For Professional Use Only

Allplex™

Candidiasis Assay

(Cat. No.SD9803X, SD10178Z)

A multiplex real-time PCR assay for detection of *Candida albicans* (CA), *Candida krusei* (CK), *Candida glabrata* (CG), *Candida dubliniensis* (CD), *Candida parapsilosis* (CP), *Candida tropicalis* (CTp), and *Candida lusitaniae* (CL) from urine, genital swab, and liquid based cytology specimens.

For use with

1. CFX96™ Real-time PCR Detection System (CFX Manager™ Software-IVD v1.6)

2. CFX96™ Dx System (CFX Manager™ Dx Software v3.1)

CE

IVD **For *in vitro* diagnostic use only**

REF **SD9803X** Σ **100** REF **SD10178Z** Σ **25**

Seegene Inc.

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EC REP **Medical Technology Promedt Consulting GmbH**

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Not available in the U.S.

TABLE OF CONTENTS

NOTICES

- For *in vitro* diagnostic use only.
- Reliability of the results depends on adequate specimen collection, storage, transport, and processing procedure.
- If this product is used with **Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS, Seegene STARlet and Seegene STARlet 96MPH**, it provides maximum 5 separate runs.
- **AIOS** combines Seegene STARlet sold by Seegene with real-time PCR equipment (CFX96 Dx, Manufacturer: Bio-Rad) and plate sealer (Manufacturer: SAMICK THK) to form an automated linkage structure of nucleic acid extraction to PCR.
- **This test has been validated for the following specimen types: urine, genital swab, and liquid based cytology specimens.** This test has not been validated for any other types of specimens.
- **Store DNA samples at ≤ -20℃ until use and keep on ice during use.**
- Sensitivity of the assay may decrease if samples are repeatedly frozen/thawed or stored for a longer period of time.
- Workflow in the laboratory should proceed in a unidirectional manner.
- Always wear disposable gloves in each area and change them before entering different areas. Change gloves immediately if contaminated or treat them with DNA decontaminating reagent.
- Dedicate supplies and equipment to separate working areas and do not move them from one area to another.
- Do not pipette by mouth.
- Do not eat, drink or smoke in laboratory work areas. Wear disposable powder-free gloves, laboratory coats and eye protections when handling specimens and reagents. Wash hands thoroughly after handling specimens and test reagents.
- Avoid contamination of reagents when removing aliquots from reagent tubes. Use of sterile aerosol resistant disposable pipette tips is recommended.
- Do not pool reagents from different lots or from different tubes of the same lot.
- Do not use the product after its expiry date.
- Do not reuse all disposable items.
- Use screw-capped tubes and prevent any potential splashing or cross-contamination of specimens during preparation.

- Please be careful not to contaminate reagents with extracted nucleic acids, PCR products, and positive control. To prevent contamination of the reagents, use of filter tips is recommended.
- Use separated and segregated working areas for each experiment.
- To avoid contamination of working areas with amplified products, open PCR reaction tubes or strips only at designated working areas after amplification.
- Store positive materials separated from the kit's reagents.
- Laboratory safety procedures (refer to Biosafety in Microbiological and Biomedical Laboratories & CLSI Documents) must be taken when handling specimens. Thoroughly clean and disinfect all work surfaces with 0.5% sodium hypochlorite (in de-ionized or distilled water). Product components (product residuals, packaging) can be considered as laboratory waste.
- Dispose of unused reagents and waste in accordance with applicable federal, state, and local regulations.
- Expiry date is 12 months from the date of manufacture at ≤ -20℃. Please refer to label for final expiry date.
- Seegene NIMBUS and Seegene STARlet are the same equipment as the Microlab NIMBUS IVD and Microlab STARlet IVD, although the manufacturer is different. Since there are no hardware changes on the device, the test results are the same.
- The brand name of "CFX96™ Real-time PCR Detection System-IVD" is changed to "CFX96™ Dx system". Since there are no hardware changes to the systems, it is expected to obtain the same results from both systems.
- "CFX Manager™ Dx Software v3.1" is an upgrade version of "CFX Manager™ Software-IVD v1.6". The upgraded software includes enhancements to the "Run" menu. These enhancements do not impact the results of data analysis; therefore, results will be the same.
- This kit is intended to aid in the differential diagnosis of target pathogen infections;
  C. albicans (CA), *C. krusei* (CK), *C. glabrata* (CG), *C. dubliniensis* (CD), *C. parapsilosis* (CP), *C. tropicalis* (CTp), and *C. lusitaniae* (CL)

INTENDED USE

Allplex™ Candidiasis Assay is a qualitative *in vitro* test for single or multiple detection of *C. albicans* (CA), *C. krusei* (CK), *C. glabrata* (CG), *C. dubliniensis* (CD), *C. parapsilosis* (CP), *C. tropicalis* (CTp), and *C. lusitaniae* (CL) from urine, genital swab, and liquid based cytology specimens.

PRINCIPLES AND PROCEDURE OVERVIEW

1. Principles

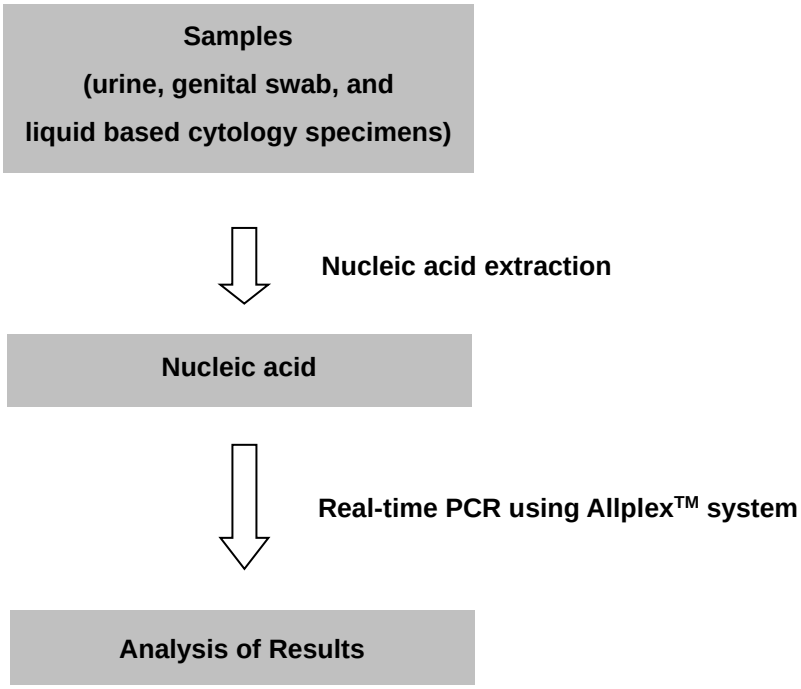
Allplex™ Candidiasis Assay exhibits Seegene's proprietary MuDT™ technology, which allows to provide multi-Ct (threshold cycle) values in a single fluorescence channel without melt curve analysis on real-time PCR instrument.

Allplex™ Candidiasis Assay is a real-time PCR assay that permits simultaneous amplification and detection of target nucleic acids of *C. albicans* (CA), *C. krusei* (CK), *C. glabrata* (CG), *C. dubliniensis* (CD), *C. parapsilosis* (CP), *C. tropicalis* (CTp), *C. lusitaniae* (CL), and Internal Control (IC).

In Allplex™ Candidiasis Assay, an endogenous human gene is used as Internal Control (IC) for monitoring the whole process from sample collection to nucleic acid extraction as well as to check for any possible PCR inhibition. PCR efficiency may be reduced by inhibitors that may be present in clinical specimens. However, due to inconsistencies in the amount of human cells contained in urine, IC is exogenously added only into urine samples and used as an exogenous whole process control. IC is co-amplified with target nucleic acids within the clinical specimen.

To prevent amplification product acting as potential contaminants, Uracil-DNA glycosylase (UDG) system is employed in Allplex™ Candidiasis Assay. The natural function of UDG is to prevent mutagenesis by eliminating uracil from DNA molecules by cleaving N-glycosylic bond and initiating base-excision repair (BER) pathway. Therefore, UDG systems are used to control cross-contamination of samples with amplicons.

2. Procedure Overview



BACKGROUND INFORMATION

Vulvovaginal candidiasis (VVC) is a very common condition that affects up to 75% of women at least once in their lifetime. VVC is most often caused by *Candida albicans*; however, other species of *Candida* such as glabrata, parapsilosis, and tropicalis are emerging.
Typical symptoms of VVC include pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge. None of these symptoms is specific for VVC. An estimated 75% of women will have at least one episode of VVC, and 40~45% will have two or more episodes.

Recurrent vulvovaginal candidiasis (RVVC), usually defined as four or more episodes of symptomatic VVC within 1 year, affects a small percentage of women (<5%). The pathogenesis of RVVC is poorly understood, and most women with RVVC have no apparent predisposing or underlying conditions. *C. glabrata* and other nonalbicans *Candida* species are observed in 10~20% of women with RVVC.

VVC may be easily and consistently treated by the standard azole drugs e.g., clotrimazole and fluconazole. However, some non-*Candida albicans* yeasts are resistant to these drugs hence making the correct identification a necessary step in VVC control. In pregnancy, VVC can be prolonged and associated with more severe symptoms, and resolution of symptoms typically requires longer courses of therapy. Only topical azoles are recommended in pregnancy.

REAGENTS

The reagents contained in one kit are sufficient for 100 reactions.

Order information (REF SD9803X)

Allplex™ Candidiasis Assay			
Symbol	**Contents**	**Volume**	**Description**
PRIMER	4X CA MOM	500 μL	MuDT Oligo Mix (MOM): - Amplification and detection reagent
PREMIX	EM1	500 μL	- DNA polymerase - Uracil-DNA glycosylase (UDG) - Buffer containing dNTPs
CONTROL +	CA PC	50 μL	Positive Control (PC) - Mixture of pathogen clones
CONTROL IC	ASTI IC	1,000 μL	Internal Control (IC) for urine specimen
WATER	RNase-free Water	1,000 μL	Ultrapure quality, PCR-grade
	User manual		

Accessory product- analysis software
Seegene Viewer*

* The analysis software is provided by Seegene Inc. or regional manager. Please use Seegene Viewer beyond V3.

The reagents contained in one kit are sufficient for 25 reactions.

Order information (REF SD10178Z)

Allplex™ Candidiasis Assay			
Symbol	**Contents**	**Volume**	**Description**
PRIMER	4X CA MOM	125 μL	MuDT Oligo Mix (MOM): - Amplification and detection reagent
PREMIX	EM1	125 μL	- DNA polymerase - Uracil-DNA glycosylase (UDG) - Buffer containing dNTPs
CONTROL +	CA PC	50 μL	Positive Control (PC) - Mixture of pathogen clones
CONTROL IC	ASTI IC	250 μL	Internal Control (IC) for urine specimen
WATER	RNase-free Water	1,000 μL	Ultrapure quality, PCR-grade
	User manual		

Accessory product- analysis software
Seegene Viewer*

* The analysis software is provided by Seegene Inc. or regional manager. Please use Seegene Viewer beyond V3.

STORAGE AND HANDLING

All components of the Allplex™ Candidiasis Assay should be stored at ≤ -20°C. All components are stable under recommended storage conditions until the expiry date stated on the label. Repeated freezing and thawing should be avoided, as this may reduce test sensitivity. If the reagents are to be used only intermittently, they should be stored in aliquots.

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable powder free gloves (latex or nitrile)
- Pipettes (adjustable) and sterile pipette tips
- 1.5 mL microcetrifuge tubes
- Ice maker
- Desktop centrifuge
- Mini plate spiner centrifuge
- Vortex mixer
- CFX96™ Real-time PCR Detection system (Bio-Rad)
- CFX96™ Dx System (Bio-Rad)
- Low-Profile 0.2 mL 8-Tube Strips without Caps (white color, Cat. No. TLS0851, Bio-Rad)
- Optical Flat 8-Cap Strips (Cat. No. TCS0803, Bio-Rad)
- Hard-Shell® 96-Well PCR Plates, low profile, thin wall, skirted, white/white (Cat. No. HSP9655, Bio-Rad)
- Hard-Shell® 96-Well PCR Plates, low profile, thin wall, skirted, white/white, barcoded (Cat. No. HSP9955, Bio-Rad)
- AIOS (Cat. No. SG72100, Seegene)
- Pierceable cap (Cat. No. 922119, SPL) (for AIOS use only)
- Permanent Clear Heat Seal (Cat. No. 1814035, Bio-Rad) *
- PX1 PCR plate sealer (auto-sealer, Cat. No. 181-4000, Bio-Rad) *
- Saline solution
- Clean bench

* Make sure to use the heat seal and the plate sealer listed above together.

PROTOCOL

1. Specimen Collection, Storage, and Transport

Note: All samples have to be treated as potentially infectious materials. Only those sample materials are permitted, which are collected, transported and stored attending strictly the following rules and instructions.

Urine specimen
Genital swab specimen
Liquid based cytology specimen

Note: To ensure high sample quality, specimens should be transported as fast as possible. The specimens should be transported at indicated temperatures.

A. Specimen Collection

Urine specimen

- The patient should be advised not to urinate for at least two hours prior to specimen collection.
- Collect 10~30 mL of first-catch urine in a clean container of polypropylene. Close and label the sample containers. Strictly adhere to the instructions given for storage and transport.

Genital swab specimen

For the collection of genital swabs, please use following materials :

- Genital swabs can be collected and transported in 1~3 mL of the following mediums :
  - ENAT PM 2ML REGULAR APPLICATOR (Copan)
  - UTM with Flocked Swabs (Copan)
  - Swab Specimen Collection Kit (Qiagen Corporation)
- Leave the swab in the transport medium. Close and label the sample container. Strictly adhere to the instructions given for storage and transport.
- Please follow a recommended protocol to collect columnar and squamous epithelium cells after removal of the cervical mucus.

Liquid based cytology specimen

- Use liquid based cytology media ThinPrep® from HOLOGIC® Inc. and SurePath™ from BD.
- Follow the manufacturer's instructions for collecting cervical cell specimens in ThinPrep® and SurePath™ media.

B. Specimen Storage & Transport

Specimen	Storage & Transport		Note
	Temp.	Duration*	
Urine specimen	2~8℃	1 week	- Performance may be affected by prolonged storage of specimens. - Specimens should also adhere to local and national instructions for transport of pathogenic material.
Genital swab specimen	2~8℃	1 week	
ThinPrep® medium	2~8℃	6 weeks	
SurePath™ medium	2~8℃	2 weeks	

* Duration: The time period from specimen collection to test including specimen storage and transport prior to the test.

2. Nucleic Acid Extraction

A. Pre-treatment of specimen

Note: The pre-treatment process for nucleic acid extraction is the same for both manual and automated extraction system.

Genital swab specimens

- Genital swab specimen is used without pre-treatment.

Urine specimens

Optional: Pre-treatment can be omitted. But, the sensitivity could be reduced compared to the case conducted pre-treatment process.

- Equilibrate samples to room temperature (19~25℃).
- Centrifuge 1 mL of urine for 15 minutes at 15,000 x *g* (13,000 rpm).
- The supernatant must be discarded. Afterwards, the pellet must be resuspended in recommended volume of Saline solution (See Recommended Vol. of 2.C) by vortexing thoroughly.
- Follow the manufacturer's protocol.

