

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

## ORDERING INFORMATION

REF: INFET-002-100  
RDM Code: 2012127/R  
Tests: 100 Reactions: 110  
CND Code: W0105040599  
Manufacturer: 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.

For in vitro diagnostic use



## PRODUCT CHARACTERISTICS

**Molecular method "NAT"** (Nucleic Acid Testing): Qualitative analysis of SARS-CoV-2 (N, ORF1ab and 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, Biorad Opus Dx and Agilent AriaDx.

The **INFET-002** kit provides reagents optimized for the 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).

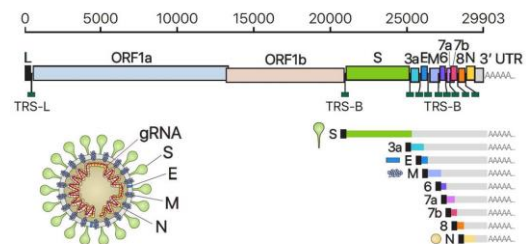
## SCIENTIFIC BACKGROUND

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.

- § 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 Neurol* 2020 Apr 30;29(2):107-119. doi: 10.5607/en.20009.
- § 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).

## 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.



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| DESCRIPTION  | LABEL             | VOLUME     | STORAGE |
|--|-------------------|------------|---------|
| Mix RT-PCR   | Mix RT-PCR 4X     | 1 x 520 µl | -20° C  |
| Mix probes and oligonucleotides<br>Mix for N, ORF1a, E envelope and RNaseP genes | Mix CoV19 Viral 3 | 1 x 520 µl | -20° C  |
| Recombinant RNA<br>Positive Control (200 copies/µl)                              | Control +         | 1 x 40 µl  | -20° C  |
| Buffer<br>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                               |
| LIMIT OF DETECTION (LOD)                        | 100 copies of viral genome   |
| LIMIT OF BLANK (LOB)                            | 0% NCN   |
| REPRODUCIBILITY                                 | 99,9%  |
| DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY | 100% /98%  |