User Guidebook

DiaPlexQ™

Novel Coronavirus (2019-nCoV) Detection Kit

02/2020 V2.1

SolGent Co., Ltd.
Solutions for Genetic Technologies

RUO (Research Use Only)

This product can be used for Research Use Only (RUO).

Table of Contents

General Information

- This product is for RUO (Research Use Only).
- This product's result analysis can be possible to check only detection of Novel Coronavirus (2019-nCoV) infections, and medical related decision from test result is limited to medical experts.
- The results are read in accordance with the result analysis in the product manual.
- Use the dedicated PCR tube for the PCR machine.
- Wear protective disposable powder powder-free gloves, a laboratory coat, and eye protection when handling specimens.
- Always wear protective disposable powder-free gloves when handling kit components in order to avoid any contamination that can affect to test result.
- Contaminated disposables (tips, gloves, test tubes etc.) cannot be reused.
- Be careful not to let the reagents in this test come into contact with skin, eyes or mucous membranes, and wash off immediately with plenty of water.
- The experimental table should be disinfected cleanly.
- All reagents should be stored by following storage conditions before and after use.
- Do not leave the reagent cap open.
- Pipette and tips are used after sterilization.
- Potential contaminants must be properly disposed of, depending on how stable the dispose of contaminants.
- Don't food intake and smoking during the experiment. Always be careful not to contaminate microorganisms when you open a reagent tube or take out contents from the reagent tube.
- Store positive clinical sample and Control Template separately in order to prevent contamination.
- Please thaw the product on the ice.
- When using the product, do not mix with other lot products.
- If the item is arrived broken or damaged during transport, contact our sales offices of the headquarters.

Product warranty and liability

- The product expiry date is 12 months after the manufacturing date.
- The result of the product is guaranteed only if using the product was used according to this guidebook.
- Exchange is not possible in case of a problem due to the user's carelessness or fault.
- Do not repeat freeze freeze-thaw over 5 times.

Safety warnings and first aid measures

- Avoid contact with eyes, skin and respiratory system.
- Eye contact Wash eyes with much of flowing water.
- Consult with physician in case of irritation.
- Skin contact: Wash affected skin area thoroughly with soap and water.
- Consult with physician in case of irritation.

Precautions

- Do not use product after expiration date.
- Should use this kit after opening it immediately.
- A different result may appear by the condition of extracted sample RNA.
- Contaminated specimen may indicate an incorrect result.
- Discard used specimens in accordance with safety regulation in laboratory.

Kit Contents

Components	Cap Color	SQD52-K100	SQD52-K020
OneStep qRT-PCR Enzyme mix (2019-nCoV)	Red	200 ㎕ x 1 ea	40 ㎕ x 1 ea
2X OneStep qRT-PCR Buffer (2019-nCoV)	Blue	1 ㎖ x 1 ea	200 ㎕ x 1 ea
Primer & Probe Mixture (2019-nCoV)	Violet	300 ㎕ x 1 ea	60 ㎕ x 1 ea
Control Template (2019-nCoV)	Green	100 ㎕ x 1 ea	20 ㎕ x 1 ea
RNase free Water	White	1 ㎖ x 1 ea	200 ㎕ x 1 ea

Storage and Handling

- **DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit** should be stored at -20℃ ± 5℃ and keep away from sunlight and All components should be stored under recommended storage conditions.

Model Name	Storage	Period of use
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	-20℃ ± 5℃	12 months

– The expiry date of each component of the product is 12 months from the date of manufacture.
– Do not use product beyond the expiration date.
– Please thaw the product on the ice.
– Do not repeat freeze freeze-thaw over 5 times. Should be kept busy when you need a certain amount because this can cause the degradation of the enzyme activity, such as the quality of the product, if frequently repeated freezing and thawing.
– If there are or have been transportation problems, or the protective packaging is damaged, contact your dealer for guidance on what to do.

Material to be supplied by User

- Microcentrifuge
- Vortexer
- Pipettes/ pipette filter tips
- Centrifuge
- RNase free consumables: Disposable latex or vinyl gloves, sterile pipette tips
- Cooling device or ice
- Micro-centrifuge tube (1.5 ㎖)
- Tube or plates: Real-time PCR tube (0.1㎖ or 0.2 ㎖ in case of instrument type usage)
- Viral RNA preparation kit

Compatible Real-Time PCR thermocycler

- Applied Biosystems™ 7500 Real-Time PCR Instrument System Recommended
- Applied Biosystems™ 7500 Fast Real-Time PCR Instrument System Recommended
- Bio-Rad CFX96™ System Recommended

Note:

1. **Use film for the plate and cap for strip.**
2. **Use the dedicated PCR tube for the PCR machine.**

Purpose

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is in vitro diagnostic reagent to qualitative detection of ORF1a, N gene of Novel Coronavirus (2019-nCoV) from extracted RNA from Nasopharyngeal swab or Oropharyngeal swab or Sputum by Multiplex OneStep qRT-PCR. Only Novel Coronavirus (2019-nCoV) can be detected, without detecting SARS-CoV and bat SARS-like coronavirus known as similar viruses.

Product description

1. Introductions

Respiratory infections caused by viruses appears mainly in children, the elderly and immunocompromised patients. The major respiratory infection viruses are known as Influenza virus, Parainfluenza virus (PIV), Respiratory syncytial virus (RSVs), Enterovirus, Adenovirus, etc. In recent years, respiratory infections of Rhinovirus, Coronavirus and Metapneumovirus (MPV) have been increasing, and Bocavirus has been included in the major respiratory virus tests.

Corona virus is a virus that can infect animals and humans. There are six known corona viruses that can infect humans. Four of them are known as viruses that cause diseases such as the common cold, and the other two are MERS-CoV(Middle East Respiratory Syndrome Coronavirus) and SARS-CoV(Severe Acute Respiratory Syndrome Coronavirus), which have been fatal to humans.

Novel Coronavirus (2019-nCoV), which originated in Wuhan, China in 2019, has also been infected and transmitted in humans, with a 14-day incubation period, which has been reported to have a lower mortality rate and a higher incidence than SARS-CoV or MERS-CoV. Sequencing of the virus revealed that the new coronavirus was 89.1% similar to bat-derived SARS (bat-derived severe acute respiratory syndrome (SARS)-like coronaviruses, bat-SL-CoVZC45, bat-SL-CoVZXC21), and 79% similar to SARS-CoV (SARs, severe Acute Respiratory Syndrome).

It is also very important to accurately diagnose Novel Coronavirus (2019-nCoV), since it has sequences similar to those of the same genus.

Respiratory virus testing requires the selection of appropriate test methods depending on the characteristics of the hospital's patient population and laboratory conditions. Antigen testing, virus culture, and molecular biological methods have been used to detect viruses. Among them, the molecular biological method using Reverse Transcriptase is highly sensitive and is recognized as a standard method for detecting viruses that cannot be cultured or exist in low concentrations. Recently, one-step RT-PCR reaction, in which reverse transcriptase reaction and polymerase chain reaction (PCR) reaction can be performed in one tube, and multiplex RT-PCR, which can simultaneously detect various viruses in one PCR reaction the introduction of the law allows for the rapid and accurate identification of many viruses.

The product's rapid and accurate detection of the Novel Coronavirus (2019-nCoV) gene allows not only to administer appropriate antiviral therapy to emergency patients, but also to reduce unnecessary antiviral use and hospitalization period, and to properly treat infected patients. It is expected to isolate the virus infected patients and block the spread of the virus in the hospital.

2. Principle

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is in vitro diagnostic reagent to qualitative detection of ORF1a, N gene of Novel Coronavirus (2019-nCoV) by Multiplex OneStep qRT-PCR.