Liquid based cervical cytology specimen

- Equilibrate samples to room temperature (19~25℃).
- Centrifuge 1 mL of liquid based cervical cytology specimen for 15 minutes at 15,000 x *g* (13,000 rpm).
- The supernatant must be discarded. Afterwards, the pellet must be resuspended in recommended volume of Saline solution (See Recommended Vol. of 2.C) by vortexing thoroughly.

Note: Process pre-treatment step using lysis buffer in extraction kit not saline solution if the samples are collected in SurePath™ medium and would be extracted with Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS, Seegene STARlet or Seegene STARlet 96MPH.

Note: SurePath™ has not been validated with the Ribo_spin vRD kit, SEEPREP32, NucliSENS® easyMAG®, Seegene STARlet 96MPH and Maelstrom ™ 9600.

- Follow the manufacturer's protocol.

B. Internal Control

Note: For other specimens, except urine, endogenous gene is used for internal control. Therefore, it does not require additional IC included in the kit.

Note: The ASTI IC is included in the kit. This allows the user to confirm not only the nucleic acid extraction procedure, but also identify any PCR inhibition.

- For urine specimen, 10 μL of the ASTI IC must be added to each specimen before the nucleic acid extraction.

C. Automated Nucleic Acid Extraction System

Note: Please use the recommended volumes of specimen and elution as indicated below. For others, refer to the manufacturer's protocol.

C-1. Microlab NIMBUS IVD

Note: See **Microlab NIMBUS IVD** operation manual.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Microlab NIMBUS IVD	Hamilton	65415-02*	-
STARMag 96 X 4 Universal Cartridge Kit	Seegene	744300.4. UC384	Specimen: 300 μL Elution: 100 μL

*If you would like to purchase this product from Seegene Inc., please use this catalog number.

C-2. Microlab STARlet IVD

Note: See **Microlab STARlet IVD** operation manual.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Microlab STARlet IVD	Hamilton	173000-075*	-
STARMag 96 X 4 Universal Cartridge Kit	Seegene	744300.4. UC384	Specimen: 300 μL Elution: 100 μL

*If you would like to purchase this product from Seegene Inc., please use this catalog number.

C-3. Seegene NIMBUS

Note: See **Seegene NIMBUS** operation manual.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Seegene NIMBUS	Seegene	65415-03	-
STARMag 96 X 4 Universal Cartridge Kit	Seegene	744300.4. UC384	Specimen: 300 μL Elution: 100 μL

C-4. Seegene STARlet

Note: See **Seegene STARlet** operation manual.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Seegene STARlet	Seegene	67930-03	-
STARMag 96 X 4 Universal Cartridge Kit	Seegene	744300.4. UC384	Specimen: 300 μL Elution: 100 μL
STARMag™ S96H Kit*	Seegene	EX00032P EX00033P EX00034P EX00035P	Specimen: 300 μL Elution: 100 μL

* SurePath™ have not been validated with the STARMag™ S96H Kit.

* STARMag™ S96H Kit is designed and validated for the use with the configuration of Seegene STARlet with CO-RE 96 Probe Head and Seegene STARlet 96MPH.

Option: Automated Linkage Structure (See AIOS operation manual)

Automated Linkage Structure	Manufacturer	Cat. No.
AIOS	Seegene	SG72100

Note: Replace the cap of the Positive Control (PC) with a pierceable cap. After finishing the operation, replace the cap of the Positive Control (PC) with the original cap.

Note: The pierceable cap is a single-use product and must be disposed of after one use.

Note: If used with AIOS, this product can be used for maximum 3 separate runs.

C-5. Seegene STARlet 96MPH

Note: See **Seegene STARlet 96MPH** operation manual.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Seegene STARlet 96MPH	Seegene	SG71101	-
STARMag™ S96H Kit*	Seegene	EX00032P EX00033P EX00034P EX00035P	Specimen: 300 μL Elution: 100 μL

Note: SurePath™ has not been validated with the Seegene STARlet 96MPH.

C-6. NucliSENS® easyMAG®

- Proceed the extraction process using **'generic protocol'**.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
NucliSENS® easyMAG®	bioMérieux	200111	Specimen: 200 μL* Magnetic Silica: 50 μL Elution: 100 μL

* In case of Urine specimen, resuspend the pellet with 200 μL of saline solution and add 10 μL of ASTI IC.

Note: SurePath™ has not been validated with NucliSENS® easyMAG®.

C-7. SEEPREP32

- Proceed the extraction process using **'Pro-Protocol A'**.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
SEEPREP32	Seegene	SG71100	-
STARMag 96 ProPrep (Plate Type)	Seegene	EX00009P	Specimen: 200 μL* Elution: 100 μL
STARMag 96 ProPrep (Tube Type)	Seegene	EX00009T	Specimen: 200 μL* Elution: 100 μL

*In case of Urine specimen, resuspend the pellet with 200 μL of saline solution and add 10 μL of ASTI IC.

Note: SurePath™ has not been validated with SEEPREP32.

C-8. Maelstrom™ 9600

- Proceed the extraction process using **'STARMAGM96'**.

Automated Extraction System	Manufacturer	Cat. No.	Recommended Vol.
Maelstrom™ 9600	Taiwan Advanced Nanotech Inc.	M9600	-
STARMag™ M96 Kit	Seegene	EX00029P EX00030P	Specimen: 200 μL* Elution: 100 μL

* Add 10 μL of ASTI IC in urine specimen.

Note: SurePath™ has not been validated with Maelstrom™ 9600.

D. Manual Nucleic Acid Extraction Kits

Note: Please use the recommended volumes of specimen and elution as indicated below. For others, refer to the manufacturer's protocol.

Extraction Kit	Manufacturer	Cat. No.	Recommended Vol.
QIAamp® DSP DNA Mini Kit	QIAGEN	61304	Specimen: 200 μL**** Elution: 50 μL
QIAamp® DNA Mini Kit*	QIAGEN	51304	Specimen: 200 μL**** Elution: 50 μL
Ribo_spin vRD** (Viral RNA/DNA Extraction Kit)	GeneAll	302-150 SG1701***	Specimen: 200 μL**** Elution: 50 μL

* Process lysis step using 180 μL of ATL buffer instead of AL buffer in case of SurePath™ media.

** Ribo_spin vRD kit is not compatible with SurePath™ media.

*** If you would like to purchase the above products from Seegene Inc., please use this catalog number.

**** In case of Urine specimen, resuspend the pellet with 190 μL of saline solution and add 10 μL of ASTI IC.

E. Summary

Extraction Method		Applicated sampling device
Microlab NIMBUS IVD/ STARlet IVD		ENAT, UTM, ThinPrep®, SurePath™, Urine
Seegene NIMBUS / STARlet*	STARMag 96 X 4 Universal Cartridge Kit	ENAT, UTM, ThinPrep®, SurePath™, Urine
	STARMag™ S96H Kit**	ENAT, UTM, ThinPrep®, Urine
Seegene STARlet 96MPH**		ENAT, UTM, ThinPrep®, Urine
NucliSENS® easyMAG®		ENAT, UTM, ThinPrep®, Urine
SEEPREP32		ENAT, UTM, ThinPrep®, Urine
Maelstrom™ 9600		ENAT, UTM, ThinPrep®, Urine
QIAamp® DNA Mini Kit QIAamp® DSP DNA Mini Kit		ENAT, UTM, Q-PAP***, ThinPrep®, SurePath™****, Urine
Ribo_spin vRD (Viral RNA/DNA Extraction Kit)		ENAT, UTM, Q-PAP***, ThinPrep®, Urine

* Optional: AIOS can be used with Seegene STARlet.

** STARMag™ S96H Kit is designed and validated for the use with the configuration of Seegene STARlet with CO-RE 96 Probe Head and Seegene STARlet 96MPH.

***Qiagen cervical sampler

****Process lysis step using 180 μL of ATL buffer instead of AL buffer in case of SurePath™ media.

3. Preparation for Real-time PCR

Note: The correct tubes and caps must be used. (see MATERIALS REQUIRED BUT NOT PROVIDED)

Note: Aerosol resistant filter tips and tight gloves must be used when preparing PCR reactions. Use extreme care to ensure no cross-contamination.

Note: Completely thaw all reagents on ice.

Note: Spin down the reagent tubes to remove drops from inside of the cap.

Note: The steps A~D are automatically processed on Microlab NIMBUS IVD and Microlab STARlet IVD, Seegene NIMBUS, Seegene STARlet, and Seegene STARlet 96MPH. Refer to each operation manual.

A. Prepare the PCR Mastermix.

5 μL	4X CA MOM
5 μL	EM1
5 μL	RNase-free Water
15 μL	Total volume of PCR Mastermix

Note: Calculate the necessary amount of each reagent needed based on the number of reactions (samples + controls).

B. Mix by inverting over 5 times or quick vortex, and spin down.

C. Aliquot 15 μL of the PCR Mastermix into PCR tubes.

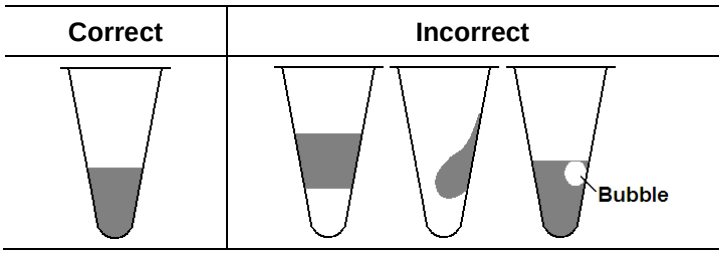
D. Add 5 μL of each sample's nucleic acids into the tube containing the PCR Mastermix.

15 μL	PCR Mastermix
5 μL	Sample's nucleic acid
20 μL	Total volume of reaction

E. Close the cap, and spin down the PCR tubes.

F. Verify that the liquid containing all PCR components is at the bottom of each PCR tube. If not, centrifuge again at a higher rpm for a longer time.

Note: The PCR tubes must be centrifuged before running PCR reaction. It needs to force the liquid to the bottom and to eliminate air bubbles.



Note: Use a new sterile pipette tip for each sample.

Note: For **Negative Control (NC)**, use 5 μL of RNase-free Water instead of sample's nucleic acid.

Note: For **Positive Control (PC)**, use 5 μL of CA PC.

Note: Please be careful not to cross-contaminate the PCR Mastermix and samples with Positive Control.

Note: Do not label the reaction tubes on its cap. Fluorescence is detected from the top of each reaction tube.

Note: Use the PX1 PCR plate sealer when using Permanent clear heat seal instead of a cap.

REAL-TIME PCR INSTRUMENT SET UP AND RESULTS ANALYSIS

1. CFX96™ Real-time PCR Detection System (CFX Manager™ Software-IVD v1.6)

1.1. Real-time PCR Instrument set up

Note: CFX96™ Real-time PCR Detection System (Bio-Rad) experiment setup can be divided into three steps: Protocol Setup, Plate Setup, and Start Run.

A. Protocol Setup

1) In the main menu, select **File** → **New** → **Protocol** to open **Protocol Editor**.

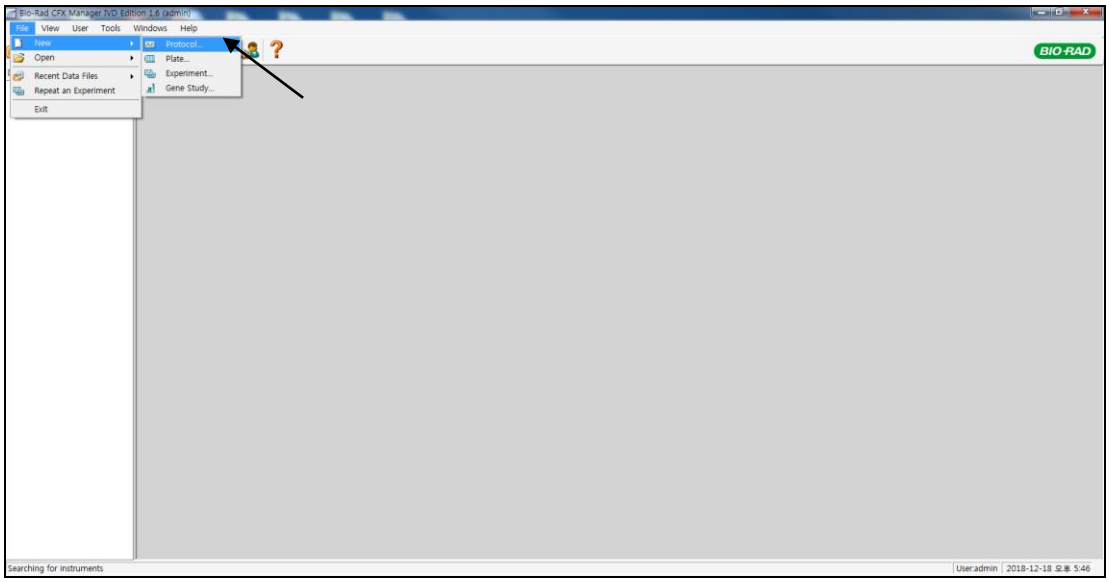


Fig. 1. **Protocol Setup**

2) In **Protocol Editor**, define the thermal profile as follows:

Step	No. of cycles	Temperature	Duration
1	1	50°C	4 min
2		95°C	15 min
3	5	95°C	30 sec
4		60°C	1 min
5		72°C	30 sec
6	GOTO 3, 4 more times		
7	40	95°C	10 sec
8*		60°C	1 min
9*		72°C	10 sec
10	GOTO 7, 39 more times		

Note*: Plate Read at Step 8 and 9. Fluorescence is detected at 60℃ and 72℃.

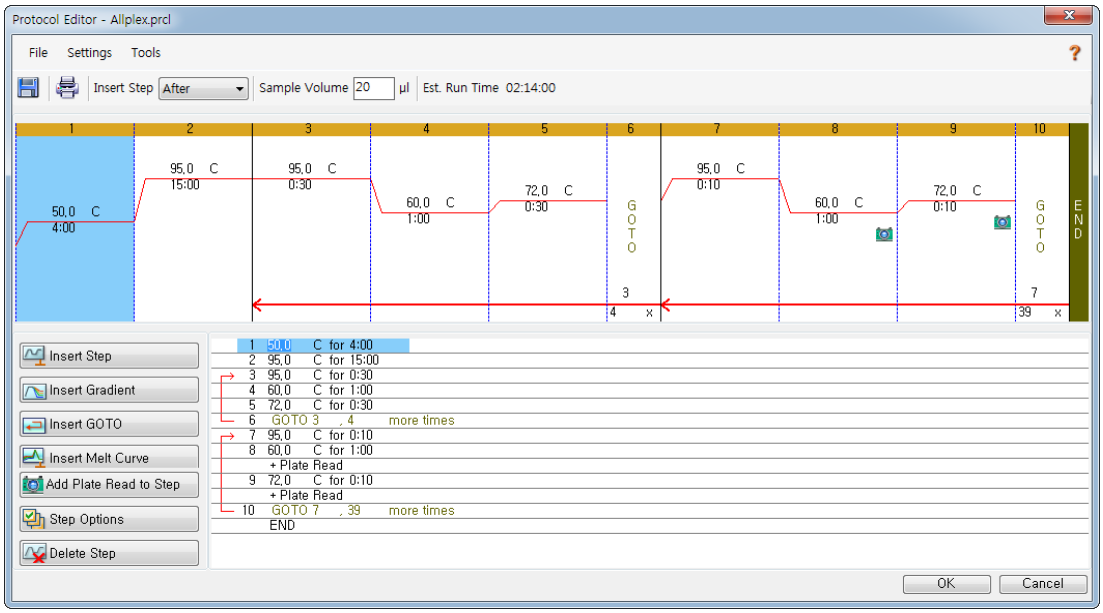


Fig. 2. **Protocol Editor**

3) Click the box next to **Sample Volume** to directly input 20 µL.

