SNP COVID-19

REAL TIME PCR KIT

Cat# 114R-10-01

CE IVD

For Emergency Use Authorization Only

For in vitro diagnostic use only

TABLE OF CONTENTS

1. KIT INFORMATION

1.1. INTRODUCTION

Coronaviruses are enveloped non-segmented positive-sense RNA viruses belonging to the family Coronaviridae and the order Nidovirales and broadly distributed in humans and other mammals. In December, 2019, a series of pneumonia cases of unknown cause emerged in Wuhan, Hubei, China, with clinical presentations greatly resembling viral pneumonia. Deep sequencing analysis from lower respiratory tract samples indicated a novel coronavirus, which was named 2019 novel coronavirus (SARS-CoV-2). The disease caused by this virus is called COVID-19.

1.2. PRINCIPLE OF THE KIT

The System can detect **RNA-dependent RNA polymerase gene** (RdRp) and **Nucleocapsid protein gene (N)** regions of **SARS-CoV-2** with high sensitivity and specificity.

Reverse Transcriptase component (M-MLV) of the kit is active at 45 or 50 °C, a half life of 230 minutes, and the activity of RNase H was reduced. HotStart Taq DNA Polymerase enzyme is a mixture of enzyme and Anti-Taq monoclonal antibodies to ensure specificity and thermostability. Buffer contains 0.2 mM of each dNTP and 3 mM $MgCl_2$. System can be used directly both with DNA and RNA samples. During the PCR reaction, the DNA polymerase cleaves the probe at the 5′ end and separates the reporter dye from the quencer dye only when the probe hybridizes perfectly to the target DNA. This cleavage results in the fluorescent signal which is monitored by Real-Time PCR detection system. An increase in the fluorescent signal (CT) is proportional to the amount of the specific PCR product.

1.3. PRODUCT SPECIFICATION

The kit provides reagents in a "ready-to-use" format for one step RT-PCR master mix which has been specifically adapted for cDNA and 5' nuclease PCR. The test system is designed for use with sequence specific primers and probes. The fluorescence of COVID-19 analysis is FAM. Also master mix contains an internal control labelled with HEX dye. Genes and related dyes can be seen in Table 1.

The limit of detection (LoD) in Covid-19 Real Time PCR Kit was determined 1 copies/Rxn.

Table 1 : Genes and Related Dyes

Tube	Regions	Dyes
Covid-19 Master Mix	Covid-19	FAM
	Internal Control	HEX

1.4. KIT CONTENTS

Reagents	**150 rxns**
Covid-19 Master Mix	1500 µl
Positive Control	60 µl
Negative Control	60 µl
User Manual	1

1.5. STORAGE

- All reagents should be stored at – 20 °C and dark.
- All reagents can be used until the expiration date on the box label.
- Repeated thawing and freezing (>5X) should be avoided, as this may reduce the sensitivity of the assay.

2. RNA EXTRACTION

- Human nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate nasal swab as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum samples should be collected with appropriate sterile swab into viral transport fluid. Inactivation & Transport Fluid Kit (Cat# 23S-04-01) for safe transport of specimens is a recommended product.
- Sample can be stored at +4°C up to one week in viral transport fluid
- Sample can be transported at RT.
- For more than one week sample should be stored at -20°C.
- The system is optimized for any RNA Isolation System such as Spin Column RNA Extraction, Automated RNA Extraction, salt extraction and phenol/chloroform RNA Extraction. We advise the SNP Viral Extraction Kit (Cat# 21S-04) especially developed for the SNP Covid-19 Real Time PCR Kit.

3. TEST SETUP

3.1. PROCEDURE

- Remove the reagents from -20°C storage and thaw it completely.
- Before starting work, mix the master mix gently by pipetting.
- Spin down each tube of master mix, postive control and negative control by short centrifuge (~5 sec.).
- For each sample, pipet **10 µl master mix** with micropipets of sterile filter tips to each optical well PCR tubes.
- Add **10 µl RNA** into each tube.
- Mix gently by pipetting / Short centrifuge (~5 sec.) the tubes in minicentrifuge.
- Run with the programme shown below.

3.2. PCR PROGRAMME SETUP

Table 2: PCR Programme*

42 °C	20 Min.	cDNA Syntesis
96 °C	25 Sec.	Holding
96 °C	2 Sec.	45 Cycles
60 °C	35 Sec.	

Fluorescent dyes are FAM and HEX.

* Real Time PCR time is **83 minutes for Bio-Rad CFX96**. This time may differ slightly depending on the device.

The following settings are valid for the Biorad CFX96 device. It may require different settings on different real time devices. For detailed information, please contact us; info@snp.com.tr

This system can be used with;

