SUGENOMICS Biotechnology

CoviDetector SARS-CoV-2 qRT-PCR Kit V1

Catalog No	Size
• DR01A100	100 Reaction

INSTRUCTIONS FOR USE

1. PRODUCT NAME:
CoviDetector SARS-CoV-2 qRT-PCR Kit V1
Cat No : DR01A100
Size : 100 reactions

2. MANUFACTURER:
SuGenomik Biyoteknoloji, METU Technopolis, Yenimahalle, Ankara.

3. INTENDED USE
The product is an in vitro diagnostic medical device that is used for qualitative detection of SARS-CoV-2 Virus by extracted ribonucleic acid (RNA) from Nasopharyngeal and Oropharyngeal swab specimens from patients suspected of having the COVID-19 infection and by using the Quantitative Real-time Reverse Transcription Polymerase Chain Reaction, qRT-PCR. This product is formulated to amplify two nCoV target genes (RdRp and N gene) in a single reaction and delivering a shorter run time.

4. KIT CONTENT

Content	100 Reaction
Multiplex Master Mix	1500 µl
Positive Control	50 µl
Negative Control	50 µl

5. STORAGE CONDITIONS
Store at -20±5°C away from light for 12 months.

6. SPECIMEN PREPARATION AND STORAGE
- Nasopharyngeal and Oropharyngeal swab specimens shall be used for the test.
- It is recommended that swab specimens shall be used immediately after collection. However, the specimens can be stored maximum 4 days at 2-8℃ in a fridge or maximum 2 months at −20℃ in a freezer if immediate use is not achievable.
- Specimens shall be divided into amounts required for one testing and stored at −20℃ in a freezer so as to avoid from thawing repeatedly.
- Specimens that are no longer needed shall be put in a container for liquids and disposed as liquid medical waste.

7. PRE-TEST PREPARATIONS
- Reagents shall be stored at −20℃ and be avoided from repeated freezing and thawing.
- Reagents shall be used after completely thawed and well mixed.
- Since the positive control RNA can be degraded, it is recommended to be aliquoted into small volumes.
- This kit was validated on ABI StepOne Plus system and compatible with standard RT-PCR machines such as ABI 7000, 7300,7500, Roche 480, MX3000P, MX3005P, Rotorgene TM6000, Icycler IQTM4/5, Bio-Rad CFX96 and LongGene Q2000B.

8. SPECIMEN PRETREATMENT
While it is possible to use various ways and kits adopted in laboratories to extract RNA and apply on this product, it is recommended that ZR Viral RNA Kit (ZymoResearch, USA) shall be used for RNA extraction and users shall follow the protocol included in the Kit Handbook. After being extracted, RNA shall be stored at −20 ± 2℃ in a freezer and shall be divided into amounts required for 1-2 tests since RNA can be degraded.

9. REAL-TIME PCR
9.1) Real-Time PCR Solution Preparation
a) Thaw kit components at room temperature.
b) Mix thoroughly to ensure homogeneity, centrifuge briefly and then put on the ice.
c) Prepare the reaction mix based on the table below.
d) It is recommended to use positive and negative controls for each test.
e) Spin down all reaction mixture and move to the qRT-PCR step.

Components	Sample RNA	Positive Control	Negative Control
Multiplex Master Mix	15 µl	15 µl	15 µl
Sample RNA	5 µl	-	-
Positive Control	-	5 µl	-
Negative Control	-	-	5 µl
TOTAL Volume	20 µl	20 µl	20 µl

9.2) Real-Time PCR Set Up Conditions
- Set up the channels of the real-time PCR device according to the table below.

Genes	Channels (Dyes)
SARS-CoV-2, RdRp and N gene	FAM
Human RNaseP Gene (Internal Control)	ROX (or Texas Red, or Cal Flour Red 610)

- For Applied Biosystems ABI (QS5, 7500 and StepOne etc) real-time PCR instruments, set to "passive reference" dye as "none".
- Set up real-time PCR temperature, time, and cycling conditions according to the table below.

Steps	Temp.	Time	Cycles
Reverse Transcription	42 ℃	15 min	1
HotStart Activation	95 ℃	5 min	1
Denaturation	95 ℃	5 sec	40
Amplification	60 ℃	35 sec (reading)	