4) Click **OK** and save the protocol to open the **Experiment Setup** window.

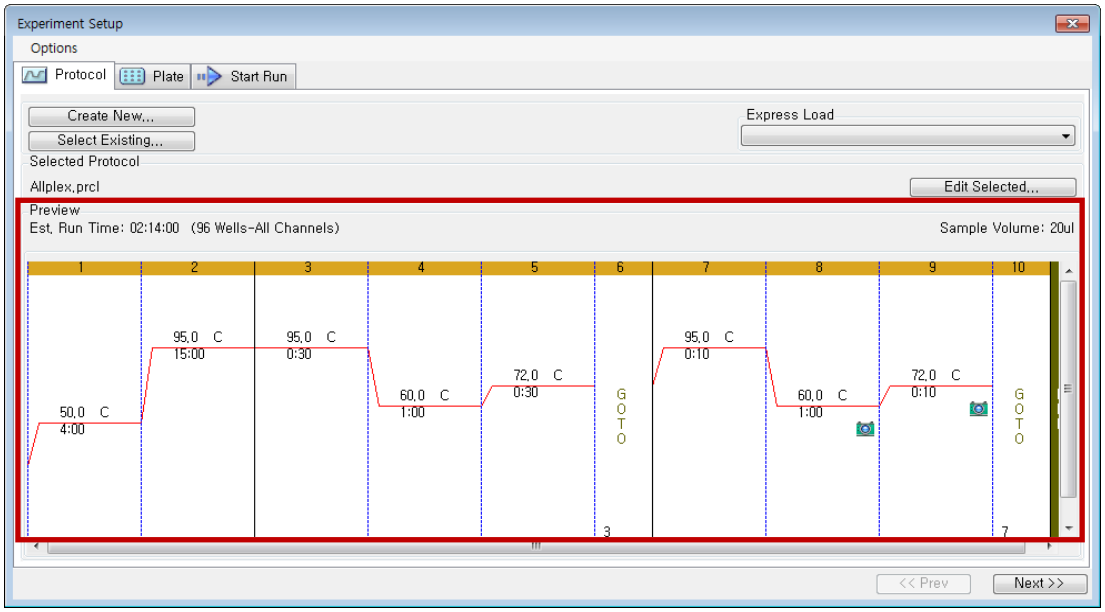


Fig. 3. **Experiment Setup: Protocol**

B. Plate Setup

1) From **Plate** tab in **Experiment Setup**, click **Create New** to open **Plate Editor** window.

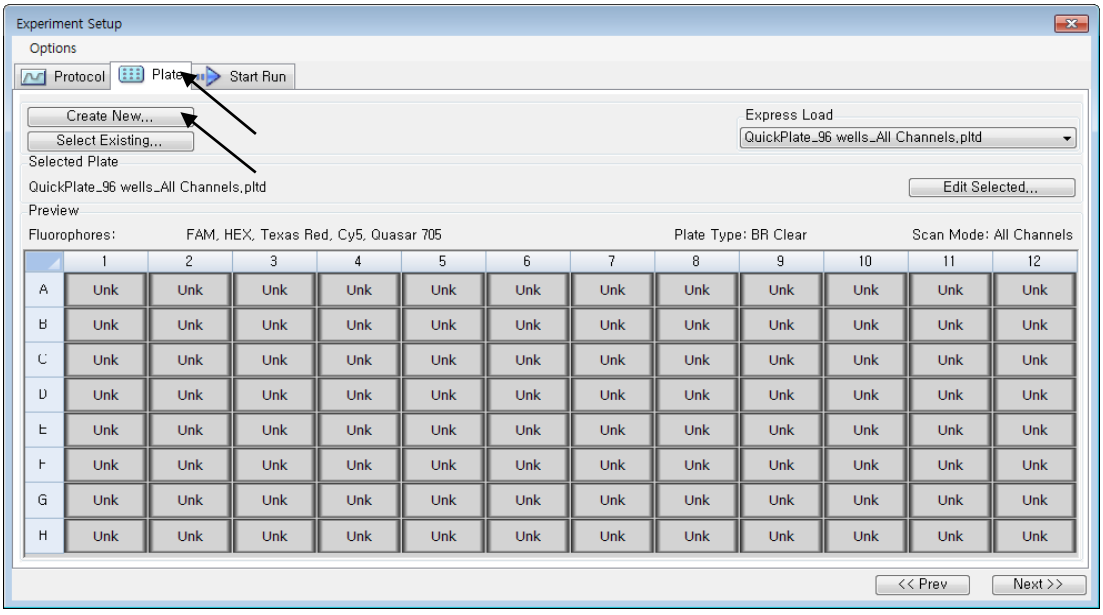


Fig. 4. **Plate Editor**

2) Click **Select Fluorophores** to indicate the fluorophores (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**) that will be used and click **OK**.

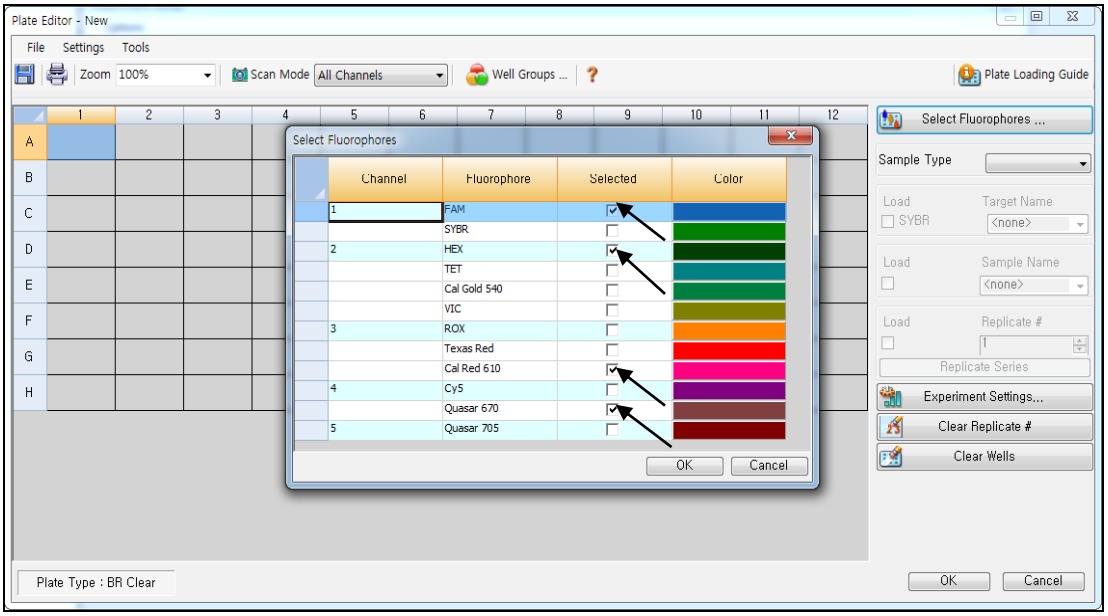


Fig. 5. **Select Fluorophores** (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**)

3) Select the wells where the PCR tube will be placed and select its sample type from the **Sample Type** drop-down menu.

- **Unknown**: Clinical samples
- **Negative Control**
- **Positive Control**

4) Click on the appropriate checkboxes (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**) to specify the fluorophores to be detected in the selected wells.

5) Type the **Sample Name** and press enter key.

6) In **Settings** of the **Plate Editor** main menu, choose the **Plate Size (96 wells)** and **Plate Type (BR White)**.

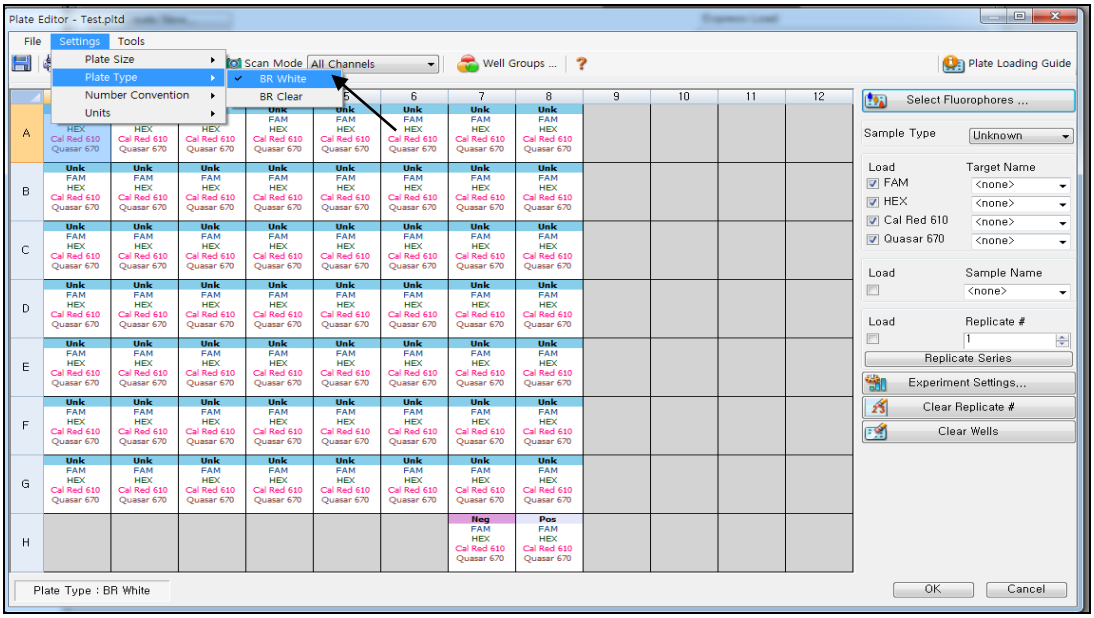


Fig. 6. **Plate Setup**

7) Click **OK** to save the new plate.

8) Return to the **Experiment Setup** window.

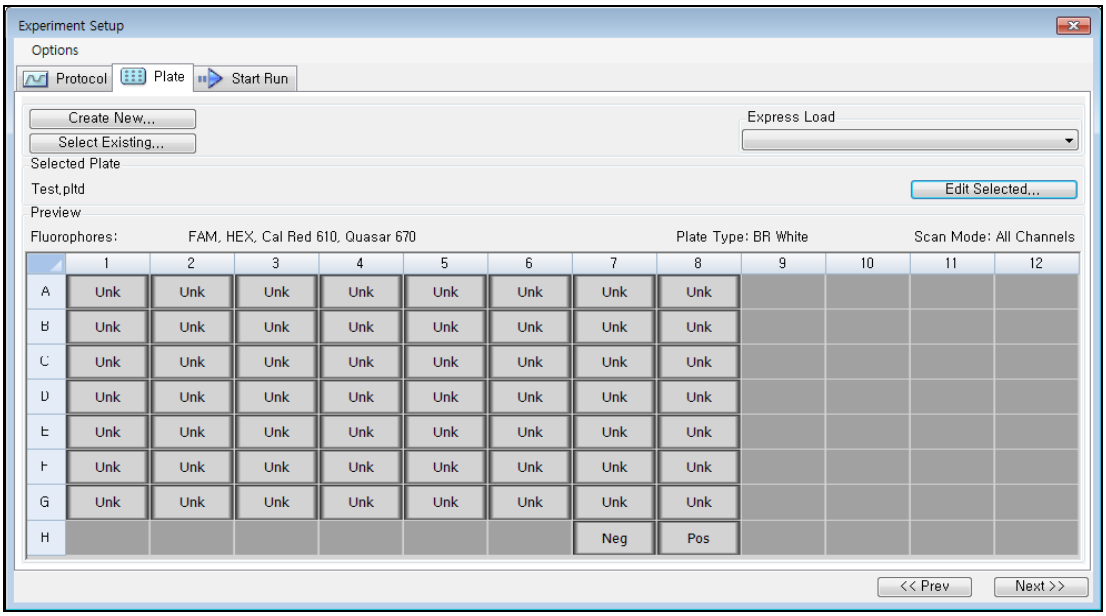


Fig. 7. **Experiment Setup: Plate**

9) Click **Next** to start run.

C. Start Run

1) From **Start Run** tab in **Experiment Setup**, click **Close Lid** to close the instrument lid.

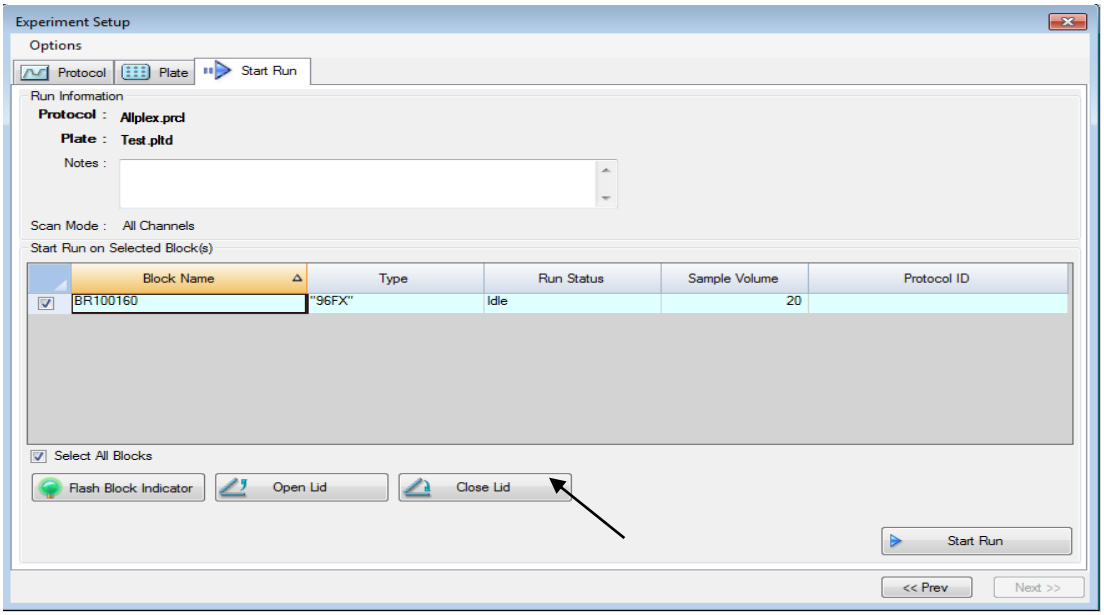


Fig. 8. **Close Lid.**

2) Click **Start Run**.

3) Store the run file either in My Documents or in a designated folder. Input the file name, click **SAVE**, and the run will start.

1.2. Data Analysis

A. Create folders for data export

1) To save data for all of amplification curve detection step from the result file, create one folder.

2) Folder name may be as desired by user (For 'Seegene Export' function, folders "QuantStep8" and "QuantStep9" are automatically created to save each amplification curve data under the folder created by user).

B. Pre-settings for Data Analysis in CFX Manager™

1) After the test, click the Quantitation tab to confirm the amplification curve results.

