Not Available in U.S.A.

• COMPONENT

Independent liquid channels	8 ea
CO-RE gripper arm for labware movements	1 set
Sample carrier : Sample carrier for 32 specimens Sample carrier for 24 specimens (optional) Sample carrier for 12 specimens (optional)	 3 ea 4 ea 8 ea
Tip carrier	2 ea
Magnetic seperater	1 ea
Heater/Shaker (up to 100 °C)	2 ea
PCR plate carrier	2 ea
Extract cartridge rack	2 ea
PCR reagent rack	2 ea

• SPECIFICATION

Power Input	115-230V, 50-60 Hz
Power consumption	Maximum 600 W
Dimensions	1124 (W)x795 (D)x903 (H) mm
Weight	140 Kg
Sample capacity	1-94 samples
TAT (94 test)	155 min for whole process
Pipetting channel	8 channels
Dispensing precision (when using 300㎕ tip)	10㎕: 2%, 50㎕: 0.75%, 200㎕: 0.75%
Dispensing precision (when using 1,000㎕ tip)	10㎕: 3.5%, 100㎕: 0.75%, 1000㎕: 0.75%
Positional accuracy	0.1 mm on X-Y-Z

• ORDERING INFORMATION

Category	Products		Cat. No.
Instrument	CFX96™	Optical Reaction Module	1845097-IVD
		Thermal Cycler	1841000-IVD
	Microlab STARlet IVD		173000-075
	Microlab NIMBUS IVD		65415-02
Extraction reagent	STARMag 96 x 4 Universal Cartridge Kit		744300.4.UC384
Consumable	Microlab NIMBUS IVD	High Volume Tips(1000㎕)	235905
		Standard Volume Tips (300 ㎕)	235903
		NIMBUS-Waste Bag	65803-01
		NIMBUS-96 Deep Well Micro Plate	SDP0096

One-step process from nucleic acid extraction to PCR setup

STARlet IVD

(Microlab STARlet IVD)

CE-IVD
Marked

Seegene

Seegene Inc.
Taewon Bldg. 91 Ogeum-ro, Songpa-gu, Seoul 05548, Republic of Korea
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E-mail : info@seegene.com

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www.seegene.com

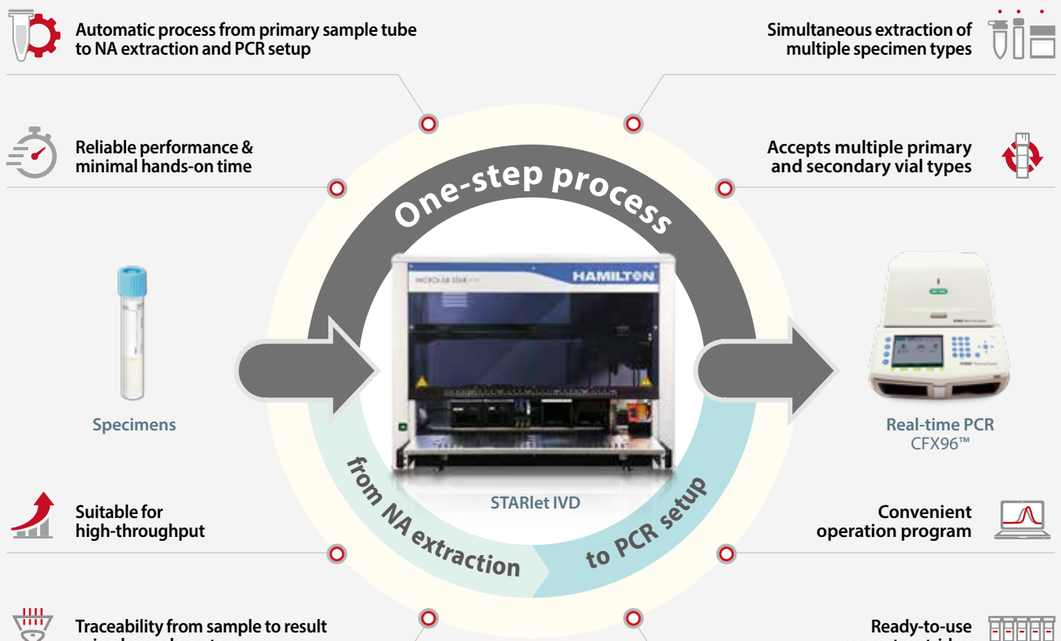
00ST-EN180212B-01

Seegene

STARlet IVD (Hamilton)

STARlet IVD is an easy-to-use liquid handling workstation from primary sample tube to nucleic acid (NA) extraction and PCR setup. It provides convenient process of your lab works by minimizing hands-on time and maximizing assay reliability.

Effortless NA extraction and PCR setup for multiple specimens

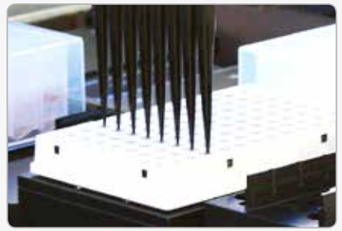


Universal Cartridge Kit Atitiktis_2

- Whole Blood
- Serum
- Plasma
- Cells
- Urine
- LBC (Liquid based cytology) specimen
- Swabs (Nasopharyngeal, Vaginal, Cervical, Urethral Rectal)
- Aspirate (Nasopharyngeal)
- BAL (Bronchoalveolar lavage)
- Sputum
- Stool
- Cary-Blair
- CSF

One-step process from NA extraction to PCR setup

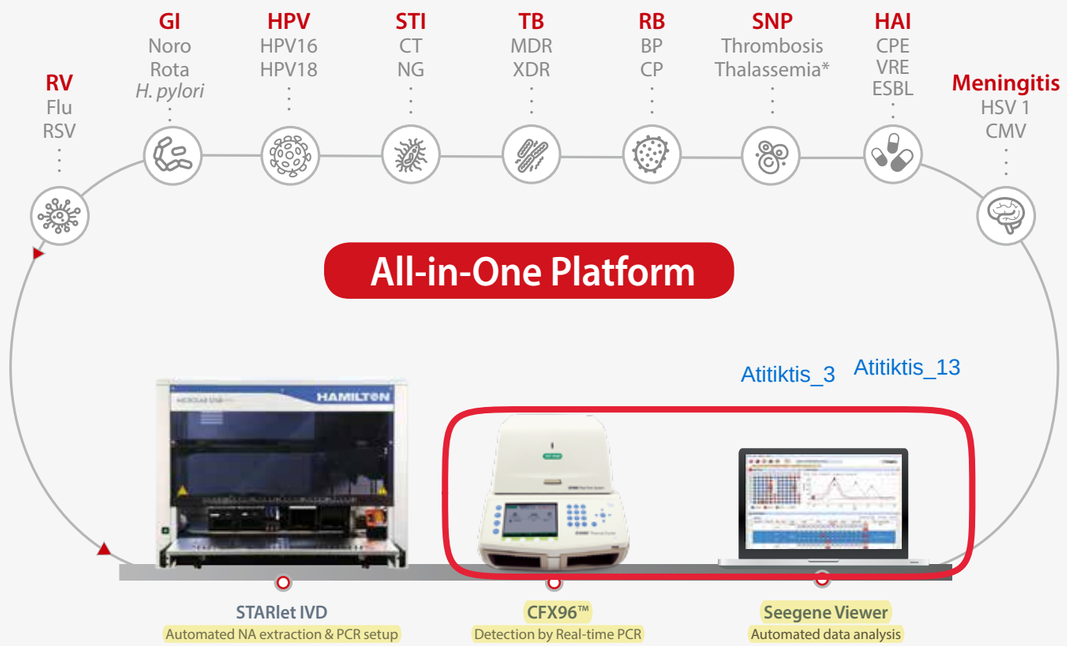
- Maximized user convenience by minimizing hands-on time
- Selectable functions : entire process from NA extraction to PCR setup, extraction only, and PCR setup only
- Reduction of potential for contamination and human error



All-in-One platform for broad multiplex MDx assays

- One platform to cover various disease areas
- Cost-effective to utilize one provider for all solution

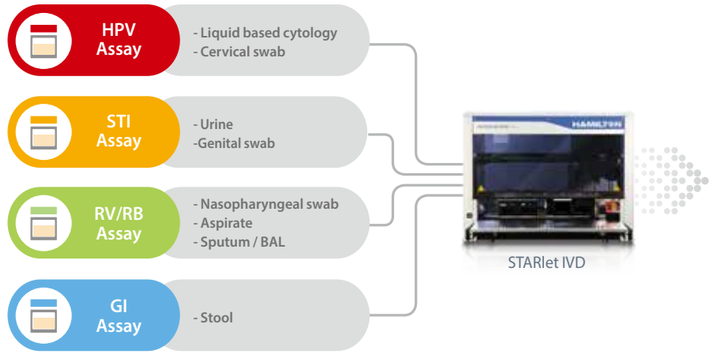
* In development

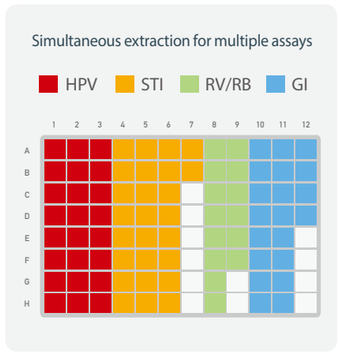


Atitiktis_1

Simultaneous nucleic acid extraction of multiple sample types

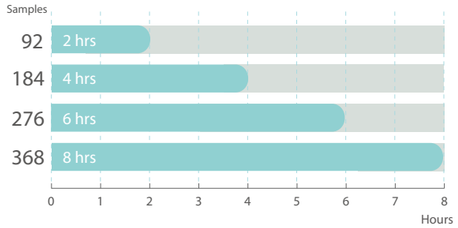
- Single set of reagent for extraction of bacterial, viral, genomic, parasitic, fungal DNA and/or RNA from multiple specimen types
- Enhanced efficiency of working hours by reducing sample process time





Suitable for high-throughput

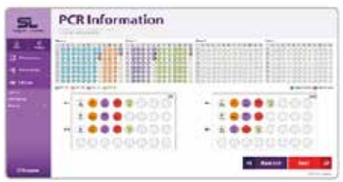
- Fast NA extraction from primary specimen
  (368 samples within 8 hours)
- Simplified workflow for medium to large clinical laboratory



Convenient operation using 'Seegene Launcher' program

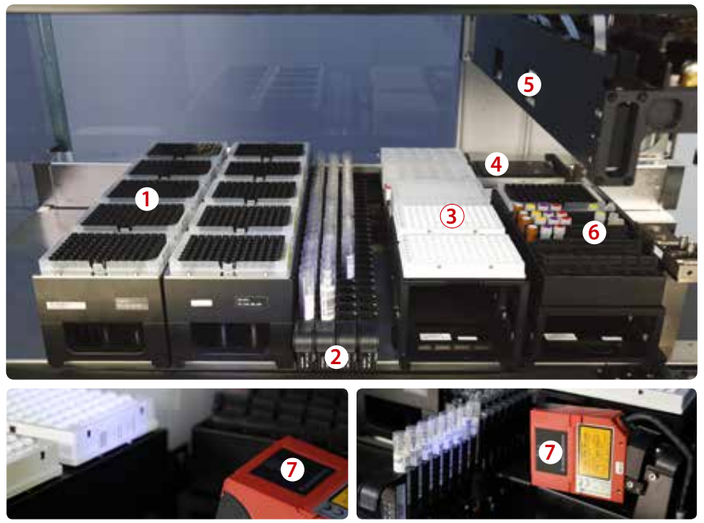
- Intuitive tutorial session for each step of entire process
- Easy integration of sample information by barcode scanner or LIS
- Convenient to trace remaining reagent volume by barcode system
- One click away to run various assays

Atitiktis_16



Direct loading of primary sample tubes

Component



1. **Disposable filter tip**
   (300㎕, 1000㎕)
2. **Sample carrier**
   for 1.5㎖ tube or primary tube
3. **Plate carrier**
   - Extraction reagent rack : 2ea
   - 96 DWP rack : 1ea
   - PCR plate rack : 2ea

   Atitiktis_5
4. **Heater and shaker**
   for increasing extraction efficiency
5. **Robotic arm**
   for accurate dispensing control of individual 8 channel
6. **PCR reagent rack**

   Atitiktis_3, 4, 15
7. **Built-in barcode scanner**
   for reading of sample and consumables

Atitiktis_5

Ready-to-use reagent cartridge system

- Predispensed extraction reagents to run 96 tests in one cartridge
- Eliminate hands-on time for reagent preparation
- Verify reagent volume by barcode system

Atitiktis_3, 4, 15

For Professional Use Only

STARMag 96 X 4 Universal Cartridge Kit
User Manual

Available automated liquid handling instrument

1. **Microlab NIMBUS IVD and Microlab STARlet IVD**
2. **Seegene NIMBUS and Seegene STARlet**

CE

IVD **For in vitro diagnostic use only**

REF **744300.4.UC384** Σ **384**

Seegene Inc.

Taewon Bldg., 91 Ogeum-ro, Songpa-gu, Seoul, Republic of Korea, 05548

Seegene Technologies

325 North Wiget lane, Suite 140 Walnut Creek, CA 94598, USA

TEL: +1-925-448-8172

E-mail: info@seegenetech.com

EC REP **Medical Technology Promedt Consulting GmbH**

Altenhofstrasse 80, D-66386 St.Ingbert, Germany

User manuals translated into other languages are available at

sgarchive.seegene.com/file/manual or can be requested from Seegene Inc.

TABLE OF CONTENTS

INTENDED USE

Atitiktis_2 Atitiktis_5 Atitiktis_7

STARMag 96 X 4 Universal Cartridge Kit is intended to be used for isolation of nucleic acid from tissue, cells, bacteria, serum, plasma, nasopharyngeal swab, nasopharyngeal aspirates, bronchoalveolar lavage (BAL), urine, stool, sputum, whole blood, genital swabs (vaginal, cervical, urethral), liquid based cytology (LBC), cerebrospinal fluid (CSF), semen and saliva specimen using automated liquid handling instruments such as the Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet.

PRINCIPLE OF THE PROCEDURE

Atitiktis_5

STARMag 96 X 4 Universal Cartridge Kit is applied to automatic nucleic acid purification system with the convenient handling of magnetic beads. The purification procedure is designed to ensure safe and reproducible handling of potentially infectious samples and comprises 4 steps: sample lysis, nucleic acid bind to magnetic beads, wash debris and purified nucleic acid elute.

※ Note ※

- Seegene recommends using Seegene Launcher for automated nucleic acid (NA) extraction with STARMag 96 X 4 Universal Cartridge Kit. Seegene Launcher is application software that controls Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet.

Atitktis_5

- STARMag Universal 1 Cartridge contains reagents for 96 tests. Each extraction reagent can only be used 10 times. Seegene Launcher software will not accept extraction kit that has been used 10 times, even if there are enough reagents remaining for additional sample extraction.

- Read the barcode attached to the cartridge, not the box of STARMag 96 X 4 Universal Cartridge Kit when using Seegene Launcher.

COMPONENTS

1. Kit components

Check integrity of all components in the kit before use.

STARMag 96 X 4 Universal Cartridge Kit (384 Test)	
Cat. No. 744300.4.UC384	
Reagents	**Volume**
Lysis Buffer Universal LB	4 X 23 mL
Binding Buffer Universal BB	4 X 68 mL
Wash Buffer 1 Universal WB1	4 X 55 mL
Wash Buffer 2 Universal WB2	4 X 10 mL
Wash Buffer 3 Universal WB3	4 X 55 mL
Elution Buffer Universal EB	4 X 18 mL
Universal Magnetic Beads	4 X 1.8 mL
Lysis Buffer Universal LB	200 mL
Universal Proteinase K (lyophilized) *	4 X 75 mg
Proteinase Buffer Universal PB	4 X 3 mL
Tub Cover	25 ea
User Manual	2 ea

*** For preparation of working solutions and storage conditions, see page 8.**

2. Material required but not provided: Consumables

- Ethanol, absolute for analysis (Cat. No. 1.00983.1011, Merck)
- Deep well plate, 96 wells with printed label (Cat. No. SDP0096, Supercon)
- Deep well plate, 96 wells with Barcode label (Cat. No. SDP0096B, Supercon)
- Disposable Pipette (25 mL) (Cat. No. 4489, Corning)

PRODUCT DESCRIPTION

1. The basic principle

The **STARMag 96 X 4 Universal Cartridge Kit** procedure is based on reversible adsorption of nucleic acids to paramagnetic beads under appropriate buffer conditions. Tissue samples, cells, bacteria, serum, plasma, nasopharyngeal swab, nasopharyngeal aspirates, bronchoalveolar lavage (BAL), urine, stool, sputum, whole blood, genital swabs (vaginal, cervical, urethral), liquid based cytology (LBC), cerebrospinal fluid (CSF), semen and saliva are lysed with SDS / Proteinase K solution (Lysis Buffer LB). For the adjustment of the binding conditions under which nucleic acids bind to the paramagnetic Binding Buffer BB and the magnetic beads are added to the lysate. After magnetic separation, the paramagnetic beads are washed two times to remove contaminants and salts using Wash Buffers WB1, WB2. Ethanol from previous wash steps is removed by a final incubation of the beads in Wash Buffer WB3. Finally, highly purified nucleic acid is eluted with low-salt Elution Buffer EB and can directly be used for downstream applications. The **STARMag 96 X 4 Universal Cartridge Kit** can be used on automated liquid handling instruments such as Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet.

2. Kit specification

STARMag 96 X 4 Universal Cartridge Kit is designed for automated preparation of highly pure nucleic acid from tissue samples, cells, bacteria, serum, plasma, nasopharyngeal swab, nasopharyngeal aspirates, bronchoalveolar lavage (BAL), urine, stool, sputum, whole blood, genital swabs (vaginal, cervical, urethral), liquid based cytology (LBC), cerebrospinal fluid (CSF), semen and saliva. The purified nucleic acid can be used directly as template for PCR or any kind of enzymatic reactions.

STARMag 96 X 4 Universal Cartridge Kit allows easy automation on common liquid handling instruments. The actual processing time depends on the configuration of the instrument and the magnetic separation system used. The kit provides reagents for the purification of up to 20 µg of pure nucleic acid from suitable samples (up to 20 mg tissue, up to 1 x 10^7 cells or up to 1 mL of an overnight culture of bacteria) with an $A_{260/280}$ ratio ≥ 1.6 - 1.9 and typical concentration of 20 - 50 ng/µL. Depending on the elution volume used concentrations of 10 - 150 ng/µL can be obtained. Yields and concentration of nucleic acid depend on sample type. The purified nucleic acids can directly be used as a template for subsequent analysis. The user is responsible for validating system performance for any procedure used in the laboratory when the Seegene performance studies do not cover those.