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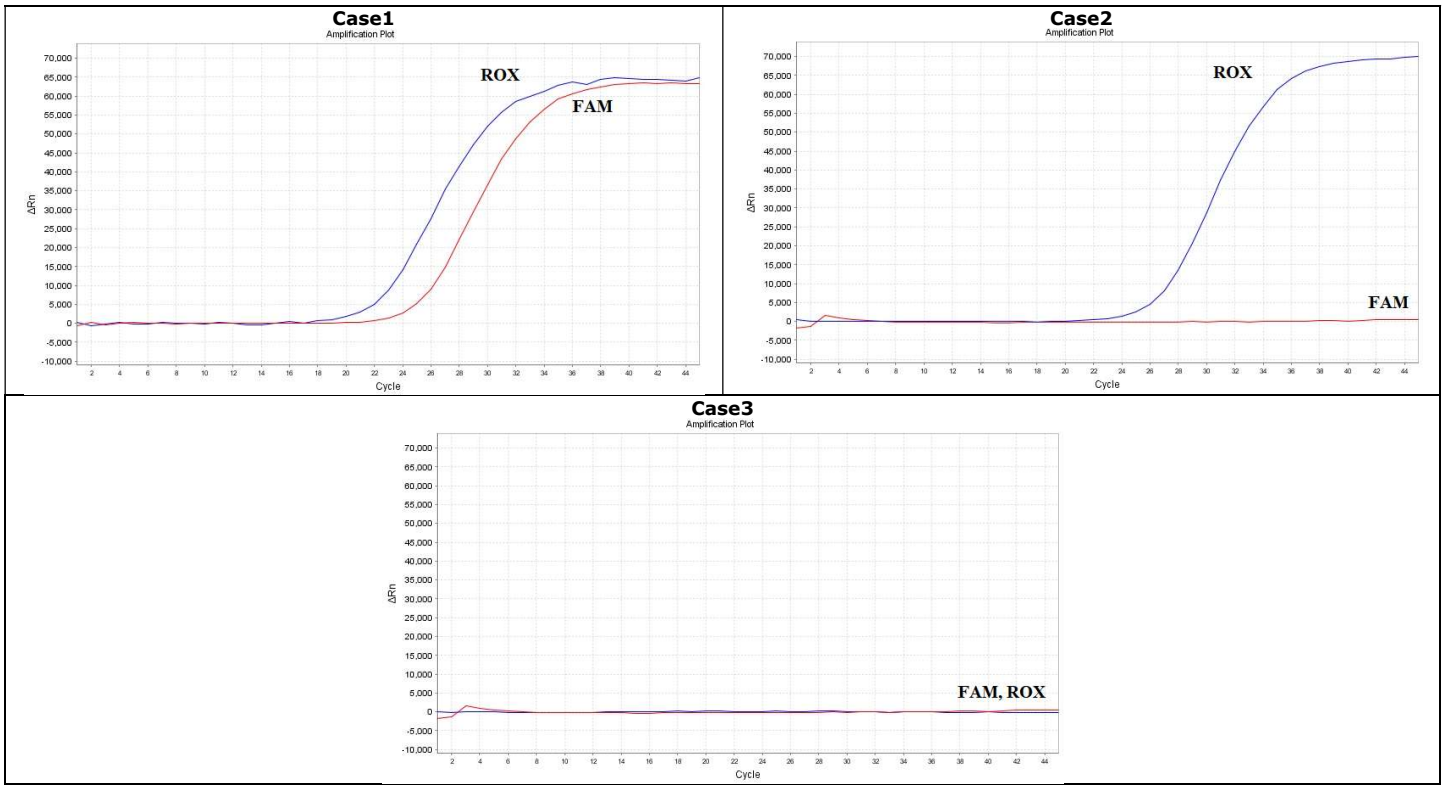
CE IVD TSE ISO 9001:2015 ISO 13485:2016 ODTÜ METU

10. EVALUATIONS of RESULTS

The results are automatically saved to machine after the reaction. Then evaluate the amplification curve of the target and internal control genes separately as described following table. If the Ct value is <35, it should be considered positive.

Case	SARS-CoV-2 RdRp and N Gene FAM	RNaseP (Internal Control) ROX	Evaluation
Case1	+	+	SARS-CoV-2, Positive
Case2	-	+	SARS-CoV-2, Negative
Case3	-	-	Invalid Result



If Ct value of ROX channel is higher than 35 without showing apparent S-shaped amplification curve, the causes can be listed as following:

1. PCR inhibitors can exist in the specimen. It is suggested to dilute specimen before test.
2. Nucleic acid extraction can be flawed. It is suggested to repeat nucleic acid extraction.
3. Specimens could not be obtained in accordance with protocol or specimens have been degraded during transportation and storage. It is suggested to perform sampling again

11. PRODUCT SPECIFICITY

1. Minimum detection limit is 10 copies.
2. Internal control gene probe was optimized with ROX dye probe.

12. LIMITATIONS

1. Test result is for the reference only in clinical practice, it cannot be the sole evidence for diagnosis.
2. Negative results can be caused by low quality of RNA extraction, improper storage conditions and storage period, and inhibitors in the specimen, nucleic acid degradation, etc.
3. False negative or false positive results are likely to be caused by inappropriate collecting, transportation and handling of specimens, or unsuitable experiment operation and environment.
4. False negative results may occur by sequence changes of target sequence of 2019-nCoV due to mutations or other reasons.

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