<Detection Target Information>

Target virus	Target genes
2019-nCoV	*N gene*
	ORF1a
	PCRC

The kit includes 2X OneStep qRT-PCR Buffer, OneStep qRT-PCR Enzyme mix (including RTase, DNA polymerase and RNase inhibitor) and Primer & Probe Mixture. We also provide a Control Template (2019-nCoV), which allows us to compare the results with clinical sample results to ensure correct interpretation of the results.

<Fluorescence Information>

Target genes	5′ Fluorophore	3′ Quencher
N gene	FAM	BHQ1
ORF1a	JOE / VIC	BHQ1
PCRC	Texas Red / Cal Fluor Red 610	BHQ2

(* ABI 7500 / 7500 Fast set in "JOE" and "Texas Red", Bio-Rad CFX96™ set in "VIC" and "Cal Fluor Red 610")

Process

This test process is optimized for DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit. This diagnostic kit is recommended to be carried out by professional personnel.

Overview

1. Sample collection

The kit can be used for nasopharyngeal swabs, oropharyngeal swabs, and sputum. Nasopharyngeal smear sample are collected from the posterior nasopharynx using a sterile swab and stored in a virus transport medium (VTM) and kept at 4 ° C ± 3 ° C for transport to the laboratory. VTM contains protein stabilizer, antibiotics for inhibiting bacterial/fungal growth, and buffer solution(Use 1~3 ㎖). Sputum samples should be rinsed with water in the morning and deeply coughed so that 1-3 ㎖ of sputum is collected in a sterile container and kept at 4 ℃ ± 3 ℃ for transport to the laboratory. Collected samples should be filled in with accurate information such as collection date, collection amount, type of sample, and patient information.

***Reference. Sample Collection and Preservation (Source: Centers for Disease Control and Prevention)**

2. RNA Isolation

This DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is used commercial RNA prep kits, it is recommended that the RNA prep kit indicated in the table below. Prepare the total RNA from samples of patients by referring to the instruction manual of the kit that you want to use.

Specimen	Kit name	Manufacturer	Cat. No.
Swab, Sputum	QIAamp Viral RNA mini kit	QIAGEN	52904/52906
	QIAamp MinElute Virus Spin Kit	QIAGEN	57704
	MagMAX™ AI/ND Viral RNA Isolation Kit	Ambion	1929
	High Pure Viral Nucleic Acid Kit	Roche	11 858 874 001

- **Wear disposable gloves before the experiment and replace them if contamination.**
- **Take care not to cross-contaminate between samples or to contaminate your skin.**
- **Remove pollutants with 70% Ethanol before and after the experiment according to the laboratory safety management guidelines.**

Note: The type of sample preparation kit, the extraction way, may influence the viral RNA yield rate, and this may influence PCR result.

3. Multiplex OneStep qRT-PCR

1) Please thaw all reagents on the ice. After vortex, spin down.
2) Prepare PCR Master Mix by adding following reagent.
3) The amount of Master mix should be prepared by calculating additional amount corresponding to at least 1~2 reaction than the number including sample, control template (2019-nCoV), and NTC (Non-Template Control).
4) Mix master mix using vortex and spin down.

Component	1 rxn	4 rxns	5 rxns	6 rxns	10 rxns
2X OneStep qRT-PCR Buffer (2019-nCoV)	10 ㎕	40 ㎕	50 ㎕	60 ㎕	100 ㎕
OneStep qRT-PCR Enzyme mix (2019-nCoV)	2 ㎕	8 ㎕	10 ㎕	12 ㎕	20 ㎕
Primer & Probe Mixture (2019-nCoV)	3 ㎕	12 ㎕	15 ㎕	18 ㎕	30 ㎕
Total master mix volume	15 ㎕	60 ㎕	75 ㎕	90 ㎕	150 ㎕

Note:

Protect the Probe from the light. When the Probe is exposed to the light for a long time, fluorescence may be reduced and may affect the result.

5) Dispense 15 ㎕ into a plate or strip tube suitable for the equipment using the manufactured master mix. (Be careful of cross contamination)
6) Add Template 5 ㎕.
   Labeling should be done to avoid confusion of template position.

Component	Volume
PCR master mix	15 ㎕
Template	5 ㎕
Total volume	20 ㎕

Note:

"Control Template (2019-nCoV)" Experiment and NTC (Non-Template Control) Experiment should be conducted at the same time to check the normal function of the product and contamination of the test space. Control Template (2019-nCoV) experiment uses Control Template (2019-nCoV) as template, NTC (Non-Template Control) experiment uses RNase free water as template.

7) After sealing with cap or film, spin down.

8) Install the prepared PCR mixture on the instrument and proceed with PCR under the following conditions.

   * Refer to Appendix for device setup and Run

No.	Step	Temperature	Acquisition	Time	Cycles
1	Reverse transcription	50°C	-	15 min	1
2	Initial PCR activation	95°C	-	15 min	1
3	Denaturation	95°C	-	20 sec	45
4	Annealing/Extension	60°C	√	40 sec	

Result Analysis

1. Amplicon information

As shown in the following figure, you can check the infection of Novel Coronavirus (2019-nCoV) by comparing with the result of amplification of Control Template (2019-nCoV).

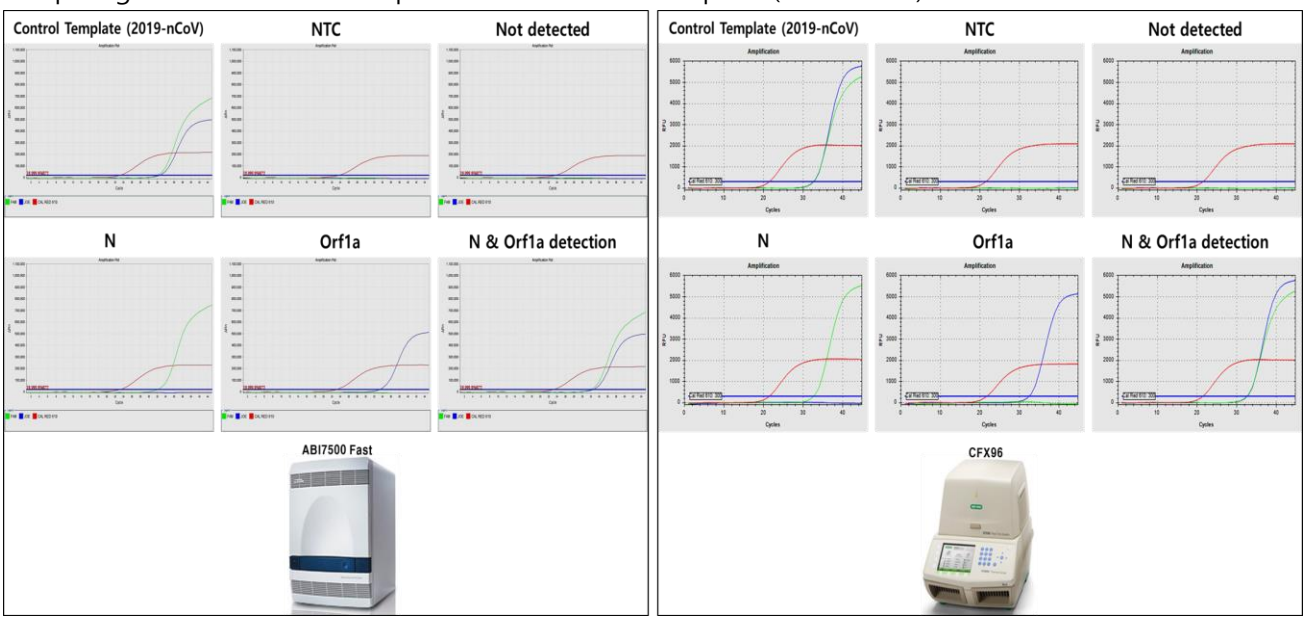

Figure 1. DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit Diagram.