Following lysis of samples with proteinase K, **STARMag 96 X 4 Universal Cartridge Kit** can be

processed completely at room temperature. However, elution at 56 °C will increase the yield by about 15 - 20 %. STARMag B-Beads are highly reactive, super paramagnetic beads. The binding capacity is 0.4 µg of gDNA per 1 µL of STARMag-B-Bead Suspension, 1 µL of suspension contains 130 µg of beads.

3. Magnetic separation systems

For the use of **STARMag 96 X 4 Universal Cartridge Kit,** the use of the magnetic separator is recommended. Separation is carried out in a 96 Deep Well Micro Plate (Supercon). If the kit is used with other common separators, see suppliers ordering information for suitable separation plates. Magnetic beads can be resuspended in the buffer by pipetting up and down several times. For fully-automated use on liquid handling workstations a gripper tool is required, that transfers the plate to the magnetic separator for separation of the beads or to the shaker module for resuspension of the beads.

4. Handling of beads

Distribution of beads

A homogenous distribution of the magnetic beads to the individual wells of the separation plate is essential for a high well-to-well consistency. Therefore, before distributing the beads make sure that the beads are completely resuspended. Shake the storage bottle well or place it on a vortexer shortly.

Magnetic separation time

Attraction of the magnetic beads to the magnetic pins depends on the magnetic strength of the magnetic pins, the selected separation plate, distance of the separation plate from the magnetic pins, and the volume to be processed. The individual times for complete attraction of the beads to the magnetic pins should be checked and adjusted on each system. It is recommended to use the separation plates or tubes specified by the supplier of the magnetic separator.

Washing the beads

Washing the beads can be achieved by shaking or mixing. In contrast to mixing by pipetting up and down mixing by shaker or magnetic mixing allows simultaneous mixing of all samples. This reduces the time and number of tips needed for the preparation. Resuspension by pipetting up and down, however, is in general more efficient than mixing by a shaker or magnetic mix.

5. Elution procedures

Purified nucleic acid can be eluted directly with the supplied Elution Buffer. It is essential to cover the STARMag Beads completely with elution buffer during the elution step. The volume of dispensed elution buffer depends on the magnetic separation system (e.g. the position of the pellet inside the separation plate). For efficient elution, the magnetic bead pellet should be resuspended completely in the elution buffer. For some separators, high elution volumes might be necessary to cover the whole pellet. Elution is possible at room temperature. However, the nucleic acid yield can be increased by 15 - 20 % if the elution step is performed at 56 °C.

STORAGE CONDITIONS AND PREPARATION OF WORKING SOLUTIONS

Attention: *Buffer BB and WB1* contain chaotropic salt. Wear gloves and goggles.

Storage conditions:

- All components of the **STARMag 96 X 4 Universal Cartridge Kit** should be stored at room temperature (18 ~ 25 °C) and are stable for up to 15 months. The kit should be stored in a dry environment without direct exposure to sunlight except dissolved Proteinase K solution.

- The expiration date of the product is indicated on the label. The cartridge remains effective for up to 15 months prior to the opening and store up to 4 months after its opening.

- **Lysis Buffer (LB)** may form a salt precipitate upon storage. To re-dissolve the salt precipitate, incubate the buffer tub and bottle at 40 °C until all of the precipitate is re-dissolved.

Before starting the **STARMag 96 X 4 Universal Cartridge Kit** protocol, prepare the following:

- **Proteinase K**: Before using the kit for the first time, add 2.6 mL Proteinase Buffer PB to each vial of the lyophilized Proteinase K. Dissolved Proteinase K solution is stable at - 20 °C for at least 6 months.

- **WB2**: Add 48 mL of absolute ethanol into WB2 tub before use. WB2 tub should to be covered with Tub Cover after using and stored at room temperature (18 ~ 25 °C).

SAFETY INSTRUCTIONS

The following components of the **STARMag 96 X 4 Universal Cartridge Kit** contain hazardous contents. Please read all safety precautions and instructions for use thoroughly before using the kit.

- This kit needs to be carried out by professionals.
- Contact can cause eye and skin irritation.
- If this kit contacts the skin or eyes, promptly wash with large amounts of water and soap. Call your doctor for medical advice.
- This kit is incompatible with bleach.
- Do not use if there is any damage to the product, labeling, or packaging.
- Do not mix reagents from different lots.
- Do not use the product after its expiry date.
- Do not eat, drink or smoke in laboratory work area.
- Wear disposable powder-free gloves, laboratory coats and eye protections during the experiment.
- Please be careful not to contaminate. To prevent contamination of reagents, use sterile filter tips.
- Wash hands thoroughly after handling.
- All specimens should be considered as potentially infectious material. Laboratory safety procedures (refer to Biosafety in Microbiological and Biomedical Laboratories & CLSI Documents) must be taken when handling specimens.
- To minimize the risk of a negative impact on diagnostic results, it is recommended to use adequate controls in downstream application.
- Dispose of materials used in this assay, including reagents, samples, and used buffer vials, according to federal, state, and local regulations.
- Follow applicable federal, state, and local regulations and your institution’s environmental waste procedures for the proper disposal of used and unused reagents.
- If the country or regional regulations do not provide clear direction on proper disposal, biological specimens, and the used product should be disposed of per WHO [World Health Organization] medical waste handling and disposal guidelines.
- For more information, see 'TROUBLESHOOTING' (page 14). If the problem is not resolved, please inquire with the manufacturer or dealer.

Note: A serious incident in relation to the use of the device must be reported to **Seegene Inc.** and the competent authority of the Member State in which the user and/or the patient is established.

GHS classification

Only harmful features do not need to be labeled with Hazard phrases (H) and Precaution phrases (P) up to 125 mL or 125 g.

Component	Hazard contents	GHS symbol	Hazard phrases	Precaution phrases
BB	Sodium perchlorate 15-40 % + ethanol 35-55 %	 Warning	H226, H302	P210, P264W, P301+P312, P330
WB1	Sodium perchlorate 15-40 % + ethanol 20-35 %	 Warning	H226, H302	P210, P264W, P301+P312, P330
Proteinase K	Proteinase K, lyophilized	 Danger	H315, H319, H334	P261sh, P342+311

Hazard phrases

H 226	Flammable liquid and vapour.
H 302	Harmful if swallowed.
H 315	Causes skin irritation.
H 319	Causes serious eye irritation.
H 334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precaution phrases

P 210	Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P 261sh	Avoid breathing dust/ vapors.
P 264W	Wash with water thoroughly after handling.
P 330	Rinse mouth.

P 301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P 342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

For further information, please see Material Safety Data Sheets.

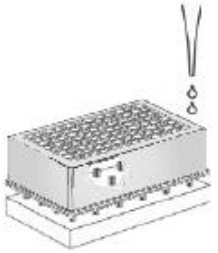
PROTOCOL

1. Lyse sample

Add Proteinase K and internal control to 96 deep well plate. And dispense Buffer LB to 96 deep well plate. Then transfer samples to 96 deep well plate and mix well by repeated pipetting up and down.

2. Bind nucleic acid to magnetic beads

Add resuspended beads to 96 deep well plate and Buffer BB to the lysed sample. Separate the magnetic beads against the side of the wells by placing the 96 deep well plate on the magnetic separator. Wait until all the beads have been attracted to the magnets. Remove and discard supernatant by pipetting.



3. WB1 wash

Remove the 96 deep well plate from the magnetic separator. Add Buffer WB1 and resuspend the beads by shaking. Separate the magnetic beads by placing the 96 deep well plate on the magnetic separator. Wait until all the beads have been attracted to the magnets. Remove and discard supernatant by pipetting.

4. WB2 wash

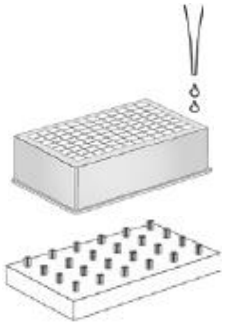
Remove the 96 deep well plate from the magnetic separator. Add Buffer WB2 and resuspend the beads by shaking. Separate the magnetic beads by placing the 96 deep well plate on the magnetic separator. Wait until all the beads have been attracted to the magnets. Remove and discard supernatant by pipetting.

5. WB3 wash

Gently add Buffer WB3 to each well and incubate while the beads are still attracted to magnets. Then aspirate and discard the supernatant.

6. Elution

Add Buffer EB to each well of the 96 deep well plate and resuspend the beads by shaking. Incubate the suspension at 56 °C. Separate the magnetic beads by placing the 96 deep well plate on the magnetic separator. Wait until all the beads have been attracted to the magnets. Transfer the supernatant containing the purified nucleic acid to either microtubes or tube strips.



TROUBLESHOOTING

Problem	Possible cause and suggestions
Degradation of Nucleic acid	*Nuclease contamination* • Make sure that there are no contaminants on consumables.
Poor yield / Low sensitivity	*Inappropriate storage of samples* • Use fresh or frozen samples. • Avoid using samples stored too long at room temperature. *Not enough cells* • The sample does not contain enough cells. For optimal number of cells to extract, refer to section “2. Kit specification” (page 5). *Wrong types of sample* • Check available type of samples at “2. Kit specification” (page 5). *Nucleic acid loss in Wash Buffer WB3 step* • Nucleic acid could be eluted at this step because this buffer is water-based.
Poor purity / Low sensitivity	*Inappropriate storage of samples* • Use fresh or frozen samples. • Avoid using samples stored too long at room temperature. *Too many cells* • Sample contains too many cells. For optimal number of cells to extract, refer to section “2. Kit specification” (page 5). *Wrong types of sample* • Check available type of samples at “2. Kit specification” (page 5).

	Abnormal extraction process • Use only the appropriate combinations of separator and plate.
Suboptimal performance of nucleic acid in downstream assays	*Carry-over of ethanol from Wash Buffer WB2* • Be sure to remove all of the ethanolic wash solution Buffer WB2, as residual ethanol interferes with downstream assays. (*e.g.,* PCR or RT-PCR) *Low purity* • Please refer to above.

EXPLANATION OF SYMBOLS

Symbol	Explanation
	In vitro diagnostic medical device
	Batch code
	Catalogue number
	Unique Device Identifier
	Reaction barcode for automated extraction system
	Use-by date
	Temperature limit
	Caution
	Consult instructions for use
	Manufacturer
	Contains sufficient for <n> test
	Authorized representative in the European Community
	Do not use if package is damaged
	Keep dry
	Fragile, handle with care
	This way up

ORDERING INFORMATION

Cat. No.	Product name	Size
65415-02	Microlab NIMBUS IVD	EA
173000-075	Microlab STARlet IVD	EA
65415-03	Seegene NIMBUS	EA
67930-03	Seegene STARlet	EA
744300.4.UC384	**STARMag 96 X 4 Universal Cartridge Kit**	**384 Tests**
EX00006C	STARMag 96 X 4 Universal plus Cartridge Kit	384 Tests
EX00013C	STARMag 96 X 4 Viral DNA/RNA 200 C Kit	384 Tests
EX00031C	STARMag™ N/S Kit	384 Tests

Powerful data analysis software for Seegene's multiplex MDx assays

Seegene Viewer

Automated data analysis for multiplex real-time PCR

Atitiktis_4, 14

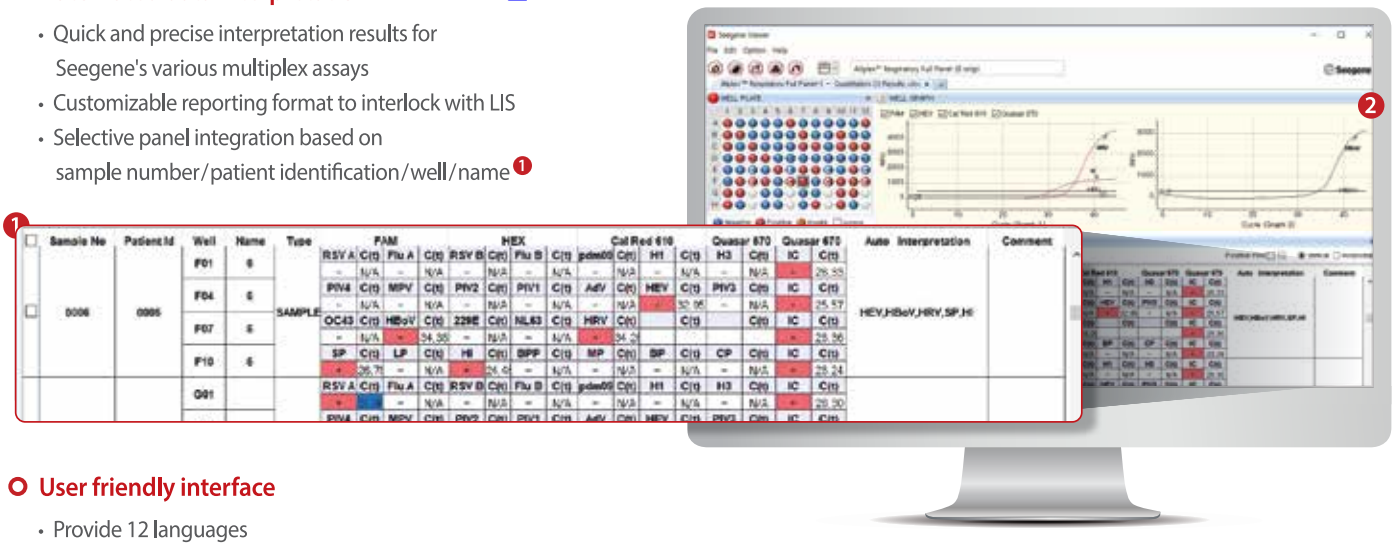
Seegene Viewer is designed to enable users to simply access to automated data analysis for Seegene's high multiplex real-time PCR assays. The software allows identification and differentiation for both Ct value of multiple targets in a single channel as well as melting curve analysis.

Automated data interpretation

Atitiktis_4, 14

- Quick and precise interpretation results for Seegene's various multiplex assays
- Customizable reporting format to interlock with LIS
- Selective panel integration based on sample number/patient identification/well/name ❶

- **Seegene Viewer User Interface** (Result of Allplex™ Respiratory Panel Assays)



User friendly interface

- Provide 12 languages
- Customized assay selection
- Convenient readout of multiple sample results by color-coded interpretation

Optimized for Seegene technology

- Two individual Ct values in a single channel ❷
- Semi-quantification analysis by cyclic-CMTA in melting curve analysis

Automated interpretation of real-time PCR result with Seegene Viewer

Laboratory Information System (LIS)

LIMS Integration

Atitktis_12

- Integration of results of various assays by patient or sample identification
- Adoption of HL7* and LIMS file(.plrn) to interlock with LIS for sample information
- Automated import and export data to LIS by .plrn

www.seegene.com

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SLSV-EN180320F-01

Operation software for NIMBUS IVD and STARlet IVD

Seegene Launcher

Optimized operation software for Seegene's simultaneous multiple assays

Seegene Launcher is an operation program which includes protocol for Seegene's various molecular diagnostic (MDx) assays.
This software can perform the entire process from nucleic acid extraction to PCR setup or selectively perform extraction or PCR setup

Atitiktis_17

User friendly interface

- Intuitive and guided user interface
- Detailed tutorial
- Include operation manual for each assay

Applicable multiple sample types

- Sample selection for each assay
- Reading sample information from barcode or LIS (HL7 is applied)

Reagent traceability

- Reduce reagent loss with installing back-up reagent
- Convenient residual quantity check with barcode system

Atitiktis_16

Multi-assay PCR setup

- Easy-to-use installation guide of multiple PCR reagents
- Simultaneous random selective PCR setup with maximum of 4 different assays

Interocking with laboratory information system (LIS)

*HL7, (Health Level Seven), is a standard for exchanging information between medical applications

Vertimas iš anglų kalbos

CFX96™ Realaus-laiko PGR Detekcijos Sistema

Atitktis_9

Techninės Specifikacijos

Matmenys ir svoris

Dydis (P x I x A)	33 x 46 x 36 cm (13 x 18 x 14")
Svoris	21 kg (47 lb)

Elektros parametrai

Voltažas	100–240 V
Dažnis	50–60 Hz
Energijos sąnaudos	850 W
Saugiklių kategorija	10 A

Veikimo sąlygos

Pagrindinės	Naudojamas patalpose
Temperatūra	Veikia esant 15–31°C aplinkos temperatūrai
Drėgmė	Didžiausia santykinė drėgmė - iki 80% (nekondensuota)
Altitudė	Iki 2,000 metrų virš jūros lygio
Triukšmo lygmuo	Atitinka 61010-1 specifikacijas
Tarša	Laipsnis 2
Instaliacija	Klasė 2

Termocikleris

Šasi	C1000 šasi
Didžiausias temperatūros kilimo greitis	5°C/s Atitktis_9
Vidutinis temperatūros kilimo greitis	3.3°C/s
Programuojamas gradiento pokytis	1–24°C
Gradiento veikimo diapazonas	0–100°C
Kaitinimo ir šaldymo metodas	Peltier
Dangčio įkaitimas	iki 105°C

Temperatūra

Diapazonas	0–100°C
Tikslumas	±0.2°C suprogramavus 90°C
Vienodumas	±0.4°C, 10 s pasiekus 90°C

Optika Atitktis_11

Eksitacija	6 filtriniai LED
Detekcija	6 filtriniai fotodiodai
Eksitacijos diapazonas/emisijos bangų ilgis	450–730 nm
Jautrumas	Aptinka 1 žmogaus DNR taikinio sekos kopiją
Dinaminis diapazonas	10 parinkčių eilės tvarka

Programa

Operacinė sistema	Windows XP, Windows Vista, Windows 7
Daugybinė detekcija	Iki 5 taikinių viename šulinėlyje

Sistema

Licencijuota RL-PGR	Taip
Mėginių skaičius	96 šulinėliai
Mėginio kiekis	1–50 µl (10–25 µl rekomenduojamas)
Komunikacija	USB 2.0

Rekomenduojamos naudoti plastikinės priemonės

CFX96 sistema tinkama tiek žemo profilio 0.2 ml mėgintuvėliams tiek plokštelėms. Bio-Rad rekomenduoja šias plastikines priemones optimalių rezultatų pasiekimui:

Atitktis_10

• MLL-9601. Low-profile 96-well unskirted plates with clear wells
• MLL-9651. Low-profile 96-well unskirted plates with white wells
• HSP-9601. Hard-Shell® 96-well skirted plates with white shell and clear wells
• HSP-9655. Hard-Shell 96-well skirted plates with white shell and white wells
• TLS-0801. Low-profile 0.2 ml 8-tube strips without caps, clear wells
• TLS-0851. Low-profile 0.2 ml 8-tube strips without caps, white wells
• TCS-0803. Optical flat 8-cap strips, for 0.2 ml tubes and plates
• MSB-1001. Microseal® ‘B’ adhesive seals, optically clear

CE IVD

Bio-Rad Laboratories, Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547

EC REP

Bio-Rad
3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Tel.: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
www.bio-rad.com

BIO-RAD

Bio-Rad Laboratories, Inc.

Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2017-06-20

UAB Diamedica
Molėtų pl. 73, Vilnius, Lietuva
Tel. 8 5 279 0080

For Professional Use Only

Allplex™

STI Essential Assay

(Cat. No.SD9801X, SD10245Z)

A multiplex real-time PCR assay for detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Mycoplasma genitalium* (MG), *Mycoplasma hominis* (MH), *Ureaplasma urealyticum* (UU), *Ureaplasma parvum* (UP), and *Trichomonas vaginalis* (TV) from urine, genital swab, liquid based cytology specimens and semen.

For use with

1. Microlab NIMBUS IVD and Microlab STARlet IVD

2. Seegene NIMBUS and Seegene STARlet

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 2797

IVD **For in vitro diagnostic use only**

REF **SD9801X** Σ 100 REF **SD10245Z** Σ 25

Seegene Inc.,

Taewon Bldg., 91 Ogeum-ro, Songpa-gu, Seoul, Republic of Korea 05548

EC REP **Medical Technology Promedt Consulting GmbH**

Altenhofstrasse 80, D-66386 St.Ingbert, Germany

Not available in the U.S.

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NOTICES

- For in vitro diagnostic use only.
- Reliability of the results depends on adequate specimen collection, storage, transport, and processing procedure.
- **This product is only for use with Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet maximum 5 separate runs.**
- **This test has been validated for the following specimen types: urine, genital swab, liquid based cytology specimens and semen.** 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.
- Wear disposable gloves and change them before entering different areas. Change gloves immediately if contaminated or treat them with DNA decontaminating reagent.
- Supplies and equipments must be dedicated to working areas and should not be moved 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. trachomatis (CT), *N. gonorrhoeae* (NG), *M. genitalium* (MG), *M. hominis* (MH), *U. urealyticum* (UU), *U. parvum* (UP), and *T. vaginalis* (TV)

INTENDED USE

Allplex™ STI Essential Assay is a qualitative *in vitro* test for single or multiple detection of *C. trachomatis* (CT), *N. gonorrhoeae* (NG), *M. genitalium* (MG), *M. hominis* (MH), *U. urealyticum* (UU), *U. parvum* (UP), and *T. vaginalis* (TV) from urine, genital swab, liquid based cytology specimens and semen.

PRINCIPLES AND PROCEDURE OVERVIEW

1. Principles

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

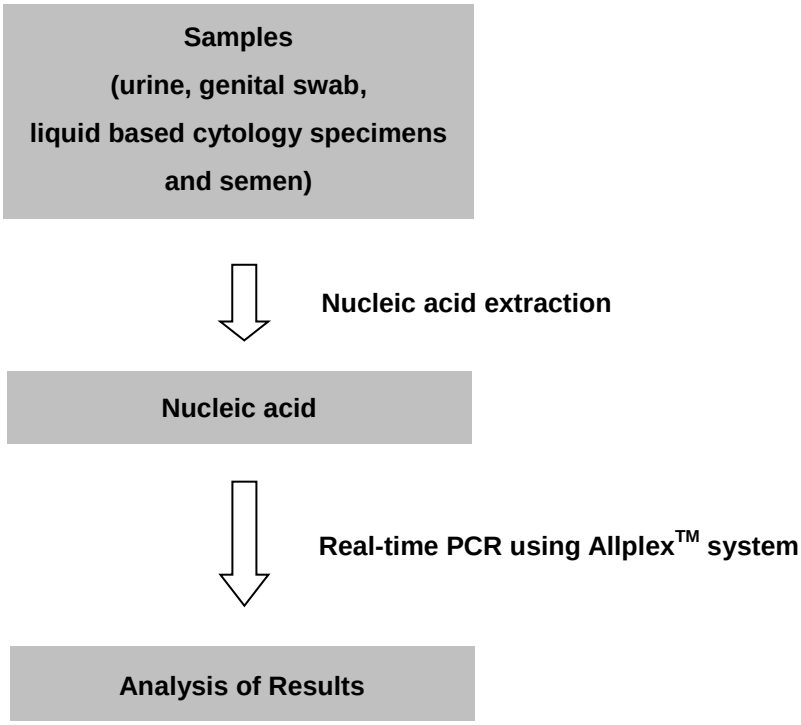
Allplex™ STI Essential Assay is a real-time PCR assay that permits simultaneous amplification and detection of target nucleic acids of *C. trachomatis* (CT), *N. gonorrhoeae* (NG), *M. genitalium* (MG), *M. hominis* (MH), *U. urealyticum* (UU), *U. parvum* (UP), *T. vaginalis* (TV) and Internal Control (IC).

In Allplex™ STI Essential 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™ STI Essential 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

The term sexually transmitted diseases (STDs) is used to refer to a variety of clinical syndromes caused by pathogens that can be acquired and transmitted through sexual activity.

More than 30 bacterial, viral, and parasitic pathogens are transmissible sexually and constitute a group of infections called to as sexually transmitted infections (STIs).

Some STIs can increase the risk of HIV acquisition three-fold or more. STIs can have serious consequences beyond the immediate impact of the infection itself, through mother-to-child transmission of infections and chronic diseases.

More than 1 million people acquire a STI every day. Each year, an estimated 500 million people become ill with one of 4 STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis.

1. *Chlamydia trachomatis*

Chlamydia trachomatis, the etiological agent of chlamydia, causes substantial morbidity and economic cost worldwide.

Chlamydial infections in women are usually asymptomatic. However, these can result in pelvic inflammatory disease (PID), which is a major cause of infertility, ectopic pregnancy, and chronic pelvic pain. As with other inflammatory STDs, chlamydial infection might facilitate the transmission of human immunodeficiency virus (HIV) infection. In addition, pregnant women infected with chlamydia can pass the infection to their infants during delivery, potentially resulting in neonatal ophthalmia and pneumonia.

2. *Neisseria gonorrhoeae*

Gonorrhea is a very common infectious disease. Most women with gonorrhea are asymptomatic. If undetected, not treated or inappropriately treated, infection can ascend to the upper genital tract and cause complicated gonococcal infection (e.g. PID and related sequelae such as ectopic pregnancy and infertility) in women, and penile oedema and epididymitis in men.

3. *Trichomonas vaginalis*

Trichomonas vaginalis is the etiological agent of the most prevalent non-viral STI worldwide. *T. vaginalis* may cause an abnormal vaginal discharge (trichomoniasis) in women and may be responsible for as much as 10~12% of non-gonococcal urethritis cases in men, the infection may be asymptomatic in at least 50% of women and 70~80% of men.

4. Genital mycoplasmas

M. genitalium and *M. hominis* and the two ureaplasma species *U. urealyticum* (previously known as *U. urealyticum*, biovar 2) and *U. parvum* (previously known as *U. urealyticum*, biovar 1) are commonly found in the human urogenital tract.

M. genitalium was first identified in the early 1980s and has recognized as a cause of male urethritis, responsible for approximately 15~20% of nongonococcal urethritis (NGU) cases, 20%~25% of nonchlamydial NGU, and approximately 30% of persistent or recurrent urethritis. *M. genitalium* is found in the cervix and/or endometrium of women with PID more often than in women without PID.

Ureaplasmas can be found in the cervix or vagina of 40~80% of sexually active, asymptomatic women, and *M. hominis* in 20~50%. Accordingly, ureaplasmas and *M. hominis* should be considered primarily as commensals when detected in the lower genital tract. Although there is an ongoing debate, evidence that these microbes cause lower genital tract diseases, including cervicitis, in women is accumulating. The accurate diagnosis of *Ureaplasma* spp. and *Mycoplasma hominis* in cervical samples is important because these microorganisms could be pathogenic and could be associated with adverse pregnancy outcomes, postpartum sepsis, neonatal systemic inflammatory response syndrome and bronchopulmonary dysplasia.

The current standard of care for clinical sexually transmitted infection (STI) screening involves the use of separate tests to detect the presence of each possible pathogen. Most commercially available tests only focus on detecting the two most prevalent bacterial causes of STIs: CT and NG. However, since most STIs do not show noticeable symptoms, it is a key to screen for a wider range of pathogens. Further complicating STI diagnosis is that different pathogens can cause similar symptoms, but the antibiotic treatment regimen may differ depending upon the pathogen. This complexity of issues makes simultaneous and accurate STI detection a major key to cost-effective patient care.

REAGENTS

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

Order information (REF SD9801X)

Allplex™ STI Essential Assay			
Symbol	**Contents**	**Volume**	**Description**
PRIMER	4X STI-EA 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 +	STI-EA 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		

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

Order information (REF SD10245Z)

Allplex™ STI Essential Assay			
Symbol	**Contents**	**Volume**	**Description**
PRIMER	4X STI-EA 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 +	STI-EA 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		

STORAGE AND HANDLING

All components of the Allplex™ STI Essential Assay should be stored at ≤ -20°C. All components are stable under recommended storage conditions until the expiry date stated on the label. This product can be used for 30 days after initial opening of the kit and performance is not affected for up to 5 freezing and thawing cycle. 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)
- Permanent Clear Heat Seal (Cat. No. 1814035, Bio-Rad) *
- PX1 PCR plate sealer (auto-sealer, Cat. No. 181-4000, Bio-Rad) *
- Saline solution

* 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
Semen

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.

Semen

- Collect semen in a clean container of polypropylene. Close and label the sample container. Strictly adhere to the instructions given for storage and transport.

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℃**	90 days	
	Room Temperature**		
SurePath™ medium	2~8℃	2 weeks	
Semen	2~8℃	1 week	

* Duration: The time period from specimen collection to test including specimen storage and transport prior to the test.
** Optimum temperature for transport is 2~25℃.

2. Nucleic Acid Extraction

A. Pre-treatment of specimen

Genital swab specimens

- Genital swab specimen is used without pre-treatment.

Urine & ThinPrep® specimens

Optional: Pre-treatment can be omitted.

Note: Performing pre-treatment process may enhance the sensitivity than that of cases without pre-treatment process.

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

SurePath™ specimens

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

Note: For the application of SurePath™ specimen in the Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS or Seegene STARlet, pellet must be resuspended in lysis buffer in the STARMag 96 X 4 Universal Cartridge Kit.

Note: Surepath™ has not been validated with STARMag 96 X 4 Viral DNA/RNA 200 C Kit.

- Follow the manufacturer's protocol.

Semen

- Equilibrate semen for 30 min in darkness until liquefaction.in the room temperature (19~25℃).
- Dilute three times with Saline solution at recommended volume (See Recommended Vol. Of 2.C) by thoroughly vortexing.
- 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 the 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
STARMag 96 X 4 Viral DNA/RNA 200 C Kit**	Seegene	EX00013C	Specimen: 300 µL Elution: 100 µL

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

** Surepath™ has not been validated with STARMag 96 X 4 Viral DNA/RNA 200 C Kit.

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
STARMag 96 X 4 Viral DNA/RNA 200 C Kit**	Seegene	EX00013C	Specimen: 300 µL Elution: 100 µL

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

** Surepath™ has not been validated with STARMag 96 X 4 Viral DNA/RNA 200 C Kit.

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
STARMag 96 X 4 Viral DNA/RNA 200 C Kit*	Seegene	EX00013C	Specimen: 300 μL Elution: 100 μL

* Surepath™ has not been validated with STARMag 96 X 4 Viral DNA/RNA 200 C Kit.

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 96 X 4 Viral DNA/RNA 200 C Kit*	Seegene	EX00013C	Specimen: 300 μL Elution: 100 μL

* Surepath™ has not been validated with STARMag 96 X 4 Viral DNA/RNA 200 C Kit.

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: Briefly centrifuge the reagent tubes to remove drops from inside of the cap.

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

A. Prepare the PCR Mastermix.

5 μL	4X STI-EA 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 briefly centrifuge.

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

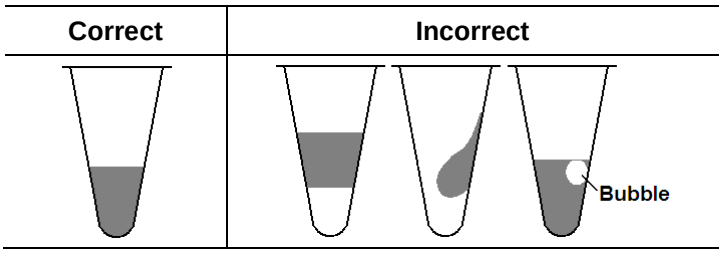
D. Add 5 μL of each sample's nucleic acids into the tube containing the PCR Mastermix.

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

E. Close the cap, and briefly centrifuge 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 STI-EA PC instead of sample's nucleic acid.

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**.