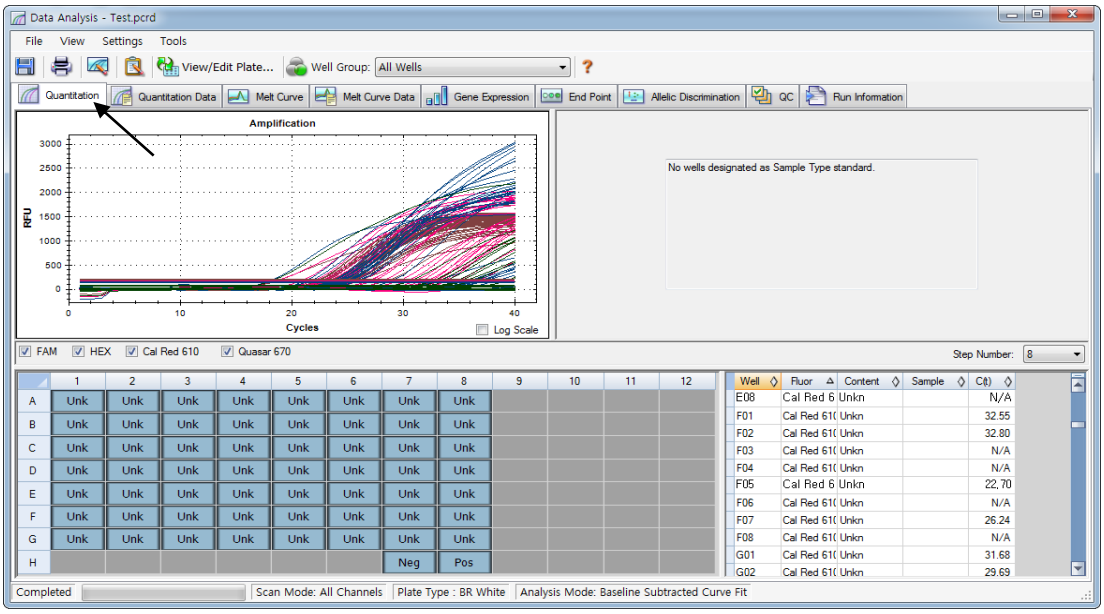


Fig. 9. **Amplification curve results**

2) Select **No Baseline Subtraction** from Analysis Mode of Settings menu.

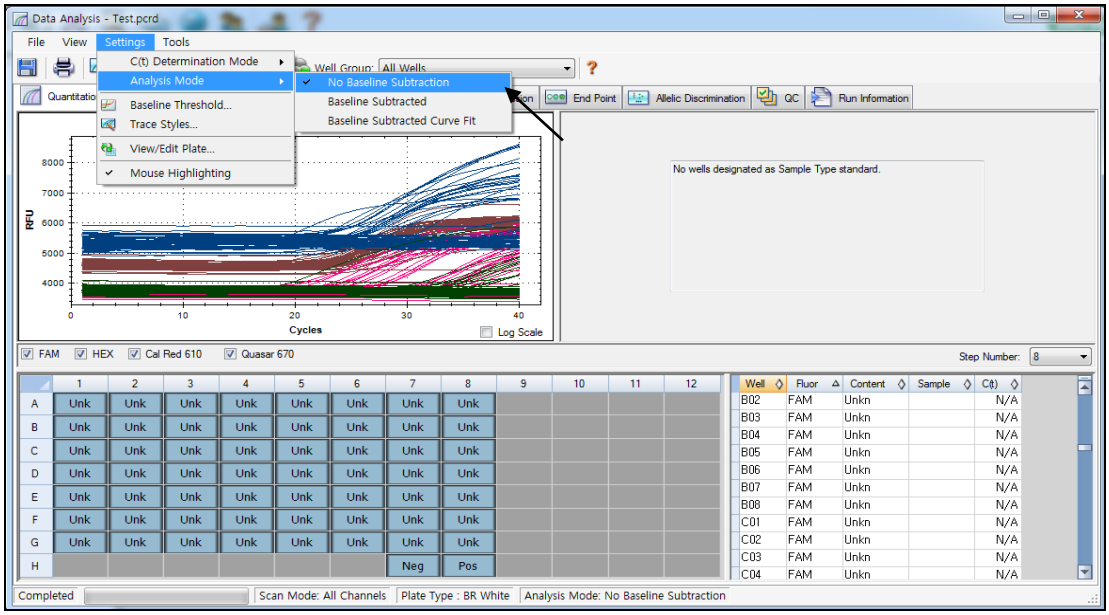


Fig. 10. **No Baseline Subtraction**

3) Select **Seegene Export** from Tools menu.

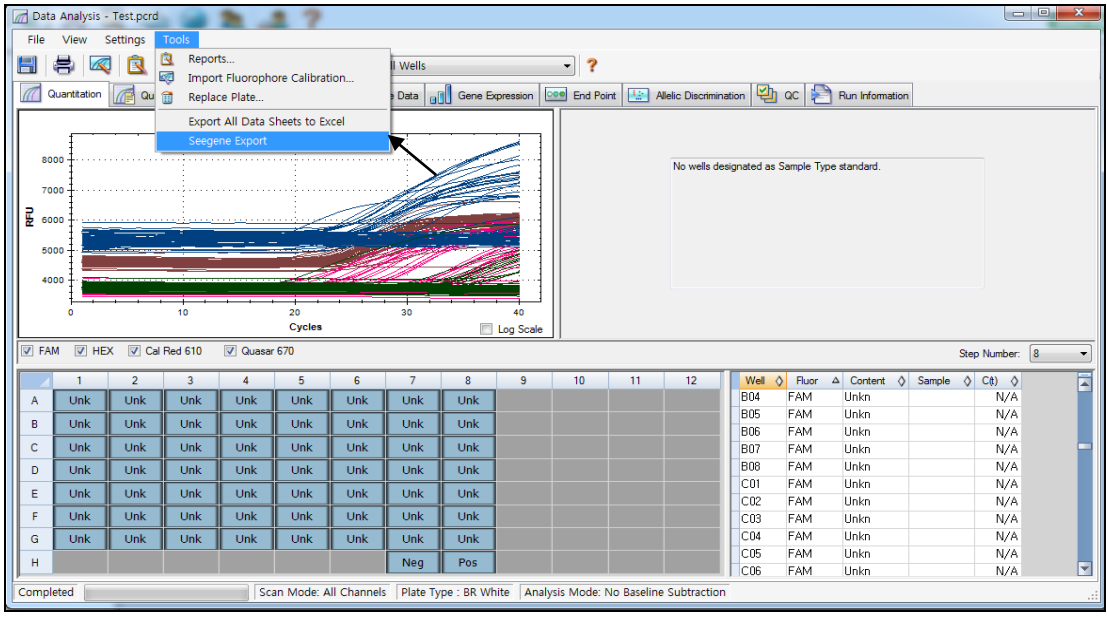


Fig. 11. **Seegene Export**

4) Choose a location to save data and click **OK**.

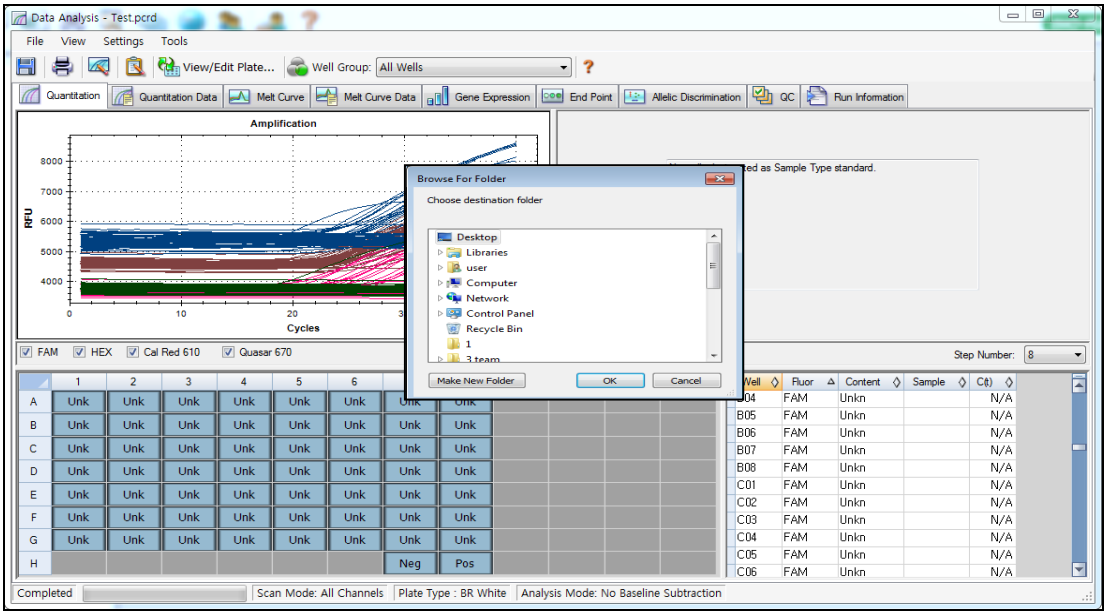


Fig. 12. **Seegene Export to designated folder**

C. Settings for Data Analysis in Seegene Viewer

1) Open Seegene Viewer program, and click **Option** to select **CFX96** in the **Instrument**.

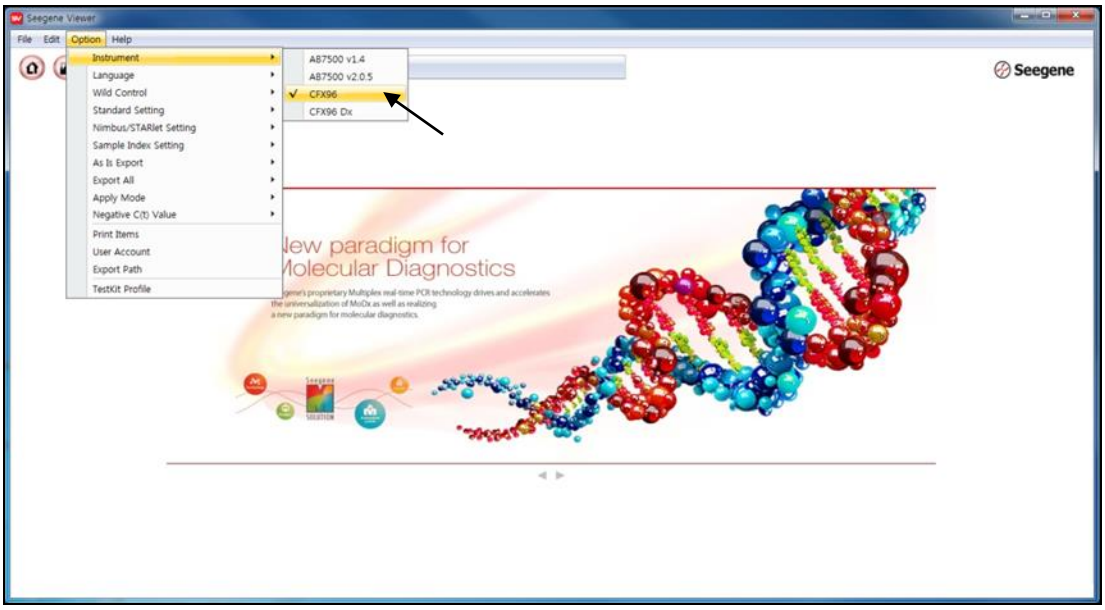


Fig. 13. **Seegene Viewer**

2) Click **Open** to find the saved file in folder “QuantStep8”, open the results file, and select the test kit from the **PRODUCT** menu.

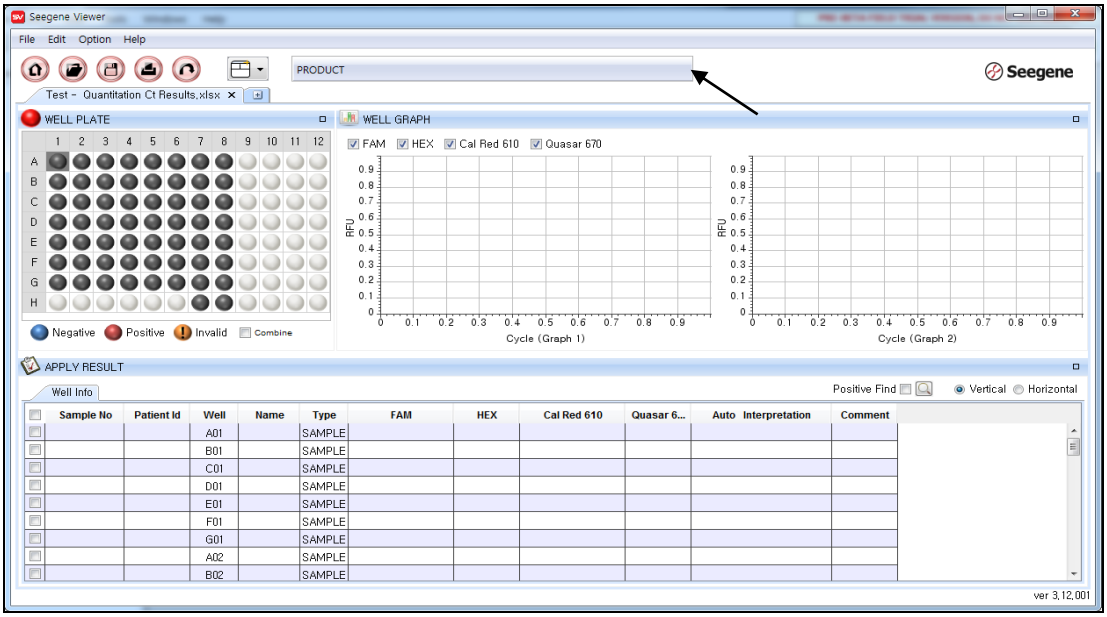


Fig. 14. **Settings for Data Analysis in Seegene Viewer**

Note: Please verify the type of tube when selecting test kit (8 strip / 96 cap / 96 film).

3) Check the result for each well.

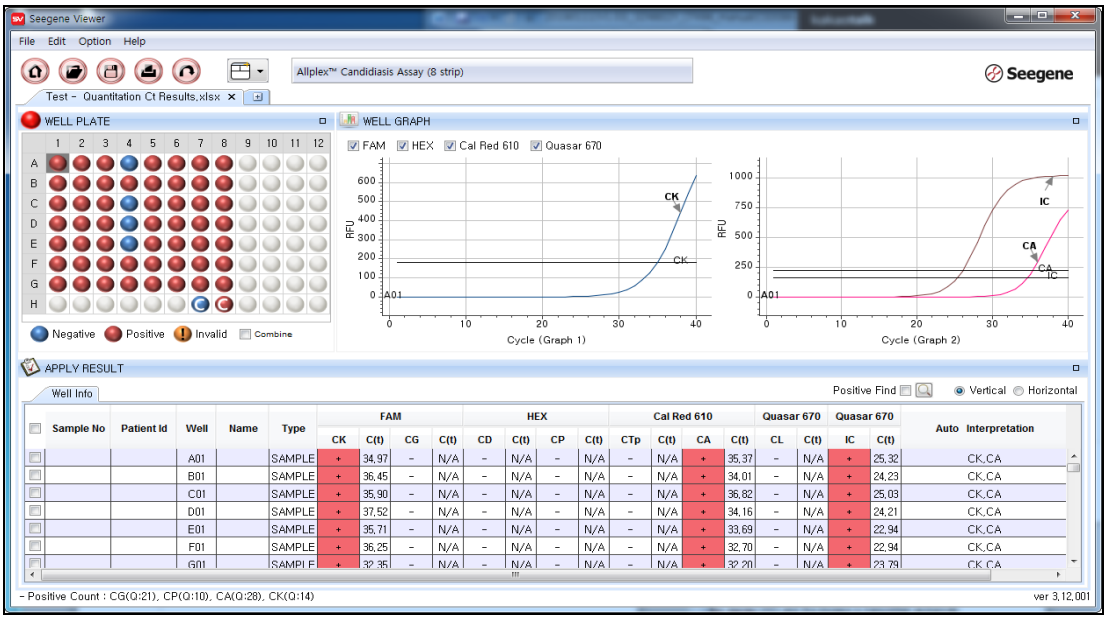


Fig. 15. **Test result on Seegene Viewer**

2. CFX96™ Dx System (CFX Manager™ Dx Software v3.1)

2.1. Real-time PCR Instrument set up

Note: CFX96™ Dx System (Bio-Rad) experiment setup can be divided into three steps: Protocol Setup, Plate Setup, and Start Run.