Bio-Rad CFX96

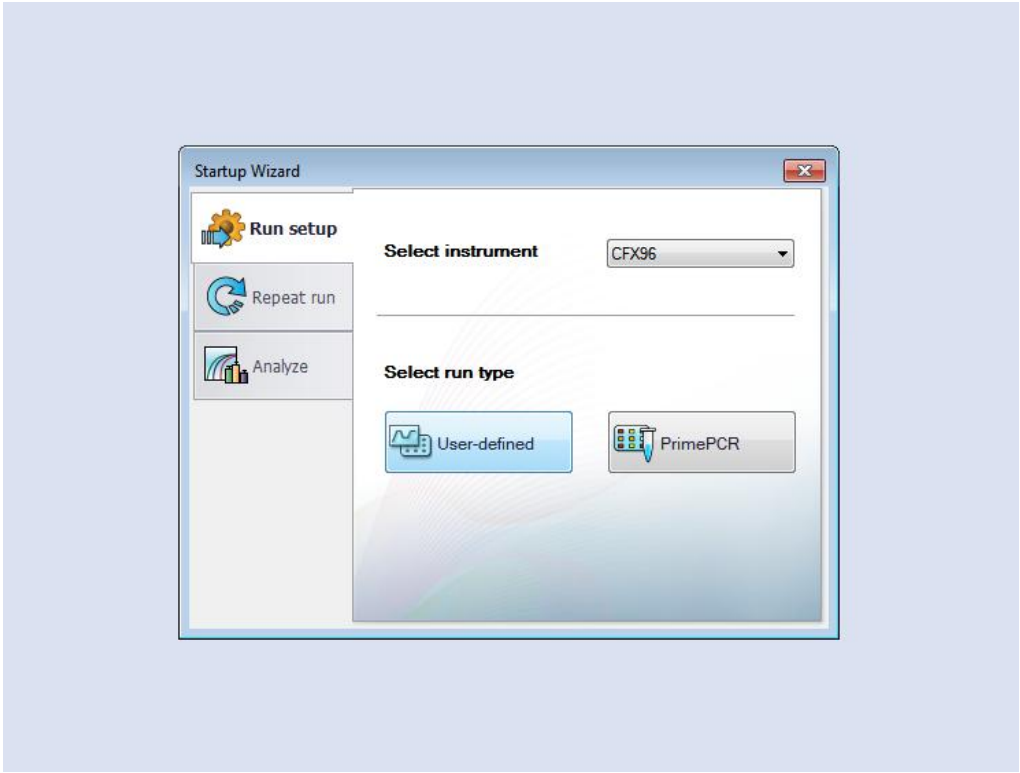

Figure 1: For the setup of PCR programme, choose **"User-Defined"**

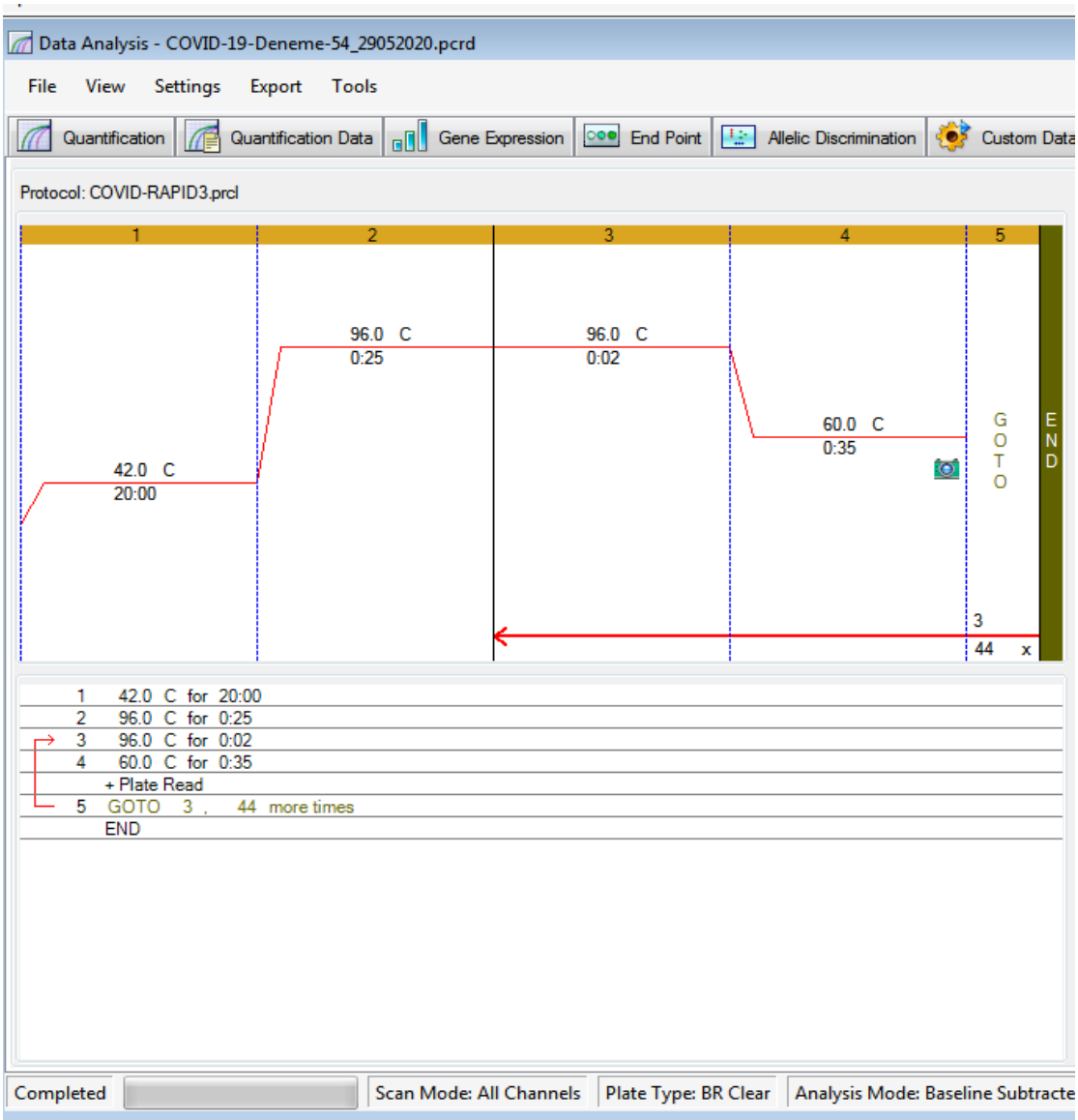

Figure 2: Set the run programme as seen table 2.

