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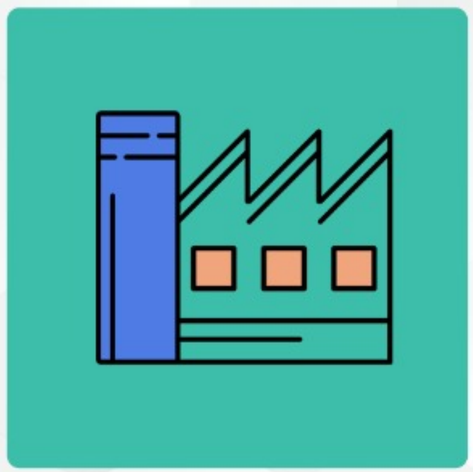

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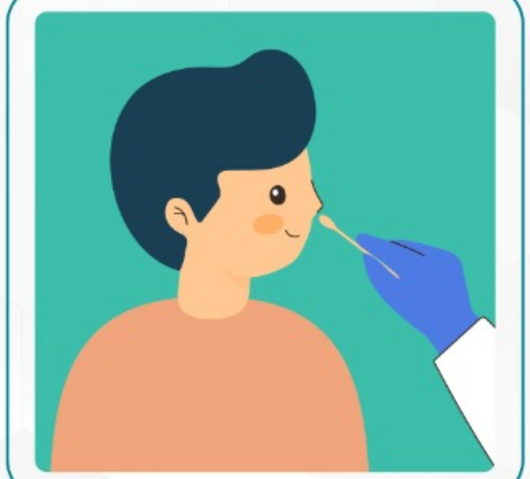

Uzman personelimiz ile
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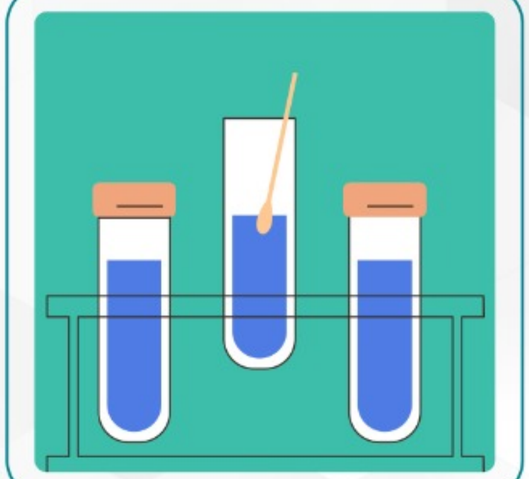


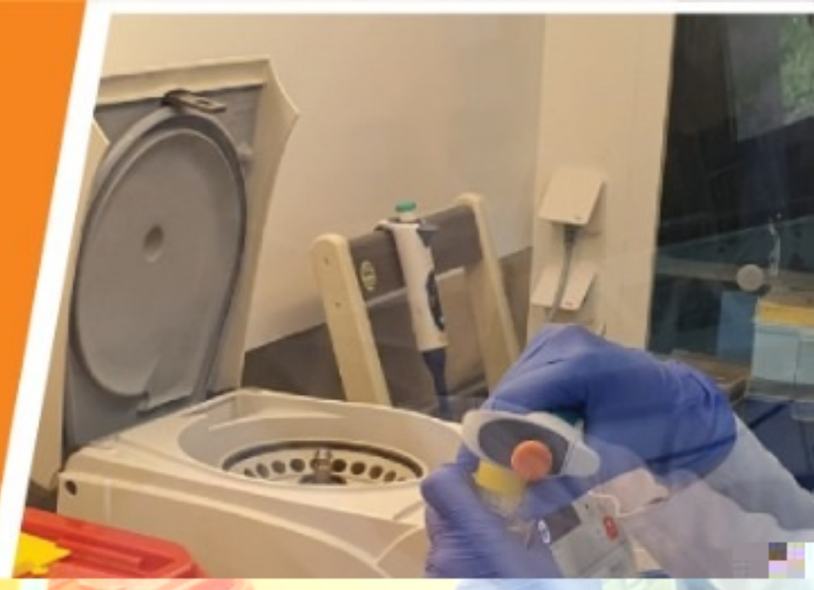
Örnekler FDA onaylı
tam tanı prosedürü
(numune alma -
viral RNA izolasyonu - PCR)
metodu ile çalışılır.

Sonuçlar en geç
24 saat içerisinde bildirilir.

ANADOLU YAKASI SORUMLUSU
BERKİN BİLGİN
0532 715 17 45

AVRUPA YAKASI SORUMLUSU
DERYA DURSUN
0534 230 66 36

RTA



DIAGNOVITAL

2019-NCOV

CERTIFICATE

EC - DECLARATION of CONFORMITY

DOCUMENT NO: RTA.UB.023

MANUFACTURER:
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.
GEPOSB CUMHURİYET CADDESİ NO:3 GEBZE / KOCAELİ / TURKEY

PRODUCT DESCRIPTION:
DIAGNOVITAL SARS-CoV-2 REAL-TIME PCR KIT (CATALOG NO: 09065025,09065050,09065100)

PRODUCT TYPE:
98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE ANNEX III PRODUCT

CONFORMITY ASSESMENT PROCEDURE:
WE HEREBY DECLARE THAT THE DESIGNATED PRODUCTS CONFORM TO ALL APPLICABLE REQUIREMENTS OF THE COUNCIL DIRECTIVE 98/79/EC PROVISION INCLUDING THE ESSENTIAL REQUIREMENTS GIVEN ON ANNEX I AND ALL APPLICABLE HARMONISED STANDARDS.

PRODUCT CLASSIFICATION: *GENERAL IVD DEVICES*

THE JUSTIFICATION FOR COMPLIANCE WITH THIS DIRECTIVE IS GIVEN ON THE PRODUCT TECHNICAL FILE.

DECLARED BY:
ŞABAN ORÇUN KALKAN - *GENERAL MANAGER*
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.

AUTHORISED SIGNATURE:

CE

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DIAGNOVITAL

SARS-CoV-2 Real-Time PCR Kit

Qualitative RT-PCR-based detection of SARS-CoV-2

For *in vitro* diagnostic use. For professional use only

CE IVD

REF Σ

09065025 25 tests

09065050 50 tests

09065100 100 tests

Table of Contents

Intended Use

This document describes the use of real-time RT-PCR assays for the in vitro qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in respiratory specimens. The SARS-CoV-2 primer and probe sets are designed for the specific detection of SARS-CoV-2.

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 using RTA Viral Nucleic Acid Isolation Kit and BIO-RAD CFX96-IVD or Rotor-Gene 3000/6000 or Applied Biosystems 7500 or QuantStudio 5 Real-Time PCR Detection Systems for amplification, detection and analysis.

The kits follow CDC's and WHO's latest detection guidelines.

Product Description

DIAGNOVITAL® SARS-CoV-2 is a real-time RT-PCR-based detection system for the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is considered a novel human coronavirus that is genetically distinct from the common human coronaviruses (229E, NL63, OC43, HKU1), which cause seasonal acute respiratory illness. It is also genetically distinct from the two newer human coronaviruses, MERS-CoV and SARS-CoV.

DIAGNOVITAL® SARS-CoV-2 detects the presence of 2 different and highly specific gene sequences of SARS-CoV-2: E gene and RdRp gene. All 2 assays must be tested positive to confirm the sample as SARS-CoV-2-positive.

Additionally, a non-infectious positive control and a negative human extraction control are included. Human Extraction Control (HEC) is needed to ensure appropriate RNA extraction, purification and reverse transcription and all reagents involved in reaction. The Human Extraction Control (HEC) master mix contains primers and probe for an endogenous human target, which is extracted from the swab during the extraction step. We don't put an external DNA or RNA template as extraction control, since we already get human target during extraction. The positive control is used to confirm functionality of the assays and overall PCR performance, the negative human extraction control is included to evaluate the quality of the RNA isolation independently from the SARS-CoV-2 assays.