A. Protocol Setup

1) In the main menu, select **File** → **New** → **Protocol** to open **Protocol Editor**.

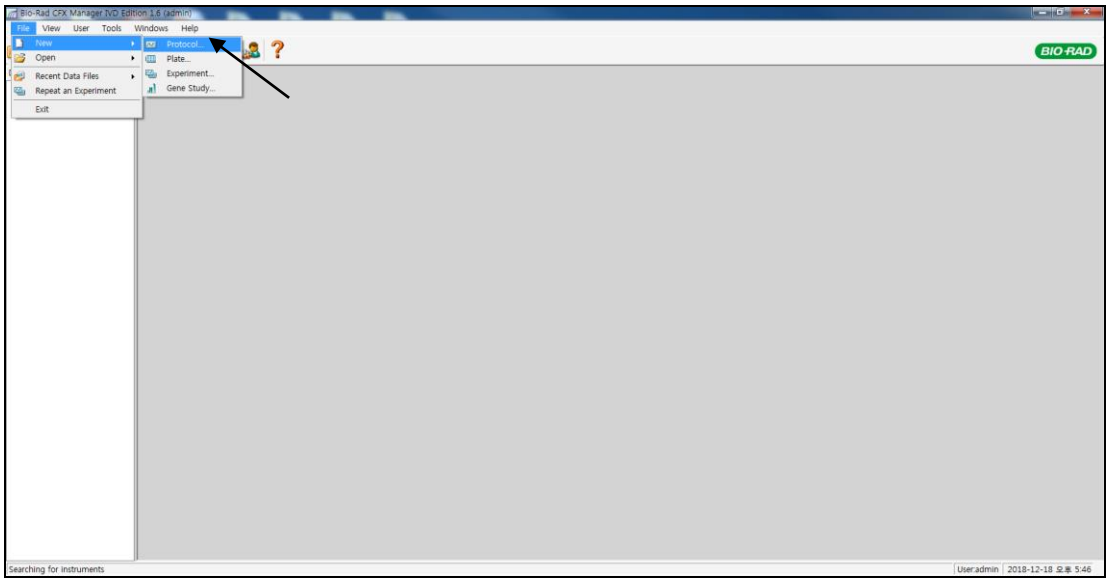


Fig. 1. **Protocol Setup**

2) In **Protocol Editor**, define the thermal profile as follows:

Step	No. of cycles	Temperature	Duration
1	1	50°C	4 min
2		95°C	15 min
3	5	95°C	30 sec
4		60°C	1 min
5		72°C	30 sec
6	GOTO 3, 4 more times		
7	40	95°C	10 sec
8*		60°C	1 min
9*		72°C	10 sec
10	GOTO Step 7, 39 more times		

Note*: Plate Read at Step 8 and 9. Fluorescence is detected at 60℃ and 72℃.

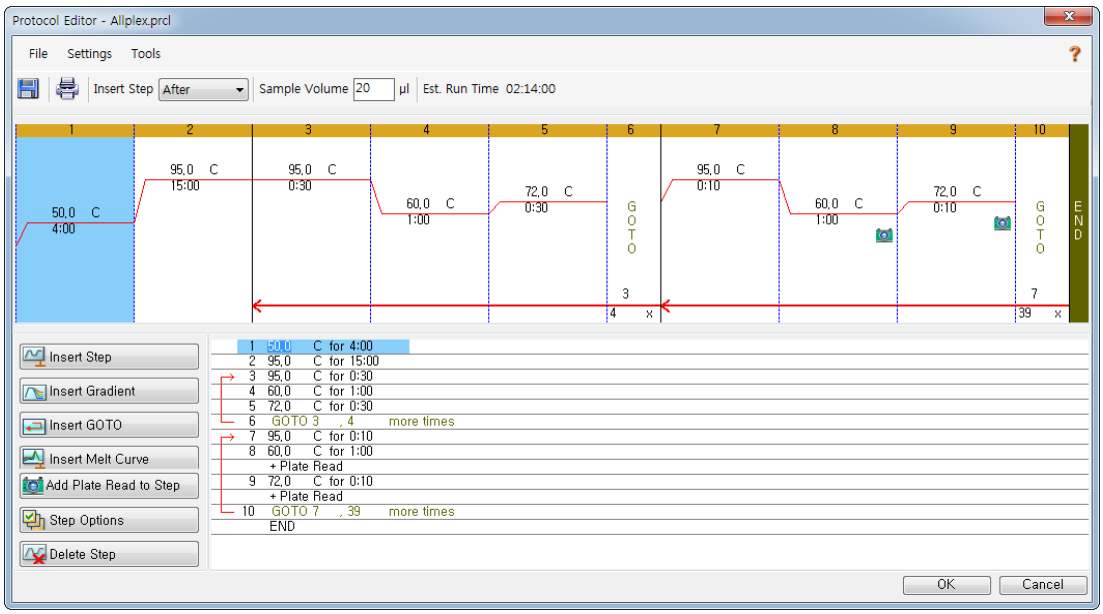


Fig. 2. **Protocol Editor**

3) Click the box next to **Sample Volume** to directly input 20 µL.

4) Click **OK** and save the protocol to open the **Run Setup** window.

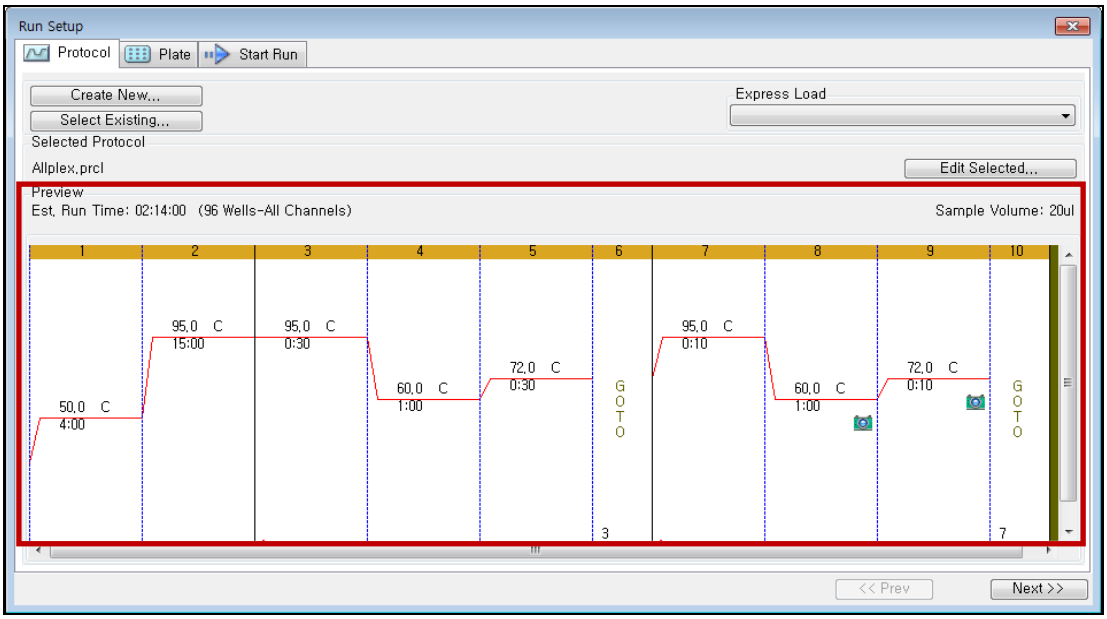


Fig. 3. **Run Setup: Protocol**

B. Plate Setup

1) From **Plate** tab in **Run Setup**, click **Create New** to open **Plate Editor** window.

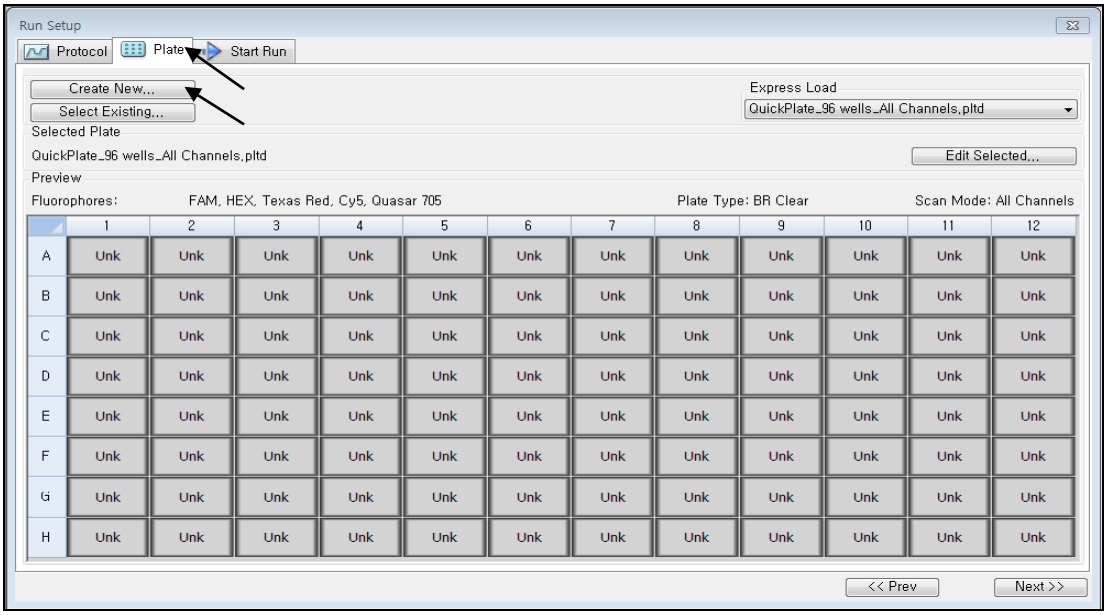


Fig. 4. **Plate Editor**

2) Click **Select Fluorophores** to indicate the fluorophores (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**) that will be used and click **OK**.

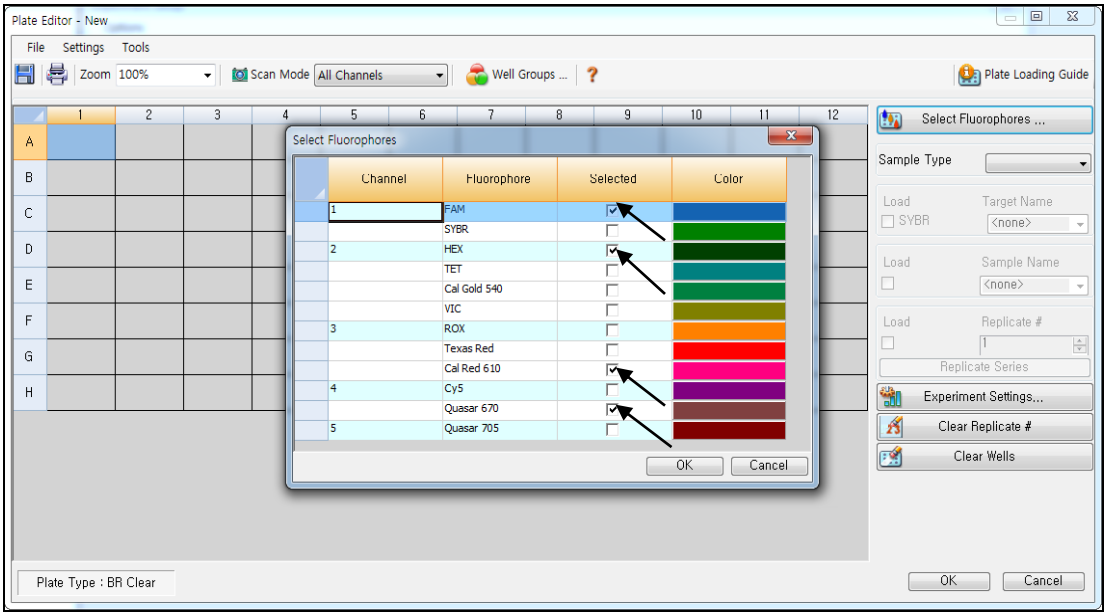


Fig. 5. **Select Fluorophores** (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**)

3) Select the wells where the PCR tube will be placed and select its sample type from the **Sample Type** drop-down menu.

- **Unknown**: Clinical samples
- **Negative Control**
- **Positive Control**

4) Click on the appropriate checkboxes (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**) to specify the fluorophores to be detected in the selected wells.

5) Type the **Sample Name** and press enter key.

6) In **Settings** of the **Plate Editor** main menu, choose the **Plate Size (96 wells)** and **Plate Type (BR White)**.

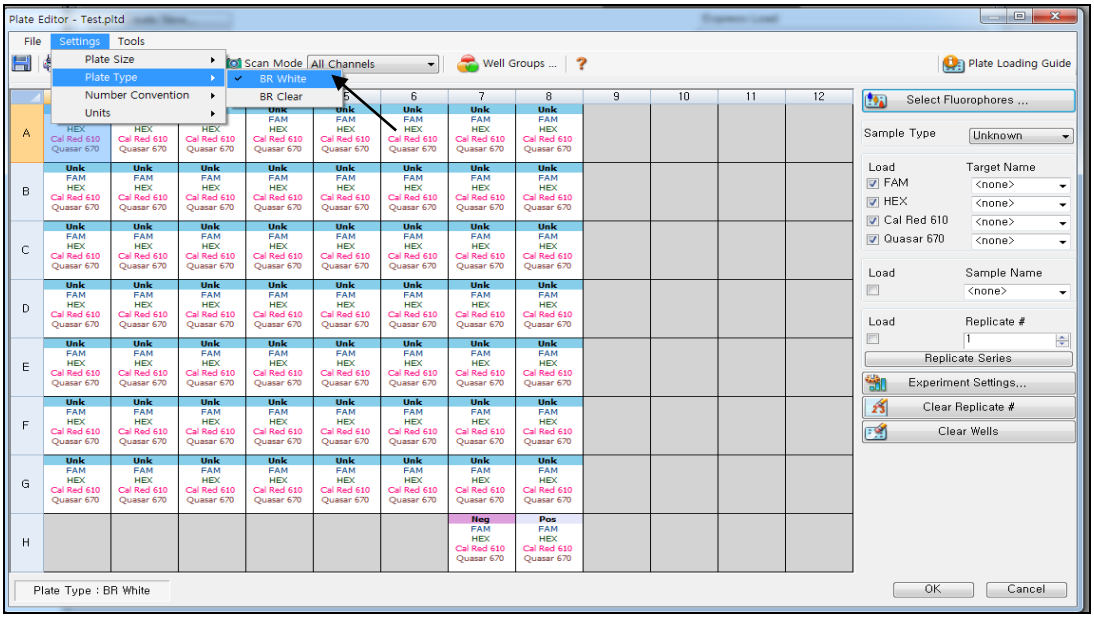


Fig. 6. **Plate Setup**

7) Click **OK** to save the new plate.