Green is N gene (FAM), Blue is Orf1a gene (JOE/VIC), Red is PCRC (Texas Red/Cal Fluor Red 610)

2. Cut-off value

① If you are using ABI 7500 or ABI7500 FAST, you can check result of Ct value as follows:
- Plate and Film: Set the Threshold 20,000
- Tube and Cap: Set the Threshold 20,000

② If you are using CFX96™, you can check result of Ct value as follows:
- Plate and Film: Set the Threshold 300
- Tube and Cap: Set the Threshold 300

③ The positive judgment of the result through the amplification plot must satisfy the following conditions.

Target virus	Target genes	5′ Fluorophore	Cut Off Ct Value
2019-nCoV	*N gene*	FAM	≤ 40
	ORF1a	JOE / VIC	≤ 40
	PCRC	Texas Red / Cal Fluor Red 610	≤ 26

(*ABI 7500 / 7500 Fast set in "JOE" and "Texas Red", Bio Rad CFX96™ set in "VIC" and "Cal Fluor Red 610")

3. Result Analysis

Type	FAM	JOE / VIC	Texas Red/ Cal Fluor Red 610	Result
Positive Control	+	+	+	Valid
Negative Control	-	-	+	Valid
NTC (Non-Template Control)	-	-	+	Valid
Sample case 1	+	-	+/-	Positive
Sample case 2	-	+	+/-	Positive
Sample case 3	+	+	+/-	Positive
Sample case 4	-	-	+	Negative
Sample case 5	-	-	-	Required Re-experiment

Note:

1. **Even if the target peak is detected only without PCRC peak (Sample Case 1 ~ 3), the target peak is available (Positive).**
   - **If the sample is high concentration, PCRC peak cannot amplify.**
   - **If PCR inhibitors are present in RNA amplification steps, PCRC peak cannot amplify.**
2. **When contamination is found in the Non-Template Control test result, reanalysis test must be done.**

※ PCRC (PCR Control)

The diagnostic system use PCR methods can make result error by variety of factors for examples PCR mixture mix error, PCR condition error, PCR equipment's use error etc. PCR control is markers for monitoring of PCR reaction success, PCRC peak can check in all reactions. If not, there is a problem with the PCR reaction, experimental procedures and all steps must be checked.

4. Required re-experiment

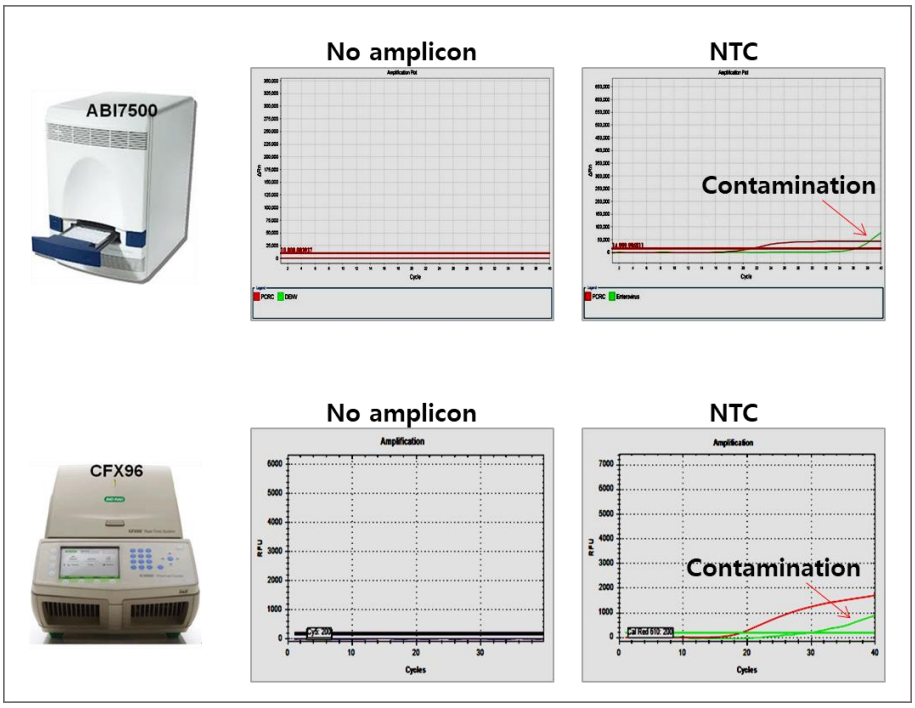

Figure 2. The failed result of curve pattern.

It would be shown the result as the figure, reanalysis test must be done.

Note:
If PCRC is not amplified, the purity of the RNA sample is not good. Thus, check it by dilute the sample (10 ~ 100 times) or extract RNA again.

This kit is only able to detection of 2019-nCoV infection. Medical-related decision from test result is limited to medical experts.

Trouble Shooting

Problem	Possible Causes	Solution
No or weak PCR product fluorescent	Wrong Storage condition	Check storage temperature and use new one if needed
	Too short time for Enzyme activation in PCR reaction	Check the PCR program for "initial PCR activation" for 15min at 95°C
	Expired shelf life	Check the expiration date and use new one if needed
	Primer and probe degraded	Check primer & probe mixture by using new primer and probe
	Low template quality	Check template quality using spectrophotometer
	Inhibitors in Template	Check the prep condition of the sample so that the inhibitor can be removed sufficiently
	Inappropriate Nucleic acid preparation	Check the concentration of nucleic acid re-isolation the nucleic acid if needed
	Template degradation	Re-prepare template
	Reagents stored for long periods at room temperature	Reagents do not leave at room temperature for extended periods of time
	Deactivation of Plate read	Re-test after activating plate read in the steps provided in the product manual when setting PCR conditions in the PCR machine
	Unassigned Fluorophore in sample well	Re-analyze the data of Fluorophore in the product manual and perform the data reanalysis
Non-specific PCR Amplification	Contamination of PCR mixture	Check the experimental location or tools that have not been contaminated
	DNA sample contamination from the extraction process	If location and tools have not been contamination, used in RNA extraction reagent and PCR reagent replace
	Contamination of Water	New nuclease free water used
False positive / PCR product with non-template control(NTC)	Cross-contamination	Use filter tip, screw-cap tubes and latex glove, and perform in hood in DNA free zone
Different results in same species	Pipette volume error	Check the Pipettes
	Cross contamination	DNA sample to be careful when you insert it in the PCR tubes
	If foreign objects with the PCR tubes or caps	Remove any debris with a soft cloth before PCR experiment.
No PCR product with positive control or false negative	Template degradation	Do no repeat freezing-thawing cycle of positive control (plasmid DNA)
	Incorrect storage	Check storage condition for kit and use new one if needed
	In appropriate Nucleic acid preparation	Check the concentration of nucleic acid re-isolation the nucleic acid if needed
	Incorrect PCR mixture (primer & premix) volume	Check the volume for mixture in case of using the pipetting
	Storage the reagents at room temperature	Do not storage the reagents at room temperature and use new one if needed

Appendix

■ Applied Biosystems™ 7500 / 7500Fast Real-Time PCR Instrument System Set up and Run