REAL TIME PCR-BASED DETECTION OF SARS-CoV-2

The first step in the detection of SARS-CoV-2 is the conversion of viral RNA into cDNA. Afterwards, the target sequences unique for SARS-CoV-2 are specifically amplified with amplification monitored in real time through the use of fluorescently labelled probes: upon incorporation into the newly amplified DNA strands, the fluorophore (FAM™) is released and an increase in fluorescence signal can be observed.

Due to the intrinsic mutation rate of coronaviruses, it is possible that mutations in the target sequence occur and accumulate over time. This can lead to false-negative results with a PCR-based detection approach. **DIAGNOVITAL® SARS-CoV-2** addresses this issue by using 3 detection assays on 3 different target sequences to minimize the chance of false-negative results caused by an altered target sequence.

If samples are tested negative in one or more assays, additional complementary testing may be required. 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.

Samples tested positive should always be confirmed through complementary methods and additional analysis in an independent laboratory.

Materials Provided

	Reagents	Quantity and Volume (25 tests)	Quantity and Volume (50 tests)	Quantity and Volume (100 tests)
1	50X VitaScript™ Reverse Transcriptase	1 × 83 µl	1 × 165 µl	1 × 330 µl
2	Diagnovital® 2X qPCR Mastermix E	1 × 420 µl	1 × 825 µl	1 × 1650 µl
3	Diagnovital® 2X qPCR Mastermix RdRp	1 × 420 µl	1 × 825 µl	1 × 1650 µl
4	Diagnovital® 2X qPCR Mastermix HEC	1 × 420 µl	1 × 825 µl	1 × 1650 µl
5	SARS-CoV-2 Target Positive Control (TPC)	1 × 45 µl	1 × 75 µl	1 × 150 µl
6	Nuclease-free dH_2O	1 × 1000 µl	1 × 1000 µl	1 × 1000 µl

Additional Materials Required

- Suitable means & equipment for nucleic acid extraction
- Real-time PCR detection system equipped for FAM™ detection
- Adjustable pipettes & fitting filtered pipette tips
- Appropriate personal protective equipment & workspaces for working with potentially infectious samples
- Surface decontaminants such as DNAZap™ (Life Technologies), DNA Away™ (Fisher Scientific), RNAse Away™ (Fisher Scientific), 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite)
- Nuclease-free tubes / strips / plates to prepare dilutions, master mixes etc.
- Nuclease-free tubes / strips / plates corresponding to the PCR device
- Suitable storage options for reagents and specimen (4°C, -20°C, -70°C)

Storage

- Store all components at -20°C and avoid repeated freeze and thaw cycles.
- Protect the 2X qPCR master mixes from light as prolonged exposure can diminish the performance of the fluorophores.
- If the kit components have been damaged during transport, contact RTA Laboratories. Do not use as performance may be compromised.
- Keep reagents separate from sample material to avoid contamination.
- Do not use after the designated expiry date.

Performance Characteristics

Analytical sensitivity

Analytical sensitivity was analyzed by use of a dilution series of DIAGNOVITAL® SARS-CoV-2 Reference samples. A dilution series of a DIAGNOVITAL® SARS-CoV-2 Reference samples was prepared to give the final concentrations of 300, 100, 30 and 10 copies/ml. Each dilution was tested in 24 replicates. Lower limit was calculated by probit analysis done by PASW Statistics 18 program. For each genotype/subtype, Limit of Detection (LoD) values and 95% confidence ranges are summarized in Table 1.

Table 1: SARS-CoV-2qPCR Kit - Limit of Detection (LoD) values and 95% confidence ranges

Target gene	Limit of Detection (copies/ml)	95% confidence lower limit	95% confidence upper limit
E	38	33	50
RdRp	38	31	58

Precision

In this study, precision of the kit was evaluated for intra-assay, inter-assay, inter-batch, by using RTA Viral NA Isolation Kit (Cat No: 09029100) and different specimen types (oropharyngeal vs. nasopharyngeal swabs). For each target gene and different assay, 24 replicates of 10^3 copies/ml DIAGNOVITAL® SARS-CoV-2 Reference samples were used. Descriptive statistics were analyzed by IBM SPSS Statistics program. Overall precision assays associated with Ct values were summarized in Table 2.

Table 2: Overall descriptive statistics of SARS-CoV-2 precision data.

Descriptive Statistics					
	N	**Mean**	**Std. Deviation**	**Variance**	**Coefficient of variation (%)**
Target gene E	**96**	**23,6175**	**0,139198**	**0,019269875**	**0,595032**
Target gene RdRp	**96**	**24,6675**	**0,084034**	**0,007553**	**0,340342**

Diagnostic specificity

SARS-CoV-2 RNA negative clinical specimens were analyzed to determine the diagnostic specificity of DIAGNOVITAL® SARS-CoV-2 Real Time PCR Kit. 30 SARS-CoV-2 RNA negative clinical oropharyngeal swab specimens and 30 SARS-CoV-2 RNA negative clinical oropharyngeal swab specimens and 30 bronchoalveolar lavage specimens were used. None of the 100 SARS-CoV-2 negative clinical specimens gave positive test result for SARS-CoV-2. Diagnostic specificity of DIAGNOVITAL® SARS-CoV-2 Real Time PCR Kit is 100 %. All of the Human Extraction Controls (HEC) of tests gave positive result.

Cross-reactivity

To examine the specificity of an assay, cross-reactivity studies should be performed for potential cross-reactive markers. In this study, the specificity of the assay was evaluated by testing. 20 reference organisms.

DIAGNOVITAL® SARS-CoV-2 Real Time PCR Kit do not show any cross-reactivity with other potential cross-reactive markers given in the table 3 below:

Table 3: Potential cross-reactive markers tested in the study

Sample	*Source*
Human Adenovirus	NIBSC (Cat. No: 16/324)
Parainfluenza virus	ATCC VR-93
Influenza A	ATCC VR-95
Influenza A H5N1	ATCC VR-1609
Influenza A H1N1	ATCC VR-1672
Influenza A H3N2	ATCC VR-822
Influenza A H7N7	ATCC VR-1641
Influenza B	ATCC VR-101
Parainfluenza 1	ATCC VR-94
Parainfluenza 2	ATCC VR-92
Parainfluenza 3	ATCC VR-93
Parainfluenza 4	ATCC VR-579
Human Metapneumovirus (hMPV)	ATCC VR-3250SD
Human Enterovirus V71	ATCC VR-1432
Human respiratory syncytial virus	ATCC VR-154
Human Coronavirus NL63	ATCC VR-3263SD
Human Coronavirus HKU1	ATCC VR-3262SD
Human Coronavirus 229E	ATCC VR-740
Betacoronavirus 1 OC43	ATCC VR-1558D
MERS Coronavirus	ATCC VR-3248SD

Considerations Before Starting

BIOSAFETY

- Wear appropriate personal protective equipment (e.g. gowns, powder-free gloves, eye protection) when working with clinical specimen.
- Specimen processing should be performed in a certified class II biological safety cabinet following biosafety level 2 or higher guidelines.
- For more information, refer to:
  Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (SARS-CoV-2)
  https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
- Biosafety in Microbiological and Biomedical Laboratories 5th Edition available at
  http://www.cdc.gov/biosafety/publications
- The use of **DIAGNOVITAL® SARS-CoV-2** is restricted to trained laboratory personnel only.

