



SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit Insert

1. Introduction

First reported from Wuhan, China, on 31 December 2019, novel coronavirus (SARS-CoV-2) is the cause of coronavirus disease 2019 (COVID-19) and generally spreads through human-to-human contact or respiratory droplet infection from coughs and sneezes and it is thought to have a zoonotic origin. The symptoms of COVID-19 include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, it can lead to pneumonia, kidney failure and even death. SMARTCHEK® novel coronavirus (SARS-CoV-2) detection kit (Genesystem Cat. # : 9799151400, 9799151401) is a real-time polymerase chain reaction (PCR) assay intended for use with GENECHECKER® UF-300 real-time PCR platform.

1.1 Method Description

SMARTCHEK® novel coronavirus (SARS-CoV-2) detection kit is based on biochip sample format and provides relatively short turn-around-time with simple workflow while it offers key benefits of real-time PCR tests. The kit contains all necessary components for PCR test including premix, primer pairs and probes pre-labeled(dehydrated) in the test chip. A test chip is designed to run 4 tests including positive control and no template control at a time. 5 test or 25 test chips are included in the package to make the pack sizes of 20 tests (Genesystem Cat. # : 9799151400) or 100 tests (Genesystem Cat. # : 9799151401) per a kit respectively. This kit is intended for *in vitro* diagnostic use. This kit adopted probe based real-time PCR for sequence-specific detection of a RdRP gene and N gene of SARS-CoV-2. This technology merges the polymerase chain reaction chemistry with the use of fluorescent reporter molecules in order to monitor the production of amplification products during each cycle of the PCR amplification.

1.2 Kit Contents

Contents	Volume/Quantity		Description
	Cat. # : 9799151400	Cat. # : 9799151401	
Test Chip	5 EA	25 EA	Individually vacuum packed
Sealing Tapes	5 EA	25 EA	Packed in plastic bag
Premix	50 µL x 5 tubes	250 µL x 5 tubes	Tubes with blue label on the cap
Nuclease Free Water	10 µL x 5 tubes	50 µL x 5 tubes	Tubes with white label on the cap
Microcentrifuge Tubes	25 EA	125 EA	For mixing premix and template

1.3 Apparatus (Not supplied with the product)

Item	Description
Real-time PCR System	GENECHECKER® UF-300 Real-time PCR System (Genesystem catalog number : 1399100200)
Pipettes & Tips	For pipetting the volume of 10µl
Centrifuge	For spin-down of premix and reaction mixture before loading in test chip
Vortex Mixer	600 ~ 3200 rpm
Personal protection items	Lab coats, gloves, masks and goggles

1.4 Storage and stability of Reagent

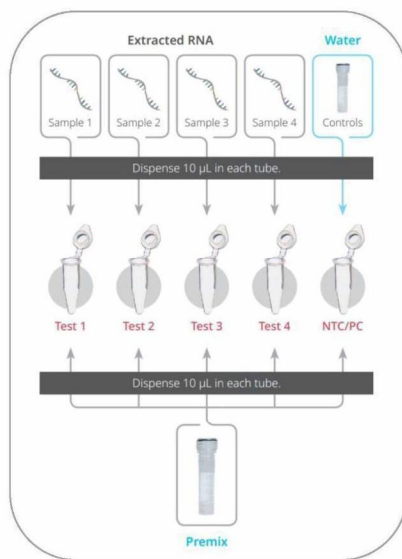
Contents	Storage Temp.	Stability
Test Chip	-25°C ~ - 20°C	12 months from date of manufacture
Premix	-25°C ~ - 20°C	12 months from date of manufacture
Nuclease Free Water	-25°C ~ - 20°C	12 months from date of manufacture



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2. Workflow

2.1 Preparation of reaction mixture



Reaction Mixture

Component	Volume / Test
Extracted RNA	10 µl
Premix	10 µl
Total	20 µl*

* For dispense into 2 reaction wells in 10 µl. Refer to 2.2 for detailed instruction.

Controls

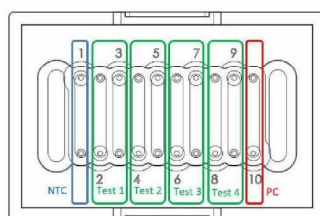
Component	Volume
Nuclease Free Water	10 µl
Premix	10 µl
Total	20 µl*

* For dispense into the positive control well and no template control well in 10 µl respectively. Refer to 2.2 for detailed instruction.

- 2.1.1 Vortex and spin-down the premix before use.
- 2.1.2 Prepare 5 microcentrifuge tubes included in the package.
- 2.1.3 Make aliquot of 10µl of premix and dispense them in 5 different microcentrifuge tubes prepared as 2.1.2.
- 2.1.4 Dispense 10µl of each extracted RNA template in four tubes.
- 2.1.5 Dispense 10µl of nuclease free water in remaining one tube.
- 2.1.6 Vortex and spin-down the tubes.

2.2 Loading the reaction mixture into the PCR chip

2.2.1 Test chip configuration



The 20µl of reaction mixtures prepared in 2.1 above is dispensed into two wells of the test chip corresponding to each target, with 10µl reaction volume. Well number 2 through 9 are used for detecting target genes while well number 1 and 10 are used for controls. Configuration of each well of the test chip is as following table.