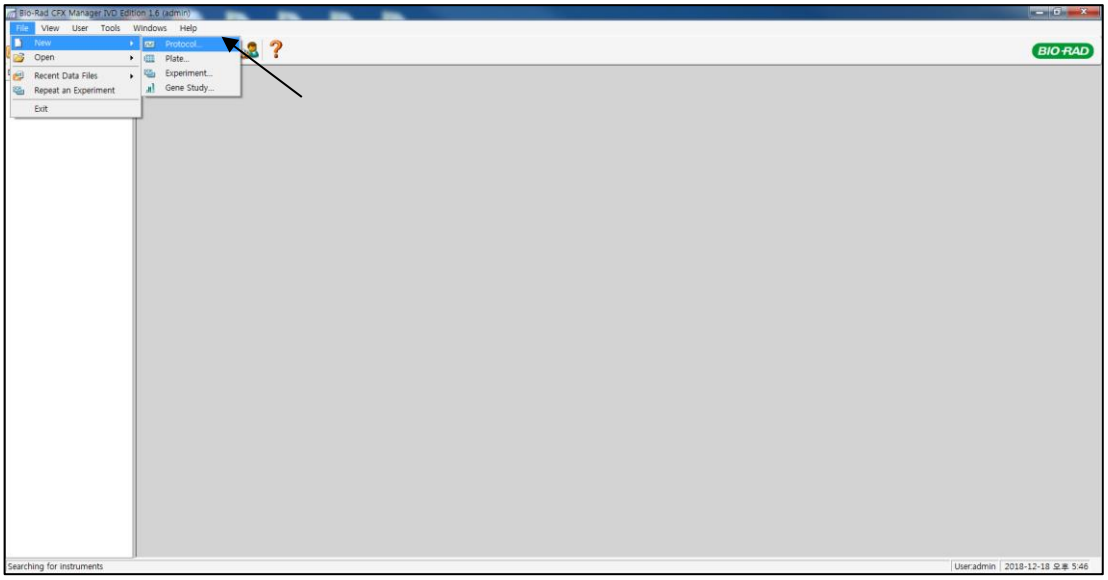


Fig. 1. **Protocol Setup**

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 Step 7, 39 more times		

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

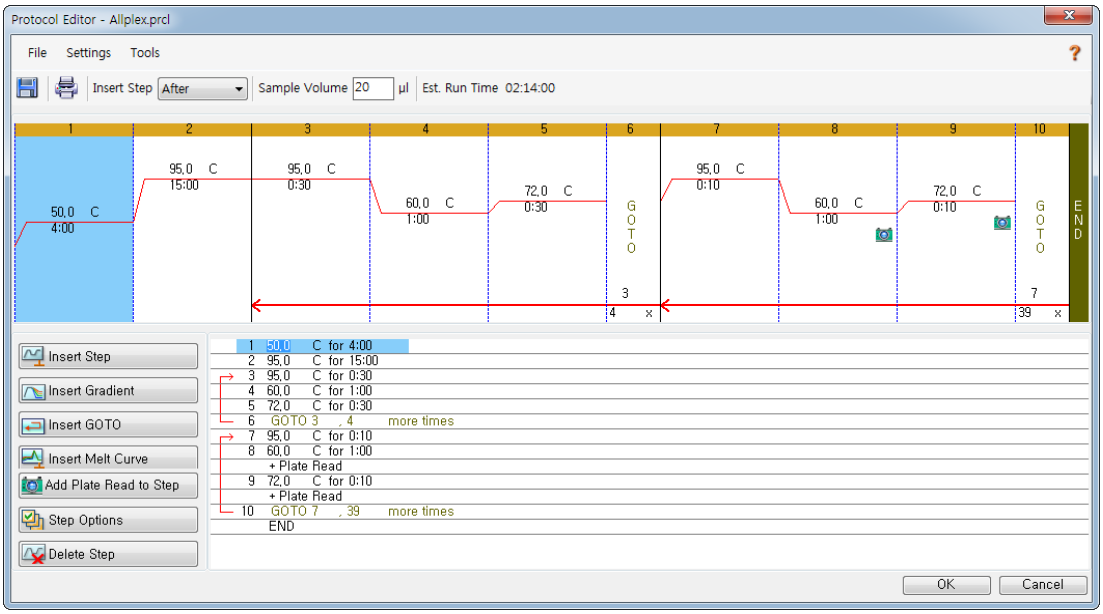


Fig. 2. **Protocol Editor**

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

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

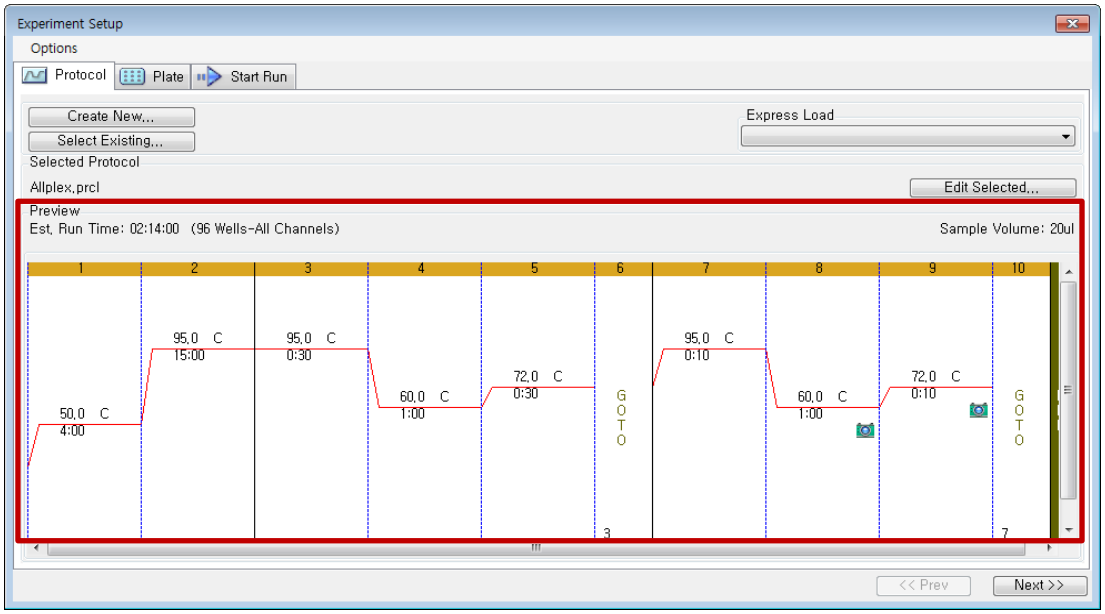


Fig. 3. **Experiment Setup: Protocol**

B. Plate Setup

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

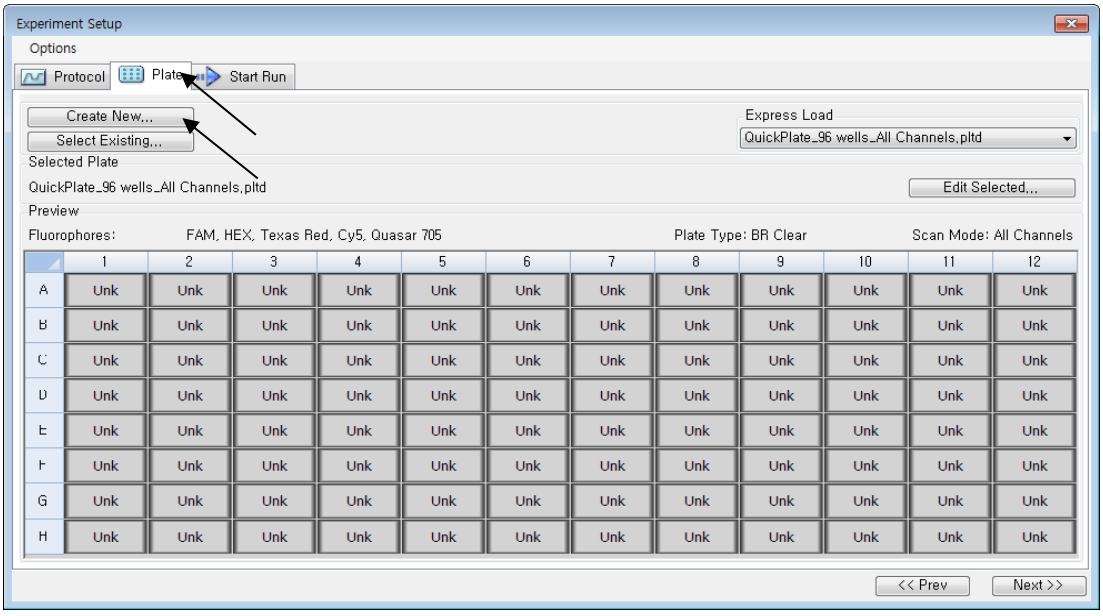


Fig. 4. **Plate Editor**

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

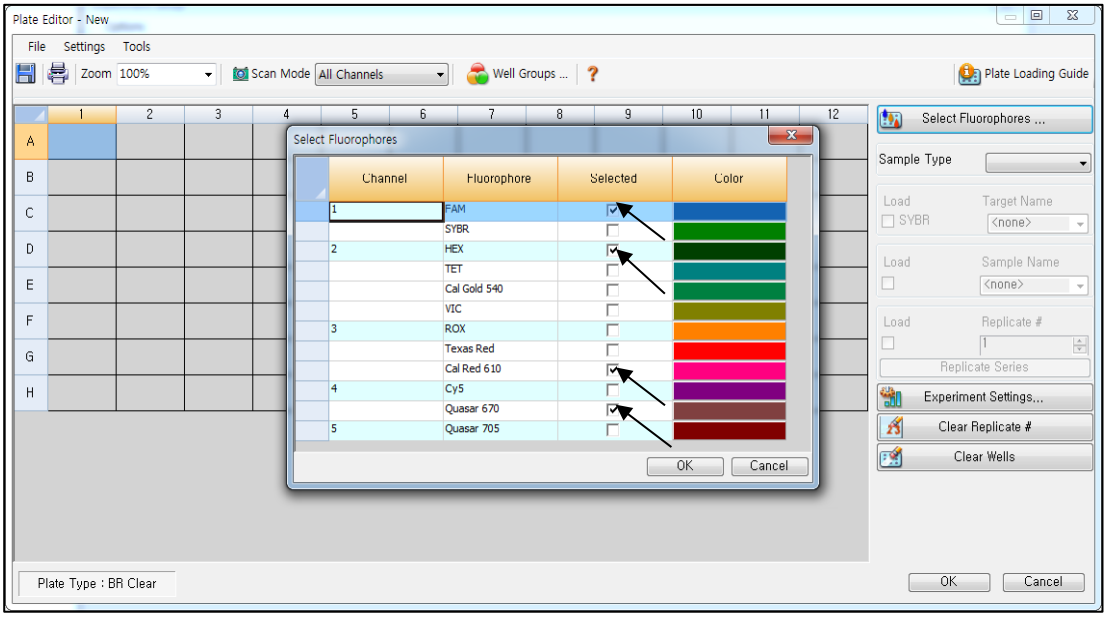


Fig. 5. **Select Fluorophores** (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**)

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)**.

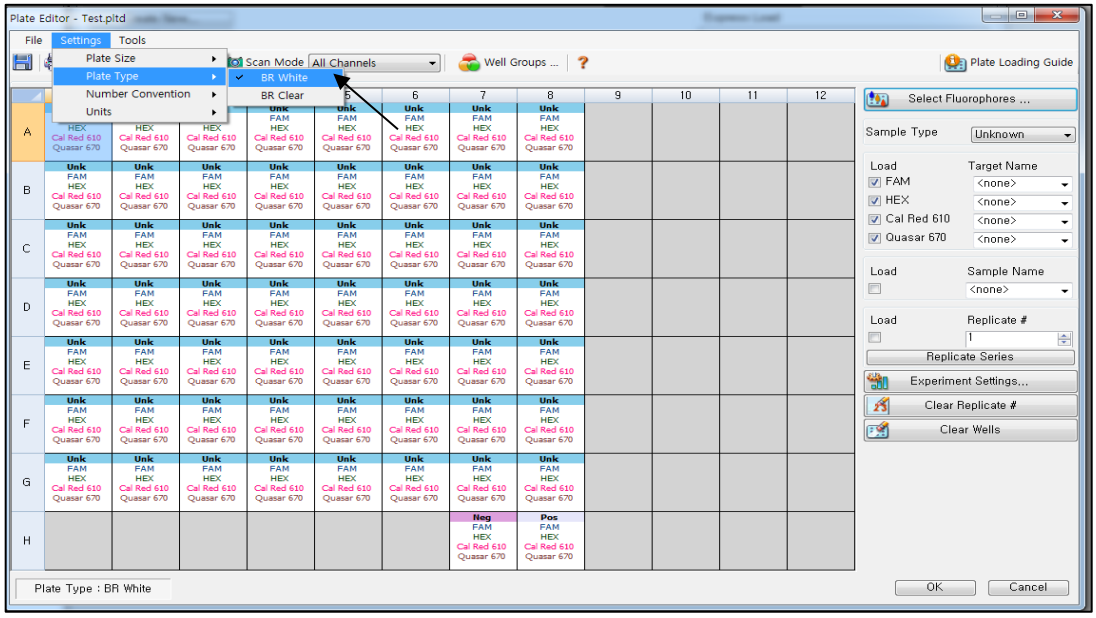


Fig. 6. **Plate Setup**

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

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

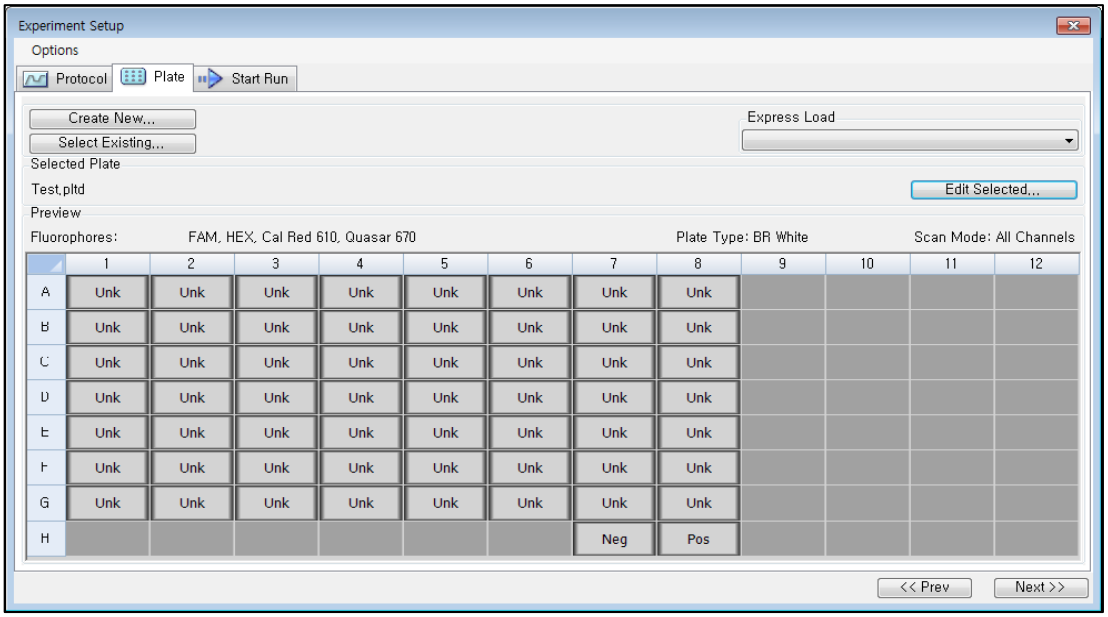


Fig. 7. **Experiment Setup: Plate**

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.

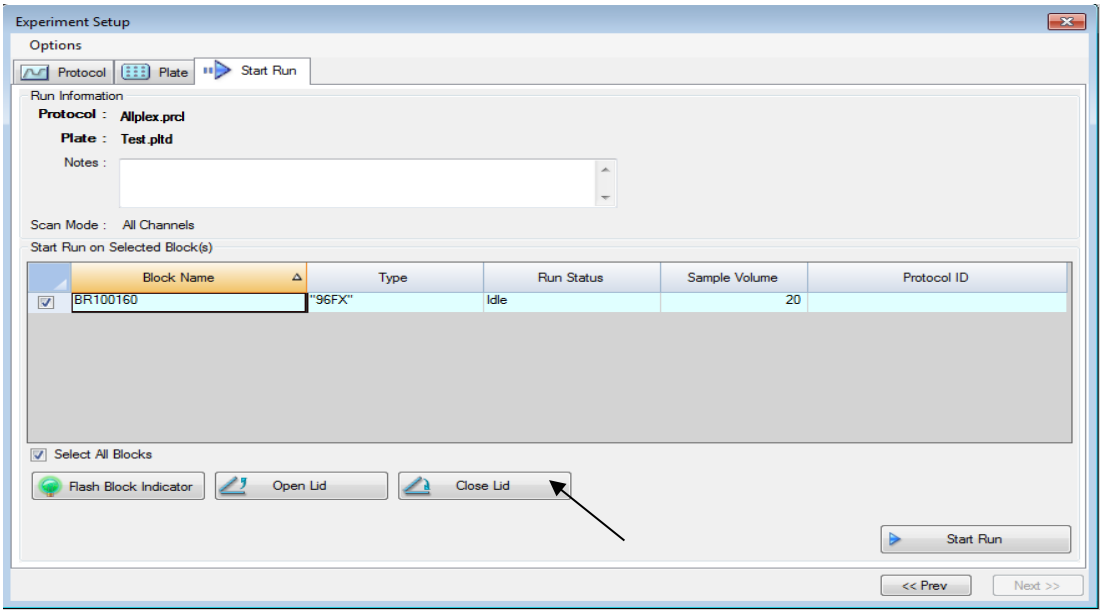


Fig. 8. **Close Lid.**

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.

