# SARS-CoV-2 RT-PCR KIT VIRAL 3

For in vitro diagnostic use

CE IVD

## ORDERING INFORMATIONS

*REF: INFET-002-100*
*RDM Code: 2012127/R*
*Tests: 100 Reactions: 110*
*CND Code: W0105040599*
*Produttore: BioMol Laboratories s.r.l.*

## CONTENTS OF THE KIT

*The kit consists of: reagents for reverse transcription and amplification in Real-Time PCR*
**the reagents for RNA extraction are not supplied in the kit.*

## PRODUCT CHARACTERISTICS

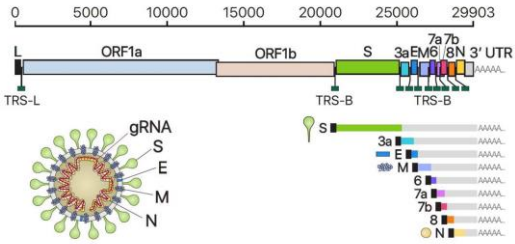
Molecular method "NAT" (Nucleic Acid Testing): Qualitative analysis of of SARS-CoV-2 (N-nucleocapsid, ORF1ab-polyprotein, E-envelope genes) viral genome and human RNase P gene by RT-PCR technique (Reverse transcriptase -polymerase chain reaction) and subsequent detection in PCR-Real-time. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx. The INFET-002 kit provides reagents optimized for qualitative analysis of viral genome even in case of infections caused by the SARS-CoV-2 variants B.1.1.7 (United Kingdom), B.1.351 (South Africa), P1 (Brazil) and Delta (India ).

## SCIENTIFIC BACKGROUND

Coronaviruses (CoV) are important pathogens capable of infecting the respiratory, gastrointestinal, hepatic and central nervous systems of humans, livestock, birds, bats, mice and many other wildlife.
SARS-CoV-2 (CoV19) is the seventh member of the family of coronaviruses that infect humans, after MERS-nCoV and SARS-nCoV. It has a diameter of 60–140 nm and a single-stranded RNA genome of 29891 bp. Genome sequence alignment revealed 79.5% sequence identity between SARS-CoV-2 and SARS-CoV and remarkable identity (93.1%) with the RaTG12 virus sequence isolated from a bat ( Rhinolophus affinis) from Yunnan province in China. These data, therefore, suggest that the SARS-CoV-2 virus could come from a virus endemic to this bat species.

## CLINICAL SIGNIFICANCE

Viral infection is cytopathic for human airway epithelial cells and also for alveolar cells. However, similarly to what has been observed in response to SARS-CoV, immune-mediated injury may play a critical role in the pathogenesis of COVID-19 infection, particularly among individuals with comorbidities. Indeed, cytokine storm is thought to be a key factor underlying both ARDS and extra-pulmonary organ failure..




§ CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel CDC, Revision 2 3/15/2020
§ https://www.who.int/emergencies/diseases/novel coronavirus-2019/technical guidance/laboratory-guidance
§ Development of a Laboratory-safe and Low-cost Detection Protocol for SARS-CoV-2 of the Coronavirus Disease 2019 (COVID-19). Exp Neurobiol 2020 Apr 30;29(2):107-119. doi: 10.5607/en20009.
§ Novel 2019 Coronavirus: Genome Structure, Clinical Trials, and Outstanding Questions. Exp Biol Med (Maywood) 2020 Apr 19;1535370220920540. doi: 10.1177/1535370220920540.
§ The Architecture of SARS-CoV-2 Transcriptome. Cell 2020 May 14;181(4):914-921.e10. doi: 10.1016/j.cell.2020.04.011. Epub 2020 Apr 23.
§ Comparative Performance of SARS-CoV-2 Detection Assays Using Seven Different Primer-Probe Sets and One Assay Kit. J Clin Microbiol 2020 May 26;58(6):e00557-20. doi: 10.1128/JCM.00557-20.
§ Gruppo di Lavoro ISS Test Diagnostici COVID-19 e Gruppo di Lavoro ISS Dispositivi Medici COVID-19. Dispositivi diagnostici in vitro per COVID-19. Parte 1: normativa e tipologie. Versione del 18 maggio 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 28/2020)
§ Gruppo di Lavoro ISS Test Diagnostici COVID-19 e Gruppo di Lavoro ISS Dispositivi Medici COVID-19. Dispositivi diagnostici in vitro per COVID-19. Parte 2: evoluzione del mercato e informazioni per gli stakeholder. Versione del 23 maggio 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 46/2020).
Dispositivi Medici COVID-19. Dispositivi diagnostici in vitro per COVID-19

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ISO 9001:2015
ISO 13485:2016



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| DESCRIPTION | LABEL | VOLUME | STORAGE |
|---|---|---|---|
| Mix RT-PCR | Mix RT-PCR 4X | 1 x 560 µl | -20° C |
| Mix probes and oligonucleotides Mix for N, ORF1a, E envelope and RNaseP genes | Mix CoV19 Viral 3 | 1 x 560 µl | -20° C |
| Recombinant RNA Positive Control (200 copies/µl) | Control + | 1 x 40 µl | -20° C |
| Buffer Negative Control | Control - | 1 x 80 µl | -20° C |

## TECHNICAL CHARACTERISTICS

COD. INFET-002- 100

| | |
|---|---|
| STABILITY | 18 months |
| REAGENTS STATUS | Ready to use |
| BIOLOGICAL MATRIX | Total RNA of cells contained in buffer rhino-oropharyngeal, in biological fluids, saliva and tissue |
| POSITIVE CONTROL | Recombinant RNA |
| VALIDATED INSTRUMENTS | Biorad CFX96 Dx, Biorad Opus Dx e Agilent AriaDx |
| TECHNOLOGY | RT-PCR (Reverse transcriptase-polymerase chain reaction) and subsequent detection with qPCR-Real-time |
| RUNNING TIME | 85 min |
| THERMAL CYCLING PROFILE | 1 cycle at 25 °C (2 min); 1 cycle at 50 °C (15 min); 1 cycle at 95 °C (2 min); 45 cycles at 95 °C (3 sec) + 60 °C (30 sec) |
| ANALYTICAL SPECIFICITY | Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity |
| ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD) | 100 copies of viral genome |
| ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB) | 0% NCN |
| REPRODUCIBILITY | 99,9% |
| DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY | 100% /98% |

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