or degradation.

Kit formats:

Ref. RTPCR003 contains 6 glass vials of lyophilized master mix. Reaction tubes are not included.

Ref. RTPCR003-LPD contains caps and 96 x 0.1ml Tear Off 8-Tube Strip Mat with pre-dispensed lyophilized master mix.

APPLICATIONS

Oropharyngeal and nasopharyngeal swab. Tracheal aspirates, bronchoalveolar lavage (BAL) and saliva. The use of saliva sample has been validated only for SARS-CoV-2 detection.

COMPATIBILITY

Extraction systems:

Qiagen (Viral RNA Mini Kit & MinElute Virus Spin Kit), bioMérieux (NucliSENS® easyMag®), Roche (MagNA Pure System), TANBead (Maelstorm 4800 and 9600), ThermoFisher (KingFisher Flex) and Bruker (GenoXtract 12) among others.

RealTime PCR thermocyclers[a]:

Ref. RTPCR003: Bio Rad (CFX96), Qiagen (Rotor-Gene Q 5plex), Agilent/Stratagene (MX3005P), Applied Biosystems (Quantstudio 5), Analytik Jena (qTOWER[3]), Azure biosystems (Cielo™), among others.

Ref. RTPCR003-LPD: Bio-Rad (CFX96), Azure biosystems (Cielo™).

[a] Alternatively, thermocyclers of 4 detection channels can be also used. In this case, the SARS-CoV-2 will be detected by one single target, the *N* gene in the FAM channel.

TARGETS

	Target	Channel
SARS-CoV-2	**N gene**	FAM
SARS-CoV-2	**E gene**	Quasar 705/Cy5.5
Influenza A	**M gene**	HEX/VIC[b]
Influenza B	**NS1 gene**	HEX/VIC[b]
RSV	**L gene**	Texas Red/ROX
Internal control	**Human RNAse P gene**	Cy5

[b] The assay does not differentiate between influenza A or influenza B virus.

PERFORMANCE

	Sensitivity	Specificity	No. of samples[c]
SARS-CoV-2	96%	100%	695
InfA	100%	100%	100
InfB	98%	100%	100
RSV	94%	100%	100

[c] Nasopharyngeal/oropharyngeal swab. In saliva samples, a sensitivity and specificity of 100% were obtained for SARS-CoV-2 (n= 600)

Analytical sensitivity - Limit of detection[d]:

	copies/ml	copies/reaction
SARS-CoV-2 (*N* gene)	**700**	**3.5**
SARS-CoV-2 (*E* gene)	**700**	**3.5**
Influenza A (*M* gene)	**1400**	**7**
Influenza B (*NS1* gene)	**1200**	**6**
RSV A (*L* gene)	**1100**	**5.5**
RSV B (*L* gene)	**2000**	**10**

[d] Data obtained using a negative matrix that simulates a nasopharyngeal swab. In saliva samples, a detection limit of 1000 copies/ml or 5 copies/reaction was obtained for the two targets, genes *N* and *E*.

INFORMATION AND RELATED PRODUCTS

Description	Reference	Content
SARS-CoV-2/FLU/RSV REALTIME PCR KIT	RTPCR003	96 tests
SARS-CoV-2/FLU/RSV REALTIME PCR KIT	RTPCR003-LPD	96 tests
AMPLIRUN® TOTAL SARS-CoV-2/ FluA/FluB/RSV CONTROL (SWAB)	MBTC031-R	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	MC110	10 vials

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