SPECIMENS
Only use appropriate specimens for testing, such as:

- Respiratory specimens including nasopharyngeal / oropharyngeal swabs and bronchoalveolar lavage.
- Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron®) with plastic shafts. Swabs with calcium alginate or cotton tips with wooden shafts are not acceptable

SPECIMENS - HANDLING AND STORAGE

- Specimens can be stored at 4°C for up to 72 hours after collection.
- If a delay in extraction is expected, store specimens at -70°C or lower.
- Extracted nucleic acids should be stored at -70°C or lower.

Do not use specimens if

- they were not kept at 2-4°C (≤ 4 days) or frozen at -70°C or below.
- they are insufficiently labelled or lack documentation.
- they are not suitable for this purpose (see above for suitable sample material).
- the specimen volume is insufficient.

Sample Preparation

- The performance of RT-PCR assays strongly depends on the amount and quality of sample template RNA. It is strongly recommended to qualify and validate RNA extraction procedures for recovery and purity before testing specimens.
- Suitable nucleic acid extraction systems successfully used in combination with **DIAGNOVITAL DETECTION KITS** include: RTA Viral NA Isolation Kit from Swabs, bioMérieux NucliSens® systems, QIAamp® Viral RNA Mini Kit, QIAamp® MinElute Virus Spin Kit or RNeasy® Mini Kit (QIAGEN), EZ1 DSP Virus Kit (QIAGEN), Roche MagNA Pure Compact RNA Isolation Kit, Roche MagNA Pure Compact Nucleic Acid Isolation Kit, and Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit, and Invitrogen ChargeSwitch® Total RNA Cell Kit.
- Store and keep residual specimens and extracted nucleic acids at -70°C.
- Only thaw the number of specimen extracts that will be tested in a single day.
- Do not freeze/thaw extracts more than once before testing as each freeze/thaw cycle will decrease the RNA quality.
- It may be possible to use patient samples directly, depending on the sample type. However, this may require a prior lysis step and titration of the amount on sample that can be used without inhibiting the reaction. This procedure has not been validated, use of isolated RNA is recommended.

Reaction Setup

1. Make sure that all necessary equipment and devices are suitable, calibrated and functional before starting the experiments.

2. Decontaminate equipment and workspace and prepare everything needed for the following experiment to keep the workflow short and repeatable.

3. Switch on the PCR detection system and program it to avoid delays after setting up the reactions.

4. Thaw all components of **DIAGNOVITAL® SARS-CoV-2** on ice and mix gently but thoroughly to ensure even distribution of components. Collect liquid at the bottom of the tube with a quick spin (via microcentrifuge).

5. Set up your **Master mix Plate**:

    a. Always prepare control reactions with nuclease-free dH_2O instead of sample material (**NTC**) to detect contamination in your reagents.

    b. Always include the assay for the negative Human Extraction Control (**HEC**) to evaluate the quality of your RNA isolate.

c. When using the provided target positive control (**TPC**), use **4 µl / reaction** (max volume of the reaction should be 20 µ).

d. > 2 replicates / samples are strongly recommended.

e. Prepare enough master mix for all planned reactions. It is recommended to prepare a master mix for 2 additional reactions to compensate for pipetting inaccuracies.

Component	**Volume**
50X VitaScript™ Reverse Transcriptase	1 µl
Diagnovital® 2X qPCR Mastermix (E / RdRp / HEC)	15 µl
isolated sample RNA / TPC	4µl

f. Distribute the master mix to your strips/plate. An example setup is given in **Fig 1**).

	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
A	E	E	E	E	E	E	E	E	E	E	E	E
B	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp	RdRp
C	HEC	HEC	HEC	HEC	HEC	HEC	HEC	HEC	HEC	HEC	HEC	HEC
D												
E												
F												
G												
H												

Figure 1: Example pipetting scheme for the distribution of master mixes with the individual assay mixes

6. Transfer the Master mix Plate to a separate workspace to add the sample material. Preparing reagents and final reaction setup in separate workspaces helps to avoid contamination of equipment and reagents with sample material.

a. Prepare negative reactions first and seal them before handling positive samples. It is recommended to only bring potentially positive sample material and the included target positive control to the workspace once the NTC is prepared and sealed.

b. Add your samples to the Master mix Plate. An example setup is given in **Fig 2**):

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
B	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
C	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
D												
E												
F												
G												
H												

Figure 2: Example pipetting scheme for the addition of samples. The bottom half of the plate could be used for replicates with an identical setup

c. Keep reactions on ice until transferring them to the PCR device.

7. Transfer the reactions to the PCR device, then proceed according to these guidelines:

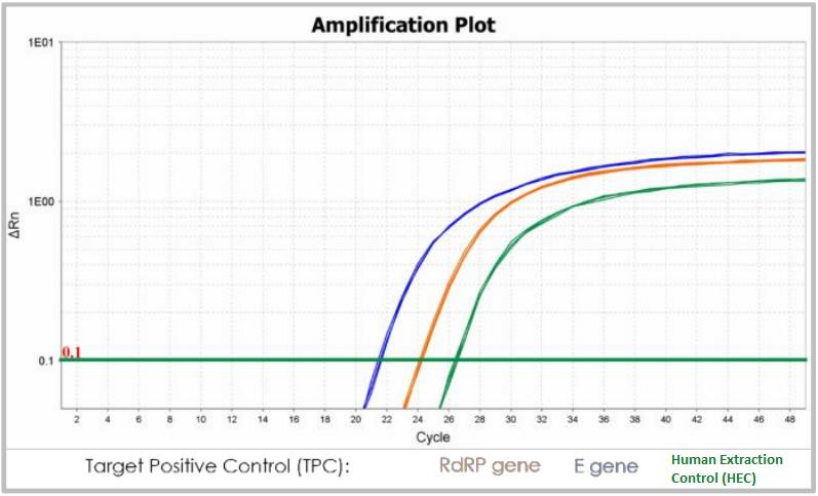
Step	**Cycles**	**Temperature**	**Duration**
Reverse Transcription	1	45°C	20 minutes
Initial Denaturation	1	95°C	10 minutes
Amplification	45	95°C	15 seconds
		58°C*	45 seconds

*Enable Data Collection for **FAM™**.

8. Once the run is finished, do not open the reaction tubes to avoid contamination and discard according to local guidelines and regulations. Do not autoclave as this may contaminate laboratory equipment with amplicons.

Analysis & Troubleshooting

EXEMPLARY RESULT



- **dH$_2$O controls (NTC) must not give a positive Ct for any assay**. If they do, the reaction was contaminated with sample RNA / DNA. Decontaminate equipment and workspace and repeat the reactions.
- **For a sample to be considered positive for SARS-CoV-2, all 2 assays (E / RdRp) must give positive Ct values**. If the **HEC** fails to amplify, the sample must still be considered positive.
- **For a sample to be considered negative for SARS-CoV-2, none of the 2 assays (E / RdRp) must give positive Ct values**. The **HEC** must give a positive Ct value (< 35 cycles) for these samples to ensure that sample material of suitable quality was present.
- **All reactions containing RNA isolate must give positive Ct values for the HEC assay. The Ct values should be < 35 cycles**. Failure to amplify the negative human extraction control indicates a flawed RNA extraction or loss of RNA isolate due to RNase contamination. The sample is not sufficient, results cannot be interpreted.
- **When using the TPC for SARS-CoV-2, a positive Ct for all 2 assays must be observed. The Ct value for the TPC should be < 35 cycles**. If the Ct value does not correspond to the expected value or not all assays are tested positive, PCR was compromised. Check the reaction setup and PCR device settings and repeat the reactions. Repeated freeze and thaw cycles of the TPC can compromise its quality resulting in late Ct values.
- **If no amplification signal is observed for any assay, PCR was inhibited**. Check reaction setup and device settings and repeat the RNA extraction if necessary. Results are invalid and cannot be interpreted.
- **If < 3 of the target assays are positive (e.g. only E gene, only RdRp gene etc.), results are inconclusive**. Check reaction setup and device settings and repeat the RNA extraction if necessary. Results are invalid and cannot be interpreted.