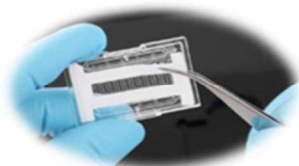

SMARTCHEK **Novel Coronavirus (SARS-CoV-2) Detection Kit Insert**

Well No.	1	2	3	4	5	6	7	8	9	10	
Test	NTC	Test 1		Test 2		Test 3		Test 4		PC	
Target gene	N/A	N	RdRP	N	RdRP	N	RdRP	N	RdRP	N	RdRP

- Corresponding primer pairs and probes along with internal controls are labeled(dehydrated) in each well of the test chip for reaction. Every well except the wells for controls includes internal control. The targets are detected from FAM channel and the internal control is detected from ROX channel of UF-300 real-time PCR system.
- Well number 1 of the test chip is used for no template control of the reaction. This well contains pre-labeled primers and probes. Well number 10 of the test chip is used for positive control of the reaction. This well contains pre-labeled primers and probes along with positive templates. FAM channel is used for detecting N gene of SARS-CoV-2 template and ROX channel is used for detecting RdRP gene of SARS-CoV-2 template in this well.

2.2.2 Loading the reaction mixtures into test chip

- ① Prepare test chip and detach the sealing tape.



- ② Aspirate 10µl of the reaction mixture with micropipette and vertically place the tip in the inlet hole of the test chip. Inlet hole is neighboring with printed well number and the diameter of this hole is a bit wider than that of outlet hole.



- ③ While sample loading, make sure that the end of the tip is securely fit into the inlet hole of the well and apply slight force downward and then slowly dispense the sample into the chip.
- ④ After dispensing reaction mixtures in to each well of the test chip, every hole of the wells should be sealed using enclosed pre-cut sealing tapes.



SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit Insert

- ⑤ Take out one strip of sealing tape, peel one piece of sealing tape from the strip using tweezers.



- ⑥ Place one end of sealing tape alongside left end of the test chip and seal entire holes. Then, scrub the surface of sealed points using finger, tweezers or scrubbing cloth enclosed in the package of GENECHECKER® UF-300 real-time PCR system.

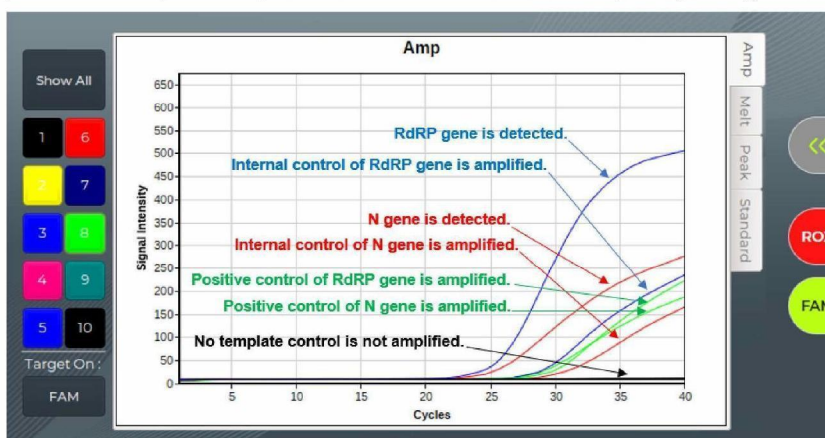
2.3 Reaction program to run with GENECHECKER® UF-300 real-time PCR system

Steps	Temperature	Time	Cycles
Reverse Transcription	50 °C	600 seconds	1
S1: Pre-denaturation	95 °C	30 seconds	1
S2: Denaturation	95 °C	5 seconds	40
S3: Annealing	58 °C	20 seconds	
S4: Extension	72 °C	5 seconds	

- Refer to the operating manual of UF-300 system for detailed instructions for use.

3. Test Result Interpretation

After completion of PCR run, the amplification curves are automatically shown on the screen of UF-300 platform. An example of the amplification curves and how the curves are interpreted by user is given below.




SMARTCHEK **Novel Coronavirus (SARS-CoV-2) Detection Kit Insert**
3.1 Result Criteria

Target	Positive Ct Value	Detection Channel
N gene of SARS-CoV-2	≤ 37.00	FAM
RdRP gene of SARS-CoV-2	≤ 40.00	FAM
Internal positive control	≤ 40.00	ROX
Positive Control	≤ 40.00	FAM and ROX
Negative Control	No detection	FAM and ROX

3.2 Result Interpretation

No.	N	RdRP	Internal control	Interpretation	PC	NTC
1	+	+	+ or -	SARS-CoV-2 Positive	Refer to below instruction.	
2	-	-	+	SARS-CoV-2 Negative		
3	-	+	+ or -	Retest		
4	+	-	+ or -	Retest		
5	-	-	-	Retest		

- Positive control should be positive and no template control (negative control) should be negative to make the test valid. All other cases make the test invalid.
- Amplification of either N gene or RdRP gene only requires the sample to be retested.
- No amplification of internal control on the negative samples requires the sample to be retested.
- Internal positive control may not be amplified due to primer competitions.

4. Notice

This kit is intended for *in vitro* diagnostic use. This kit was registered at EU as medical device (Registration No. : DE/CA29/000114881/D030). This kit was approved as medical device by Ministry of Food and Drug Safety of South Korea (License No. : 20-291).

Genesystem guarantees the product performance during warranty period but any data obtained by the testing protocol other than what is recommended by Genesystem cannot be applied to the warranty.

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