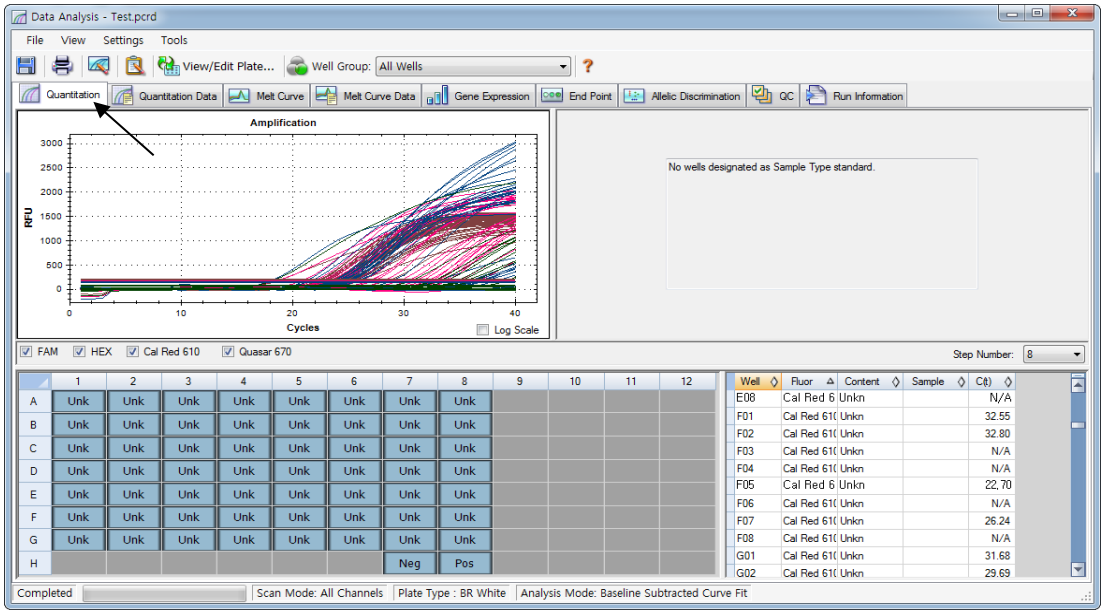


Fig. 9. **Amplification curve results**

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

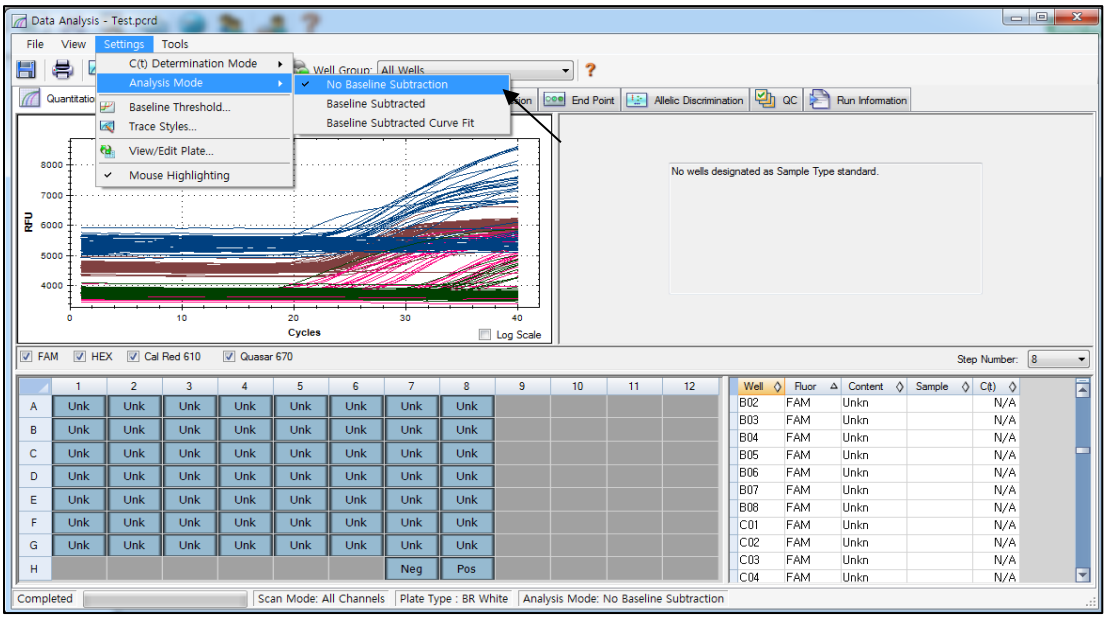


Fig. 10. **No Baseline Subtraction**

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

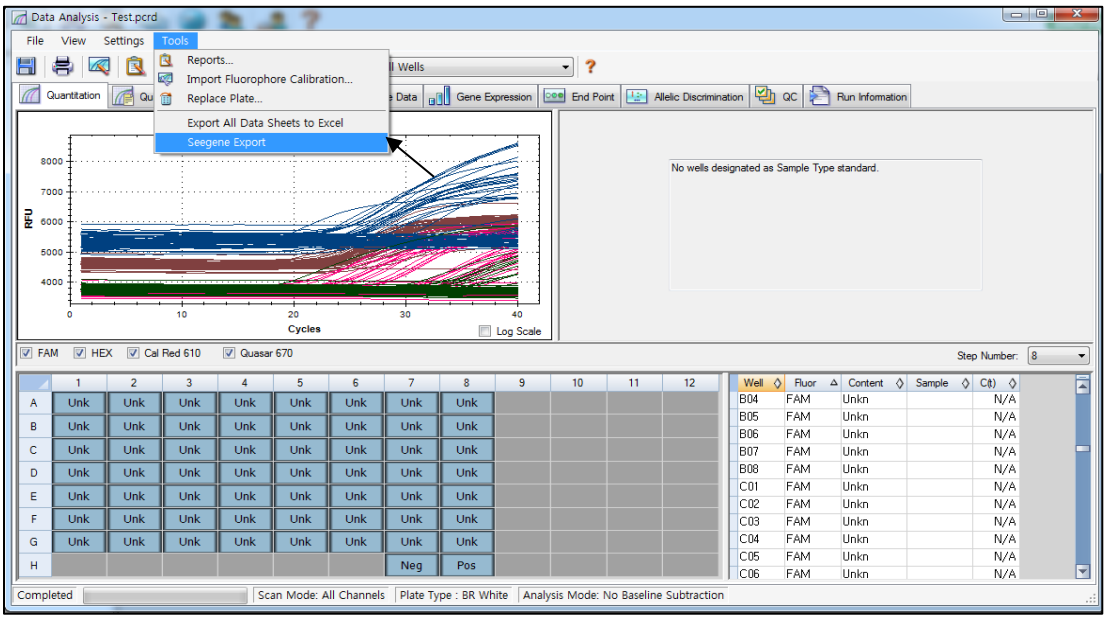


Fig. 11. **Seegene Export**

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

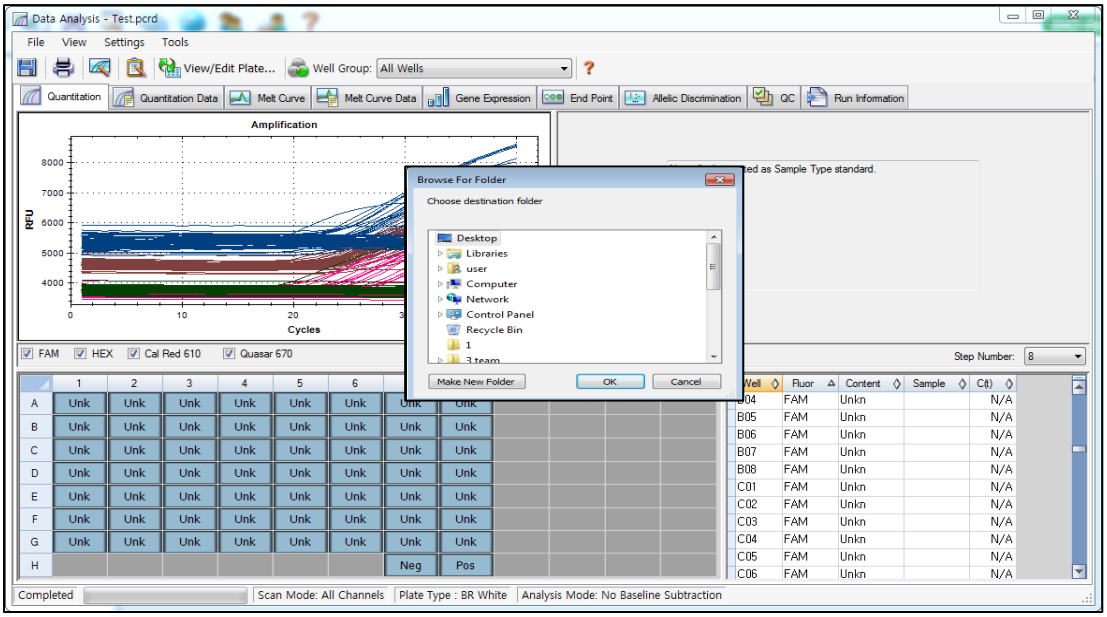


Fig. 12. **Seegene Export to designated folder**

C. Settings for Data Analysis in Seegene Viewer

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

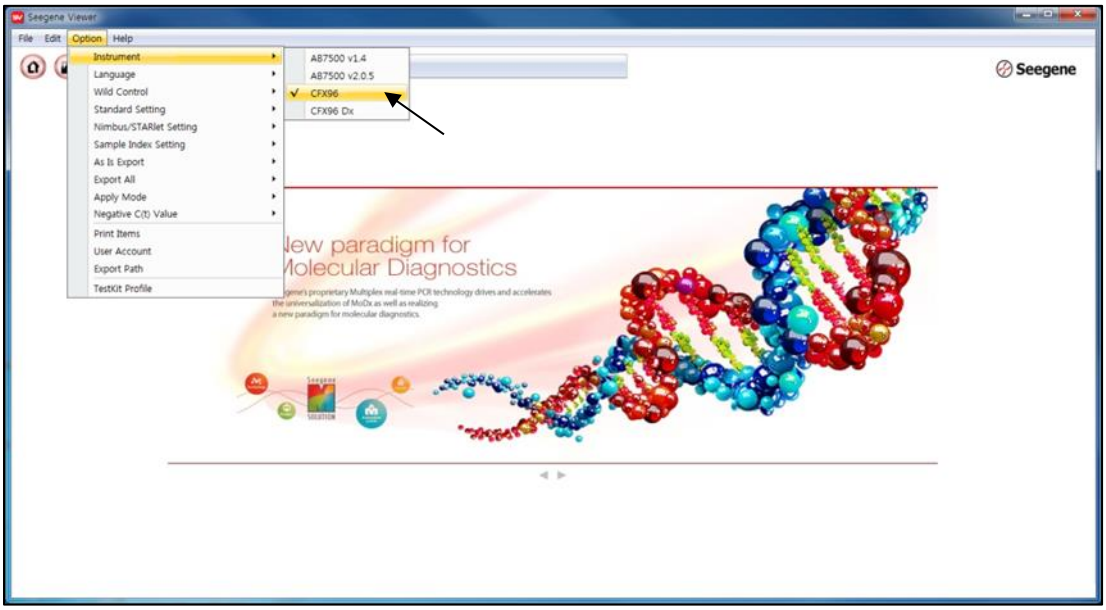


Fig. 13. **Seegene Viewer**

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

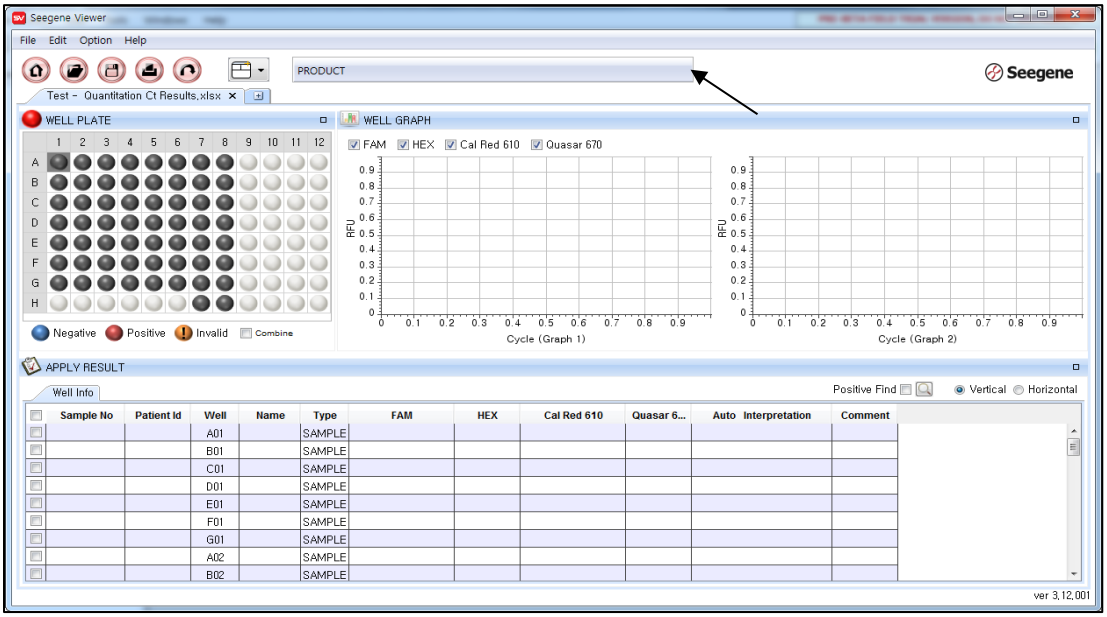


Fig. 14. **Settings for Data Analysis in Seegene Viewer**

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

3) Check the result for each well.

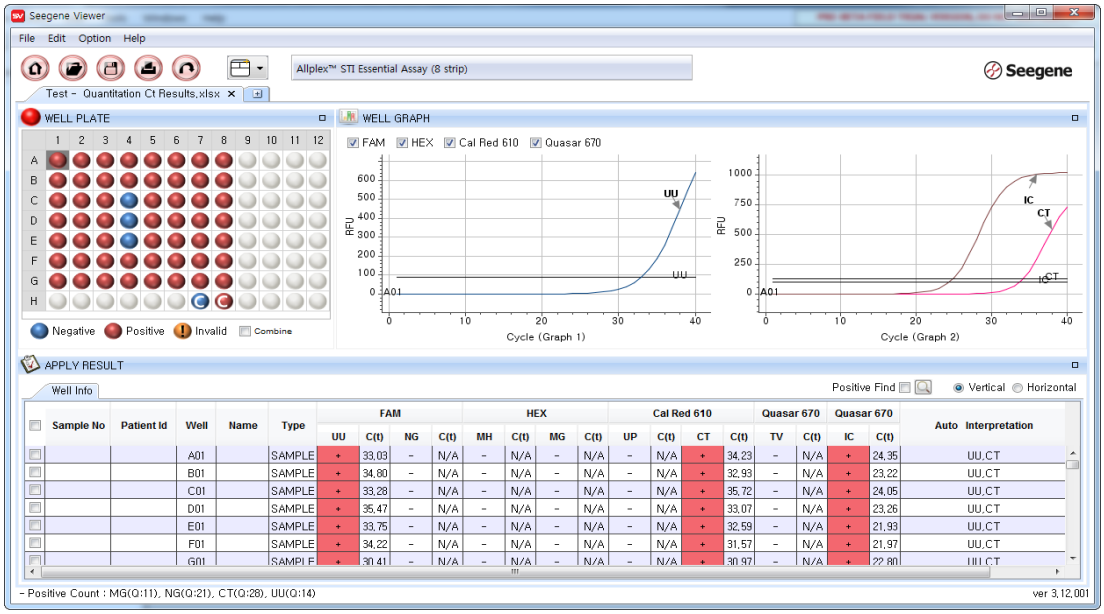


Fig. 15. **Test result on Seegene Viewer**

4) Validity Criteria of Control Results

a. Valid Assay Run

To confirm the validity of experiments, the PCR runs should be accompanied with PC (Positive Control) and NC (Negative Control). Assay run is determined as valid when all of the following criteria are met:

Control	Seegene Viewer Result								
	FAM (C_t)		HEX (C_t)		Cal Red 610 (C_t)		Quasar670 (C_t)		Auto Interpretation
	UU	NG	MH	MG	UP	CT	TV	IC	
Positive Control	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	Positive Control(+)
Negative Control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Negative Control(-)

b. Invalid Assay Run

In cases of a validity failure, the sample results should not be interpreted or reported, and the run must be repeated.

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**.

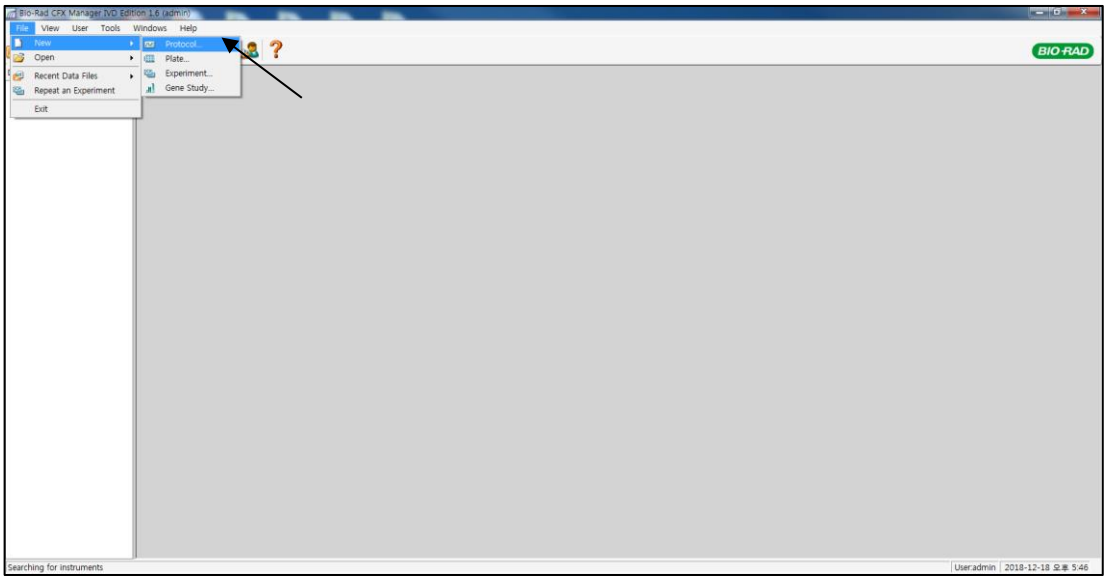


Fig. 1. **Protocol Setup.** Create a new protocol or load an existing protocol for the run

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℃.

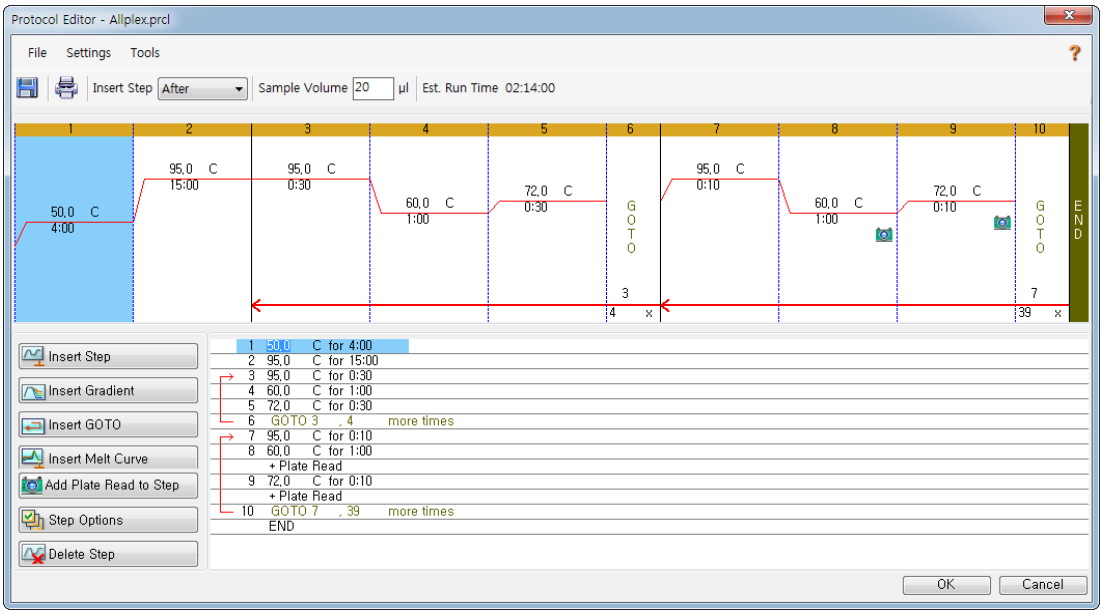


Fig. 2. **Protocol Editor**

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.

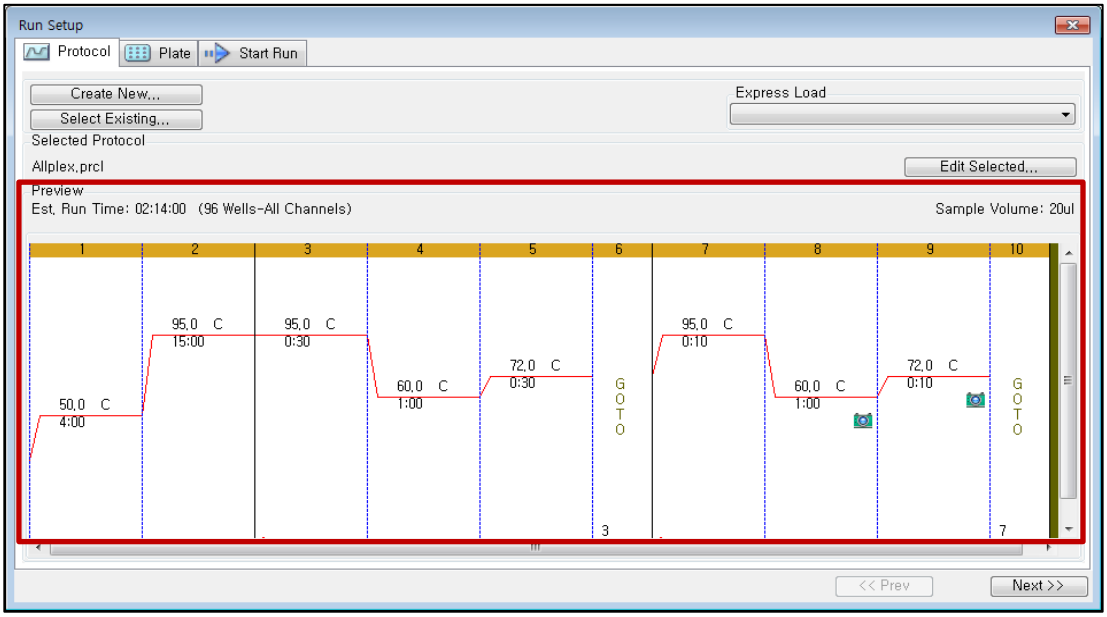


Fig. 3. **Run Setup: Protocol**

B. Plate Setup

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

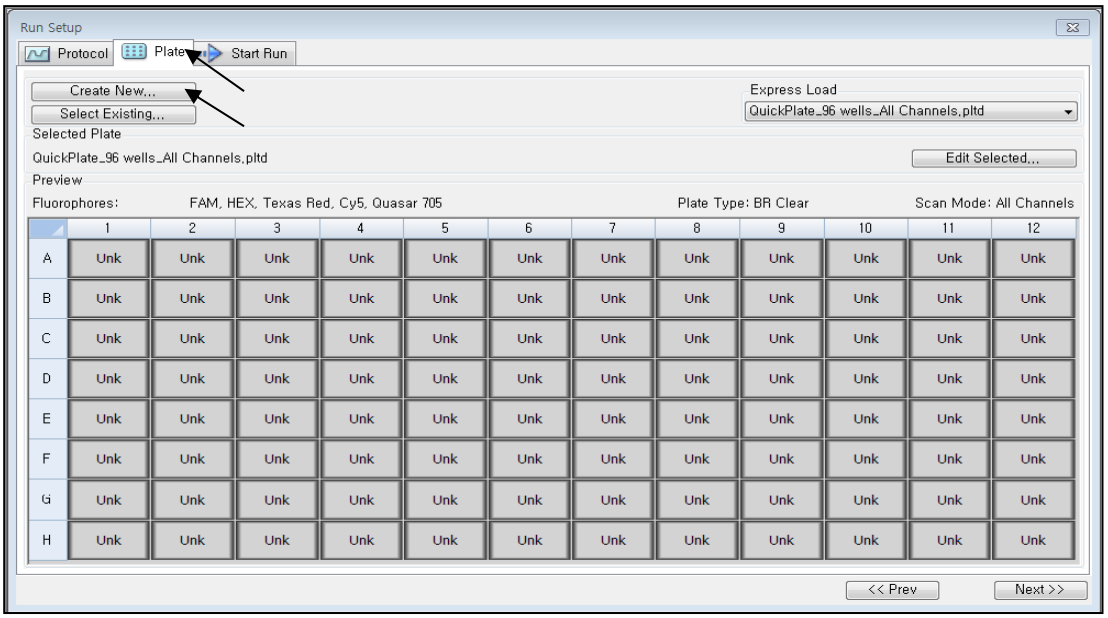


Fig. 4. **Plate Editor**. Create a new plate

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

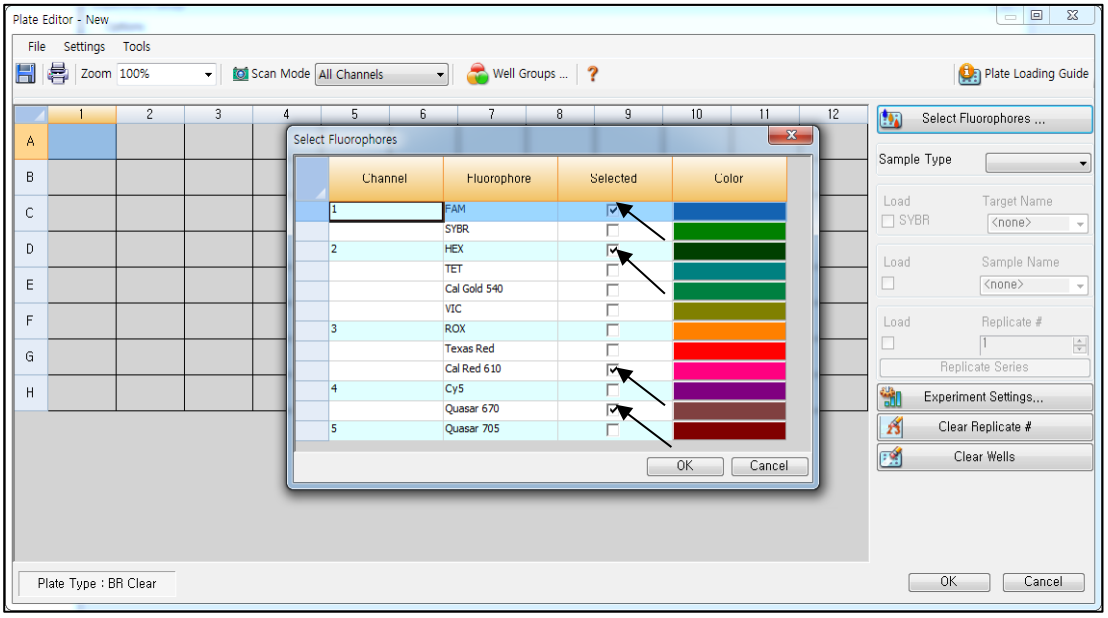


Fig. 5. **Select Fluorophores** (**FAM**, **HEX**, **Cal Red 610**, and **Quasar 670**)

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)**.

