

# COVID-19

THE HIGHEST  
PRECISION AND  
VERSATILITY IN  
MOLECULAR  
DIAGNOSIS

## 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.

### PRODUCT FEATURES

- Universal kit- suitable for any qPCR cyclers with FAM/HEX (VIC) detection.
- Double target assay: specific for COVID-19 (N gene) and other SARS- related coronavirus (E gene).
- Endogenous human RNase P control.
- Fast and reliable results in 90 minutes.
- No cross reaction with common human respiratory CoV or MERS.
- Lyophilized presentation to ensure stability and reduce transportation costs.
- In compliance with international guidelines: WHO, CDC and ECDC\*.



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





## CONTENT

Master mix A and B, Reconstitution solution, Positive control and Negative control. Each mix includes an internal control that allows detecting improper sample collection or degradation.



## APPLICATIONS

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



## COMPATIBILITY

### Extraction systems:

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

### RealTime PCR thermocyclers:

- Bio-Rad: CFX96, iCycler\*, MyiQ.
- Cepheid: SmartCycler®.
- Qiagen: Rotor-Gene 3000, Rotor-Gene 6000, Rotor-Gene Q.
- Roche: Lightcycler® 96, Lightcycler® 480.
- Agilent (Stratagene): Aria MX\*, MX3000P\*, MX3005P\*, MX4000P\*.
- Applied Biosystems: 7000\*, 7300\*, 7500\*, 7500 FAST\*, 7700\*, 7900\*, Quantstudio series\*, StepOne\*, StepOne Plus\*, Viiia7\*.

\* ROX option must be selected as "none".



## PERFORMANCE

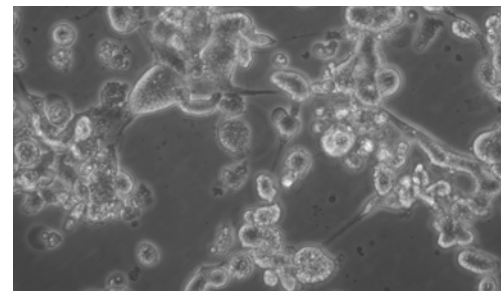
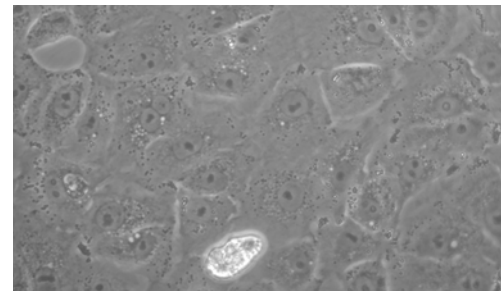
Sensitivity <b>100%</b>	Specificity <b>100%</b>	No. of samples <b>41 POS 39 NEG</b>
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Analytical Sensitivity: 100% in three serial dilutions of 5000, 500 and 50 copies/tube. Ct values between 25-30, consistent with the reference technique.

External validation in the Spanish National Centre for Microbiology (NCM-ISCIII) using Qiagen kit for extraction and CFX (Bio-Rad) for amplification/ detection.

Validated specificity with purified RNA and/or clinical samples including the following virus: HCoV-OC43, HCoV-229E, HCoV-HKU, MERS-CoV, 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
SARS-COV-2 REALTIME PCR KIT	RTPCR001	48 tests
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)	MBTC030	10 vials
AMPLIRUN® SARS-CoV-2 RNA CONTROL	MBC137-R	12,500-20,000 copies/µl