3.3. PLATE SETUP

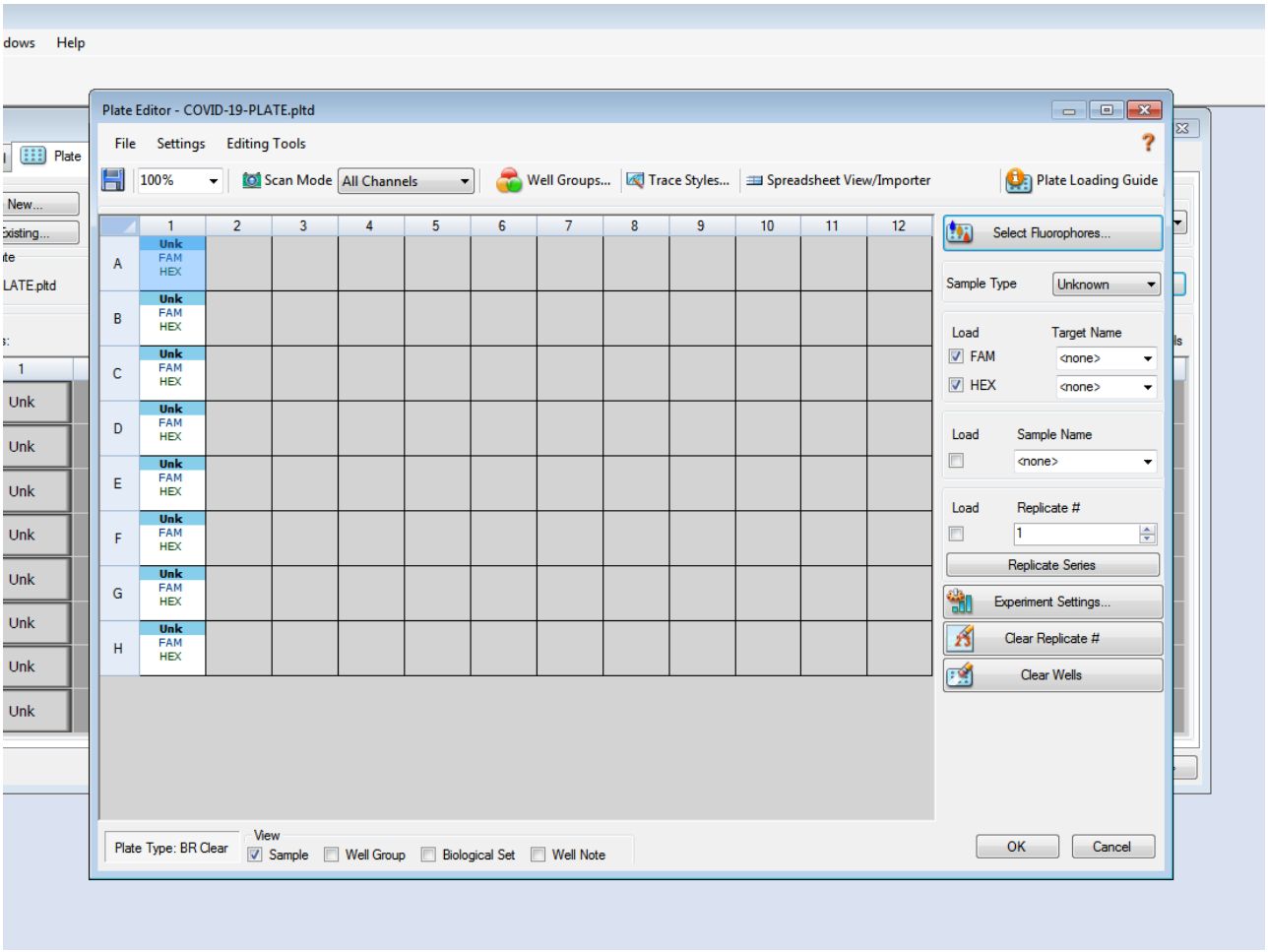

Figure 3: Select the type of wells to work as **unknown** and mark with **FAM** and **HEX.**

4. RESULTS ANALYSIS

After the run is completed data are analysed using the software with both dyes (Table 3). The below results were studied with Bio-Rad CFX96. Threshold values of both dyes should be adjusted to 600 for Bio-Rad CFX96. The CT value of internal controls should be X ≤ 35 according to RNA concentration (Figure 4). Amplification plots in FAM dye should be accepted as **"Positive"** for COVID-19 (Figure 5). You can give "**Negative"** results to samples that are no amplification in FAM Dye (Figure 6).

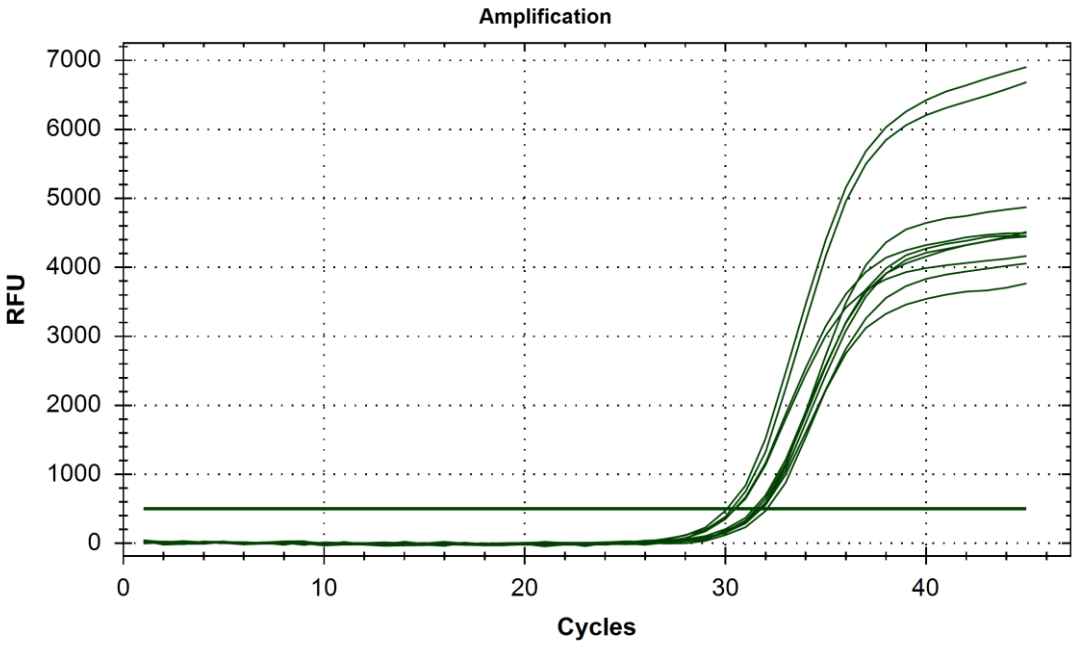

Figure 4: Internal Control Plots (HEX Dye)

Table 3: Results Interpretation and Evaluation.