E	RdRp	HEC	Interpretation
+	+	+	All 2 target sequences for SARS-CoV-2 and the HEC were amplified. The sample is considered positive for SARS-CoV-2.
/	+	+	SARS-CoV-2 target sequence is detected and sample is considered as SARS-CoV-2 positive. A positive SARS-CoV-2 and a negative Sarbecovirus result is suggestive for low viral NA concentration or mutation in Sarbeco sequence.
/	/	+	Only the target sequence for the HEC was amplified. The sample is considered negative for SARS-CoV-2.
+	/	+	Sample is presumptive positive for SARS-CoV-2. This result suggests low viral RNA, a mutation in SARS-CoV-2 sequence or may indicate other Sarbecovirus (SARS or SARS-related Coronavirus) infection.
/	/	/	PCR was inhibited, results are invalid.
+	+	/	Expected result for TPC.

Limitations

- For reliable results, it is essential to adhere to the guidelines given in this manual. Changes in reaction setup or cycling protocol may lead to failed experiments.
- Depending on the sample matrix, inhibitors may be present in the isolated RNA and disable reverse transcription and/or PCR amplification. If this is the case, another sample type or isolation method may be beneficial.
- Spontaneous mutations within the target sequence may result in failure to detect the target sequence.
- Results must always be interpreted in consideration of all other data gathered from a sample. Interpretation must be performed by personnel trained and experienced with this kind of experiment.

RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.
Geposb Cumhuriyet Cad. No:3
41400 Gebze / Kocaeli / Turkey

Tel: +90 262 648 5300

June 12, 2020

Jennifer Henry
Protrim Enterprises, Inc./Parcha LLC
Representing: RTA Laboratories Biological Products Pharmaceutical and Machinery Industry
(RTA Laboratuvarları Biyolojik Urunler Ilac ve Makine San)
7212 Waring Ave
Los Angeles, CA 90046

Device:	Diagnovital SARS-CoV-2 Real-Time PCR Kit
Company:	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal and mid-turbinate nasal swabs, nasopharyngeal or oropharyngeal swabs, nasopharyngeal wash/aspirates or nasal aspirates and bronchoalveolar lavage (BAL) specimens from individuals who are suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Ms. Henry:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to RTA Laboratories Biological Products Pharmaceutical and Machinery Industry
[2] For ease of reference, this letter will use the term "your product" to refer to the Diagnovital SARS-CoV-2 Real-Time PCR Kit used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a Real-Time PCR qualitative test for the detection of nucleic acid from SARS-CoV-2 in anterior nasal and mid-turbinate nasal swabs, nasopharyngeal or oropharyngeal swabs, nasopharyngeal wash/aspirates or nasal aspirates and bronchoalveolar lavage (BAL) specimens from individuals who are suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal and mid-turbinate nasal swabs, nasopharyngeal or oropharyngeal swabs, nasopharyngeal wash/aspirates or nasal aspirates or bronchoalveolar lavage (BAL) specimens.

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[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.* § *360bbb-3*. 85 FR 7316 (February 7, 2020).

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The purified nucleic acid is then reverse transcribed into cDNA followed by amplification using real-time (RT)-PCR and detection of fluorescence using an authorized RT-PCR instrument. The Diagnovital SARS-CoV-2 Real-Time PCR Kit includes the following materials or other authorized materials: enzyme, master mix for each target, positive control, and nuclease-free water.

Your product requires the following control materials, or other authorized control materials, that are processed in the same way as the specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control - RNase P control in clinical samples: The RNase P Mix contains the primer and probe set and is included in each run to test for human RP, which controls for specimen quality, potential inhibitors and demonstrates that nucleic acid was generated by the extraction process.
- Positive Template Control - contains synthetic RNA templates for the E and RdRP genes that is intended to monitor for failures of RT-PCR reagents and reaction conditions.
- Negative Control - molecular grade water to monitor cross-contamination during experimental setup, and nucleic acid contamination of reagents.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product, is authorized to be accompanied with labeling entitled "Diagnovital SARS-CoV-2 Real-Time PCR Kit Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Diagnovital SARS-CoV-2 Real-Time PCR Kit
- Fact Sheet for Patients: Diagnovital SARS-CoV-2 Real-Time PCR Kit

The above described product, when accompanied by the instructions for use (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistently with the Scope of Authorization of this letter

(Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[5] "Authorized Distributor(s)" are identified by you, in your EUA submission, as an entity allowed to distribute your device.

C. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (You)

H. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You may request to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product, but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You will comply with the following requirements under FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your

product for distribution in the US. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

N. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

U. You will evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, You will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

Authorized Laboratories

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

W. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

X. Authorized laboratories using your product will use your product as outlined in the "Diagnovital SARS-CoV-2 Real-Time PCR Kit Instructions for Use." Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

Y. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Z. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

AA. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: rta@rtalabs.com.tr or ge@parcha.la) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

BB. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (You), Authorized Distributors and Authorized Laboratories

CC. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

DD. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

EE. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

FF. All descriptive printed matter, including advertising and promotional materials, relating

to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

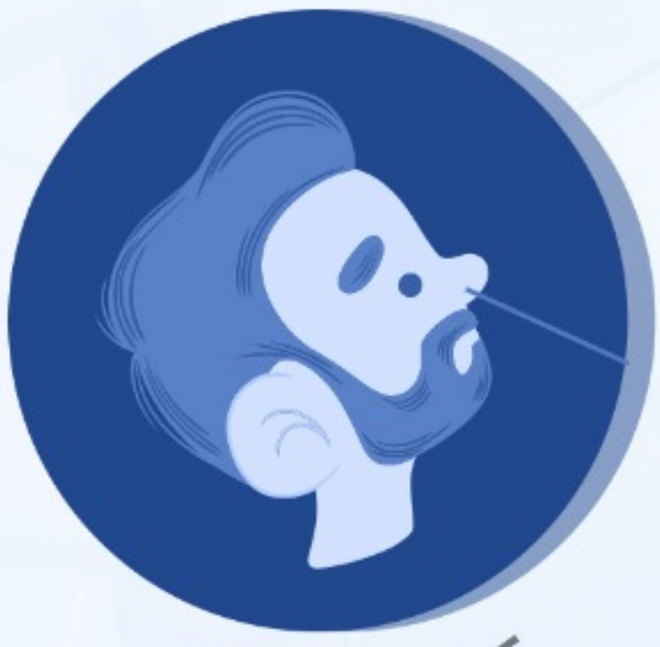
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

RTA

DiagnoVTM / DiagnoVTM v2.0 VİRAL SAMPLİNG and TRANSPORT KİT

DiagnoVTM and DiagnoVTM v2.0 works to transport secretions from the nasal cavity (nasopharynx) and throat (oropharynx) from the collection site to the test laboratory. Samples collected by Swab are stored in this viral transport medium. Thus, it can be used for virus testing and isolation by the Polymerase Chain Reaction (PCR) method.



The Diagnoswab package is carefully opened and the tip is carefully applied to the area to be sampled (nasopharynx or oropharynx) without deteriorating sterility.

The sample taken is immersed into the opened DiagnoVTM and the bar is broken from the marked section and the lid is carefully closed.

The necessary information is carefully written on the tube and made ready for the process.

