TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit Package Leaflet

CE IVD

1. Product Description

TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit is a single-step Real time PCR in-vitro diagnostic kit prepared for the qualitative detection of the genomic RNA of the SARS-CoV-2 coronavirus, the causative agent of COVID-19, using the specific Taqman probe system.

2. Description of the Kit

Coronaviruses (CoV) are viruses belonging to the RNA virus family that can cause disease by infecting animals and birds belonging to the mammalian class.

The SARS-CoV-2 virus, which emerged in Wuhan, China, is a new coronavirus that causes respiratory system infection (COVID-19), in which approximately 2% of cases result in death.

The kit works with lower respiratory tract samples (sputum, bronchoalveolar lavage) and upper respiratory tract samples (nasopharyngeal-oropharyngeal swab) taken from individuals showing clinical symptoms for the disease.

The test is used to detect the Orf1ab and N genes in viral RNA, respectively. The "RNAseP" gene was chosen as the internal control gene for the quality and inhibition control of the nasopharyngeal and oropharyngeal swab samples.

3. Devices and Equipment to be provided by the User

1. Biological Cabinet
2. Viral RNA Extraction Kit
3. Real time PCR Device
4. Real time PCR test tubes/strips/plates
5. Adjustable Micropipettes (0.5µL – 1000µL)
6. Filtered Micropipette Tips
7. 1.5 mL Microcentrifuge Tube
8. Cooler Working Block
9. Powder-free disposable inspection glove
10. Medical Waste Container
11. Cooler Cabinets (+4/-20 °C)
12. Desktop centrifuge (Max 2.000 g)
13. Vortex mixer

4. Storage Conditions

(-15 °C) – (-25 °C), 12 months.

5. Contents of the Kit

Kit contents	Quantity
	1000 reactions
Master Mix	4 x 1250 µL
Primer Mix	2 x 1250 µL
Negative Control	1 x 1000 µL
Positive Control	1 x 250 µL

Table 1. *Contents of the kit*

The positive control sample supplied with TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit is a fragment containing synthetically produced target gene regions and was extracted by manual method. Nuclease-free water (NFW), used in routine laboratory work, is used as the negative control.

6. Preparation of the Reaction Mixture

Component	Reaction (µL) (per sample)
RT-qPCR 2X Master Mix	5
Primer Mix	2,5
Total RNA	2,5
Final	The final volume should be 10 µL.

Table 2*. Preparation of the reaction*

* Master mix and primer mix mixtures are calculated 10% more than the number of samples and mixed in a sterile tube at a ratio of 2: 1. The mixture is homogenized by slowly turning it over and 7,5 µl is distributed to the wells for each sample. It is recommended to use a white strip or plate.

7. Protocol

Number of Cycle	Temperature	Time	Fluorescent Channels	
1	42°C	5 min.		
1	95°C	1 min	FAM (Green)	Orf1ab&N
39	95°C	1 sec.	HEX (Yellow)	RNaseP
	60°C	1 sec. (Fluorescent reading)		

Table 3. *Protocol*

SBT Sağlık Bilim ve Teknolojileri A.Ş.
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Web: www.sbtas.com.tr
E-mail: info@sbtas.com.tr
Phone Number: 0 312 920 11 06

8.Interpretation of Results

Result	Expected Ct Values		Evaluation
	FAM (Orf1ab&N)	HEX (RnaseP)	
Negative Control	-	-	Expected NTC
Positive Kontrol	≤38	≤38	Expected PC
1.	≤38	≤38 /-	COVID-19 Positive
2.	-	-	Retest
3.	-	≤38	COVID-19 Negative

Table 4. *Evaluation of reactions results*

***The mean trashold value of the FAM and HEX channels was determined as 100 RFU. The RFU value is not a fixed value and may vary depending on the viral load of the sample and the sigmoid structure of the graph.**

***For In-vitro Diagnostic Medical Devices Directive (98/79/EC) compliance; We declare the full compatibility of TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit for use with NAEEKTS (Nucleic Acid Extractor and Preservative Transport Fluid) branded TÜSEB DiaVnat Extraction and Transfer Tube with reference number SBTvNAT2022-100.**