Sample	Internal Control (HEX)	RdRp & N Gene (FAM)	Results	Interpretation
Case 1	+	+	SARS-CoV-2 **Positive**	All results are valid SARS-CoV-2 RNA is detected.
Case 2	+	+		
Case 3	+	+		
Case 4	+	-	SARS-CoV-2 **Negative**	All results are valid SARS-CoV-2 RNA is not detected.
Case 5	+	-		
Case 6	-	-	Invalid	Dilute to extracted RNA or re-extract clinic sample.
Case 7	-	-		

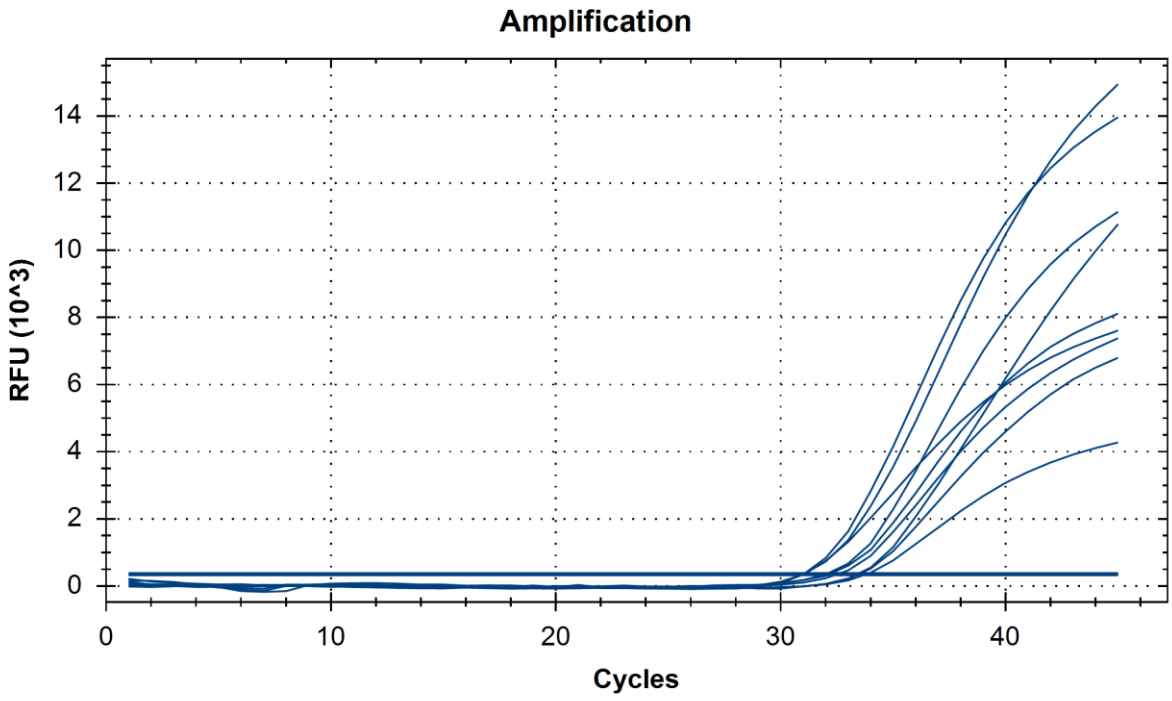

Figure 5: Positive Samples Plots (FAM Dye)

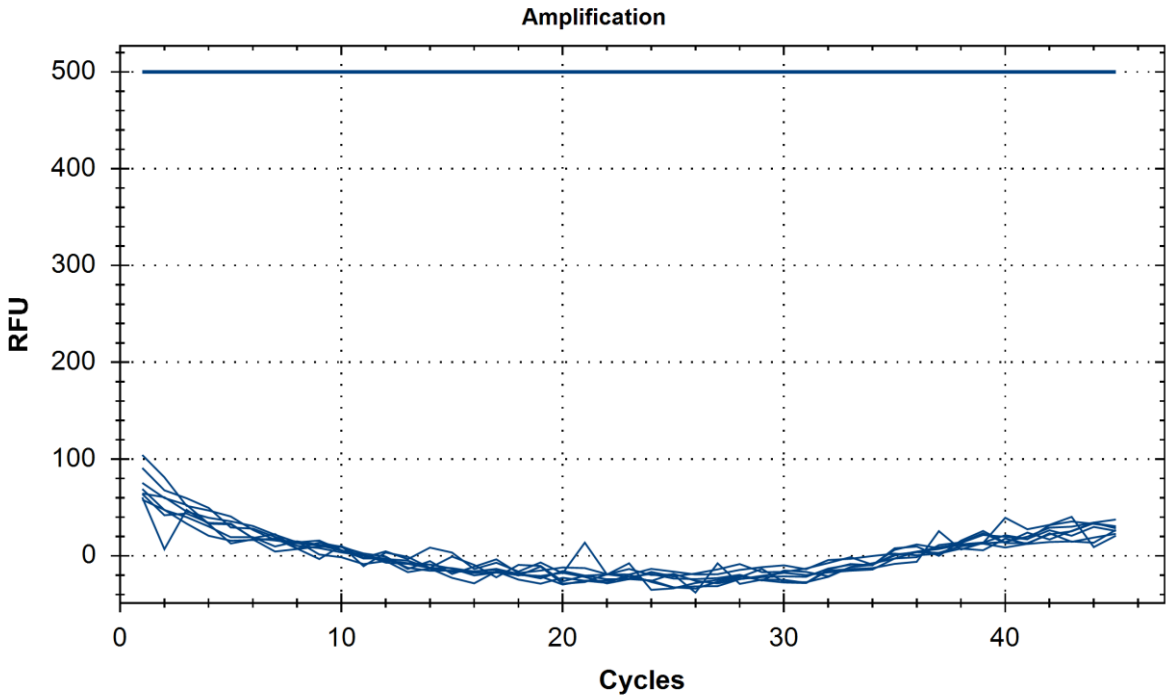

Figure 6: Negative Samples Plots (FAM Dye)

5. LIMITATIONS

1. The use of this assay as an in vitro diagnostic under FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

2. This kit is used for qualitative detection of SARS-CoV-2 RNA from human nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate nasal swab as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum specimens. The results do not reflect the viral load in the original specimens.