1. Click 'Advanced Setup' on the main screen.

Figure 3. Main

2. Enter the file name (or Experiment Properties screen).

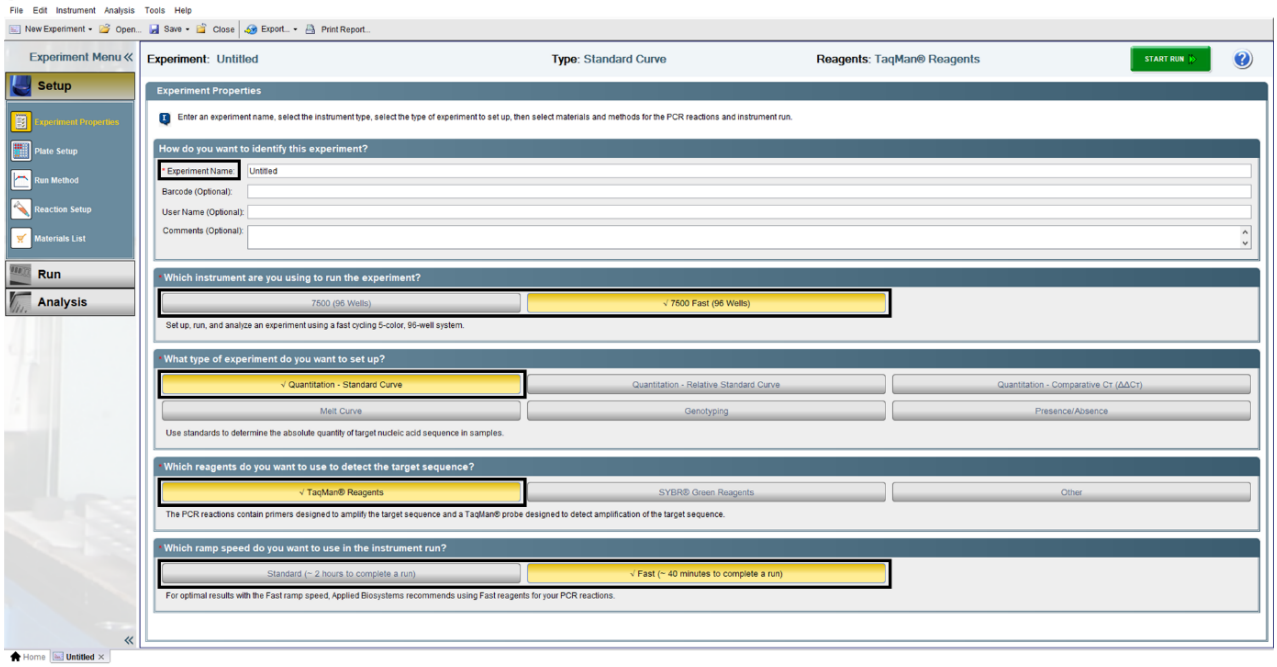

Figure 4. Experiment Properties

2-1. Fill in "Experiment Name"

2-2. "Which instrument are you using to run the experiment?"

→ Check 7500 (96 Wells) or 7500 Fast (96 Wells)

2-3. "What type of experiment do you want to set up?"

→ Check Quantitation – Standard Curve

2-4. "Which reagents do you want to use to detect the target sequence?"

→ Check TaqMan® Reagents

2-5. "Which ramp speed do you want to use in the instrument run?"

→ Check Standard (~ 2 hours to complete a run) or Fast (~40 minutes to complete a run)

3. At the 'Define Targets and Samples' Tap in Plate Setup screen, please set up as follows.

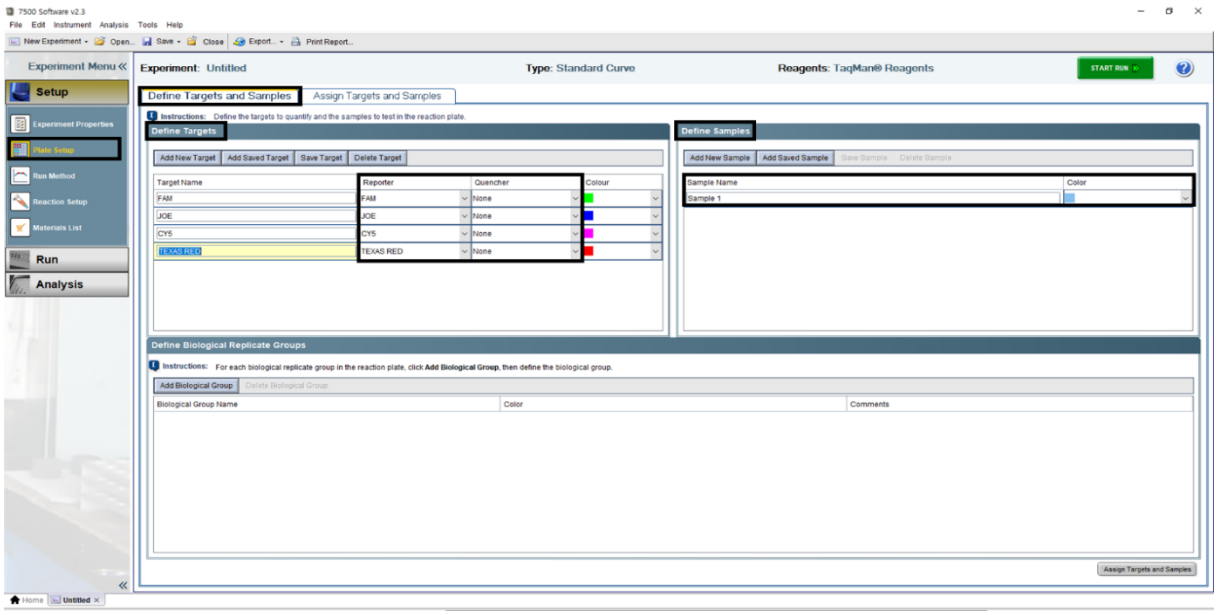

Figure 5. Plate Setup - Define Targets and Samples

3-1. Click 'Add New Target' at Define Targets. Setup 'Reporter' and 'Quencher' as follows:
(Target Name and Color can be setup randomly.)

Reporter	Quencher
FAM	none
JOE	none
Texas Red	none

3-2. If you want to fill out sample name, you can assign randomly at 'Define Samples'.

4. At 'Assign Targets and Samples' Tap in 'Plate Setup' screen, please set up as follows.

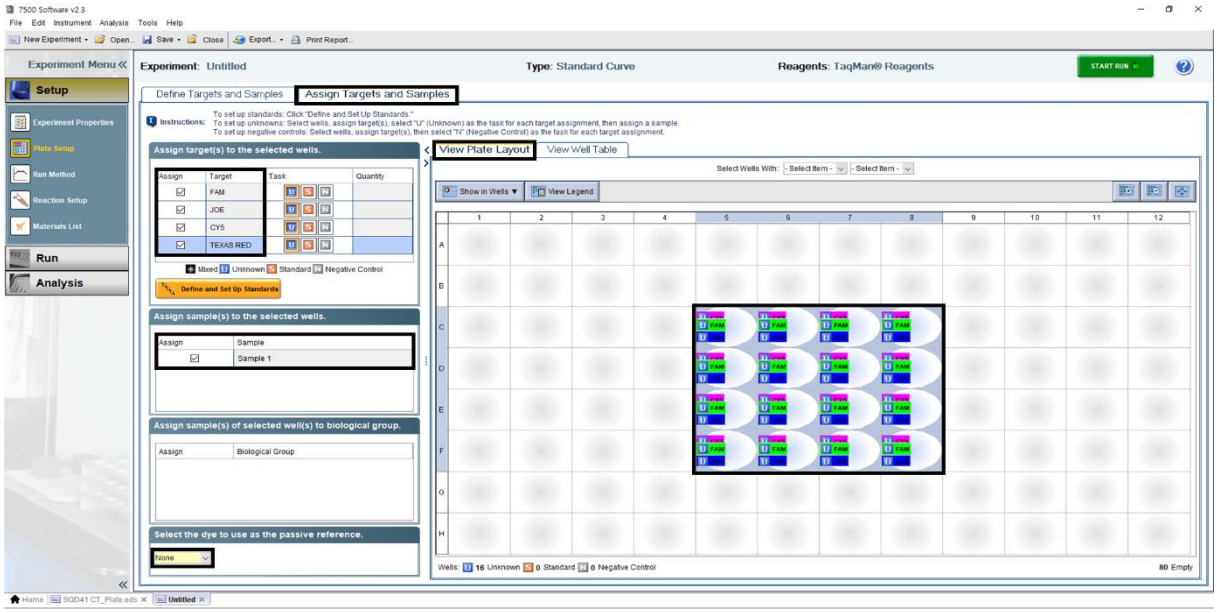

Figure 6. Plate Setup - Assign Targets and Samples

4-1. "View Plate Layout" Select well according to the position of the PCR mixture reaction solution.