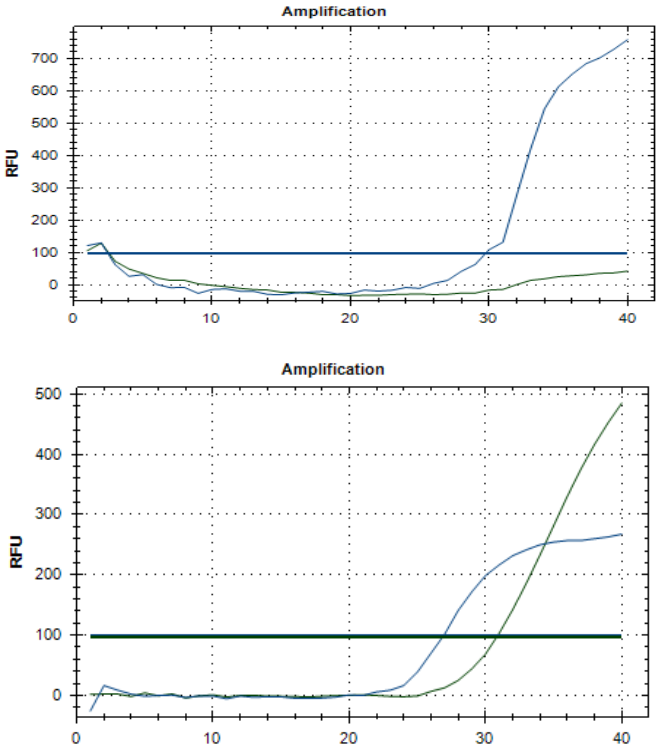

Figure 1: *COVID-19 Positive*

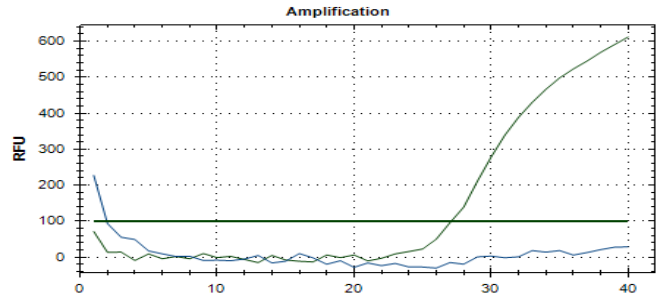

Figure 2: *COVID-19 Negative*

9. Statement of Validation

The validation study of TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit was performed in triplicate with samples containing synthetic SARS-CoV-2 RNA fragment between 107/ µL copy number and 100/ µL copy number. The reaction results and optimum graphs are given below. TÜSEB DiaKit SingleStep SARS-CoV-2 RT-qPCR Diagnostic Kit; It can even detect 1 (one) copy number per microliter.

10. Reaction results of solutions prepared with TÜSEB DiaVnat Extraction and Transfer Tube

Number of copies/ µL	Cq Values		
	1	2	3
10^7	14.02	11.31	13.58
10^6	17.18	15.16	17.26
10^5	19.22	19.37	20.22
10^4	21.02	20.38	22.10
10^3	23.83	24.9	24.96
10^2	24.02	24.03	23.24
10^1	-	24.92	24.42
10^0	24.43	24.35	24.23

Table 5. *Reaction results of solutions prepared with TÜSEB DiaVnat Extraction and Transfer Tube*

11. Reaction results of solutions prepared with TÜSEB DiaVnat Extraction and Transfer Tube

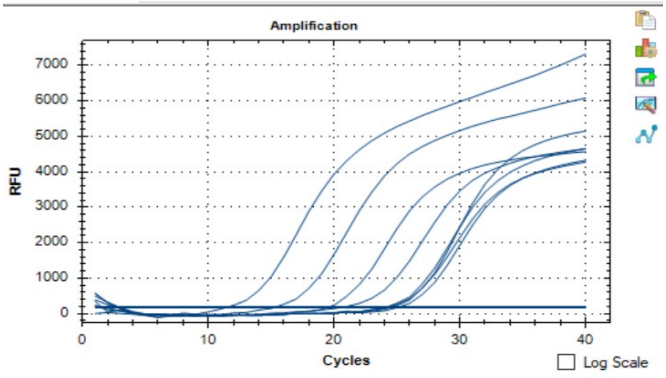

Table 6. *Graphical views of solutions prepared with TÜSEB DiaVnat Extraction and Transfer Tube*