3. The performance of the SNP COVID-19 Real-Time PCR Kit was established using contrived nasopharyngeal swab and sputum specimens. Anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid are also considered acceptable specimen types for use with the SNP COVID-19 Real-Time PCR Kit. Testing of nasal and mid-turbinate nasal swabs (self-collected or collected by a healthcare provider) is limited to

patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information. http://www.snp.com.tr/EN,38/covid-19.html

4. SNP COVID-19 Real-Time PCR Kit performance has only been established with nasopharyngeal swabs and sputum specimens.

5. The specimens to be tested shall be collected, processed, stored and transported in accordance with the conditions specified in the instructions. Inappropriate specimen preparation and operation may lead to inaccurate results.

6. Extraction and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.

7. Amplification and detection of SARS-CoV-2 with the SNP COVID-19 Real-Time PCR Kit has been validated with the Bio-Rad CFX96 Real-Time PCR and Applied Biosystem 7500 Real Time PCR instruments. Use of other instrument systems may cause inaccurate results.

8. The limit of detection (LoD) is determined based on a 99% confidence of detection. When SARS-CoV-2 presents at the LoD concentration in the test specimen, there will be a low probability that SARS-CoV-2 is not detected. When SARS-CoV-2 presents below the LoD concentration in the test specimen, there will also be a certain probability that SARSCoV- 2 can be detected.

9. Primers and probes for this kit target highly conserved regions within the genome of SARS- CoV-2. Mutations occurred in these highly conserved regions (although rare) may result in RNA being undetectable.

10. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other management decisions.

11. Laboratories are required to report all positive results to the appropriate public health authorities.

6. CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The SNP COVID-19 Real-Time PCR Kit's Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.....
However, to assist clinical laboratories using the SNP COVID-19 Real-Time PCR Kit, the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriatemethods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product will use your product as outlined in theInstructions for Use. Deviations from the authorized procedures, including theauthorized 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.

C. Authorized laboratories that receive your product will notify the relevant public health http://www.snp.com.tr/EN,31/contact.html authorities of their intent to run your product prior to initiating testing.

D. 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.

E. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-IR/OPEQ/CDRH (via email: CDRH-14-EUAreporting@ fda.hhs.gov) and You (via email: info@snp.com.tr) 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.

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

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

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests" as "authorized laboratories."

7. ANALYTICAL VERIFICATION

7.1. VALIDATION

Table 4: Abbreviations

TP	True Positive
FP	False Positive
TN	True Negative
FN	False Negative

Table 5: Analytical verification formula

Sample			
Method	**Positive (Presence)**	**Negative (Absence)**	**Total**
Positive	TP	FP	TP+FP
Negative	FN	TN	FN+TN
Total	TP+FN	FP+TN	TP+FN+FP+TN

Table 6: Values of verification

Covid-19			
Method	**Positive (Presence)**	**Negative (Absence)**	**Total**
Positive	30,00	-	30,00
Negative	-	30,00	30,00
Total	30,00	30,00	60,00

Table 7: Results of Verification

Accuracy	(TP+TN)/(TP+TN+FP+FN)	(30+30)/ 60	1
Sensivity	TP/(TP+FN)	30/30	1
Specificity	TN/(TN+FP)	30/30	1
False Positive	FP/(TN+FP)	0/30	0
False Negative	FN/(TP+FN)	0/30	0
Efficiency	(TP+TN)/(TP+TN+FP+FN)	(30+30)/ 60	1

7.2. CROSS ACTIVITY AND STABILITY

7.2.1. Cross Reactivity

Cross-reactivity studies are performed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The lists of organisms to be analyzed in silico and wet testing are provided in the table 8 and 9.

Table 8: List of organisms to be analyzed in silico.

High priority organisms likely in the circulating area	**Other high priority pathogens from the same genetic family**
Adenovirus (e.g. C1 Ad. 71)	Human coronavirus OC43
Human Metapneumovirus (hMPV)	Human coronavirus HKU1
Parainfluenza virus 1-4	Human coronavirus NL63
Influenza A & B	SARS-coronavirus
Enterovirus (e.g. EV68)	MERS-coronavirus
Respiratory syncytial virus	
Rhinovirus	
Chlamydia pneumoniae	
Haemophilus influenzae	
Legionella pneumophila	
Mycobacterium tuberculosis	
Streptococcus pneumoniae	
Streptococcus pyogenes	
Bordetella pertussis	
Mycoplasma pneumoniae	
Pneumocystis jirovecii (PJP)	
Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract	
Candida albicans	
Pseudomonas aeruginosa	
Staphylococcus epidermis	
High priority organisms likely in the circulating area	

Table 9: List of organisms in wet testing. For wet testing, concentrations of $1x10^5$ pfu/ml or higher for viruses and $1x10^6$ cfu/ml for organisms.

High priority organisms likely in the circulating area	**Other high priority pathogens from the same genetic family**
Adenovirus (e.g. C1 Ad. 71)	Human coronavirus OC43
Human Metapneumovirus (hMPV)	Human coronavirus HKU1
Parainfluenza virus 1-4	Human coronavirus NL63
Influenza A & B	SARS-coronavirus
Respiratory syncytial virus	MERS-coronavirus
Rhinovirus	
Haemophilus influenzae	
Mycobacterium tuberculosis	
Streptococcus pneumoniae	
Streptococcus pyogenes	
Mycoplasma pneumoniae	
Pneumocystis jirovecii (PJP)	
Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract	
Candida albicans	
Pseudomonas aeruginosa	
Staphylococcus epidermis	

7.2.2. Microbial Interference Studies:

The primers and probes used within the kit were controlled via special software (OligoYap 8.0) in our laboratory and were found to be 100% homologous of SARS-CoV-2. Cross-reaction studies were checked using by the pathogens in Table 8 and 9 to detect cross reaction. And no cross-reaction was detected. In addition, with the limit of detection (LoD) study, the lowest amount that the kit can detect was determined. During all these studies, each sample was repeated at least three times during the same study.