4-2. "Assign target(s) to the selected wells" Select Target (3-1).

4-3. "Assign samples(s) to the selected wells" Select Sample (3-2).

4-4. "Select the dye to use as the passive reference" Select None.

5. Set the PCR temperature condition as follows, enter the reaction volume in 20 ㎕ and click 'Start Run'.

No.	Step	Temperature	Acquisition	Time	Cycles
1	Reverse transcription	50°C	-	15 min	1
2	Initial PCR activation	95°C	-	15 min	1
3	Denaturation	95°C	-	20 sec	45
4	Annealing/Extension	60°C	√	40 sec	

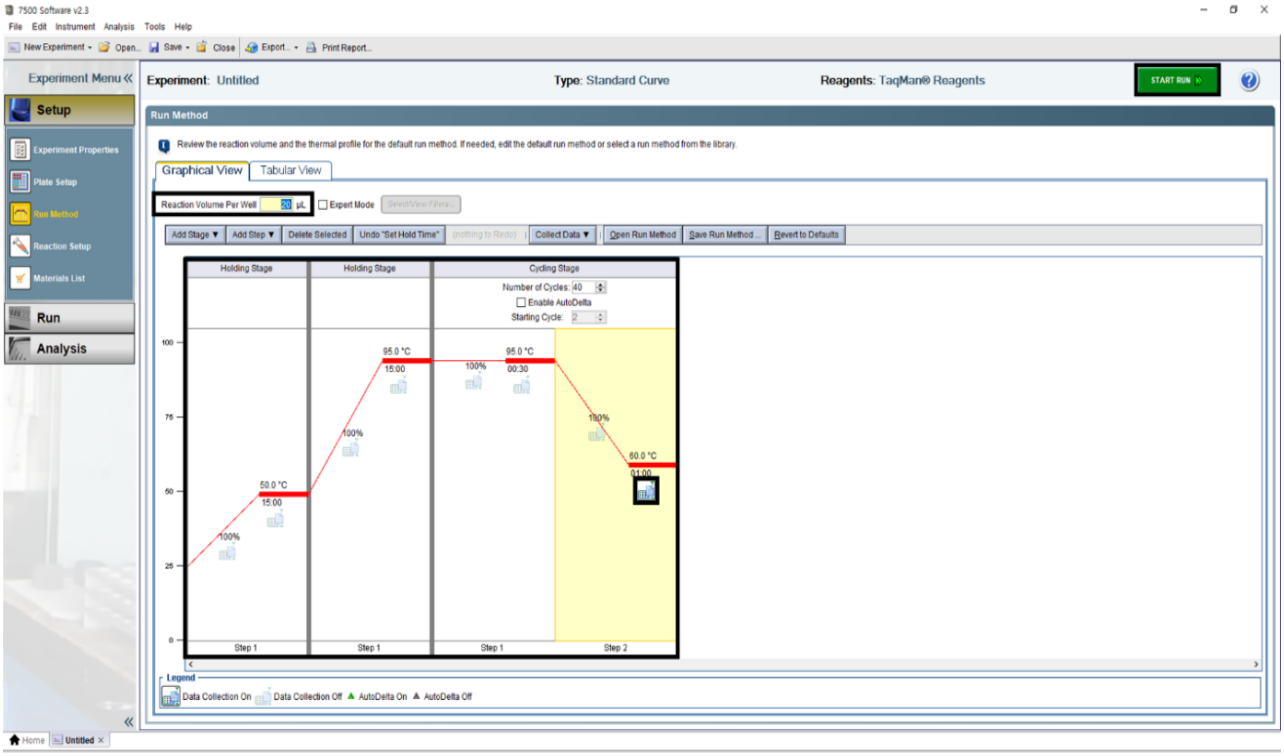

Figure 7. Run Method

Note: In Step 6, check Collect Data On Hold to collect data.

6. Select 'START RUN' and set the location where the data will be saved.

■ Bio-Rad CFX96™ System Setup and Run

1. Turn on the instrument.
2. Run Bio-Rad CFX Manager.

3. Click 'File' → 'New' → 'Protocol'.

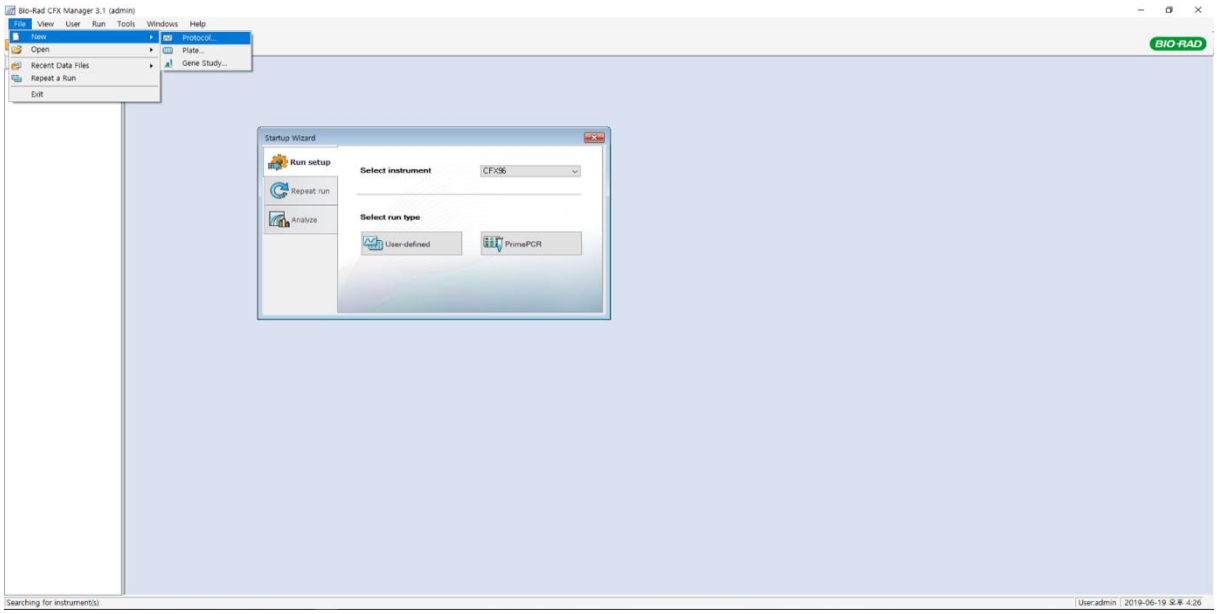

Figure 8. Main

4. In the Protocol Editor screen, enter Sample Volume 20 ㎕, set the PCR Condition, and click 'OK'

No.	Step	Temperature	Acquisition	Time	Cycles
1	Reverse transcription	50°C	-	15 min	1
2	Initial PCR activation	95°C	-	15 min	1
3	Denaturation	95°C	-	20 sec	45
4	Annealing/Extension	60°C	√	40 sec	

