

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



vircell 
MICROBIOLOGISTS



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*, Viia7*.

* ROX option must be selected as "none".



PERFORMANCE

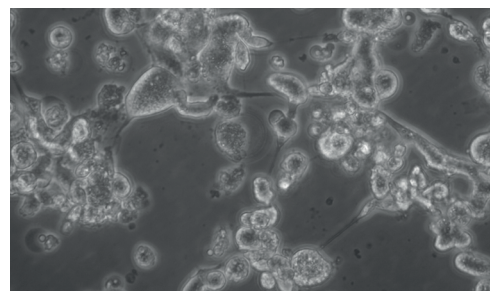
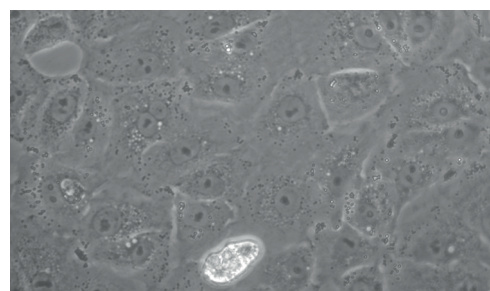
Sensitivity 100%	Specificity 100%	No. of samples 41 POS 39 NEG
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Analytical Sensitivity: 100% in three serial dilutions of 5000, 500 and 50 copies/tube. Ct values between 25-30, consistent with the reference technique.

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-R	10 vials
AMPLIRUN® SARS-CoV-2 RNA CONTROL	MBC137-R	12,500-20,000 copies/μl