7.2.3. Stability

To evaluate the stability, the kit was freezed and thawed in different numbers and studied with the same RNA sample. In addition, both positive and negative samples were repeated 5 times in the same study (Figures 7, 8 and 9). The shelf life of the kit under -20ºC condition is 12 months.

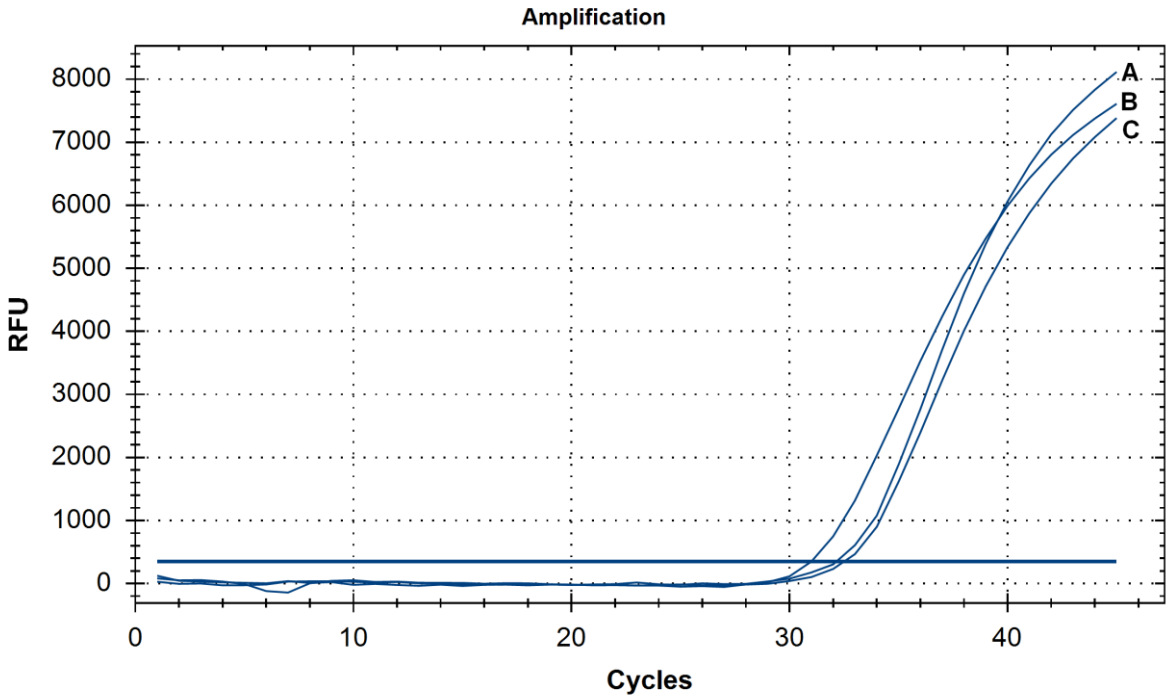

Figure 7: Amplification plots of the same sample freezed and thawed for FAM Dye. **A:** First thaw, **B:** Third thaw **C:** Fifth thaw.

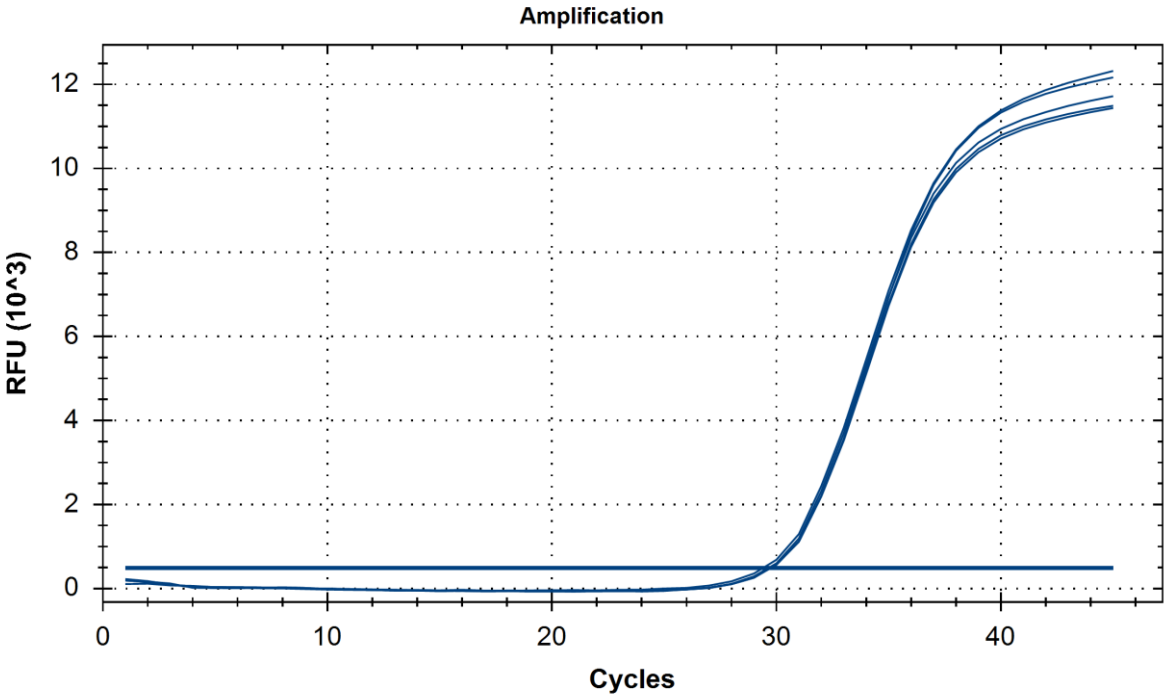

Figure 8: Amplification plots of the positive sample were repeated 5 times in FAM dye.