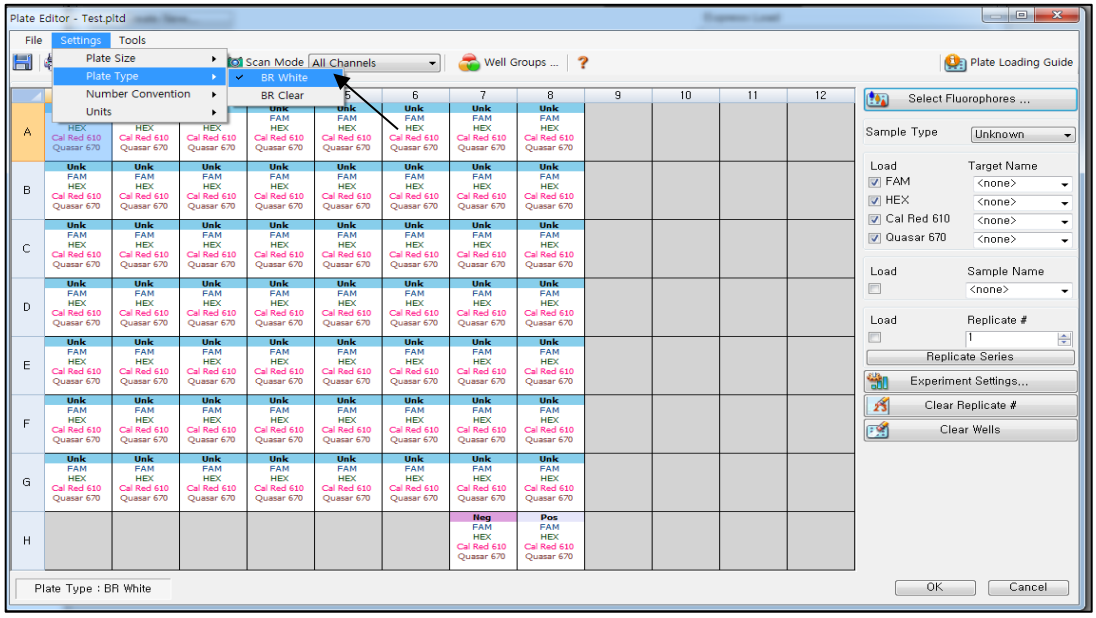


Fig. 6. **Plate Setup**

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

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

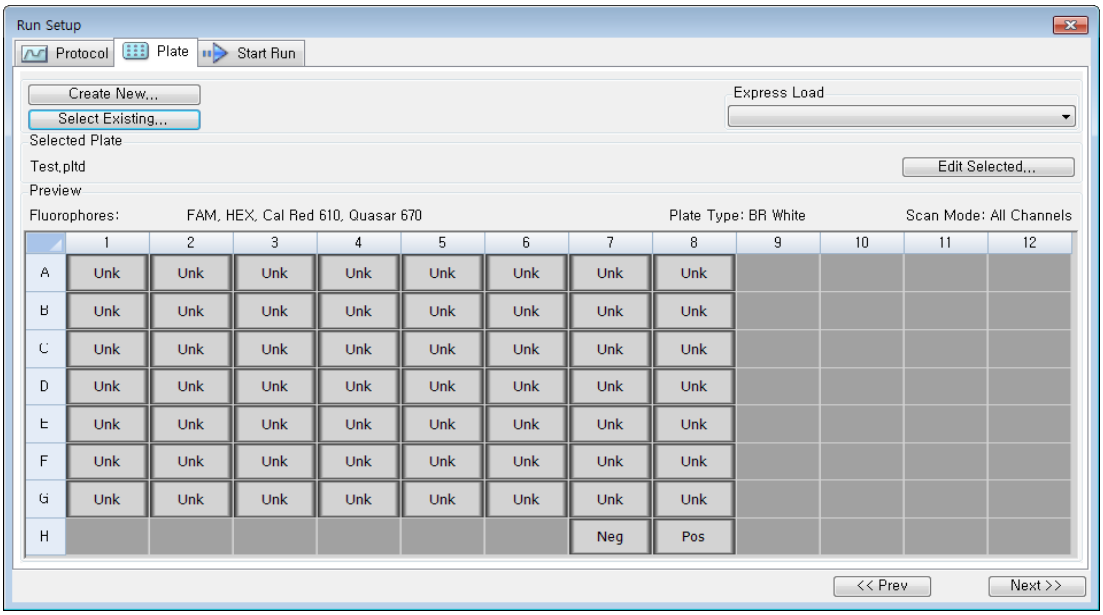


Fig. 7. **Run Setup: Plate**

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.

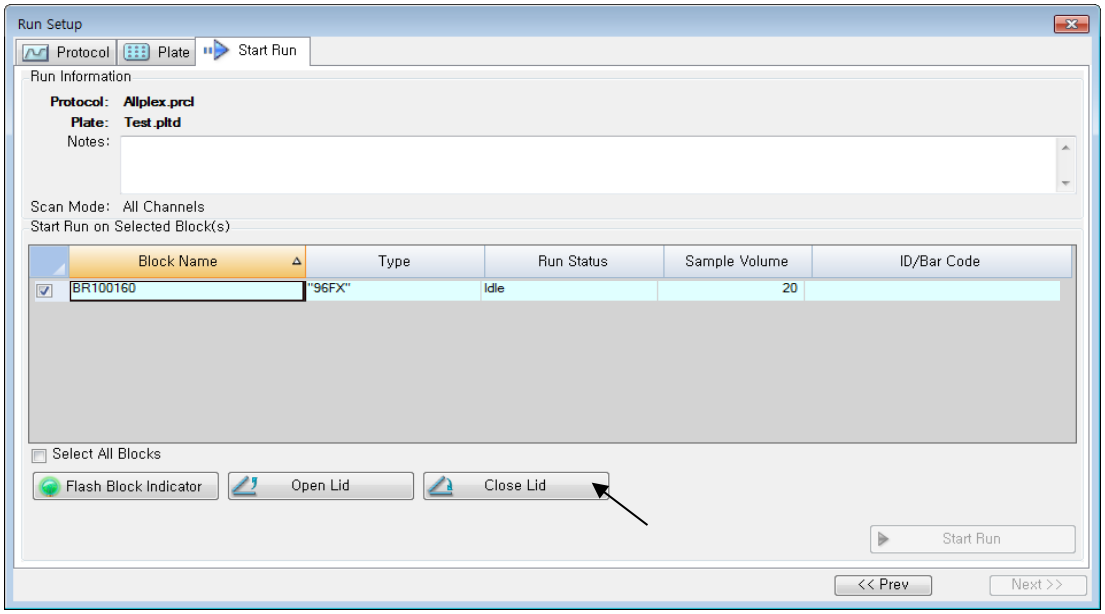


Fig. 8. **Close Lid.**

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 Quantitation tab to confirm the amplification curve results.