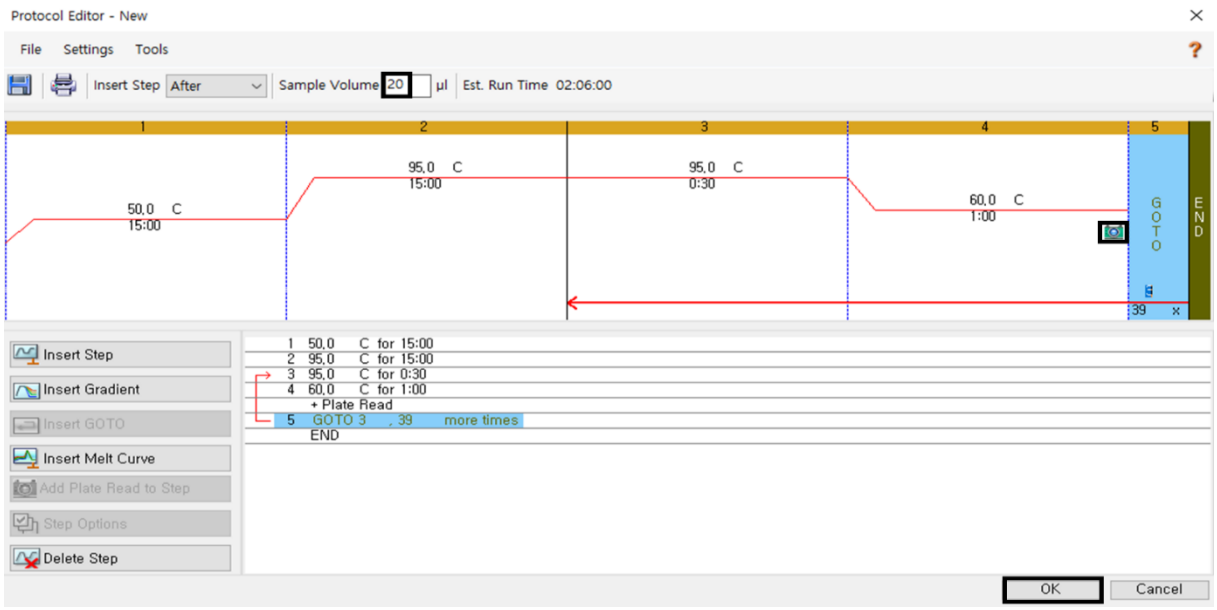

Figure 9. Protocol Editor

Note: In Step 4, check 'Collect Data On Hold' to collect data.

5. Click 'Create New' in the plate tap. In 'Plate Editor' screen, click 'Select Fluorophores' and setup fluorophore.

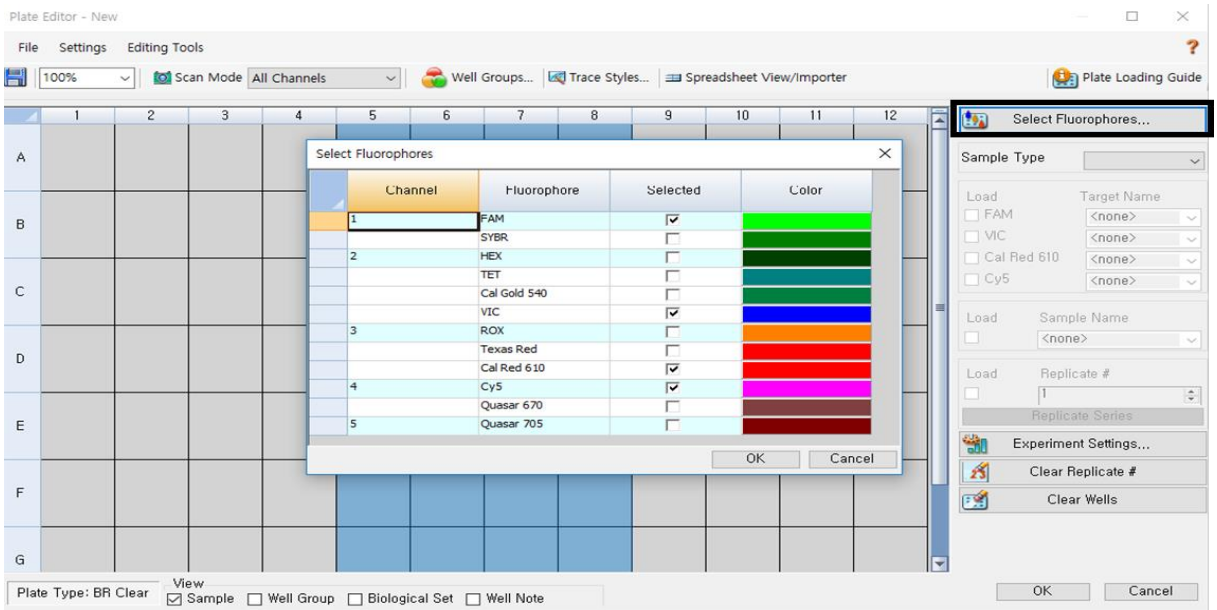

Figure 10. Plate Editor - 1

Fluorophore
FAM
VIC
Cal Fluor Red 610

6. After selecting well according to the position of PCR mixture reaction solution, designate 'Sample Type' and 'Fluorophore'.

Figure 11. Plate Editor - 2

7. Settings → Plate Type → click 'BR White' or 'BR Clear' according to the type you are using.

Figure 12. Plate Editor - 3

8. On the 'Start Run' tab in 'Run Setup', click 'Close Lid' to close the lid of the instrument, select the active 'Start Run' and set the location where the data will be saved.

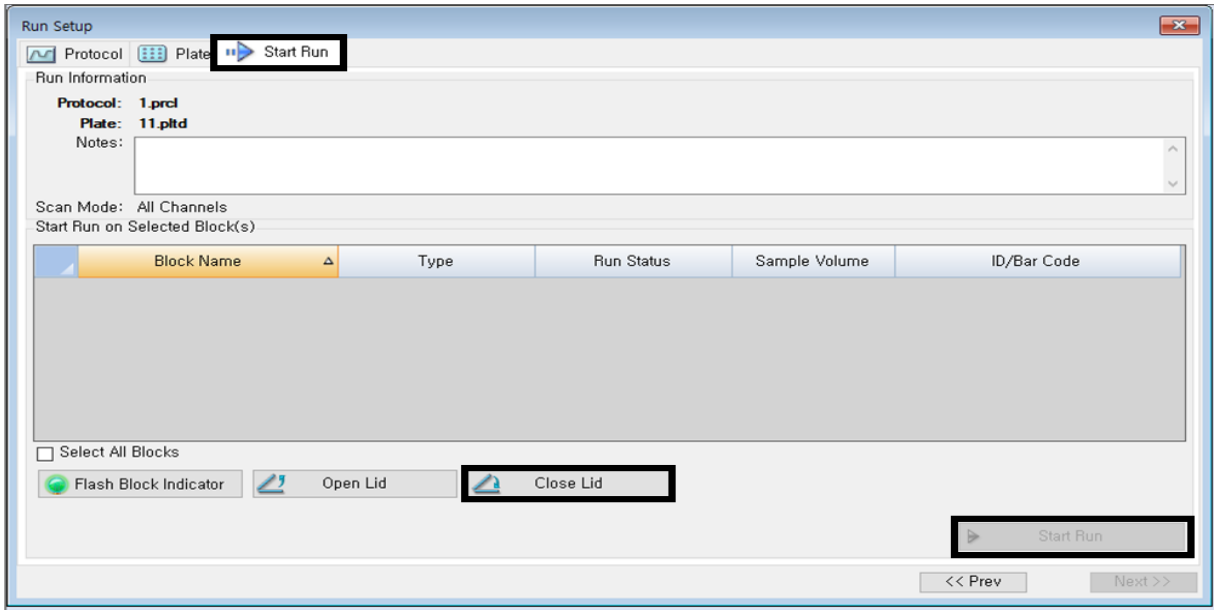

Figure 13. Run Setup

■ Applied Biosystems™ 7500 / 7500Fast Real-Time PCR Instrument System setup for result analysis

1. After Real-Time PCR is finished, set 'Plot Settings' on the 'Amplification Plot screen' as below and select 'Analysis Settings'.