CERTIFICATE

EC - DECLARATION of CONFORMITY

DOCUMENT NO: RTA.UB.024

MANUFACTURER:
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.
GEPOSB CUMHURİYET CADDESİ NO:3 GEBZE / KOCAELİ / TURKEY

PRODUCT DESCRIPTION:
DIAGNO VTM (CATALOG NO: 09080001)

PRODUCT TYPE:
98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE ANNEX III PRODUCT

CONFORMITY ASSESMENT PROCEDURE:
WE HEREBY DECLARE THAT THE DESIGNATED PRODUCTS CONFORM TO ALL APPLICABLE REQUIREMENTS OF THE COUNCIL DIRECTIVE 98/79/EC PROVISION INCLUDING THE ESSENTIAL REQUIREMENTS GIVEN ON ANNEX I AND ALL APPLICABLE HARMONISED STANDARDS.

PRODUCT CLASSIFICATION: *GENERAL IVD DEVICES*

THE JUSTIFICATION FOR COMPLIANCE WITH THIS DIRECTIVE IS GIVEN ON THE PRODUCT TECHNICAL FILE.

DECLARED BY:
ŞABAN ORÇUN KALKAN - *GENERAL MANAGER*
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.

AUTHORISED SIGNATURE:

CE

RTA Laboratuvarları Biyolojik Ürünler
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DiagnoVTM / DiagnoVTM v2.0

VİRAL ÖRNEK ALMA VE TAŞIMA KİTİ

Kullanım Kılavuzu

Kullanım amacı:

DiagnoVTM ve ***DiagnoVTM v2.0*** Burun boşluğu (nazofarenks) ve boğazdan (orofarenks) alınan sekresyonların toplama bölgesinden test laboratuvarına virüs içeren klinik örneklerin toplanması ve taşınması için tasarlanmıştır. Swab tarafından toplanan örnekler bu viral taşıma ortamında muhafaza edilir. Laboratuvarda Polimeraz Zincirleme Tepkimesi (PCR) yöntemi ile virüs testi ve izolasyonu için kullanılabilir.

Genel bilgi:

Virüsleri içeren klinik örneklerin toplanması, taşınması, bakımı ve uzun süreli dondurucuda saklanması için uygun bir onaylı sistemdir. Taşıma ortamı bir plastik, vidalı kapaklı tüpten oluşur ve organizmaların oda sıcaklığında veya soğutulmuş sıcaklıkta 48 saat yaşayabilirliğini korur. Toplamadan sonra örnek 2-25 ° C'de saklanmalı ve 48 saat içinde işlenmelidir. Teslimat ve işleme 48 saati aşarsa, numuneler kuru buzda ve bir kez -70 ° C veya daha soğukta dondurulmuş laboratuarda taşınmalıdır.

Alınan örneklerde bulunan hücrelerden PCR gibi yöntemlerle nükleik asitlerin çoğaltılması, çeşitli enfeksiyon etkenlerinin saptanması, türlerin belirlenmesi, genetik hastalıklara yol açan gen dizilerinin belirlenmesi gibi çok önemli amaçlar için kullanılmaktadır.

DiagnoVTM ve ***DiagnoVTM v2.0*** numunelerin yüksek hassaslıkla alınması ve steril olarak taşınması amacıyla tasarlanmıştır.

Yöntemin esası:

DiagnoVTM ve ***DiagnoVTM v2.0*** örnek alma ve taşıma için tasarlanmıştır. Kullanım öncesi steril paketinde bulunan kuru diagnoswab dikkatlice açılır ve numune alındıktan sonra kolay kırılım olanağı sağlayan diagnoswap çubuk tüp içerisine dikkatli bir şekilde yerleştirilir.

Kit İçeriği:

DiagnoVTM v2.0

Katalog numarası: 09080001

1) 16x100 mm Vidalı kapaklı plastik tüpte 3ml virüs taşıma ortamı; 1 adet
2) Ambalajlı poşette gama steril NAZOFARENKS örnekleri için diagnoswab; 1 adet

DiagnoVTM

Katalog numarası: 09081001

1) 16x100 mm Vidalı kapaklı plastik tüpte 3ml virüs taşıma ortamı; 1 adet
2) Ambalajlı poşette gama steril NAZOFARENKS örnekleri için diagnoswab; 1 adet
3) Ambalajlı poşette gama steril OROFARENKS örnekleri için diagnoswab; 1 adet

Uyarılar ve Önlemler:

- Tek kullanımlıktır. Yalnızca profesyonel in vitro kullanım için tasarlanmıştır.
- Son kullanma tarihinden sonra kullanmayınız.
- **DiagnoVTM** ve **DiagnoVTM v2.0** ortamlarını, numuneyi almadan önce diagnoswab çubuğunu önceden ıslatmak veya örnekleme alanlarını durulamak/sulamak için kullanmayınız.
- Kültür için toplanan numunenin durumu, zamanlaması ve hacmi güvenilir kültür sonuçları elde etmede önemli değişkenlerdir. Örnek toplama için önerilen yönergeleri takip ediniz.
- Kullanılan çubukları tekrar steril etmeyiniz.
- Yeniden paketlemeyiniz.
- Virüs, dışındaki mikroorganizmaları toplamak ve taşımak için uygun değildir.
- Virüs aranmasına yönelik örnekler, kişisel koruyucu kullanılarak toplanmalı ve kullanılmalıdır.
- Yayınlanmış kılavuz ve yönergelere göre biyolojik riske karşı ekipman kullanınız.
- Numunelerin tekrar tekrar dondurulması ve çözülmesi, canlı organizmaların geri kazanımını azaltabilir.
- Virüs taşıma ortamında dondurularak saklanmış örnekler, eritildikten sonra tekrar dondurulmamalı, eritme işlemi nükleik asit saflaştırma işleminin hemen öncesinde yapılmalıdır.
- Tüm çalışmalarda mutlaka eldiven takınız.
- Örneğin temas ettiği yüzeyleri %2,5 hipoklorit çözeltisi ile temizleyiniz.
- Atıklar yerel mevzuata uygun olarak imha edilmelidir. Gerekirse enfekte olmuş materyal için uygun önlemleri alınız.

Saklama koşulları:

2-25 ºC'de saklayınız.

Kutu içeriği:

DiagnoVTM iki birimden oluşmuştur:

1) Plastik vidalı kapaklı tüp içerisinde steril viral taşıma ortamı.
2) Kapalı ambalaj içerisinde steril nazofarenks örnekleri için diagnoswab

DiagnoVTM v2.0 üç birimden oluşmuştur:

1) Plastik vidalı kapaklı tüp içerisinde steril viral taşıma ortamı
2) Kapalı ambalaj içerisinde steril nazofarenks örnekleri için diagnoswab
3) kapalı ambalaj içerisinde steril orofarenks örnekleri için diagnoswab

Satın alınan her kutu içerisinde kullanım kılavuzu yer almaktadır.

Bozulma belirtileri:

Özellikle üç parametreye dikkat edilmelidir;
Vidalı kapaklı tüplerdeki taşıma ortamı için;

- Taşıma tüpünde bulanıklık olması
- Sıvı miktarındaki belirgin azalma

Swablar için;

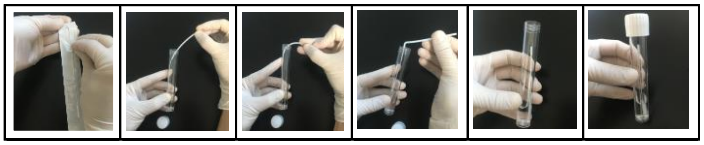
- Yırtılmış veya deforme olmuş swab ambalajı

Bu üç durumdan en az birinin görülmesi durumunda kullanımı uygun değildir.

Uygulama yöntemi

Örnek alma:

1. Diagnoswabı steriliteye dikkat edilerek açılır ve uç kısmı numune alınacak bölgeye (nazofarenks yada orofarenks) dikkatlice sürülmelidir.
2. Numune alındıktan sonra Diagnoswab çubuğu dikkatlice uygun boyda kırınız.
3. Numune alma tüpünün kapağını açarak çubuğu tüp içerisine batırınız.
4. Hasta ve örnek hakkındaki gerekli bilgileri tüpün üzerine dikkatlice yazdıktan sonra laboratuvara iletiniz.



