COVID-19 Molecular Diagnosis

For easier extraction, convenience and higher throughput

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 cycler.
- 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
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 m2000rs), Bio-Rad (CFX96), Cepheid (SmartCycler®), Qiagen (Rotor-Gene 3000, Rotor-Gene 6000, Rotor-Gene Q), Roche (Lightcycler®480, COBAS®480), 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®480 (Roche). Ref. RTPCR002 does not include reaction tubes and can therefore be used with any FAM/Cy5/HEX (VIC) qPCR cycler.

**Performance**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>No. of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>96%</td>
<td>100%</td>
<td>48 POS 39 NEG</td>
</tr>
</tbody>
</table>

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 simples including the following virus: HCoV-OC43, HCoV-NL63, MERS-CoV, SARS-CoV (2003), InfA H1N1, 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**

<table>
<thead>
<tr>
<th>Description</th>
<th>Reference</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIRECT SARS-COV2 REALTIME PCR KIT</td>
<td>N28-RTPCR002</td>
<td>96 tests</td>
</tr>
<tr>
<td>DIRECT SARS-COV2 REALTIME PCR KIT (predispensed in strips)</td>
<td>N28-RTPCR002-LP</td>
<td>96 tests</td>
</tr>
<tr>
<td>DIRECT SARS-COV2 REALTIME PCR KIT (predispensed in plate)</td>
<td>N28-RTPCR002-LPP</td>
<td>96 tests</td>
</tr>
<tr>
<td>DIRECT RNA EXTRACTION KIT</td>
<td>N28-RTEXT001</td>
<td>96 tests</td>
</tr>
<tr>
<td>SARS-COV2 REALTIME PCR KIT</td>
<td>N28-RTPCR01</td>
<td>48 tests</td>
</tr>
<tr>
<td>OPTITROL NAT SARS-COV2 POSITIVE CONTROL</td>
<td>N15-NT040032</td>
<td>10 x 0.6 mL</td>
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