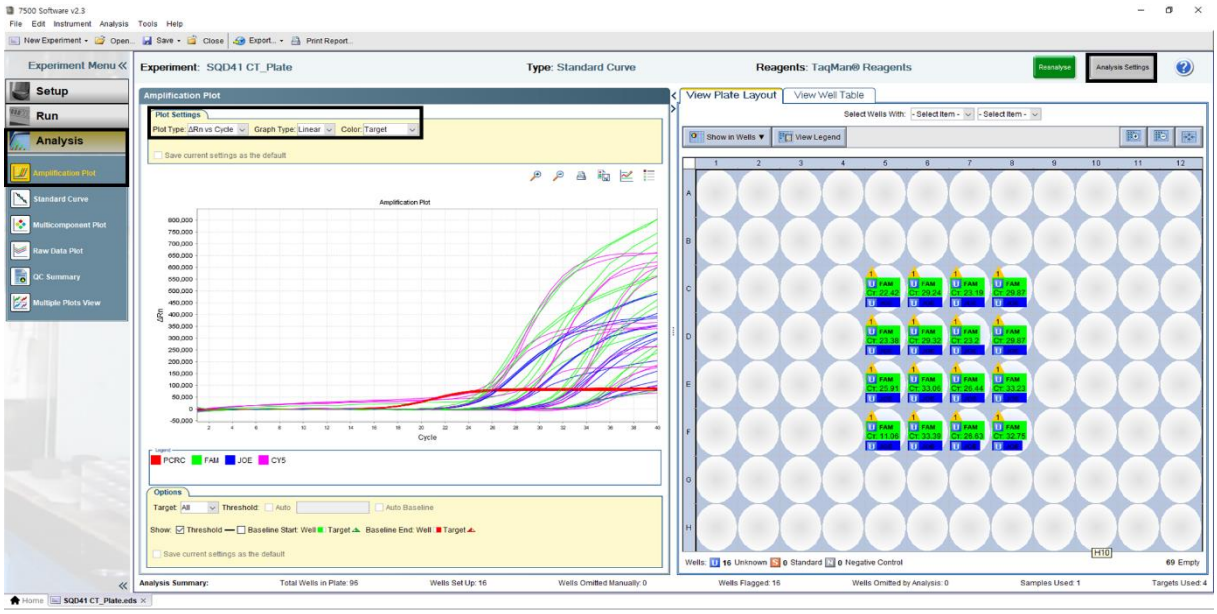

Figure 14. Amplification Plot

1-1. "Plot Type" ΔRn vs Cycle / "Graph Type" Linear / "Color" Target

3. In 'Analysis Settings', specify the Threshold value for each Fluorophore, and then click 'Apply Analysis Settings'. * Threshold: 20,000 (Plate / Strip tube)