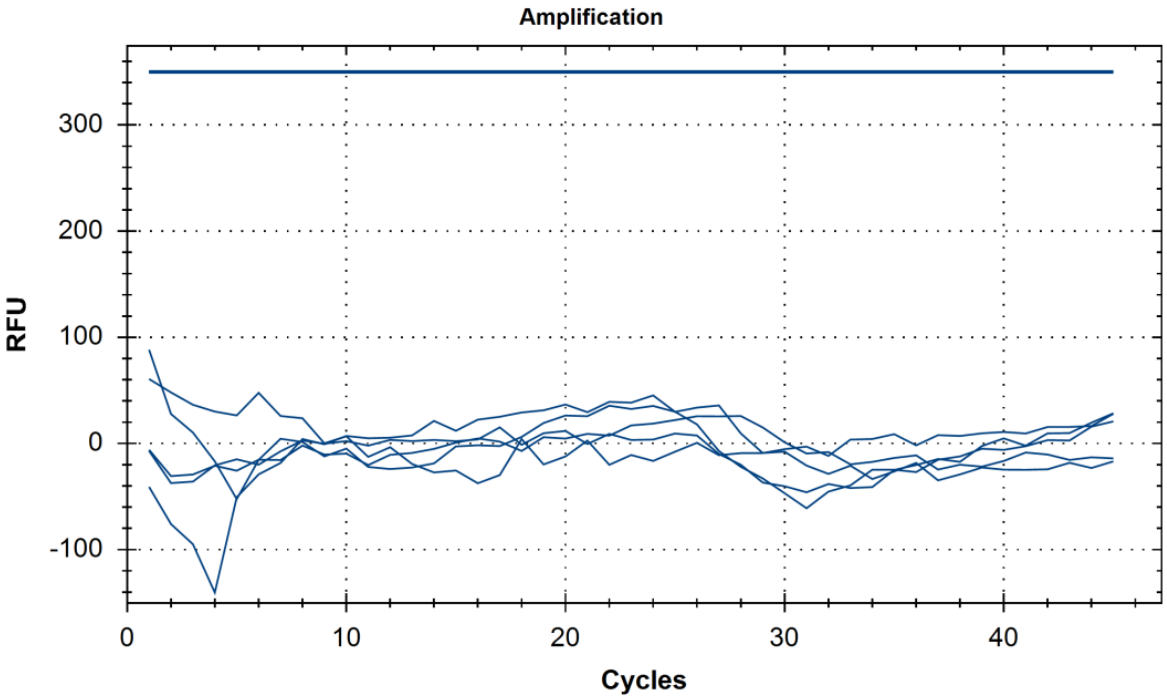

Figure 9: Amplification plots of the negative sample were repeated 5 times in FAM dye.

7.2.4. Limit of Detection:

In the LoD determination study, 5 fold serial dilutions were prepared and then tested in three replicates. The tentative LoD determined was 100 copies/mL (Table 10). For confirmation of LoD, 20 replicates of 100 copies/mL and 20 copies/mL were tested. The final LoD was determined as 100 copies/mL (1 copy/rxn.) with 20/20 positive results (Table 11).

Table 10 : Tentative LoD Evaluation

Sample	Target Ct Value 1	Target Ct Value 2	Target Ct Value 3	Target Mean Ct	Copies / Rxn	Copies / mL
1.25×10^{2}	30,15	30,00	29,74	29,96	125,00	12.500,00
2.5×10^{1}	31,62	32,01	31,31	31,65	25,00	2.500,00
5×10^{0}	33,44	33,63	33,78	33,62	5,00	500,00
1×10^{0}	35,34	34,05	34,95	34,78	1,00	100,00
2×10^{-1}	-	37,42	37,49	37,45	0,20	20,00

Table 11 : Final LoD Evaluation

Sars-CoV-2 Confirmatory LoD BIO-RAD CFX 96						
Target Genes: RdRp Gene and N-Gene						
Sample	**Target Copy Number / Rxn**	**Target Copy Number / mL**	**Valid Results**	**Positive**	**Mean Ct**	**Detection Rate**
1×10^{0}	1	100	20	20	34,72	100%
2×10^{-1}	0,2	20	20	8	38,79	40%

7.2.5. Inclusivity:

"Turkish Ministry of Health, General Directorate of Public Health, Department of Microbiology Reference Laboratories and Biological Products (HSGM)" has tested and confirmed the inclusivity of the COVID-19 Real Time PCR Kit with 190 different clinical specimens that were previously studied.

7.2.6. Clinical Evaluation:

Clinical evaluation of SNP COVID-19 Real Time PCR Kit was performed by comparing 30 positive and 30 negative samples with FDA-EUA approved DiaPlex Q Novel Coronavirus (2019-nCoV) Detection Kit. According to the comparison results, positive and negative percent agreement of SNP COVID-19 Real Time PCR Kit is evaluated as 100% (95% CI: 88,4%-100.0%). The results are shown at Table 12 and Table 13.

Table 12 : Clinical Evaluation ct values.