8) Return to the **Run Setup** window.

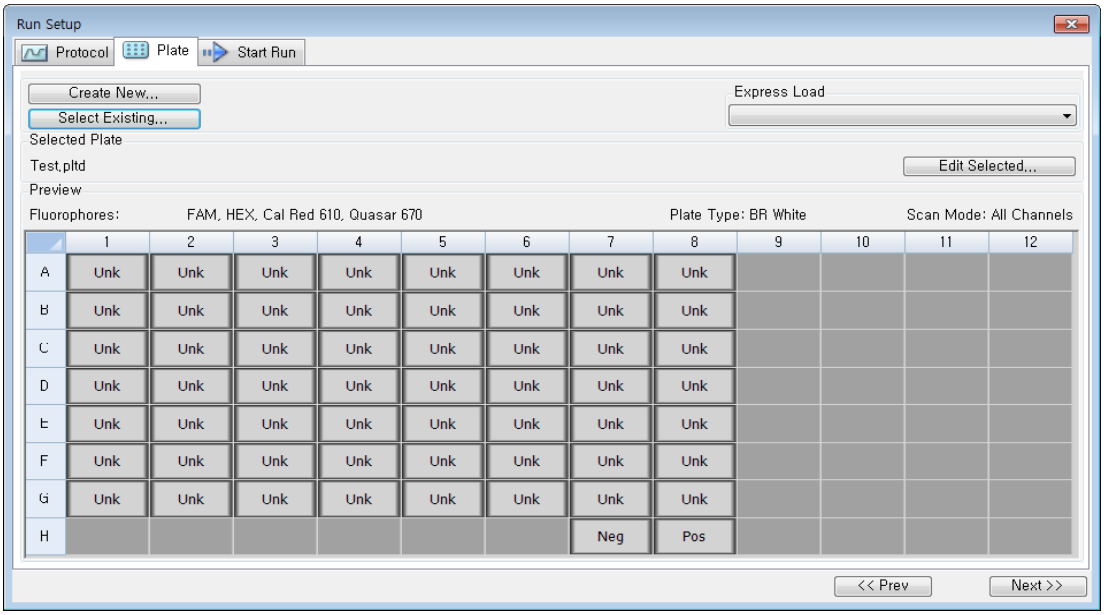


Fig. 7. **Run Setup: Plate**

9) Click **Next** to start run.

C. Start Run

1) From **Start Run** tab in **Run Setup**, click **Close Lid** to close the instrument lid.

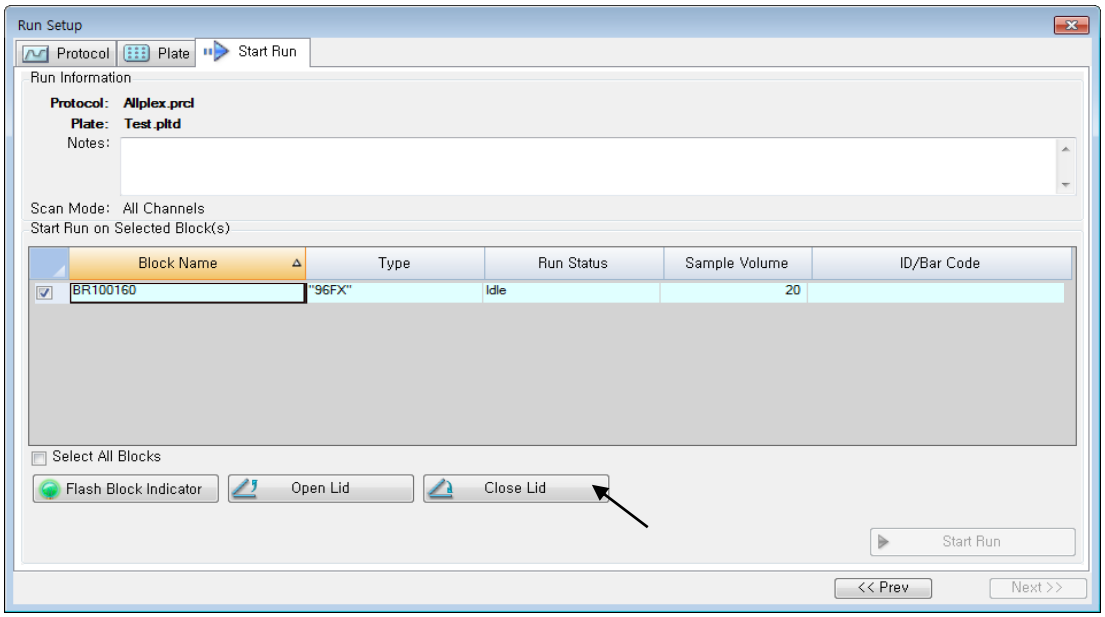


Fig. 8. **Close Lid.**

2) Click **Start Run**.

3) Store the run file either in My Documents or in a designated folder. Input the file name, click **SAVE**, and the run will start.

2.2. Data Analysis

A. Create folders for data export

1) To save data for all of amplification curve detection step from the result file, create one folder.

2) Folder name may be as desired by user (For 'Seegene Export' function, folders "QuantStep8" and "QuantStep9" are automatically created to save each amplification curve data under the folder created by user).

B. Pre-settings for Data Analysis in CFX Manager™

1) After the test, click the Quantification tab to confirm the amplification curve results.

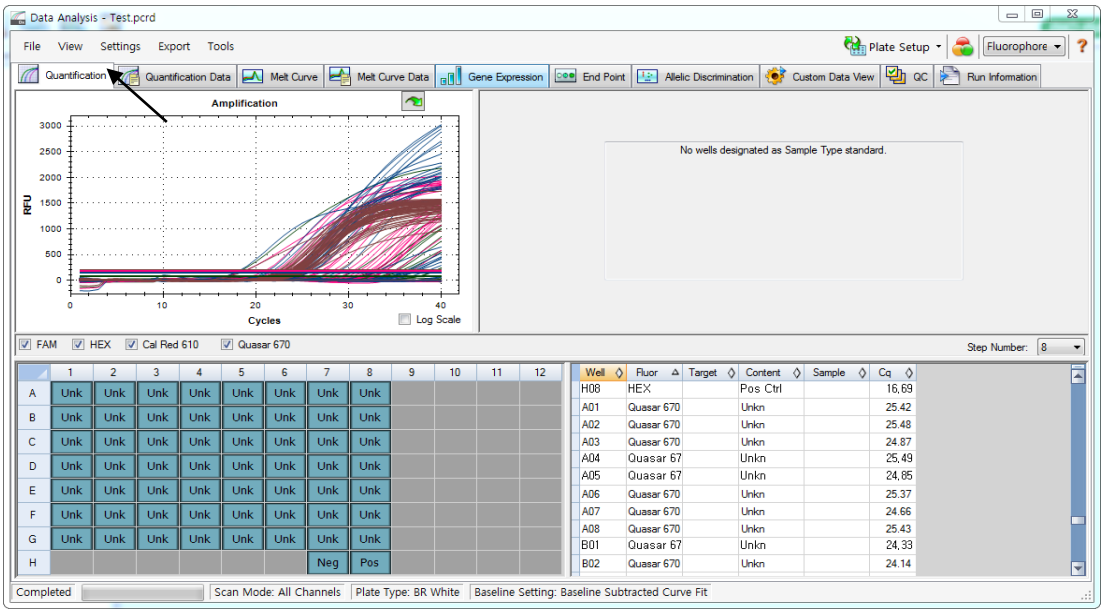


Fig. 9. **Amplification curve results**

2) Select **No Baseline Subtraction** from **Baseline Setting** of Settings menu.

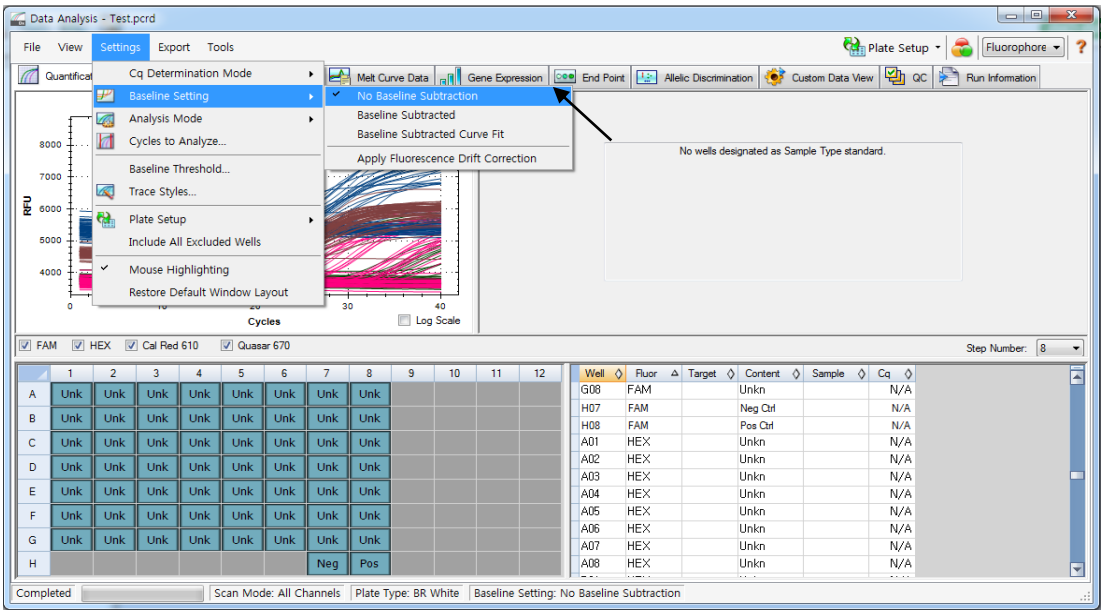


Fig. 10. **No Baseline Subtraction**

3) Select **Seegene Export** from **Export** menu.

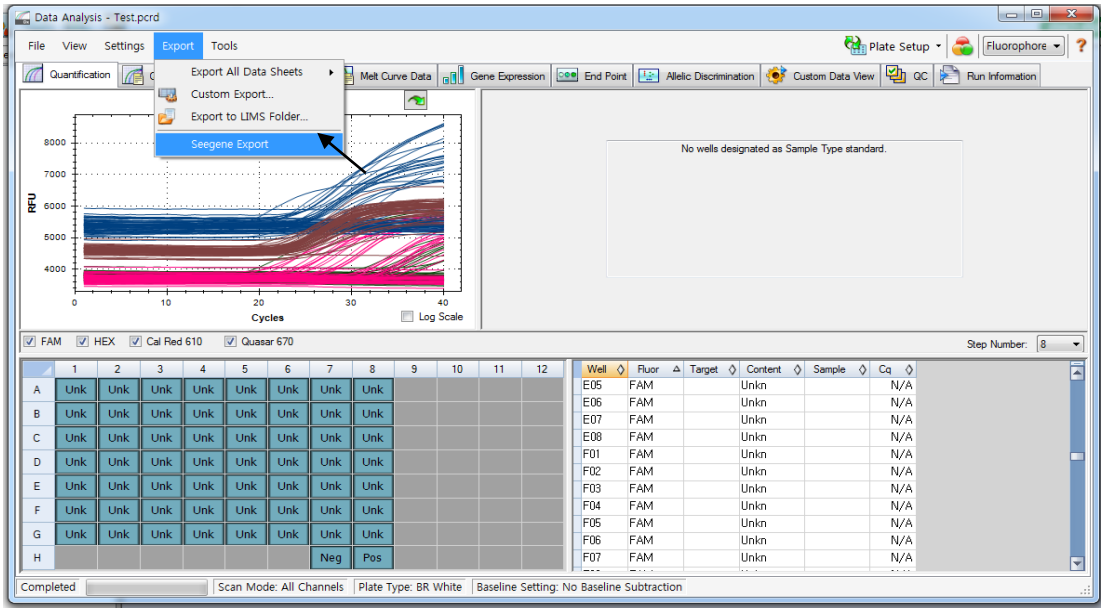


Fig. 11. **Seegene Export**

4) Choose a location to save data and click **OK**.

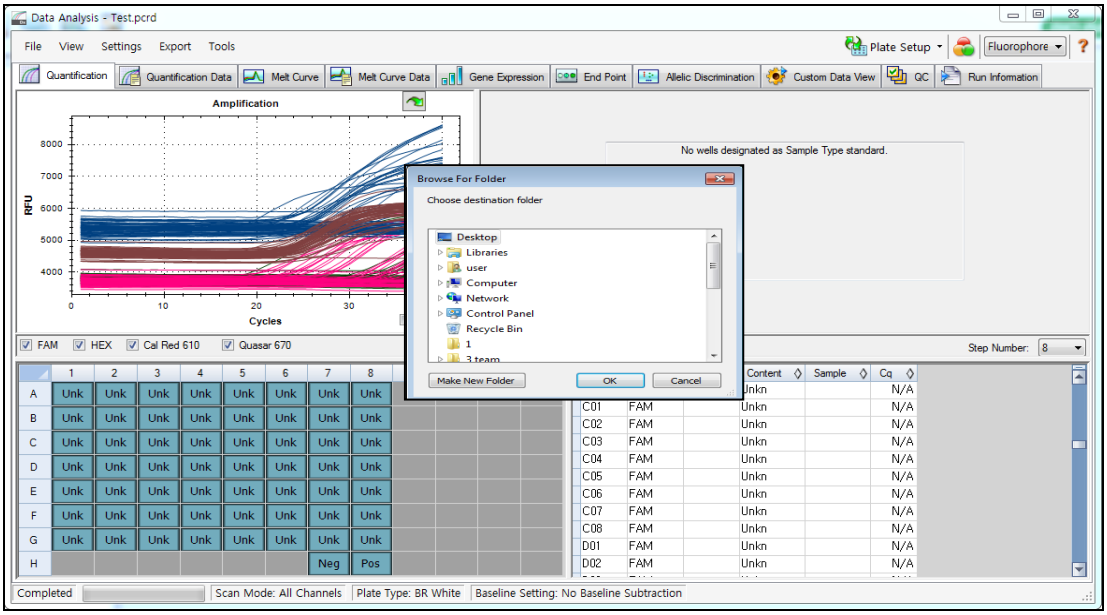


Fig. 12. **Seegene Export to designated folder**

C. Settings for Data Analysis in Seegene Viewer

1) Open Seegene Viewer program, and click **Option** to select **CFX96 Dx** in the **Instrument**.