Laboratuvar işlemleri:

Virüsün çubuktan sıvıya geçmesini sağlamak amacıyla gelen tüpler kullanımdan önce iyice vortexlenmelidir. Ancak bu sıvı, ileriki basamaklarda kullanıma uygundur.

Kalite kontrol:

DiagnoVTM ve ***DiagnoVTM v2.0*** ile alınan ve saklanan numunelerin kalite kontrolü PCR analizi gerçekleştirilir.

Performans özellikleri:

Numune alma tüpü içerisinde bulunan 10 kopya DNA bulunmaktadır. Alınan numunenin taşıma tüpüne alındıktan yapılan PCR işleminde bu 10 kopya DNA saptanabilmektedir.

Kaynaklar:

1. Hall, C. B., and R. G. Douglas. 1975. Clinically useful method for the isolation of respiratory syncytial virus. J. Infect. Dis. 131:1–5
2. Covalciuc, K. A., K. H. Webb, and C. A. Carlson. 1999. Comparison of four clinical specimen types for detection of influenza A and B viruses by optical immunoassay (FLU OIA test) and cell culture methods. J. Clin. Microbiol. 37:3971–3974.
3. Jensen, C., and F. B. Johnson. 1994. Comparison of various transport media for viability maintenance of herpes simplex virus, respiratory syncytial virus, and adenovirus. Diagn. Microbiol. Infect. Dis. 19:137–142.

Üretici:

RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.
Plastikçiler Organize Sanayi Bölgesi, Cumhuriyet Cad. No:3 41400
Gebze/Kocaeli/TÜRKİYE
Tel: +90 262 648 53 00
Faks: +90 262 751 06 77
E-mail: rta@rtalabs.com.tr
Web: www.rtalabs.com.tr

İn vitro kullanım içindir. CE

COVID-19 IgM/IgG Antibody Test

Covid-19 Coronavirus IgG/IgM antikor testi ürünümüz yüzlerce Covid-19 hastası üzerinde test edilerek PCR kit sonuçları ile ayrıca kıyaslanarak CE ve ISO sertifikalarına da sahiptir. Maxsure Covid-19 IgM ve IgG antikor testimiz hem ilk seviye bulaş (IgM) hem de geçirilmiş (IgG) Covid-19 tespit özelliğine sahiptir.

Web sitemizi ziyaret için Qr Kodu Okutunuz.

- Kullanımı kolaydır. Laboratuvara ihtiyaç yoktur.
- Hızlı antikor tanı kiti 15dk
- Hassasiyet : %92,85
- Ek cihaz gerektirmez
- Özgüllük : %99,20

Dakikalar içinde sonuç

Oda sıcaklığında kullanım

Yüksek hassasiyet

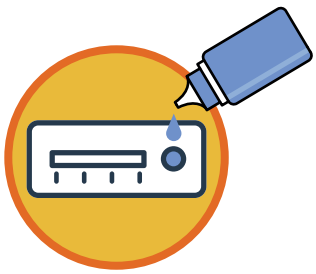
Erken tanı ve hastalık tespiti

Dikkat : Özel durumlar farklı kullanım gerektirebilir.

Nasıl Kullanılır

Oda sıcaklığında kiti ambalajından çıkartın

10 µl serum veya plazma veya 20 µl kaset yuvasına kutuya damlatın



2 Damla çözeltiyi kaset yuvasına damlatın

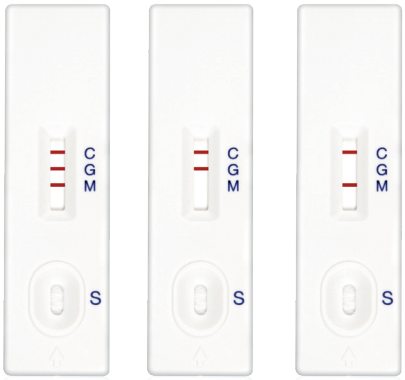
Hastalık durumunun tespiti

Kutu İçeriği

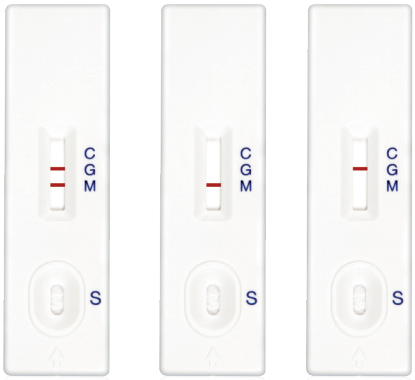
Test Kasedi, Test Solüsyonu, Tek Kullanımlık Damlalık

Sonuçların Yorumlanması

Sadece C çizgisi
oluşmuşsa Negatif

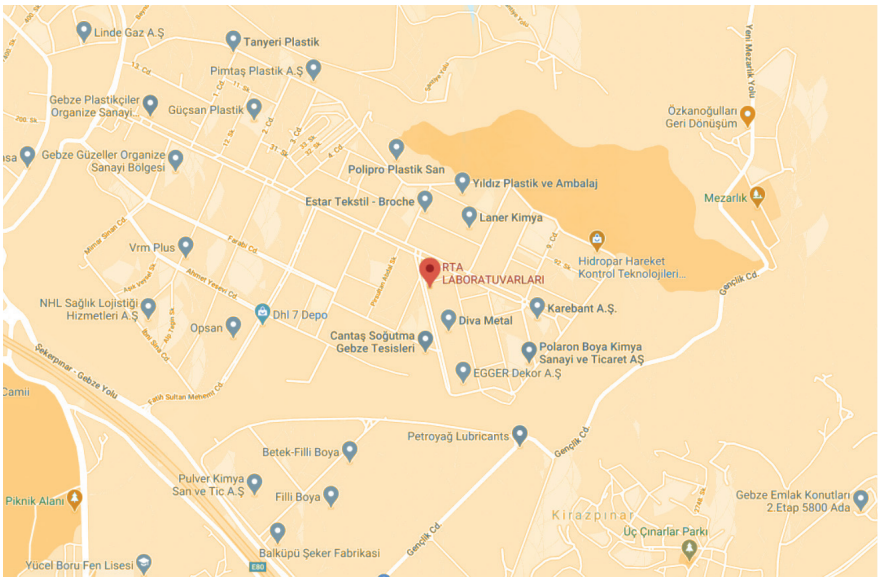


C G M Tüm çizgiler Pozitif
C G Çizgiler - IgG Pozitif - Geçirmiş
C M Çizgiler - IgM Pozitif - Başlangıcı



G M Çizgiler - Geçersiz
M Çizgisi - Geçersiz
G Çizgisi - Geçersiz

RTA Laboratuvarları Biyolojik Ürünler İlaç ve Makine San. Tic. A. Ş.