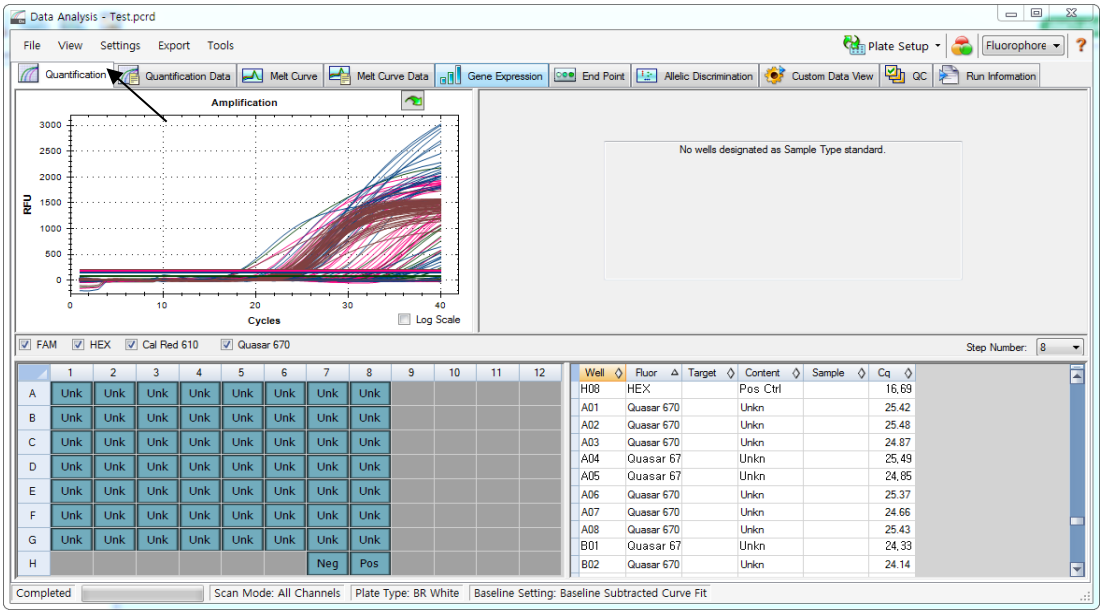


Fig. 9. **Amplification curve results**

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

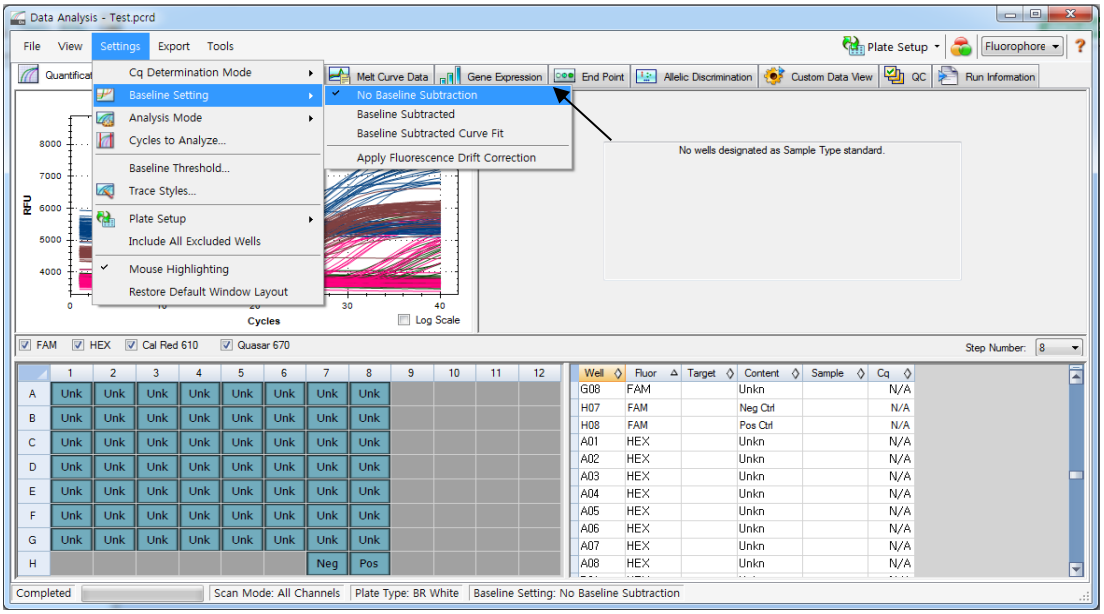


Fig. 10. **No Baseline Subtraction**

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

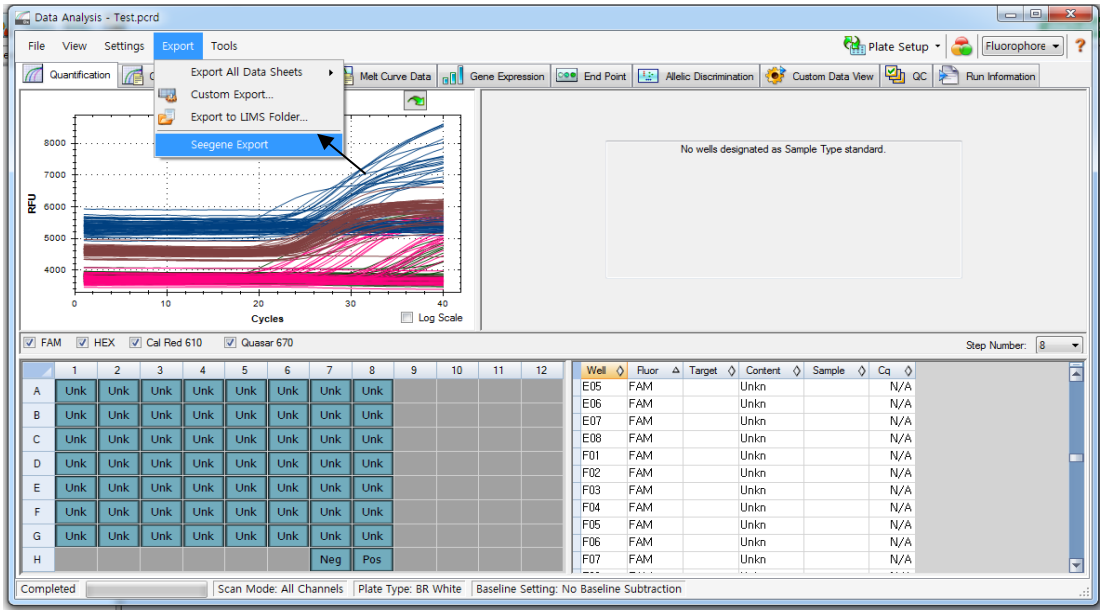


Fig. 11. **Seegene Export**

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

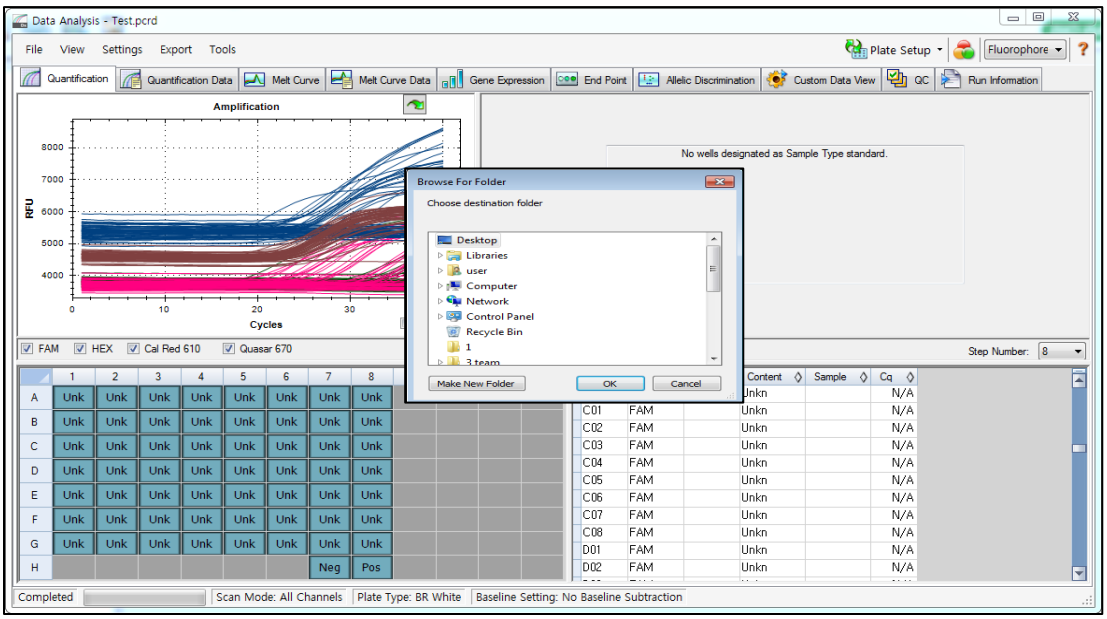


Fig. 12. **Seegene Export to designated folder**

C. Settings for Data Analysis in Seegene Viewer

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

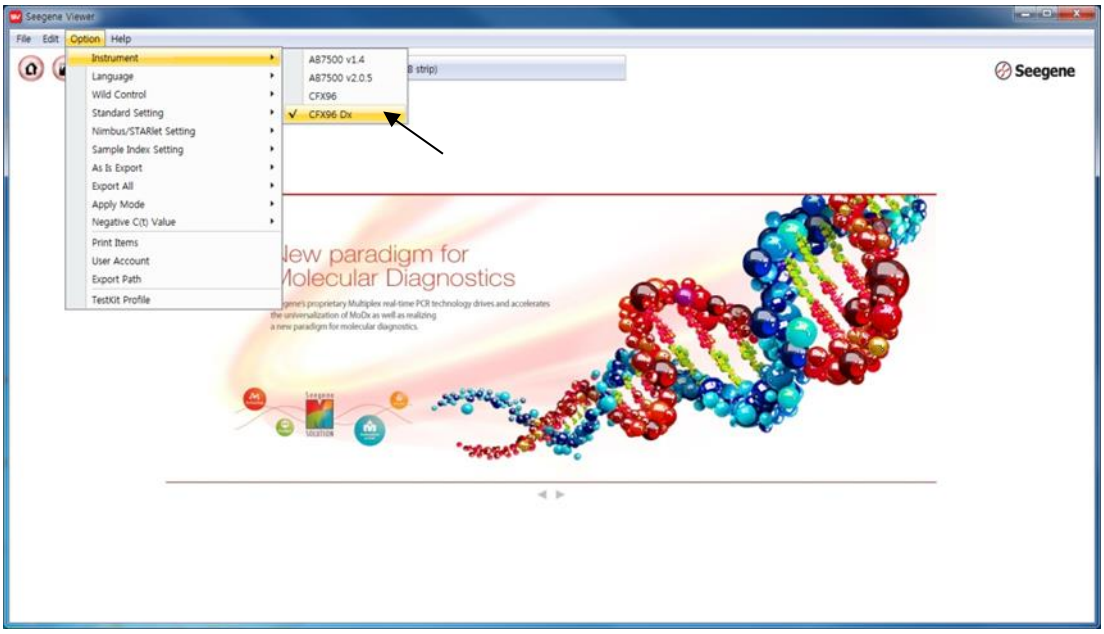


Fig. 13. **Seegene Viewer**

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

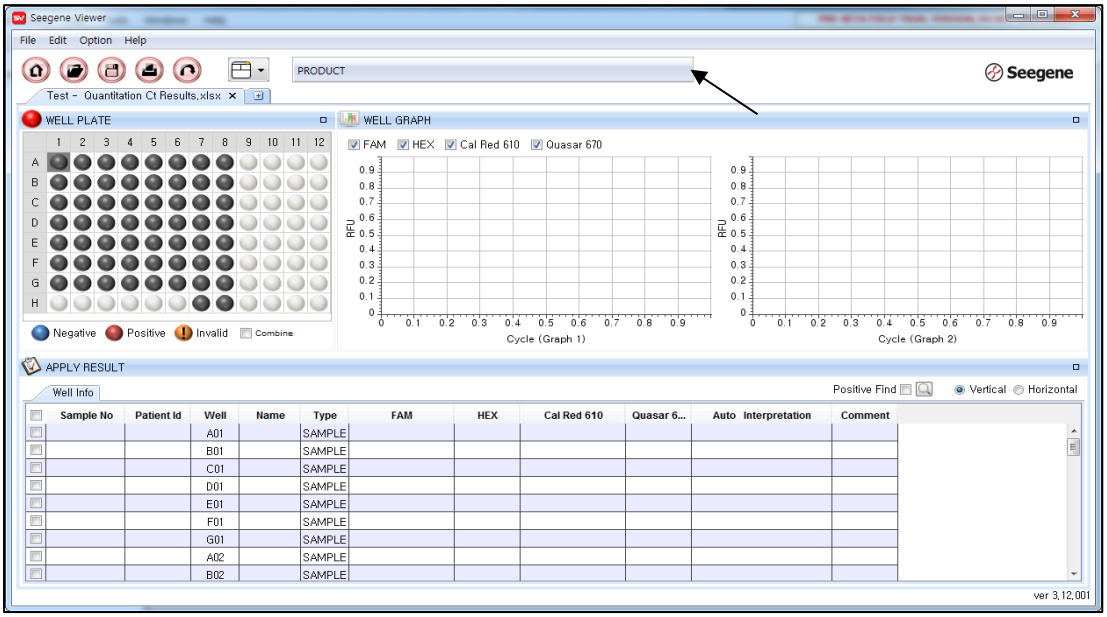


Fig. 14. **Settings for Data Analysis in Seegene Viewer**

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

3) Check the result for each well.

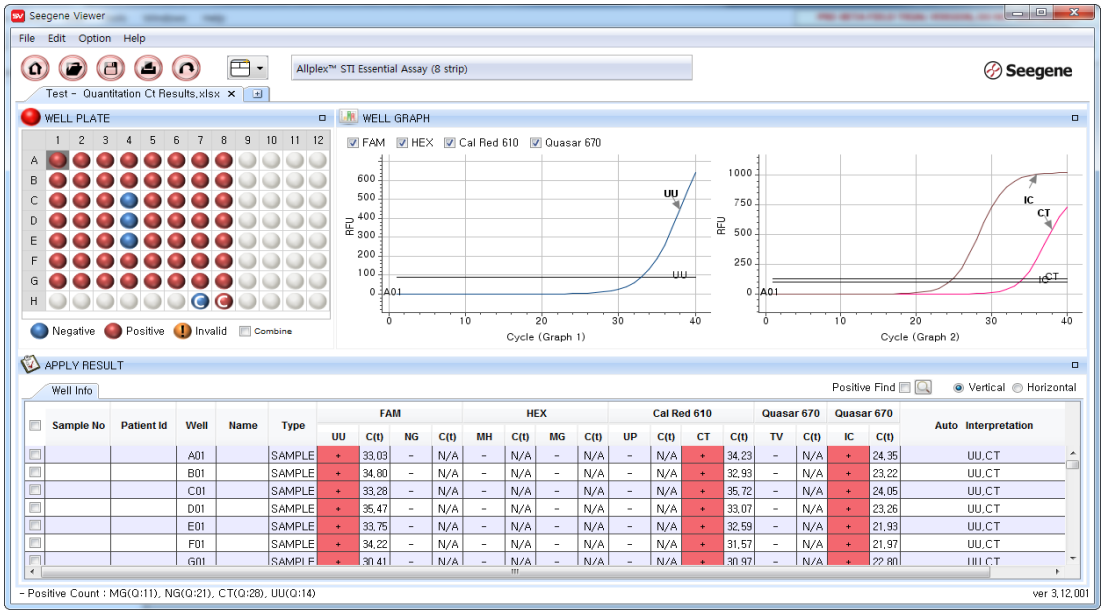


Fig. 15. **Test result on Seegene Viewer**

4) Validity Criteria of Control Results

a. Valid Assay Run

To confirm the validity of experiments, the PCR runs should be accompanied with PC (Positive Control) and NC (Negative Control). Assay run is determined as valid when all of the following criteria are met:

Control	Seegene Viewer Result								
	FAM (C_t)		HEX (C_t)		Cal Red 610 (C_t)		Quasar670 (C_t)		Auto Interpretation
	UU	NG	MH	MG	UP	CT	TV	IC	
Positive Control	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	≤ 40	Positive Control(+)
Negative Control	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Negative Control(-)

b. Invalid Assay Run

In cases of a validity failure, the sample results should not be interpreted or reported, and the run must be repeated.

RESULTS

1. Analytes Information

Fluorophore	Analyte	
	Graph 1	Graph 2
FAM	*Ureaplasma urealyticum* (UU)	*Neisseria gonorrhoeae* (NG)
HEX	*Mycoplasma hominis* (MH)	*Mycoplasma genitalium* (MG)
Cal Red 610	*Ureaplasma parvum* (UP)	*Chlamydia trachomatis* (CT)
Quasar 670	*Trichomonas vaginalis* (TV)	Internal Control (IC)

2. Interpretation of Results

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

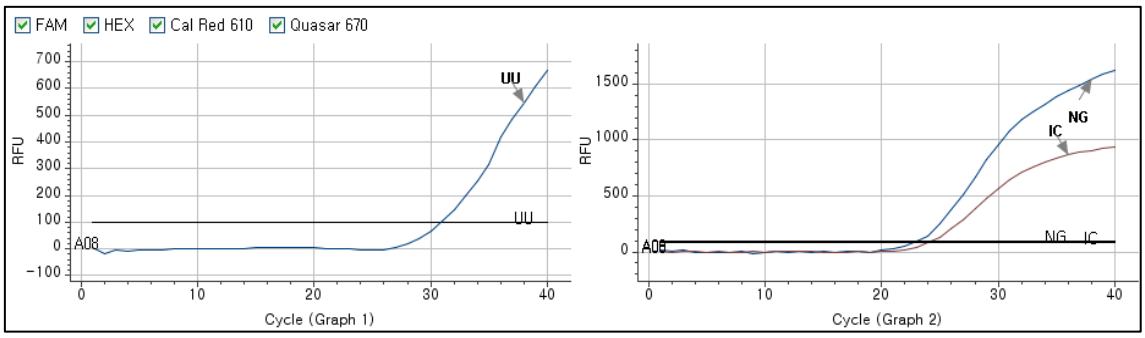
Target Result		IC Result	Interpretation
Graph 1	Graph 2		
+	-	+	**Target Nucleic acid, Detected**
-	+		
+	+		
+	-	-	**Target Nucleic acid, Detected*** - Additional STI targets that were not detected may be present.
-	+		
+	+		
-	-	+	**Target Nucleic acid, Not detected**
-	-	-	**Invalid**** - Negative 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.

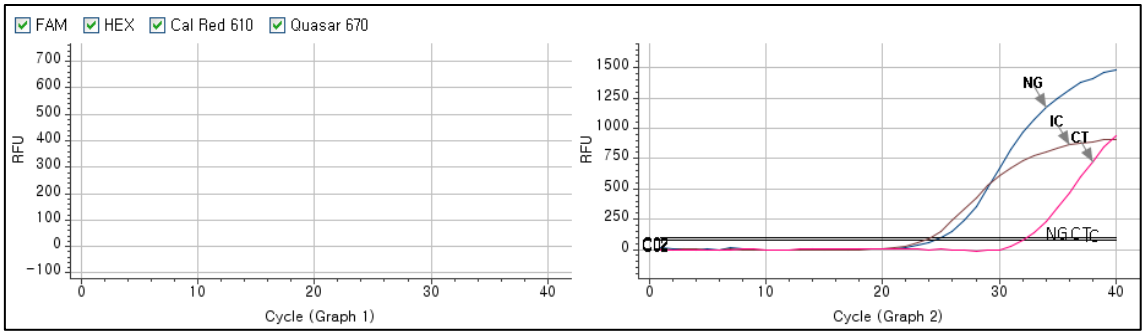
** If none of the signals including Internal Control is not observed, see TROUBLESHOOTING.

3. Application to Clinical Samples

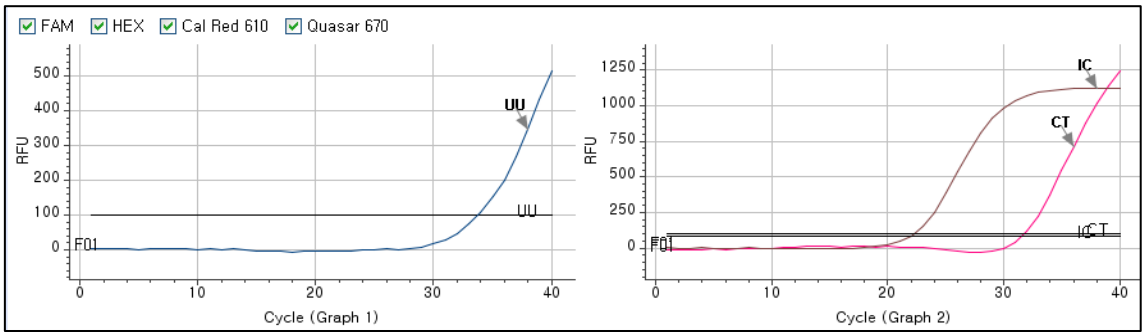
Sample 1



Sample 2



Sample 3



Sample	FAM				HEX				Cal Red 610				Quasar 670		Quasar 670		Auto Interpretation
	UU	C(t)	NG	C(t)	MH	C(t)	MG	C(t)	UP	C(t)	CT	C(t)	TV	C(t)	IC	C(t)	
1	+	30.96	+	23.19	-	N/A	-	N/A	-	N/A	-	N/A	-	N/A	+	23.97	UU,NG
2	-	N/A	+	25.09	-	N/A	-	N/A	-	N/A	+	32.42	-	N/A	+	23.76	NG,CT
3	+	33.76	-	N/A	-	N/A	-	N/A	-	N/A	+	31.80	-	N/A	+	21.82	UU,CT

TROUBLESHOOTINGS

Allplex™ STI Essential 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 11) 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™ STI Essential 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™ STI Essential Assay is ensured by the oligos designed specifically for the targets of interest and the set reaction conditions. Allplex™ STI Essential Assay was tested for cross-reactivity to 123 different pathogens, and PCR amplification and detection was only identified in the specified targets.

NO.	Organism	Source	Isolate No.	Result †
1	Chlamydia trachomatis	ATCC	VR-1500	CT Detected
2	Chlamydia trachomatis (LGV I)	ATCC	VR-901BD	CT Detected
3	Chlamydia trachomatis (LGV II)	ATCC	VR-902BD	CT Detected
4	Chlamydia trachomatis (LGV III)	ATCC	VR-903D	CT Detected
5	Chlamydia trachomatis (serovar A)	ATCC	VR-571B	CT Detected
6	Chlamydia trachomatis (serovar B	ATCC	VR-573	CT Detected
7	Chlamydia trachomatis (serovar Ba)	ATCC	VR-347	CT Detected
8	Chlamydia trachomatis (serovar C)	ATCC	VR-1477	CT Detected
9	Chlamydia trachomatis (serovar D)	ATCC	VR-885	CT Detected
10	Chlamydia trachomatis (serovar E)	ATCC	VR-348B	CT Detected
11	Chlamydia trachomatis (serovar F)	ATCC	VR-346	CT Detected
12	Chlamydia trachomatis (serovar G)	ATCC	VR-878	CT Detected
13	Chlamydia trachomatis (serovar H)	ATCC	VR-879	CT Detected
14	Chlamydia trachomatis (serovar I)	ATCC	VR-880	CT Detected
15	Chlamydia trachomatis (serovar J)	ATCC	VR-886	CT Detected
16	Chlamydia trachomatis (serovar K)	ATCC	VR-887	CT Detected
17	Mycoplasma genitalium	ATCC	33530	MG Detected
18	Mycoplasma hominis	ATCC	15488	MH Detected
19	Neisseria gonorrhoeae	ATCC	700825	NG Detected
20	Neisseria gonorrhoeae	NCTC	13798	NG Detected
21	Neisseria gonorrhoeae	NCTC	13800	NG Detected
22	Trichomonas vaginalis	ATCC	30238	TV Detected
23	Ureaplasma parvum	ATCC	27815	UP Detected
24	Ureaplasma urealyticum	ATCC	27813	UU Detected

25	Atopobium vaginae	KCTC	15240	Not Detected
26	Acinetobacter baumannii	KCCM	35401	Not Detected
27	Acinetobacter schindleri	KCTC	12409	Not Detected
28	Acinetobacter ursingii	KCTC	12410	Not Detected
29	Atopobium parvulum	KCOM	1530	Not Detected
30	Bacteroides caccae	ATCC	43185	Not Detected
31	Bacteroides fragilis	KCTC	5013	Not Detected
32	Bacteroides ovatus	KCTC	5827	Not Detected
33	Bacteroides vulgatus	ATCC	8482	Not Detected
34	Bacteroides xylanisolvens	KCOM	3242	Not Detected
35	Bifidobacterium adolescentis	KCTC	3216	Not Detected
36	Bifidobacterium longum	KCTC	3421	Not Detected
37	Bifidobacterium minimum	KCTC	3273	Not Detected
38	Candida albicans	ATCC	10231D-5	Not Detected
39	Candida dubliniensis	KCTC	17427	Not Detected
40	Candida glabrata	KCCM	50044	Not Detected
41	Candida krusei	KCCM	11426	Not Detected
42	Candida lusitaniae	KCCM	50541	Not Detected
43	Candida orthopsilosis	ATCC	96139	Not Detected
44	Candida parapsilosis	KCTC	7653	Not Detected
45	Candida tropicalis	KCCM	32008	Not Detected
46	Candida metapsilosis	ATCC	96144D	Not Detected
47	Chlamydophila pneumonidae	ATCC	VR-1310	Not Detected
48	Chlamydophila psittaci	Vircell	MBC013	Not Detected
49	Clostridium difficile (Toxin A+ / B+)	NCTC	11209	Not Detected
50	Clostridium perfringens	KCTC	3269	Not Detected
51	Cytomegalovirus (CMV)	NIBSC	09/162	Not Detected
52	Enterococcus avium	ATCC	14025	Not Detected
53	Epstein Barr Virus	ATCC	VR-1492	Not Detected
54	Escherichia coli	ATCC	25922	Not Detected
55	Gardnerella vaginalis	KCTC	5096	Not Detected
56	Haemophilus ducreyi	ATCC	700724D-5	Not Detected
57	Haemophilus influenzae	KCTC	15481	Not Detected
58	Hepatitis A virus (HAV)	ATCC	VR-1541	Not Detected

59	Hepatitis B virus (HBV)	ATCC	VR-3232SD	Not Detected
60	Hepatitis C virus (HCV)	ATCC	VR-3233SD	Not Detected
61	Human herpesvirus 1	KBPV	VR-1493	Not Detected
62	Human herpesvirus 2	KBPV	VR-734	Not Detected
63	Human herpesvirus 3	ATCC	VR-1367	Not Detected
64	Human Papilloma Virus 16	KCLB	30035	Not Detected
65	Human Papilloma Virus 16	KCLB	21550	Not Detected
66	Human Papilloma Virus 18	KCLB	10002	Not Detected
67	Lactobacillus acidophilus	KCTC	3140	Not Detected
68	Lactobacillus amylovorus	KCTC	3179	Not Detected
69	Lactobacillus brevis	KCTC	3498	Not Detected
70	Lactobacillus casei	KCTC	3260	Not Detected
71	Lactobacillus crispatus	KCTC	5054	Not Detected
72	Lactobacillus delbrueckii subsp. Delbrueckii	KCTC	13730	Not Detected
73	Lactobacillus fermentum	KCTC	3112	Not Detected
74	Lactobacillus gallinarum	KCTC	5048	Not Detected
75	Lactobacillus gasseri	KCTC	3163	Not Detected
76	Lactobacillus helveticus	KCTC	15060	Not Detected
77	Lactobacillus iners	CCARM	0123	Not Detected
78	Lactobacillus intestinalis	KCTC	5052	Not Detected
79	Lactobacillus jensenii	KCTC	5194	Not Detected
80	Lactobacillus johnsonii	KCTC	3801	Not Detected
81	Lactobacillus kefiranofaciens	KCTC	5075	Not Detected
82	Lactobacillus oris	KCCM	40993	Not Detected
83	Lactobacillus parabuchneri	KCTC	3503	Not Detected
84	Lactobacillus pentosus	KCTC	3120	Not Detected
85	Lactobacillus plantarum	ATCC	700934	Not Detected
86	Lactobacillus reuteri	KCTC	3594	Not Detected
87	Lactobacillus rhamnosus	KCCM	32405	Not Detected
88	Lactobacillus salivarius subsp. Salicinius	KCTC	3600	Not Detected
89	Lactobacillus sanfrancisensis	KACC	12431	Not Detected
90	Lactobacillus ultunensis	KCTC	5857	Not Detected
91	Lactobacillus vaginalis	KCTC	3515	Not Detected
92	Mobiluncus curtisii	ATCC	35241	Not Detected