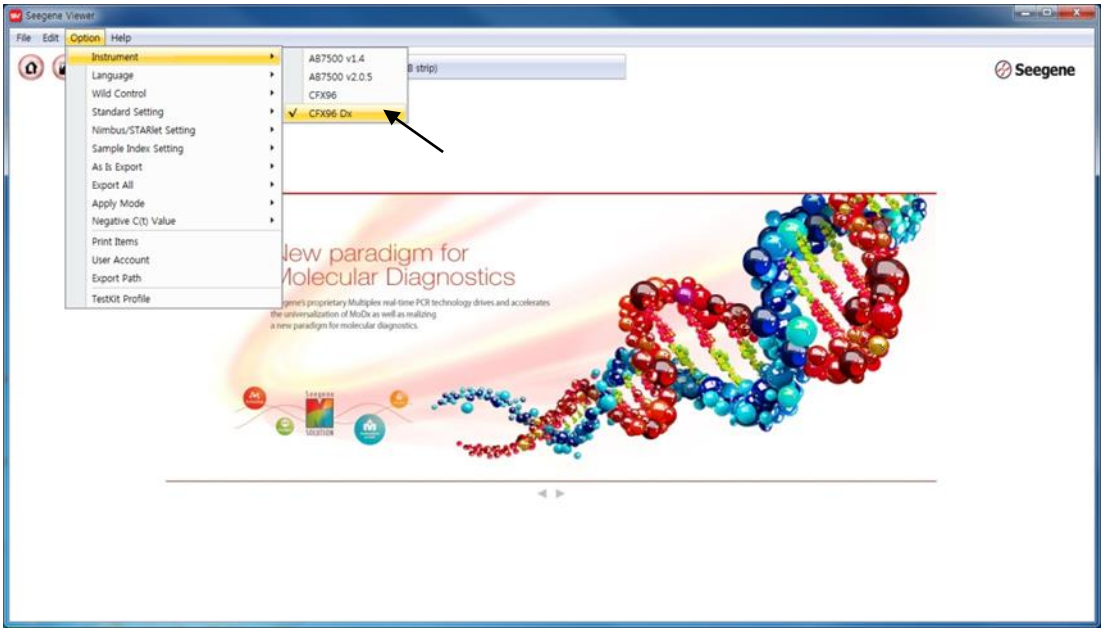


Fig. 13. **Seegene Viewer**

2) Click **Open** to find the saved file in folder “QuantStep8”, open the results file, and select the test kit from the **PRODUCT** menu.

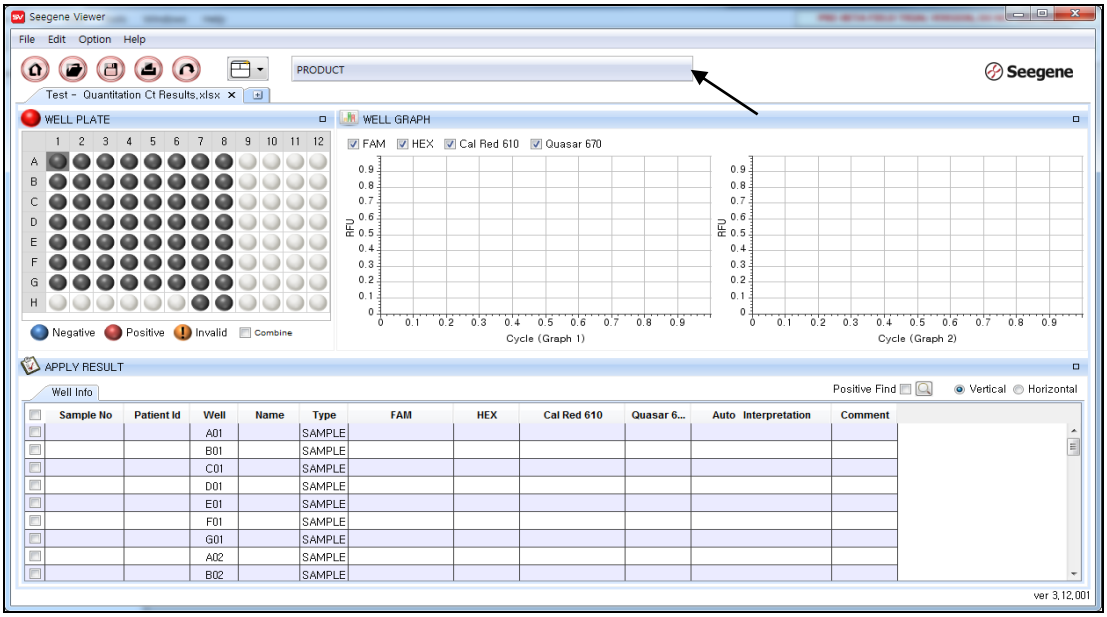


Fig. 14. **Settings for Data Analysis in Seegene Viewer**

Note: Please verify the type of tube when selecting test kit (8 strip / 96 cap / 96 film).

3) Check the result for each well.

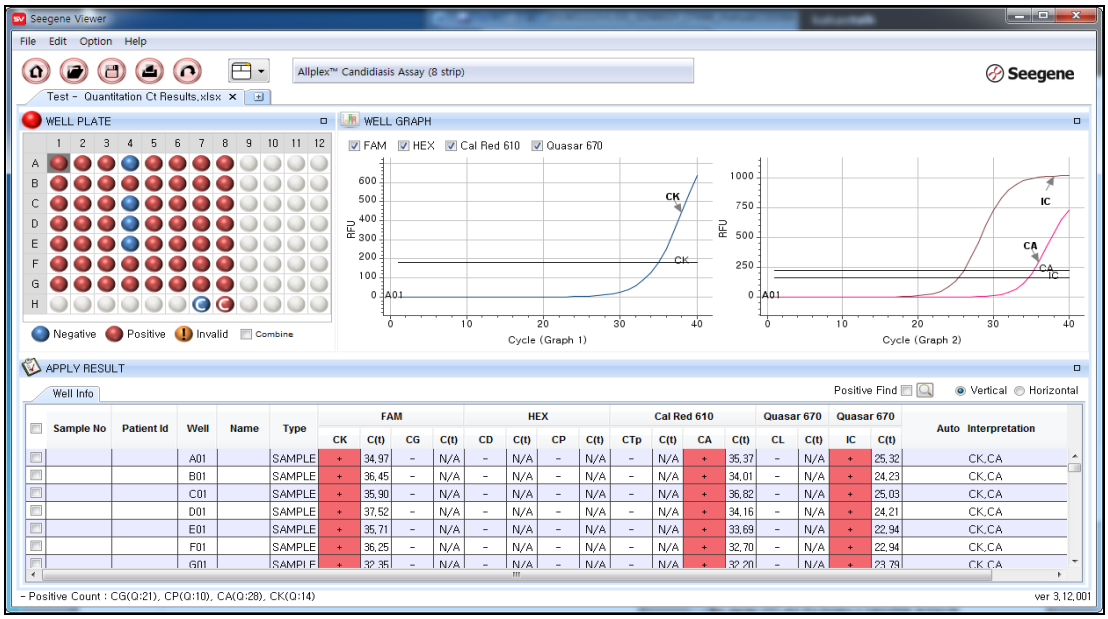


Fig. 15. **Test result on Seegene Viewer**

RESULTS

1. Analytes Information

Fluorophore	Analyte	
	Graph 1	Graph 2
FAM	*Candida krusei* (CK)	*Candida glabrata* (CG)
HEX	*Candida dubliniensis* (CD)	*Candida parapsilosis* (CP)
Cal Red 610	*Candida tropicalis* (CTp)	*Candida albicans* (CA)
Quasar 670	*Candida lusitaniae* (CL)	Internal Control (IC)

2. Interpretation of Results

Analyte	Ct value	Result
Targets	≤ 40	Detected (+)
	N/A	Not detected (-)
IC	≤ 40	Detected (+)
	N/A	Not detected (-)

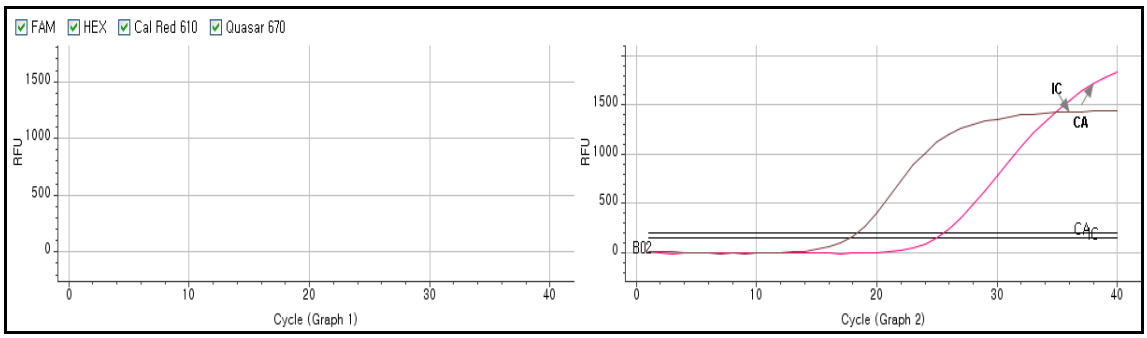
Target Result		IC Result	Interpretation
Graph 1	Graph 2		
+	-	+	**Target Nucleic acid, Detected**
-	+		
+	+		
+	-	-	**Target Nucleic acid, Detected*** - Additional Candida targets that were not detected may be present.
-	+		
+	+		
-	-	+	**Target Nucleic acid, Not detected**
-	-	-	**Invalid**** - Weak or negative IC signal suggests inadequate specimen collection, processing or presence of inhibitors. - Repeat the test from the nucleic acid extraction using another aliquot of the original specimen. - If the same result is shown in the re-extracted nucleic acid, please dilute (1/3~1/10) the specimen in saline solution and repeat the test from the extraction.

* Detection of Internal Control in the Quasar 670 channel is not required for positive results of target pathogens. High titer of another analyte may lead to reduced or absent Internal Control signal.

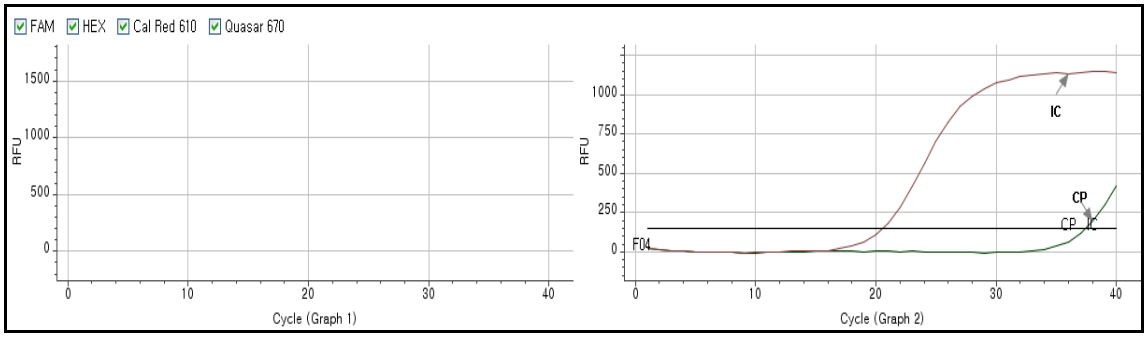
** If none of the signals including Internal Control is observed, see TROUBLESHOOTINGS.

3. Application to Clinical Samples

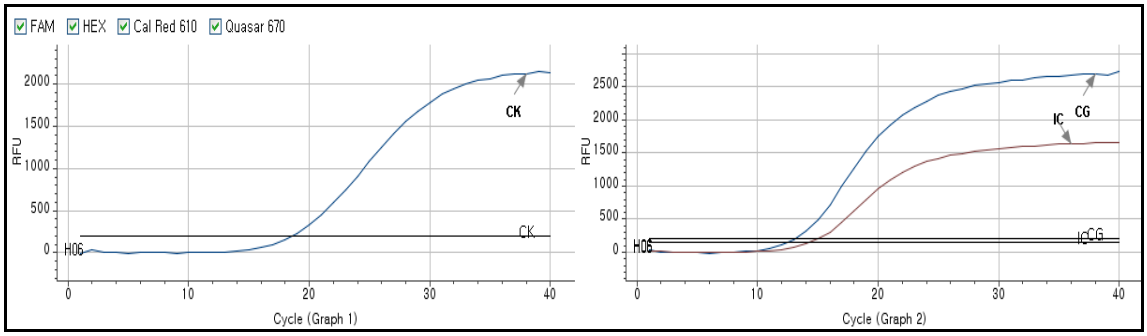
Sample 1



Sample 2



Sample 3



Sample	FAM				HEX				Cal Red 610				Quasar 670		Quasar 670		Auto Interpretation
	CK	Ct	CG	Ct	CD	Ct	CP	Ct	CTp	Ct	CA	Ct	CL	Ct	IC	Ct	
1	-	N/A	-	N/A	-	N/A	-	N/A	-	N/A	+	25.59	-	N/A	+	17.80	CA
2	-	N/A	-	N/A	-	N/A	+	37.41	-	N/A	-	N/A	-	N/A	+	20.59	CP
3	+	18.57	+	13.13	-	N/A	-	N/A	-	N/A	-	N/A	-	N/A	+	14.35	CK, CG

TROUBLESHOOTINGS

Allplex™ Candidiasis Assay		
OBSERVATION	**PROBABLE CAUSES**	**SOLUTION**
No signal	The fluorophores for data analysis do not comply with the protocol	Select the correct fluorophores for data analysis.
	Incorrect setting of real-time thermal cycler	Please check the thermal cycling conditions and repeat the test under the correct settings.
	Incorrect storage or past expiration date of the test kit	Please check the storage conditions (See page 10) and the expiration date (refer to label) of the test kit and use a new kit if necessary.
	Nucleic acid extraction failure	If IC had been added to the specimen prior to extraction, absent signal of IC may indicate loss of nucleic acid during the extraction. Make sure that you use recommended extraction method. If due to inhibitors, re-extract the original specimen or the specimen may be diluted with saline solution 1/3~1/10 fold and then add ASTI IC to the diluted specimen. ASTI IC should be used only for urine specimen.
No Internal Control signal	High load of pathogen's nucleic acid	If target pathogen signal is observed but not IC, then IC amplification may have been inhibited by high titer of target pathogen.
	Presence of PCR Inhibitor	Please dilute the template nucleic acid (1/10~1/100) in RNase-free Water and repeat the test with the diluted nucleic acid. If specimen is still present, dilute the specimen (1/10~1/100) in Saline solution and repeat the test with the diluted specimen.
Spikes in any cycles of amplification curve	Bubble in the PCR tube	Centrifuge the PCR tube before run.

Allplex™ Candidiasis Assay		
OBSERVATION	**PROBABLE CAUSES**	**SOLUTION**
Putative False positive or target signals observed in Negative Control	Contamination	Decontaminate all surfaces and instruments with sodium hypochlorite and ethanol. Only use filter tips throughout the procedure and change tips between tubes. Repeat the entire procedure from nucleic acid extraction with the new set of reagents.
Putative False negative or no signal observed in Positive Control	Error in specimen collection	Please check the specimen collection method, and re-collect the specimen.
	Incorrect storage of the specimen	Please re-collect the specimen and repeat the entire procedure. Ensure that the specimen is stored as recommended.
	Error in nucleic acid extraction	Please check the nucleic acid extraction procedure as well as nucleic acid concentration, and re-extract the nucleic acid.
	Error in adding nucleic acid to corresponding PCR tubes	Check the sample numbers of tubes containing nucleic acid and make sure to add nucleic acid into the correct PCR tubes and carefully repeat the test if necessary.
	Presence of inhibitor	Please dilute the template nucleic acid (1/10~1/100) in RNase-free Water and repeat the test with the diluted nucleic acid. If specimen is still present, dilute the specimen (1/10~1/100) in saline solution and repeat the test with the diluted specimen.
	Incorrect PCR mixture	Confirm that all components are added to the PCR mixture (Sensitivity is compromised with pre-composed premix). All reagents must be homogenized and spun down before use.