Plastikçiler Organize Sanayi Bölgesi (GEPOSB)
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RTA

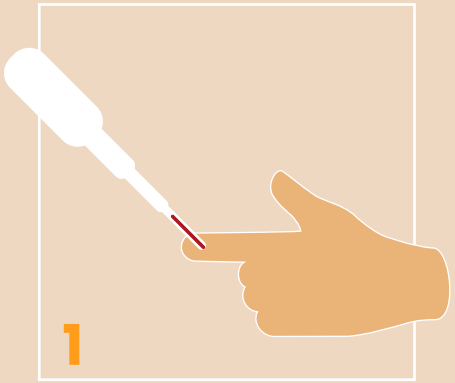
RTA Laboratuvarları

rtalaboratuvarlari

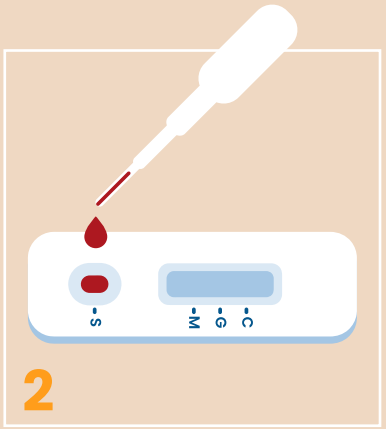
MAX sure

COVID - 19

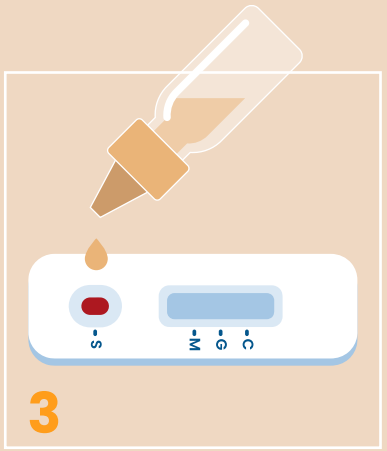
TEST KİTİ KULLANIMI



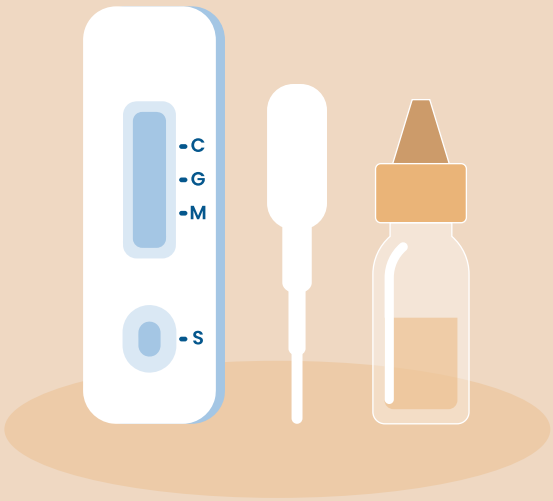
Pipetin ikinci işaret noktasına kadar parmaktan kan alın.

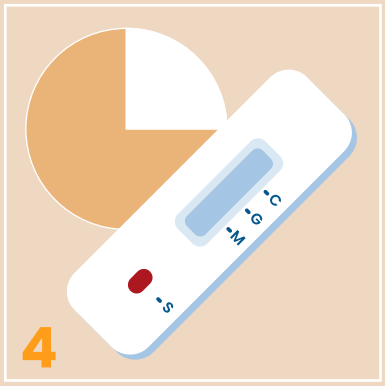


Pipete çektiğiniz kanı kasetin örnek kuyusuna (S) damlatın.

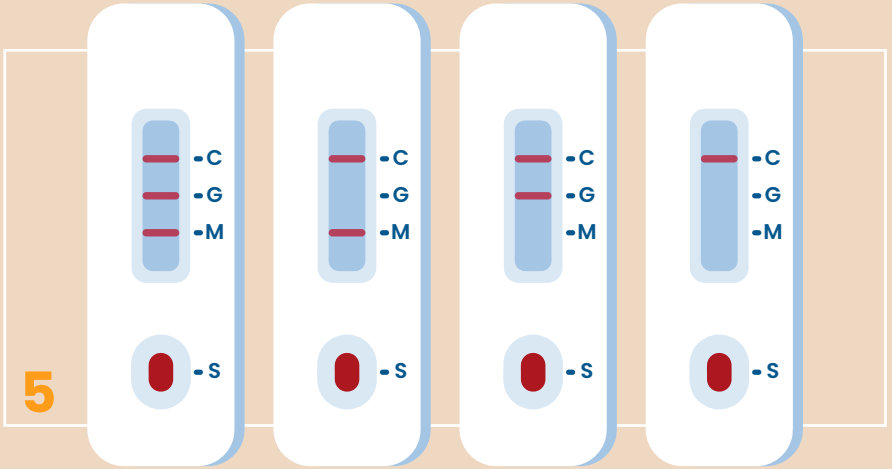


Kanın ardından örnek kuyusuna (S) 2 damla test solüsyonu damlatın.





Sonucun netleşmesi için 15 dakika bekleyin.



IgM & IgG Pozitif

IgM Pozitif

IgG Pozitif

Negatif

Sonuçların yorumlanması:
M harfinin yanında çizgi oluşması IgM tipi antikorların, G harfinin yanında çizgi oluşması ise IgG tipi antikorların kanda bulunduğunu gösterir. IgM tipi antikorlar hastalığın erken evrelerinde görülür ve hastalığın devam ettiği anlamına gelir. IgG tipi antikorlar ise hastalığın ileri evrelerinde ve iyileşme sonrasında görülür. IgG tipi antikorun tek başına bulunması hastalığın geçirilmiş olduğuna işaret eder.

Lütfen dikkat: Ürünün kullanma kılavuzunu dikkatle okuyun ve anlayın. Bu test kendi başına hastalığın kesin teşhisinin yapılması için değildir. Kesin teşhis için mutlaka uzman hekimin diğer klinik bulguları değerlendirmesi gerekir.

CERTIFICATE

EC - DECLARATION of CONFORMITY

DOCUMENT NO: RTA.UB.033

MANUFACTURER:
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.
GEPOSB CUMHURİYET CADDESİ NO:3 GEBZE / KOCAELİ / TURKEY

PRODUCT DESCRIPTION:
MAX SURE COVID19 IgM&IgG ANTIBODY TEST (CATALOG NO: 05033020)

PRODUCT TYPE:
98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE ANNEX III PRODUCT

CONFORMITY ASSESMENT PROCEDURE:
WE HEREBY DECLARE THAT THE DESIGNATED PRODUCTS CONFORM TO ALL APPLICABLE REQUIREMENTS OF THE COUNCIL DIRECTIVE 98/79/EC PROVISION INCLUDING THE ESSENTIAL REQUIREMENTS GIVEN ON ANNEX I AND ALL APPLICABLE HARMONISED STANDARDS.

PRODUCT CLASSIFICATION: *GENERAL IVD DEVICES*

THE JUSTIFICATION FOR COMPLIANCE WITH THIS DIRECTIVE IS GIVEN ON THE PRODUCT TECHNICAL FILE.

DECLARED BY:
ŞABAN ORÇUN KALKAN - *GENERAL MANAGER*
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.

AUTHORISED SIGNATURE:

CE

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Instructions for Use

Intended Use

MaxSure COVID-19 IgM/IgG Antibody Test is a rapid and qualitative immunochromatographic *in vitro* assay for differential detection of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (EDTA, Heparin) and whole blood samples.

The device is designed to aid in the determination of recent or previous exposure to SARS-CoV-2 virus, tracking the body's immunity status after infection by the SARS-CoV-2 virus. It only provides a preliminary result.

Negative results do not exclude SARS-CoV-2 infection. Patient management decisions should combine negative results with clinical observations, patient history, and epidemiological information.

A positive result does not necessarily mean a current infection but represents a different stage of the disease after infection. Current infection should be confirmed by Real-Time Reverse Transcriptase (RT-PCR) or viral gene sequencing.

The test is *in vitro* diagnostic (IVD) device for professional use only.

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in early 2020 with human cases in Wuhan, China (Zhou et al., 2020; Zhu et al., 2020). It has rapidly rampaged worldwide, causing a pandemic of coronavirus disease (COVID-19) that ranges from fever and breathing difficulty to acute respiratory distress and death (Huang et al., 2020; Zhu et al., 2020) due to massive alveolar damage and progressive respiratory failure. On March 11, 2020, the World Health Organization (WHO) has declared the global outbreak of COVID-19 a pandemic associated with substantial morbidity and mortality. SARS-CoV-2 causes the most severe disease in older patients and people with co-morbidities, including heart disease, diabetes, and other health conditions (Wu and McGoogan, 2020).