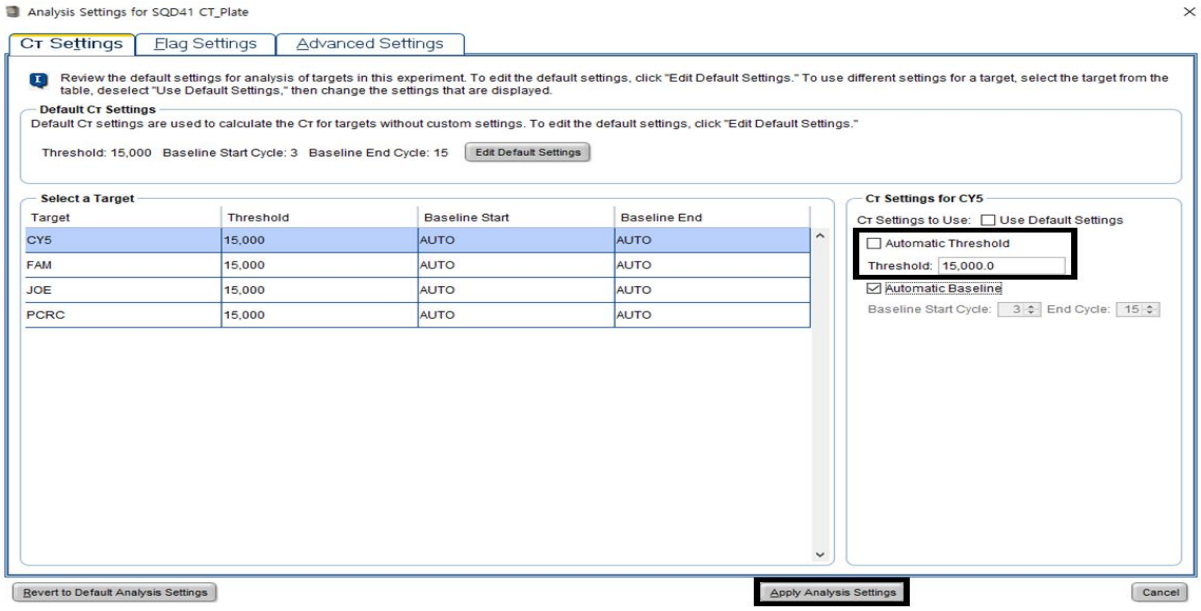

Figure 15. Analysis Settings

3. Interpret the results by referring to the result analysis.

■ Bio-Rad CFX96™ System Setup for result analysis

1. After Real-Time PCR is finished, check 'Fluorophore' in Data Analysis screen and click Settings → Baseline Threshold.

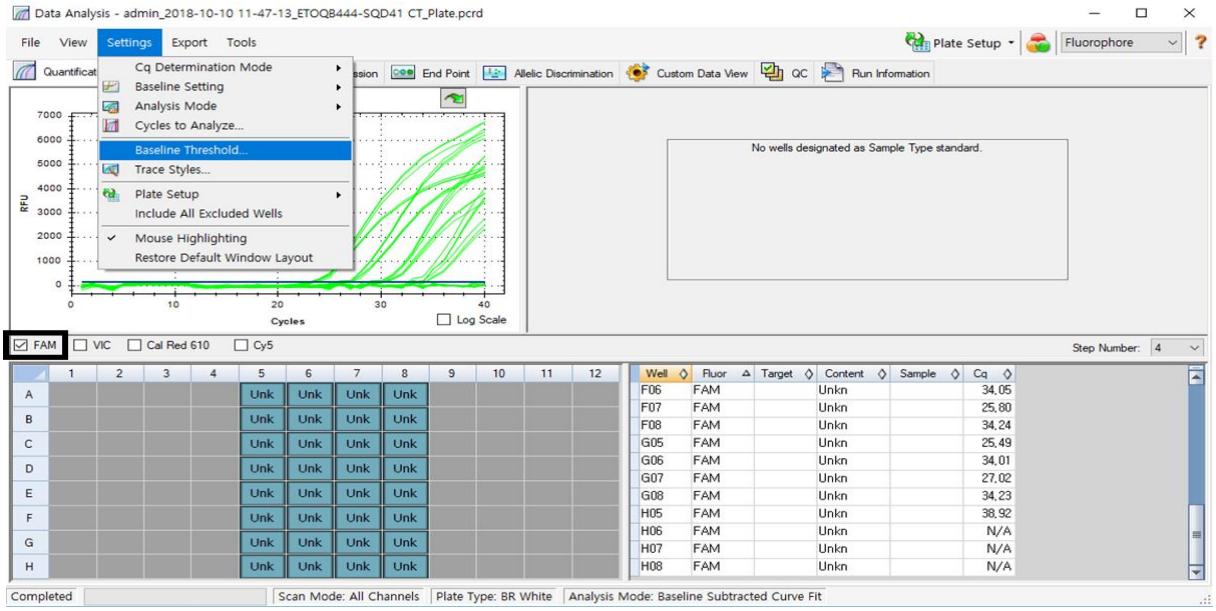

Figure 16. Data Analysis

2. In the Baseline Threshold Screen, specify the Threshold value for each fluorophore and click OK.
   * Threshold: 300 (Plate / Strip tube)

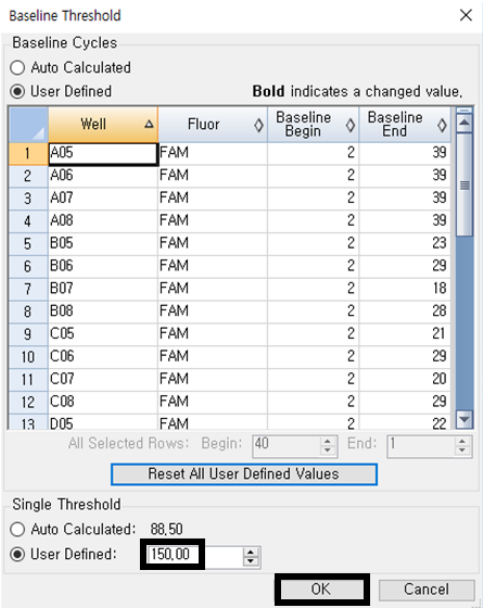

Figure 17. Baseline Threshold

3. Interpret the results by referring to the result analysis.

Performance evaluation

1. Sensitivity

The minimum detection limit for this product is **10 copies/reaction**. To confirm this, the samples were diluted from 10^4 to 10^0 copies reaction using In Vitro transcripted RNA containing target gene.

Target gene	1 x 10^4 copies	1 x 10^3 copies	1 x 10^2 copies	1 x 10^1 copies	1 x 10^0 copies
N	24/24 (100%)	24/24 (100%)	24/24 (100%)	23/24 (95.8%)	1/24 (4.2%)
Orf1a	24/24 (100%)	24/24 (100%)	24/24 (100%)	23/24 (95.8%)	0/24 (0.0%)

2. Specificity

To confirm the cross-amplification was performed using respiratory viral RNA and viral DNA, pneumococcal gDNA, Mycobacterium tuberculosis gDNA and human total RNA. As a result, cross-amplification with other viruses or bacteria did not occur, and it was confirmed that qRT-PCR amplification products were specifically generated only in the RNA transcript of the detection target virus (Novel Coronavirus (2019-nCoV)).

No.	Viruses / Bacteria	Ct Value
1	*Parainfluenza I*	N/D
2	*Parainfluenza II*	N/D
3	*Parainfluenza III*	N/D
4	*Parainfluenza IV*	N/D
5	*Influenza A*	N/D
6	*Influenza B*	N/D
7	*Adenovirus*	N/D
8	*Respiratory syncytial virus A*	N/D
9	*Respiratory syncytial virus B*	N/D
10	*Rhino 8, A*	N/D
11	*Bocavirus*	N/D
12	*Metapneumovirus*	N/D
13	*Beta Coronavirus OC43*	N/D
14	*Alpha Coronavirus 229E*	N/D
15	*Enterovirus*	N/D
16	*Acinetobacter baumannii*	N/D
17	*Bordetella parapertussis*	N/D
18	*Bordetella pertussis*	N/D
19	*Chlamydophila pneumoniae*	N/D

20	*Haemophilus influenza*	N/D
21	*Klebsiella pneumoniae*	N/D
22	*Legionella pneumophila*	N/D
23	*Moraxella catarrhalis*	N/D
24	*Mycoplasma pnemoniae*	N/D
25	*Pseudomonas aeruginosa*	N/D
26	*Serratia marcescens*	N/D
27	*Staphylococcus aureus*	N/D
28	*Stenotrophomonas maltophilia*	N/D
29	*Streptococcus pneumoniae*	N/D
30	*Mycobacterium abscessus*	N/D
31	*Mycobacterium avium*	N/D
32	*Mycobacterium bovis*	N/D
33	*Mycobacterium chelonae*	N/D
34	*Mycobacterium intracellulare*	N/D
35	*Mycobacterium kansasii*	N/D
36	*Mycobacterium scrofulaceum*	N/D
37	*Mycobacterium tuberculosis*	N/D
38	Human total RNA (10ng/μl)	N/D
39	*N gene (RNA transcript)*	Detection
40	*Orf1a (RNA transcript)*	Detection

3. Precision Test

The In Vitro transcripted RNA with the target gene was used as 1 X 10^5, 1 X 10^3, 1 X 10^1 copies, and the precision was evaluated for 10 days with 2 replicates of 2 reagents once a day. As a result, the standard deviation of detection between lots & test days was less than 1 and less than 5% for% CV.

Precision test result between Lot					
Target gene	Copies No.	Lot 1 Average Ct value	Lot 2 Average Ct value	Standard Deviation between Lot	%CV between Lot
N	1 X 10^5	22.1	22.2	0.083	0.377
	1 X 10^3	29.2	29.4	0.111	0.380
	1 X 10^1	35.7	36.0	0.139	0.388
Orf1a	1 X 10^5	22.8	22.9	0.087	0.379
	1 X 10^3	29.7	29.8	0.119	0.399
	1 X 10^1	36.6	36.5	0.062	0.169

Repeatability test results between test days				
Target gene	Copies No.	Average of Ct value	Standard Deviation	%CV
N	1×10^5	22.0	0.148	0.669
	1×10^3	29.1	0.214	0.728
	1×10^1	35.8	0.245	0.681
Orf1a	1×10^5	22.7	0.174	0.762
	1×10^3	29.6	0.247	0.831
	1×10^1	36.6	0.219	0.599

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Symbol Information

Symbol	Used for	Example of Usage
	Temperature limit	2 °C 8 °C
	Use-by date	2005-09-15
LOT	Batch code	LOT ABC123
REF	Catalog number	REF ABC123
	Manufacturer	Company Address
	Date of Manufacture	2001-06
SN	Serial number	SN ABC123
Σ	Contains sufficient for <*n*> tests	Σ 100

Symbol	Used for
	Caution
	Consult instructions for use
RUO	Research use only
CE	CE mark
IVD	*In vitro* diagnostic medical device
EC REP	Authorized representative in the European Community
CONTROL +	Positive control
	Keep away from sunlight

Ordering Information

Cat. No.	Name	Size
SQD52-K100	DiaPlexQ™ Novel Coronavirus (2019-CoV) Detection Kit	100 reactions/Kit
SQD52-K020		20 reactions/Kit

43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
Tel: 1544-5695, 042-864-5695 Fax: 042-864-5690
Web site : http://www.solgent.com

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