PERFORMANCE

1. Specificity

The high specificity of Allplex™ Candidiasis Assay is ensured by the oligos designed specifically for the targets of interest and the set reaction conditions. Allplex™ Candidiasis Assay was tested for cross-reactivity to 122 different pathogens, and PCR amplification and detection was only identified in the specified targets.

NO.	Organism	Source	Isolate No.	Result †
1	*Candida albicans*	ATCC	10231D-5	CA Detected
2	*Candida dubliniensis*	KCTC	17427	CD Detected
3	*Candida glabrata*	ATCC	36909D	CG Detected
4	*Candida krusei*	KCCM	50633	CK Detected
5	*Candida lusitaniae*	KCCM	50541	CL Detected
6	*Candida parapsilosis*	KCTC	7653	CP Detected
7	*Candida tropicalis*	KCTC	7212	CTp Detected
8	*Acinetobacter baumannii*	ATCC	15308	Not Detected
9	*Acinetobacter schindleri*	KCTC	12409	Not Detected
10	*Acinetobacter ursingii*	KCTC	12410	Not Detected
11	*Atopobium parvulum*	KCTC	3663	Not Detected
12	*Atopobium vaginae*	ATCC	BAA-55	Not Detected
13	*Bacteroides caccae*	KCTC	5132	Not Detected
14	*Bacteroides fragilis*	KCTC	3688	Not Detected
15	*Bacteroides ovatus*	KCTC	5827	Not Detected
16	*Bacteroides vulgatus*	KCCM	11423	Not Detected
17	*Bacteroides xylanisolvens*	KCTC	15192	Not Detected
18	*Bifidobacterium adolescentis*	KCCM	11206	Not Detected
19	*Bifidobacterium longum*	KCCM	11953	Not Detected
20	*Bifidobacterium minimum*	KCTC	3273	Not Detected
21	*Candida orthopsilosis*	ATCC	96139	Not Detected
22	*Candida metapsilosis*	ATCC	96144D	Not Detected
23	*Chlamydia trachomatis*	ATCC	VR-1500	Not Detected
24	*Chlamydia trachomatis* (LGV I)	ATCC	VR-901B	Not Detected

25	*Chlamydia trachomatis* (LGV II)	Advanced	08-931-000	Not Detected
26	*Chlamydia trachomatis* (LGV III)	ATCC	VR-903	Not Detected
27	*Chlamydia trachomatis* (serovar A)	ATCC	VR-571B	Not Detected
28	*Chlamydia trachomatis* (serovar B)	ATCC	VR-573	Not Detected
29	*Chlamydia trachomatis* (serovar Ba)	ATCC	VR-347	Not Detected
30	*Chlamydia trachomatis* (serovar C)	ATCC	VR-1477	Not Detected
31	*Chlamydia trachomatis* (serovar D)	ATCC	VR-885	Not Detected
32	*Chlamydia trachomatis* (serovar E)	ATCC	VR-348B	Not Detected
33	*Chlamydia trachomatis* (serovar F)	ATCC	VR-346	Not Detected
34	*Chlamydia trachomatis* (serovar G)	ATCC	VR-878	Not Detected
35	*Chlamydia trachomatis* (serovar H)	ATCC	VR-879D	Not Detected
36	*Chlamydia trachomatis* (serovar I)	ATCC	VR-880	Not Detected
37	*Chlamydia trachomatis* (serovar J)	ATCC	VR-886	Not Detected
38	*Chlamydia trachomatis* (serovar K)	ATCC	VR-887	Not Detected
39	*Chlamydophila pneumonidae*	ATCC	VR-1360	Not Detected
40	*Chlamydophila psittaci*	ATCC	VR-125	Not Detected
41	*Clostridium difficile* (Toxin A+ / B+)	ATCC	9689	Not Detected
42	*Clostridium perfringens*	ATCC	13124	Not Detected
43	*Cytomegalovirus* (CMV)	ATCC	VR-807	Not Detected
44	*Enterococcus avium*	ATCC	49603D	Not Detected
45	Epstein Barr Virus	ATCC	VR-602	Not Detected
46	*Escherichia coli*	ATCC	15489	Not Detected
47	*Gardnerella vaginalis*	ATCC	49145D	Not Detected
48	*Haemophilus ducreyi*	ATCC	700724D-5	Not Detected
49	*Haemophilus influenzae*	ATCC	51907D	Not Detected
50	Hepatitis A virus (HAV)	ATCC	VR-1402	Not Detected
51	Hepatitis B virus (HBV)	NIBSC	10/264	Not Detected
52	Hepatitis C virus (HCV)	NIBSC	06/102	Not Detected
53	Human herpesvirus 1	ATCC	VR-260	Not Detected
54	Human herpesvirus 2	ATCC	VR-734	Not Detected
55	Human herpesvirus 3	ATCC	VR-1367	Not Detected
56	Human Papilloma Virus 16	ATCC	45113D	Not Detected
57	Human Papilloma Virus 18	ATCC	45152D	Not Detected
58	*Lactobacillus acidophilus*	KCCM	32820	Not Detected

59	*Lactobacillus amylovorus*	KCCM	40431	Not Detected
60	*Lactobacillus brevis*	KCCM	40399	Not Detected
61	*Lactobacillus casei*	KCCM	12452	Not Detected
62	*Lactobacillus crispatus*	KCTC	5054	Not Detected
63	*Lactobacillus delbrueckii* subsp. *delbrueckii*	KCCM	35468	Not Detected
64	*Lactobacillus fermentum*	KCCM	40401	Not Detected
65	*Lactobacillus fornicalis*	ATCC	700934	Not Detected
66	*Lactobacillus gallinarum*	KCCM	40987	Not Detected
67	*Lactobacillus gasseri*	KCTC	3163	Not Detected
68	*Lactobacillus helveticus*	KCCM	41823	Not Detected
69	*Lactobacillus iners*	ATCC	55195	Not Detected
70	*Lactobacillus intestinalis*	KCCM	40990	Not Detected
71	*Lactobacillus jensenii*	KCTC	5194	Not Detected
72	*Lactobacillus johnsonii*	KCCM	32825	Not Detected
73	*Lactobacillus kefiranofaciens*	KCCM	41275	Not Detected
74	*Lactobacillus oris*	KCCM	40993	Not Detected
75	*Lactobacillus parabuchneri*	KCTC	3503	Not Detected
76	*Lactobacillus pentosus*	KCCM	40997	Not Detected
77	*Lactobacillus plantarum*	KCCM	12116	Not Detected
78	*Lactobacillus reuteri*	KCCM	23272	Not Detected
79	*Lactobacillus rhamnosus*	KCCM	32405	Not Detected
80	*Lactobacillus salivarius* subsp. *salicinius*	KCCM	40998	Not Detected
81	*Lactobacillus sanfrancisensis*	ATCC	27651	Not Detected
82	*Lactobacillus ultunensis*	KCTC	5857	Not Detected
83	*Lactobacillus vaginalis*	KCCM	49540	Not Detected
84	*Mobiluncus curtisii*	ATCC	35241	Not Detected
85	*Mobiluncus mulieris*	ATCC	35240D-5	Not Detected
86	*Mycoplasma arginini*	ATCC	23838D	Not Detected
87	*Mycoplasma felis* Cole et al.	ATCC	23391	Not Detected
88	*Mycoplasma genitalium*	ATCC	33530D	Not Detected
89	*Mycoplasma hominis*	ATCC	23114D	Not Detected
90	*Mycoplasma iowae* Jordan et al.	ATCC	33552	Not Detected
91	*Mycoplasma leonicaptivi* Hill	ATCC	49890	Not Detected
92	*Mycoplasma pneumonia*	ATCC	29342	Not Detected

93	*Mycoplasma pulmonis*	ATCC	19612	Not Detected
94	*Mycoplasma spumans*	ATCC	19526	Not Detected
95	*Neisseria cinerea*	ATCC	14685	Not Detected
96	*Neisseria flavescens*	ATCC	13120	Not Detected
97	*Neisseria gonorrhoeae*	ATCC	700825D	Not Detected
98	*Neisseria lactamica*	ATCC	23970	Not Detected
99	*Neisseria meningitidis*	ATCC	700532D	Not Detected
100	*Neisseria mucosa*	ATCC	19696	Not Detected
101	*Neisseria perflava*	ATCC	14799D-5	Not Detected
102	*Neisseria sicca*	ATCC	5415	Not Detected
103	*Neisseria subflava*	ATCC	19243	Not Detected
104	*Prevotella bivia*	KCTC	5454	Not Detected
105	*Prevotella buccalis*	KCTC	5496	Not Detected
106	*Prevotella disiens*	KCTC	5499	Not Detected
107	*Prevotella intermedia*	KCTC	3692	Not Detected
108	*Prevotella melaninogenica*	KCTC	5457	Not Detected
109	*Pseudomonas aeruginosa*	ATCC	47085	Not Detected
110	Putative BVAB2	Korean isolate		Not Detected
111	Putative *Megasphaera* type-1	Korean isolate		Not Detected
112	*Saccharomyces cerevisiae*	KCCM	50511	Not Detected
113	*Salmonella enteritidis*	KCCM	12021	Not Detected
114	*Salmonella typhimurium*	KCCM	40253	Not Detected
115	*Staphylococcus aureus*	ATCC	700699D-5	Not Detected
116	*Streptococcus agalactiae*	ATCC	BAA-611D	Not Detected
117	*Streptococcus pneumoniae*	ATCC	BAA-255D	Not Detected
118	*Trichomonas vaginalis*	ATCC	30001D	Not Detected
119	*Treponema pallidum*	Vircell	MBC109	Not Detected
120	*Ureaplasma parvum*	ATCC	27815	Not Detected
121	*Ureaplasma urealyticum*	ATCC	33695	Not Detected
122	*Vibrio parahaemolyticus*	ATCC	27969	Not Detected

† To prove the availability of the results, the experiment was repeated three times.

※ ATCC: American Type Culture Collection
KCTC: Korean Collection for Type Culture
KCCM: Korean Culture Center of Microorganisms
NIBSC: National Institute for Biological Standards and Control
Vircell: Vircell microbiologists
Advanced: Advanced Biotechnologies Inc.

2. Sensitivity

In order to determine the sensitivity of Allplex™ Candidiasis Assay, a standard serial dilution was set up from 10^4 to 10^0 cloned target DNA copies/reaction and was analyzed with Allplex™ Candidiasis Assay. Detection limit for Allplex™ Candidiasis Assay was 100 copies/reaction.

3. Reproducibility

Reproducibility tests were carried out at 2 different time points in the course of 5 days, 3 different experimenters, 3 different product lots, and 3 different sites. The same results were obtained in every test, confirming the reproducibility of Allplex™ Candidiasis Assay.

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KEY TO SYMBOLS

Key to symbols used in the manual and labels.

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Use-by date
	Upper limit of temperature
PRIMER	Oligonucleotide mix for amplification and detection
PREMIX	PCR Master Mix or Detection Mix
WATER	RNase-free Water
CONTROL +	Positive Control (PC)
CONTROL IC	Internal Control (IC)
	Consult instructions for use
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community
	Caution
	Contains sufficient for <n> tests

Symbol	Explanation
UDI	Unique Device Identifier
rxns	Reaction barcode for automated extraction system

ORDERING INFORMATION

Cat. No.	Product	Size
Allplex™ series		
SD10177Z	Allplex™ Genital ulcer Assay	25 rxns
SD9802Y	Allplex™ Genital ulcer Assay	50 rxns
SD9802X	Allplex™ Genital ulcer Assay	100 rxns
SD10245Z	Allplex™ STI Essential Assay	25 rxns
SD9801Y	Allplex™ STI Essential Assay	50 rxns
SD9801X	Allplex™ STI Essential Assay	100 rxns
SD10318Z	Allplex™ STI Essential Assay Q(MH,UU)	25 rxns
SD10201Y	Allplex™ STI Essential Assay Q(MH,UU)	50 rxns
SD10202X	Allplex™ STI Essential Assay Q(MH,UU)	100 rxns
SD10178Z	**Allplex™ Candidiasis Assay**	**25 rxns**
SD9803Y	Allplex™ Candidiasis Assay	50 rxns
SD9803X	**Allplex™ Candidiasis Assay**	**100 rxns**
SD9804X	Allplex™ Bacterial Vaginosis Assay	100 rxns
SD10320Z	Allplex™ Bacterial Vaginosis plus Assay	25 rxns
SD10159X	Allplex™ Bacterial Vaginosis *plus* Assay	100 rxns
SD10317Z	Allplex™ CT/NG/MG/TV Assay	25 rxns
SD9400Y	Allplex™ CT/NG/MG/TV Assay	50 rxns
SD9400X	Allplex™ CT/NG/MG/TV Assay	100 rxns
SD10319Z	Allplex™ MG & AziR Assay	25 rxns
SD10169Y	Allplex™ MG & AziR Assay	50 rxns
SD10170X	Allplex™ MG & AziR Assay	100 rxns
SD10232Z	Allplex™ MG & MoxiR Assay	25 rxns
SD10233Y	Allplex™ MG & MoxiR Assay	50 rxns
SD10234X	Allplex™ MG & MoxiR Assay	100 rxns
SD10368Z	Allplex™ NG & DR Assay	25 rxns
SD10367X	Allplex™ NG & DR Assay	100 rxns
SD7700Y	Anyplex™ II STI-7 Detection (V1.1)	50 rxns
SD7700X	Anyplex™ II STI-7 Detection (V1.1)	100 rxns
SD7500Y	Anyplex™ II STI-5 Detection	50 rxns
SD7500X	Anyplex™ II STI-5 Detection	100 rxns

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SD10323Z	Anyplex™ II STI-7e Detection	25 rxns
SD7701Y	Anyplex™ II STI-7e Detection	50 rxns
SD7701X	Anyplex™ II STI-7e Detection	100 rxns
SD7200Y	Anyplex™ CT/NG Real-time Detection (V3.1)	50 rxns

* In case of SmartCycler® II System, total rxn number is reduced to 40 rxn from 50 rxn. (50 rxns→40 rxns)

Seeplex® series		
HS6200Y	Seeplex® HSV2 ACE Detection	50 rxns
SD6401Y	Seeplex® STD4D ACE Detection (V2.0)	50 rxns
SD6600Y	Seeplex® STD6 ACE Detection (V2.0)	50 rxns
SD6511Y	Seeplex® STI Master Panel 1 (V2.0)	50 rxns

Accessory products		
SG1701	Ribo_spin vRD (Viral RNA/DNA Extraction Kit)	50 preps

Automated extraction Systems		
65415-02	Microlab NIMBUS IVD	EA
173000-075	Microlab STARlet IVD	EA
65415-03	Seegene NIMBUS	EA
67930-03	Seegene STARlet	EA
SG71101	Seegene STARlet 96MPH	EA
744300.4.UC384	STARMag 96 X 4 Universal Cartridge Kit	384T / 1box
EX00032P	STARMag™ S96H Kit	48T / 1box
EX00033P	STARMag™ S96H Kit	480T / 1box
EX00034P	STARMag™ S96H Kit	96T / 1box
EX00035P	STARMag™ S96H Kit	960T / 1box
SG71100	SEEPREP32	EA
EX00009P	STARMag 96 ProPrep (Plate Type)	96T / 1box
EX00009T	STARMag 96 ProPrep (Tube Type)	96T / 1box
M9600	Maelstrom™ 9600	EA
EX00029P	STARMag™ M96 Kit	96T / 1box
EX00030P	STARMag™ M96 Kit	960T / 1box
SG72100	AIOS	EA