Clinical Study of Sars-CoV-2 - Nasal and Nasopharyngeal Swabs- BIO-RAD CFX96											
POSITIVE SAMPLES						**NEGATIVE SAMPLES**					
	SNP COVID-19 Real Time PCR Kit		**DiaPlex Q Novel Coronavirus (2019-nCoV) Detection Kit**				**SNP COVID-19 Real Time PCR Kit**		**DiaPlex Q Novel Coronavirus (2019-nCoV) Detection Kit**		
	Ct Values						**Ct Values**				
Sars-CoV-2 Samples	**RdRp and N Gene**	**Internal Control**	**ORF1a**	**N gene**	**Internal Control**	**Sars-CoV-2 Samples**	**RdRp and N Gene**	**Internal Control**	**ORF1a**	**N gene**	**Internal Control**
Positive 1	31,83	32,80	37,06	N/A	21,10	**Negative 1**	N/A	27,29	N/A	N/A	20,12
Positive 2	31,10	34,29	37,14	N/A	20,49	**Negative 2**	N/A	29,32	N/A	N/A	20,56
Positive 3	34,12	31,98	34,15	N/A	20,22	**Negative 3**	N/A	27,66	N/A	N/A	20,38
Positive 4	30,26	33,06	38,70	N/A	20,21	**Negative 4**	N/A	27,19	N/A	N/A	20,24
Positive 5	31,28	32,83	39,06	37,17	20,48	**Negative 5**	N/A	29,05	N/A	N/A	20,33
Positive 6	33,50	28,63	36,20	N/A	20,29	**Negative 6**	N/A	25,50	N/A	N/A	20,39
Positive 7	32,44	31,95	35,77	N/A	20,63	**Negative 7**	N/A	27,04	N/A	N/A	20,40
Positive 8	32,30	29,02	38,66	N/A	20,50	**Negative 8**	N/A	27,19	N/A	N/A	20,25
Positive 9	29,38	29,15	38,79	37,89	20,40	**Negative 9**	N/A	26,73	N/A	N/A	20,31
Positive 10	32,35	31,68	32,07	30,17	25,93	**Negative 10**	N/A	25,27	N/A	N/A	19,90
Positive 11	34,27	28,46	38,32	37,02	30,84	**Negative 11**	N/A	22,39	N/A	N/A	20,32
Positive 12	31,18	27,48	33,37	31,73	39,23	**Negative 12**	N/A	27,61	N/A	N/A	20,40
Positive 13	32,19	30,34	30,44	28,60	21,68	**Negative 13**	N/A	29,30	N/A	N/A	20,49
Positive 14	27,53	29,92	29,29	28,15	27,09	**Negative 14**	N/A	29,03	N/A	N/A	20,39
Positive 15	32,30	26,25	33,25	31,57	24,56	**Negative 15**	N/A	23,53	N/A	N/A	20,27
Positive 16	32,02	29,59	34,35	33,88	21,84	**Negative 16**	N/A	27,16	N/A	N/A	19,93
Positive 17	31,42	30,14	29,67	28,70	20,58	**Negative 17**	N/A	27,11	N/A	N/A	20,20
Positive 18	32,37	28,55	32,72	29,89	25,65	**Negative 18**	N/A	28,76	N/A	N/A	20,02
Positive 19	31,14	30,64	35,23	33,23	23,71	**Negative 19**	N/A	25,08	N/A	N/A	20,12
Positive 20	31,24	27,67	30,18	28,52	24,37	**Negative 20**	N/A	26,13	N/A	N/A	20,12
Positive 21	33,14	27,62	32,18	30,33	25,85	**Negative 21**	N/A	25,95	N/A	N/A	20,32
Positive 22	33,96	33,20	33,10	43,85	23,42	**Negative 22**	N/A	30,06	N/A	N/A	20,22
Positive 23	27,67	25,87	28,87	28,26	24,38	**Negative 23**	N/A	23,86	N/A	N/A	20,28
Positive 24	34,14	32,06	35,24	32,71	23,59	**Negative 24**	N/A	26,75	N/A	N/A	19,83
Positive 25	29,03	27,80	30,56	29,88	26,92	**Negative 25**	N/A	30,06	N/A	N/A	19,87
Positive 26	29,62	31,65	34,74	29,42	23,41	**Negative 26**	N/A	26,60	N/A	N/A	20,27
Positive 27	33,00	26,61	34,00	33,30	24,57	**Negative 27**	N/A	28,71	N/A	N/A	20,35
Positive 28	25,22	29,60	25,29	25,16	29,65	**Negative 28**	N/A	27,07	N/A	N/A	20,05
Positive 29	31,08	28,26	36,05	35,33	26,48	**Negative 29**	N/A	24,27	N/A	N/A	20,26
Positive 30	32,22	31,37	38,33	37,52	24,14	**Negative 30**	N/A	28,04	N/A	N/A	19,97
TPC	28,29	28,46	31,07	32,08	24,40	**TNC**	N/A	30,16	-	-	-
NTC	N/A	N/A	N/A	N/A	27,84						

Table 13: The Comparison of Two Kits for Detection of SARS-CoV-2.

Clinical Study of Sars-CoV-2 - Nasal and Nasopharyngeal Swabs BIO-RAD CFX96			
POSITIVE SAMPLES			
	Valid Result (n)	**Positive Result**	**Negative Result**
SNP Covid-19 Real Time PCR Kit	30	30	0
DiaPlex Q Novel Coronavirus (2019-nCoV) Detection Kit	30	30	0
Positive Percent Agreement: 30/30 = 100% (95% CI: 88,4%-100.0%)			
NEGATIVE SAMPLES			
	Valid Result (n)	**Positive Result**	**Negative Result**
SNP Covid-19 Real Time PCR Kit	30	0	30
DiaPlex Q Novel Coronavirus (2019-nCoV) Detection Kit	30	0	30
Negative Percent Agreement: 30/30 = 100% (95% CI: 88,4%-100.0%)			

Sensitivity=%100
Specifity=%100
Positive predictive value=%100
Negative predictive value=%100

7.3. QUALITY CONTROL RESULTS

Table 14: Quality Control Results for Master Mix and Control RNAs

TEST	**SPECIFICATION**	**RESULT**
Sterility	DNAse-RNAse Free	Pass*
Appearance	Clear, Solution	Pass
Amplification Performance on Control RNAs	Figure 4-5-6 and Table 3	Pass

***All reagents tested with Real Time PCR for DNAse-RNAse free specification.**

8. TROUBLESHOOTING AND CAUTIONS

8.1. TROUBLESHOOTING

If internal control doesn't work;

- Unloaded well.
- Sample is containing PCR inhibitor(s).

If target plots start late;

Compare positive control and sample. If there is no problem in positive control;

- The amount of target RNA may be low.
- Target RNA quality is not good. Please dilute RNA by adding 1 to 1 PCR grade water.

Please contact us for your questions. tech@snp.com.tr

8.2. CAUTIONS

- In case of contact, it may irritate skin.
- Do not use without gloves.
- In case of contact, immediately wash skin with copious amounts of water.
- All reagents should be stored at defined conditions.
- Do not use the PCR master mix forgotten at room temperature.
- Thaw PCR master mix at room temperature and slowly mix by pipetting before use.
- Shelf-life of PCR master mix is 12 months. Please check the manufacturing date before use.
- For in vitro diagnostic use.

9. SYMBOLS

REF	Catalogue Number		Expiration Date
LOT	Lot Number		Manufacturer
IVD	In vitro Diagnostic Medical Device		Temperature Limitation (Storage temperature)
CE	Conformite European		

10. REFERENCES

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