Subgenomic N(sgN) SARS-CoV-2 ONE-STEP RT-PCR KIT

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: INFET-004-100
RDM Code: 2218988/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.*

PRODUCT CHARACTERISTICS

"NAT" (Nucleic Acid Testing) molecular method: qualitative determination of the viral genome of SARS-CoV-2 (ORF1ab-polyprotein gene, E-envelope gene and subgenomic-N transcript) and human RNase P gene by RT-PCR (Reverse transcriptase -polymerase chain reaction) technique and subsequent detection by PCR-Real-time. sgN mRNA expression, in particular, reflects a stage of viral replication and discriminates between an active phase of replication and a medium-long term carrier state, in which there is accumulation of viral genomic material without being more infectious. The INFET-004 kit detects the presence of known SARS-CoV-2 variants. The kit is optimized for Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx.

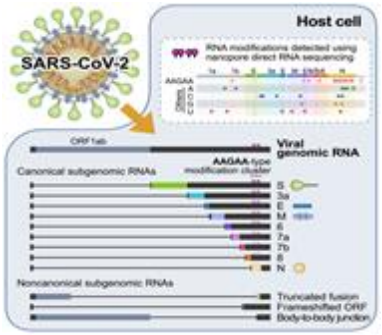
SCIENTIFIC BACKGROUND

SARS-CoV-2 is an enveloped virus with a single-stranded RNA genome of ~30 kb belonging to the betacoronavirus genus. It is known that coronaviruses produce subgenomic RNA fragments (sgRNAs) and that these fragments can be considered markers of viral replication. In fact, subgenomic RNAs are particularly abundant during early infection (up to 70 times more abundant than virus genomic RNA at the peak of RNA transcription). The expression of sgN mRNA, in particular, reflects a stage of viral replication and allows to discriminate between an active phase of replication and a medium-long term carrier state, in which there is accumulation of viral genomic material without being more infectious.

§ The Architecture of SARS-CoV-2 Transcriptome Kim D, Lee JY, Yang JS, Kim JW, Kim VN, Chang H. Cell. 2020 May 14;181(4):914-921.e10.
§ SARS-CoV-2 Subgenomic N (sgN) Transcripts in Oro-Nasopharyngeal Swabs Correlate with the Highest Viral Load, as Evaluated by Five Different Molecular Methods. Zollo M, Ferrucci V, Izzo B, Quarantelli F, Domenico CD, Comegna M, Paolillo C, Amato F, Siciliano R, Castaldo G, Capoluongo E. Diagnostics (Basel). 2021 Feb 12;11(2):288.
§ Test on stool samples improves the diagnosis of hospitalized patients: Detection of SARS-CoV-2 genomic and subgenomic RNA.
Moreira LVL, de Souza Luna LK, Barbosa GR, Perosa AH, Chaves APC, Conte DD, Carvalho JMA, Bellei N. J Infect. 2020 Dec 1:S0163-4453(20)30753-2. doi: 10.1016/j.jinf.2020.11.034.
§ Diagnostic usefulness of subgenomic RNA detection of viable SARS-CoV-2 in patients with COVID-19. Kim JY, Bae JY, Bae S, Cha HH, Kwon JS, Suh MH, Lee HJ, Jung J, Kim MJ, Cui C, Park H, Lee J, Park MS, Kim SH. Clin Microbiol Infect. 2022 Jan;28(1):101-106. doi: 10.1016/j.cmi.2021.08.009. Epub 2021 Aug 13.
PMID: 34400343.
§ SARS-CoV-2 Subgenomic RNA Kinetics in Longitudinal Clinical Samples. Verma R, Kim E, Martínez-Colón GJ, Jagannathan P, Rustagi A, Parsonnet J, Bonilla H, Khosla C, Holubar M, Subramanian A, Singh U, Maldonado Y, Blish CA, Andrews JR. Open Forum Infect Dis. 2021 Jun 11;8(7):ofab310. doi: 10.1093/ofid/ofab310. eCollection 2021 Jul. PMID: 34295944
§ Viral Culture Confirmed SARS-CoV-2 Subgenomic RNA Value as a Good Surrogate Marker of Infectivity. Santos Bravo M, Berengua C, Marín P, Esteban M, Rodriguez C, Del Cuerpo M, Miró E, Cuesta G, Mosquera M, Sánchez-Palomino S, Vila J, Rabella N, Marcos MÁ. J Clin Microbiol. 2022 Jan 19;60(1):e0160921. doi: 10.1128/JCM.01609-21. Epub 2021 Oct 20. PMID: 34669457
§ Loss of Detection of sgN Precedes Viral Abridged Replication in COVID-19-Affected Patients-A Target for SARS-CoV-2 Propagation
Ferrucci V, de Antonellis P, Quarantelli F, Asadzadeh F, Bibbò F, Siciliano R, Sorice C, Pisano I, Izzo B, Di Domenico C, Boccia A, Vargas M, Pierri B, Viscardi M, Brandi S, Fusco G, Cerino P, De Pietro L, Furfaro C, Napolitano LA, Paolella G, Festa L, Marzinotto S, Conte MC, Gentile I, Servillo G, Curcio F, de Cristofaro T, Broccolo F, Capoluongo E, Zollo M. Int J Mol Sci. 2022 Feb 9;23(4):1941. doi: 10.3390/ijms23041941.Dispositivi Medici COVID-19. Dispositivi diagnostici in vitro per COVID-19. Parte 2: evoluzione del

CLINICAL SIGNIFICANCE

The search for the SARS-Cov-2 viral genome can be carried out on a naso-oropharyngeal swab using the NAT (Nucleic Acid Testing) molecular method in order to identify the subjects in which the infection is present. This approach, in fact, allows to identify the presence of viral genes in the naso-oropharyngeal swab in a highly specific and sensitive way. However, commonly used tests do not provide information on the presence of an active viral load or not. In fact, it is known that the viral load reaches an early peak in SARS-CoV-2 infections and then gradually declines, with small amounts of viral RNA that can remain in the nasopharyngeal tract for weeks or sometimes months.



Cell 2020 May 14;181(4):914-921.e10.

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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 subN, ORF1a, E envelope and RNaseP genes	Mix sgN SARS-CoV-2	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-004- 100

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Total RNA of cells contained in nasopharyngeal and/or oropharyngeal swab
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	75 min
THERMAL CYCLING PROFILE	1 cycle at 50 °C (15 min); 1 cycle at 95 °C (2 min); 44 cycles at 95 °C (5 sec) + 60 °C (45 sec)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	30 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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