

DIAGNOVITAL SARS-CoV-2 REAL-TIME PCR

DIAGNOVITAL® SARS-CoV-2 Real-Time PCR Kit is an *in vitro* nucleic acid amplification assay for qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in respiratory specimens

TRIPLE TARGET DETECTION

- Two independent viral targets
- Reduces false negative results
- Targets: SARS-CoV-2 specific RdRp gene, pan-Sarbecovirus E gene and a specific Human Extraction Control (HEC) (Design follows recommendations of WHO)
- Validated specimen types include nasopharyngeal, oropharyngeal swabs and bronchoalveolar lavage (BAL)

NON INFECTIONOUS POSITIVE CONTROL

- The positive control is used to confirm functionality of the assays and overall PCR performance.
- The original target sequences for SARS-CoV-2 are included as a non infectious target positive control (TPC) to check the integrity of the detection assays.

EXTRACTION CONTROL

- Human Extraction Control (HEC) master mix is designed to detect a housekeeping gene region of human extracts (RNase P)
- The detection of RNase P indicates the correct sampling, RNA Isolation and Reverse Transcriptase PCR-amplification

KIT CONTENTS

- 50X VitaScript™ Reverse Transcriptase
- Diagnovital® 2X qPCR Mastermix E
- Diagnovital® 2X qPCR Mastermix RdRP
- Diagnovital® 2X qPCR Mastermix HEC
- SARS-CoV-2 Target Positive Control (TPC)
- Nuclease-free dH₂O




**COMPATIBLE WITH A WIDE RANGE OF
REAL-TIME PCR DEVICES**


TYPE OF ANALYSIS	Qualitative
TARGET REGIONS	RdRp gene and E gene
ANALYTICAL SENSITIVITY	38 copies/ mL for both regions (LOD with 95% probability)
DIAGNOSTIC SPECIFICITY	SARS-CoV-2, 100 % (All negative samples were negative)
EXTRACTION CONTROL	Human Extraction Control (Rnase P)
VALIDATED SPECIMEN TYPES	Nasopharyngeal/ oropharyngeal swabs and and bronchoalveolar lavage (BAL) specimens
NUMBER OF PER WELL PER SAMPLE	3 wells required per patient sample
NUMBER OF CLINICAL SAMPLES PER PCR PLATE	30 samples (if considered a 96 well plate)
STORAGE	-15°C to -25°C
VALIDATED EXTRACTION METHODS	RTA Viral NA Isolation Kit RTA Viral RNA Isolation Kit
COMPATIBLE EXTRACTION METHODS	Please refer to our website (http://a1lifesciences.com.tr/Products/Detail/38) for a list of compatible extraction methods
VALIDATED THERMOCYCLERS	QuantStudio 5 DX Real Time PCR Detection System BioRad CFX96™ Real-Time PCR Detection System Applied Biosystems 7500 Real-Time PCR System Rotor Gene 3000/6000
COMPATIBLE THERMOCYCLERS	Please refer to our website (http://a1lifesciences.com.tr/Products/Detail/38) for a list of compatible thermocycler
REQUIRED DETECTION CHANNELS	FAM
REGULATORY STATUS	CE-IVD

Product Name	Cat. No.	Kit Format
DIAGNOVITAL SARS-CoV-2 Real Time PCR Kit	10873722	50 Tests
	10873723	100 Tests

A1 Life Sciences Headquarters

 A1 Yaşam Bilimleri İlaç Tanı
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Legal Manufacturer

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