Before 2019, six α- and β-coronaviruses were known to cause respiratory diseases of different severity, including four common cold coronaviruses (229E, NL63, OC43, and HKU1) and two highly pathogenic coronaviruses (severe acute respiratory syndrome [SARS-CoV] and Middle East respiratory syndrome [MERS- CoV], which emerged in 2003 and since 2012, respectively) (As- siri et al., 2013; Huang et al., 2020). Importantly, with massive hospitalization rates and high mortality, SARS-CoV-2 remains a major threat to humankind and intervention strategies are being rapidly pursued.

Principle of the Test

MaxSure COVID-19 IgM/IgG Antibody Test is an antibody-capture immunochromatographic assay for the simultaneous detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 virus. When the sample (human serum, plasma or whole blood) is added in the sample well, the specific antibodies, if any in the sample, will react with the SARS-CoV-2 specific antigens conjugated to colloidal gold. As the immunocomplex migrates along the strip, IgM and IgG antibodies are captured on the respective areas where anti-human IgM and IgG antibodies were immobilized and red/violet lines appear, indicating positive results. A colored procedure control line always forms at the end of the test area marked "C". If SARS-CoV-2 antibodies are absent in the sample, no red/violet line will form in the test lines (G and M), indicating a negative result.

Materials Provided

- 5 test devices, individually packed
- 1 dropper bottle containing buffer reagent (2.5 ml)
- 5 sample transfer pipettes, individually packed
- Instructions for use

Other Materials Required

- Lancets
- Blood collection tubes
- Micropipette
- Alcohol wipe
- Timer

Storage and Stability

Store the kit components between 2°C-30°C (36°F-86°F). Do not freeze.
Keep away from direct sunlight, moisture and heat.
The kit can be used until the expiry date indicated on the label.

Warnings and Precautions

- Read the instructions carefully before using the test.
- This test is designed for in vitro diagnostic use and professional use only.
- Do not use beyond the expiry date indicated on the package.
- The test is for single use only. Do not reuse the test.
- Do not use the test if the protective package is damaged.
- Samples may be infectious. Do not pipette by mouth, wear disposable gloves and lab coat. Avoid splashing or aerosol formation. Wipe spills thoroughly using an appropriate disinfectant.
- Dispose all samples, kit components and other test materials in a biohazard container according to local regulations.
- A definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

- If any result is found doubtful then one should seek for confirmation using other test methods.
- The test should be performed between 15°C-30°C (59°F-86°F). If stored refrigerated, ensure that kit components are brought to operating temperature before testing.

Specimen Collection and Handling

- Human serum, plasma and whole blood specimens can be used as test samples.
- Collect the specimens aceptically by venipuncture or fingerstick ways.
- Follow your facility's routine procedures to collect samples.
- Whole blood samples should be tested immediately. Serum or plasma samples can be stored at 2°C-8°C upto 7 days or at -20°C upto 6 months before being tested. Avoid freeze and thaw cycles.
- If serum /plasma samples have to be transported for testing they should be in leak-free tubes and should be transported in cold chain (2°C-8°C).
- Only clear and clean specimens should be tested. Hemolyzed, contaminated, grossly lipemic or turbid samples should not be used as test material.
- Handle all specimens as they are infectious. Follow regulations and take necessary precautions when handling infectious materials.
- Discard all specimens and materials which come in contact with the specimens as infectious waste.

Test Procedure

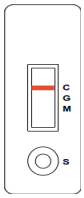
1. Remove the testing device from the sealed pouch and place it on a flat, dry surface. The opened test kit should be better used within 4 hours.
2. For fingerstick or venous whole blood: Using a micropipette, collect the fingerstick whole blood or whole blood (20 µl). For serum/plasma: Using a pipette, collect the serum/plasma (10 µl).
3. Add the collected sample to upper area (close to test window) of sample well on the test device without air bubbles.
4. Wait for 20-30 seconds; add 2 drops (around 90 µl) of the sample buffer to the Sample Well of the test device.
5. Read the results in 15-30 minutes. Strong positive specimens may produce positive result in the first minutes.

Quality Control

The device contains an internal quality control, a red/violet colored band in the control region (C). An external control is not provided with the test kit, however, good laboratory practice recommends the daily use of an external control to ensure proper device performance. External quality control samples should be tested according to the standard quality control requirements established by individual laboratory.

Interpretation of Results

Negative Result



A colored line only on the control zone (C) of the test area.

A negative results means there is no IgG and IgM antibodies against SARS-CoV-2 in the specimen or the antibody concentration is below the detection limit of the test.

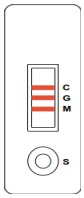
Positive Results

A colored line on the G zone and a colored line on the C zone of the test area.

This result indicates that the tested sample contains IgG antibodies against SARS-CoV-2.

A colored line on the M zone and a colored line on the C zone of the test area.

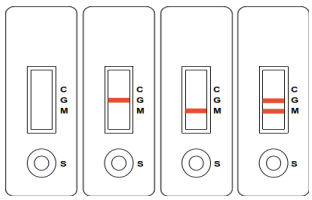
This result indicates that the tested sample contains IgM antibodies against SARS-CoV-2.



A colored line on the G zone, a colored line on the M zone and a colored line on the C zone of the test area.

This result indicates that the tested sample contains IgG and IgM antibodies against SARS-CoV-2.

Invalid Results



When there is no colored line on the control "C" zone of the test area other lines are disregared and the results is invalid. The sample should be retested on a new device or another sample should be collected.

Limitations of the Test

- The test qualitatively detects the presence of human IgG and IgM antibodies against SARS-CoV-2 in the specimen.
- A negative test result does not rule out the possibility of a SARS-CoV-2 infection.
- The reagent can only be used to determine the immune status of the body to SARS-CoV-2 after infection, but not directly to diagnose current SARS-CoV-2 infection.
- Although the test demonstrates superior accuracy in detecting antibodies against SARS-CoV-2, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. A definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance of the Test

Sensitivity and Specificity
87 K2EDTA plasma samples of PCR confirmed Covid-19 patients were tested using CE marked and FDA EUA granted ELISA kits and their antibody status were determined. The samples then tested with MaxSure COVID-19 IgM/IgG Antibody Test and the sensitivity of the test was calculated as follows:

IgM (NCP) Sensitivity: 92.85 %

IgG (NCP) Sensitivity: 92.85 %

IgG (spike) Sensitivity: 95.23 %

The specificity of MaxSure IgM/IgG Antibody Test was evaluated with 126 plasma samples which had been collected before December 2019. Only one sample produced an equivocal IgG signal. Thus, the specificity of MaxSure IgM/IgG Antibody Test was calculated as:

Specificity: 99.2%

Repeatability and Reproducibility
Tests showed positive results with all positive samples and showed negative results with negative samples. There was no significant difference observed for the same sample when repeatedly testing 10 tests in the same batch. No appreciable intra and inter lot variation were observed among different tests for each lot, different lots, different operators at different test sites in different time for the same sample.

The results demonstrated that the repeatability and reproducibility of MaxSure COVID-19 IgM/IgG Antibody Test are satisfactory.

References

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Symbols

CE	CE Mark
IVD	For in vitro diagnostic use only
	Read the instructions manual before use
REF	Catalog number
LOT	Lot / batch number
Σ	Number of test in the final package
	Use until the specified date
	Store at specified temperature range
	Do not use if the package is damaged
	Do not reuse the test and reagents
	Manufacturer

RTA Laboratuvarları

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