93	Mobiluncus mulieris	ATCC	35243	Not Detected
94	Mycoplasma arginini	ATCC	23838	Not Detected
95	Mycoplasma felis Cole et al.	ATCC	23391	Not Detected
96	Mycoplasma iowae Jordan et al.	ATCC	33552	Not Detected
97	Mycoplasma leonicaptivi Hill	ATCC	49890	Not Detected
98	Mycoplasma pneumonia	ATCC	15531	Not Detected
99	Mycoplasma pulmonis	ATCC	19612	Not Detected
100	Mycoplasma spumans	ATCC	19526	Not Detected
101	Neisseria cinerea	ATCC	14685	Not Detected
102	Neisseria flavescens	CCARM	9264	Not Detected
103	Neisseria lactamica	ATCC	23970	Not Detected
104	Neisseria meningitidis	ATCC	700532D	Not Detected
105	Neisseria mucosa	ATCC	19696	Not Detected
106	Neisseria perflava	ATCC	14799D-5	Not Detected
107	Neisseria sicca	ATCC	29256	Not Detected
108	Neisseria subflava	ATCC	49275	Not Detected
109	Prevotella bivia	KCTC	5454	Not Detected
110	Prevotella buccalis	KCTC	5496	Not Detected
111	Prevotella disiens	KCTC	5499	Not Detected
112	Prevotella intermedia	KCTC	5692	Not Detected
113	Prevotella melaninogenica	KCTC	5457	Not Detected
114	Pseudomonas aeruginosa	KCCM	11328	Not Detected
115	Saccharomyces cerevisiae	KCTC	7968	Not Detected
116	Salmonella enteritidis	CCARM	8570	Not Detected
117	Salmonella typhimurium	CCARM	0270	Not Detected
118	Staphylococcus aureus	KCTC	1621	Not Detected
119	Streptococcus agalactiae	ATCC	BAA-611D-5	Not Detected
120	Streptococcus pneumoniae	ATCC	BAA-255D	Not Detected
121	Treponema pallidum	ATCC	BAA-2642SD	Not Detected
122	Trichomonas tenax	ATCC	30207	Not Detected
123	Vibrio parahaemolyticus	KCTC	2471	Not Detected

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

※ ATCC: American Type Culture Collection
NCTC: National Collection of Type Cultures
KCTC: Korean Collection for Type Culture
KCCM: Korean Culture Center of Microorganisms
NIBSC: National Institute for Biological Standards and Control
Vircell : Vircell microbiologists
CCARM: Culture Collection of Antimicrobial Resistant Microbes
KACC: Korean Agricultural Culture Collection
KBPV: Korea Bank for Pathogenic Viruses
KCLB: Korean Cell Line Bank

2. Sensitivity

The sensitivity is defined as the lowest concentration of organism that can be consistently detected (≥ 95% of positive results among all tested sample). It was confirmed per target when the correct organism/assay results were obtained from at least 40 of the 40 samples (40/40 = 100%) tested.

The sensitivity of Allplex™ STI Essential Assay was determined using target strain from each sample unit of quantitative about 10^3 ~ 10^0. Detection limits for UU, NG, MH, MG, UP and TV target were as shown in the table below.

No.	Target	LoD
1	Ureaplasma urealiticum	100 CFU/ml
2	Neisseria gonorrhoeae	1 CFU/ml
3	Mycoplasma hominis	50 CFU/ml
4	Mycoplasma genitalium	50 CCU/ml
5	Ureaplasma parvum	50 CCU/ml
6	Trichomonas vaginalis	10 cells/ml

In case of *Chlamydia Trachomatis*, the sensitivity of Allplex™ STI Essential Assay was conducted using two kind of materials (ATCC VR-1500 and ZMC 0801775) ;

1) Nucleic acids which are extracted and quantified as genomic copies/rxn
2) Cell status which are quantified as IFU/ml

The sensitivity for *Chlamydia Trachomatis* was confirmed to be the lowest concentration for which at least ≥ 95% replicates were detected as following;

	Genomic copies/rxn		IFU/ml[1)]	
Chlamydia Trachomatis	ATCC VR-1500	10 copies/rxn	ATCC VR-1500	10 IFU/ml
	ZMC 0801775	10 copies/rxn	ZMC 0801775	40 IFU/ml

In case of using functional titer as IFU/ml, there could be discordance between which standard organisms will be used.

[1)] Note: The IFU unit is a method of measuring the functional titer rather than the absolute value, and is affected by the measurement protocol of the institution, the person, time, and the state of the strain at the time of measurement. Therefore, it means the difference in IFU unit according to the characteristics of the strain used in the experiment at the time, not the difference in sensitivity performance of the product itself by strain.

3. Reproducibility

The reproducibility panel of 21 simulated analytes was prepared that included High negative (0.1 X LoD), Low positive (1X LoD) and Moderate positive (3X LoD) samples. At each testing site, the panel was tested for five days, two runs per day by two different operators and triplicate of each panel per run from one extraction. It was tested with a single lot of Allplex™ STI Essential Assay at three different sites and three lots at one in-house site. The positive rates were observed for each analytes for reproducibility study: 100.00% for Moderate positive samples, ≥100.00% for Low positive samples and ≥7.33% for High negative samples.

The reproducibility of Allplex™ STI Essential Assay was evaluated between sites, product lots and experimenters.

The results were satisfied with the Criteria set above, thus confirming the reproducible performances of Allplex™ STI Essential Assay.

4. Interfering substances

This test was conducted using interfering substances composed of 10 substances in order to confirm the performance of the Allplex™ STI Essential Assay in the presence of potential interfering substances. There was no effect on the result by adding the substances: non-specific detection or inhibition on target amplification. Based on the results, 10 interfering substances had no effect on Allplex™ STI Essential Assay results.

No.	Interfering substances	Concentration
1	Metronidazole	701 µmol/L
2	Amoxicillin	206 µmol/L
3	Bilirubin	342 µmol/L
4	Hemoglobin human	200 g/L
5	Progesterone	20 ng/mL
6	Beta Estradiol	4.41 nmol/L
7	Acetylsalicylic Acid (aspirin)	3.62 mmol/L
8	Glucose	55 mmol/L
9	Albumin (BSA)	60 g/L
10	Mucin	3 mg/mL
11	Testosterone	41.6 nmol/L
12	Luteinizing hormone (LH)	70 IU/L
13	Follicle Stimulating Hormone (FSH)	100 IU/L
14	Cortisol	828 nmol/L
15	Fructose	1000 µmol/L

5. Clinical study

A total of 226 clinical specimens were tested with Allplex™ STI Essential Assay and reference assay.

The agreements between Allplex STI Essential Assay (V2.0) and reference assay, with reflection of sequencing confirmation, were 99.12%, 100%, 100%, 100%, 100%, 99.56% and 99.56% for detection of CT, NG, MG, TV, MH, UU, and UP, respectively.

The clinical validity of STI Essential Assay (V2.0) has proven in diagnosing seven STI analytes, as the results satisfy the success criteria.

Analyte	PPA (compared to reference assay)			NPA (compared to reference assay)			Agreement		
	TP/ (TP+FN)	%[a]	95% CI[c]	TN/ (TN+FP)	%[b]	95% CI[c]	(TP+TN) /Total	%[d]	95% CI[c]
Ureaplasma urealiticum (UU)	30/30	100.00	88.43 ~ 100.00	195/196	99.49	97.19 ~ 99.99	225/226	99.56	97.56 ~ 99.99
Neisseria gonorrhoeae (NG)	53/53	100.00	93.28 ~ 100.00	173/173	100.00	97.89 ~ 100.00	226/226	100.00	98.38 ~ 100.00
Mycoplasma hominis (MH)	45/45	100.00	92.13 ~ 100.00	181/181	100.00	97.98 ~ 100.00	226/226	100.00	98.38 ~ 100.00
Mycoplasma genitalium (MG)	35/35	100.00	90.00 ~ 100.00	191/191	100.00	98.09 ~ 100.00	226/226	100.00	98.38 ~ 100.00
Ureaplasma parvum (UP)	83/83	100.00	95.65 ~ 100.00	142/143	99.30	96.17 ~ 99.98	225/226	99.56	97.56 ~ 99.99
Chlamydia trachomatis (CT)	37/38	97.37	86.19 ~ 99.93	187/188	99.47	97.07 ~ 99.99	224/226	99.12	96.84 ~ 99.89
Trichomonas vaginalis (TV)	31/31	100.00	88.78 ~ 100.00	195/195	100.00	98.13 ~ 100.00	226/226	100.00	98.38 ~ 100.00

a) PPA (Positive percent agreement) (%): 100 X TP/(TP+FN)

b) NPA (Negative percent agreement) (%): 100 X TN/(FP+TN)

c) The two-sided 95% confidence intervals were calculated.

d) Agreement (%): 100 X (TP+TN)/(TP+TN+FP+FN)

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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

ORDERING INFORMATION

Cat. No.	Product	Size
Allplex™ series		
SD10245Z	**Allplex™ STI Essential Assay**	**25 rxns***
SD9801Y	Allplex™ STI Essential Assay	50 rxns
SD9801X	**Allplex™ STI Essential Assay**	**100 rxns***
SD10177Z	Allplex™ Genital ulcer Assay	25 rxns*
SD9802Y	Allplex™ Genital ulcer Assay	50 rxns
SD9802X	Allplex™ Genital ulcer Assay	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
SD10159X	Allplex™ Bacterial Vaginosis *plus* Assay	100 rxns
SD9400Y	Allplex™ CT/NG/MG/TV Assay	50 rxns
SD9400X	Allplex™ CT/NG/MG/TV Assay	100 rxns*
SD10169Y	Allplex™ MG & AziR Assay	50 rxns
SD10170X	Allplex™ MG & AziR Assay	100 rxns*

* For use with Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet only

Anyplex™ series		
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*
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**

* For use with Microlab NIMBUS IVD, Microlab STARlet IVD, Seegene NIMBUS and Seegene STARlet only

** 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
744300.4.UC384	STARMag 96 X 4 Universal Cartridge Kit	384T / 1box
EX00013C	STARMag 96 X 4 Viral DNA/RNA 200 C Kit	384T / 1box
SGprep32-180701	SGprep32	EA
EX00003P	STARMag 96 UniPlate	96T / 1box
EX00004T	STARMag 96 UniTube	96T / 1box
SG71100	SEEPREP32	EA
EX00009P	STARMag 96 ProPrep (Plate Type)	96T / 1box
EX00009T	STARMag 96 ProPrep (Tube Type)	96T / 1box
EX00017P	STARMag 96 ProPrep C (Plate Type)	96T / 1box
EX00017T	STARMag 96 ProPrep C (Tube Type)	96T / 1box

Seegene Viewer

HL7 Protocol Specification

1. Outline

1.1 Purpose

Atitiktis_20

This document is intended to be a guide for a host to communicate with Seegene Viewer application using HL7 v2.5 protocol. The host interface is supported by Seegene Viewer application. A host could be a Laboratory System (LIS) or a Data Management System (DMS). In this document, you will find detailed information about all data that can be used for exchanging between the Seegene Viewer system and the host.

1.2 Document Organization

The interface of Seegene Viewer is implemented on the basis of HL7 standards; however there are some interpretations of HL7 standard if it does not offer detailed information to develop HL7 standards on Seegene Viewer. Therefore, there is some alternation for HL7 standards in case of facilitating the development of interface using HL7.

1.3 Definitions and abbreviations

Host	Laboratory Information System(LIS), Data Management System (DMS)
LIS	Laboratory Information System
DMS	Data Management System
SV	Seegene Viewer

1.4 Reference

SEQ	Reference
1	HL7 v.2.5 *Health Level 7 Messaging Standard*
2	HL7 version 2.5 appendix C "Lower Layer Protocols"
3	http://www.hl7.org/documentcenter/public_temp_58C975E8-1C23-BA17-CB2BAFDA3151D8C/wg/inm/mllp_transport_specification.pdf
4	Seegene Viewer for Real time Instruments V3 Manual (Eng_ver 1.0)

1.5 Character set

The character encoding of Seegene Viewer's data sent to LIS is UTF-8

2. Physical layer

The Seegene Viewer LIS interface is developed on the top of TCP/IP Protocol. It is also assumed that the LIS and Seegene Viewer reside in the same network protected by a firewall. The transmission of information between the two systems is in clear text.

The way of connection

- Server: LIS (Laboratory Information System)

- Client: Seegene Viewer

3. Minimal Lower Layer Protocol (MLLP)

3.1 Background

The data-link layer is responsible for framing, flow control, error control and sequence control. The application messages passed from the upper layer are framed and then transmitted. The received frames are packaged and then passed to upper layer. A primary function of this layer is to prevent loss of data between two systems.

3.2 Introduction

MLLP protocol has a long story of use within the HL7 community, although it has never been formally part of the HL7 standard itself, but MLLP is the protocol that is widely used in HL7 community and only used in network environment. Most of the details of error detection and correction are handled by the lower levels of any reasonable network protocol.

3.3 Purpose

The goal of this minimal lower layer protocol is to provide an interface between HL7 and the network that uses minimal overhead. This protocol is extensively used for the transport of HL7 version 2 messages and is constructed as block structure.

HL7 content is enclosed by special character to form block

Element	Description
<SB>	Start block. ASCII<VT>, i.e., < 0x0B>
Data	HL7 content block and carriage <CR>
<EB>	End Block character ASCII < FS>, i.e., <0x1C>
<CR>	Carriage Return <CR>

3.4 Example

1. HL7 v2 message

```
<SB>
MSH|^~\&|ZIS|1^AHospital|||199605141144||ADT^A01|20031104082400|P|2.3|||
AL|NE|||8859/15|<CR>EVN|A01|20031104082400.0000+0100|20031104082400
PID||""|10||Vries^Danny^D.^^de||19951202|M|||Rembrandlaan^7^Leiden^^7301TH^""
^^P||""|""||""|||||||""|""<CR>PV1||I|3w^301^""^01|S|||100^van den Berg^^A.S.
^^""^dr|""||9||||H||||20031104082400.0000+0100<CR>
<EB><CR>
```

2. HL7 v3 message

```
<SB>
<?xml version="1.0" encoding="ISO-8859-15"?>
        <Message xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
        <id extension="10213" root="2.16.840.1.113883.2.4.99.1.700222.1"/>
        <creationTime value="20030216140000"/>
        <versionId>V3PR1_ballot5</versionId>
        <interactionId extension="MFMT_IN100010NL" root="2.16.840.1.113883"/>
        <processingCode code="P"/>
        . . .
        . . .
        </Message>
<EB><CR>
```

4. HL7 Message Structure and Content

Messages consist of a hierarchy of various types of records. A record can be defined as a set of fields describing one aspect of the complete message. A field can be seen as a specific attribute of a record, which may contain a set of data elements that define the basic attribute.

4.1 Message Length

The standard of HL7 does not limit a maximum record length. It is necessary for HL7 message to have required records but not optional records. Therefore, outgoing message can be of any length.

4.2 Message Type

The message transported between two systems is atomic data. Messages consist of the sequenced segment group defined by HL7 message. This defines the purpose of use. For example, Admit Discharge Transfer (ADT) Message is used to carry patient information from one system to another system. Three characters of message identify the type of message.

Message used in Seegene Viewer like below table.

Message	Full Name
ORU	Observation Result Message
ACK	General Acknowledgment Message

ORU message is used for sending information about patient diagnosis result of Seegene Viewer. ACK message is used for acknowledging whether LIS has been successfully received the message transported from Seegene Viewer or not.

4.3 Segment

One segment is the logical group of fields. The segment of message is required or optional. Also, it can be used more than once in a message and has a unique name. For example, ADT message has the segments as follows: Message Header (MSH), Event Type (EVN), Patient ID (PID), and Patient Visit (PV1)

Each segment has the unique three characters codes and that used in Seegene viewer is like the table below.

Segment	Full Name
MSA	Message Acknowledgment
ACK	General Acknowledgment Message
PID	Patient Identification
OBR	Observation Request
OBX	Observation
NTE	Notes and Comments

4.4 Field

1. Structure

   A field is the attribute of a record that consists of data set.

2. Length

   A field can be any of length. It cannot contain more characters than the maximum length that the standard defines.

   Ex) The field that standard defines maximum number of characters as ten can only contain up to ten characters and it is separated by delimiters.

3. Data type

   Data type defines the kind of data used in fields. String, formatted text, timestamp, address, and coded element can be the example of data type. Each data type contains additional types that can be referenced as component and subcomponent. Fields are

identified by position, which is determined by counting number of delimiters at the front of a record. If last filed is null value, delimiter is not included.

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The types used in HL7 message of Seegene Viewer application are like table below.

Type	Full Name
ST	String
TX	Text data
SI	Sequence ID
DT	Date
TM	Time
TS	Time stamp

4. Delimiter

Delimiters are used to establish separate sections within message. There are five different delimiters which standard provides.

The delimiters used in HL7 message of Seegene Viewer application are like table below.

Delimiter	ASCII character
Field delimiter – vertical bar	ASCII 124 (|)
Component delimiter – caret	ASCII 94 (^)
Repeat delimiter – at	ASCII 126 (~)
Escape delimiter – backslash	ASCII 92 (\ )
Subcomponent delimiter	ASCII 38 (&)

5. Observation result Message Structure and Content

The message type used in Seegene Viewer is ORU (Observation result message). Type of observation reported in the ORU message include clinical lab results, Imaging study reports, EKG pulmonary function study results, Patient condition or other data, etc. ORU message of Seegene Viewer transmit patient diagnosis result. The table below shows segments used in it and the structure of segments.

SEQ	OPT	RPT	GROUP	Name
1	R	1		MSH - Message Header
	O	*	Y	--PATIENT
2	R	1	Y	PID - Patient identification
3	O	1		PD1 - Patient demographic
4	O	*		NTE - Notes and comments
	O	1	Y	--VISIT
5	R	1		PV1 - Patient visit
6	O	1		PV2 – Additional information
	R	*	Y	--ORDER OBSERVATION
7	O	1		ORC - Common order
8	R	1		OBR - Observation request
9	O	*		NTE - Notes and comments
	R	*	Y	-- OBSERVATION
10	O	1		OBX - Observation
11	O	*		NTE – Notes and comments

The structure of Seegene Viewer ORU message and segments are like table below.

SEQ	OPT	RPT	GROUP	Name
1	R	1		MSH - Message Header
	O	*	Y	--PATIENT
2	R	1	Y	PID - Patient identification
	R	*	Y	--ORDER OBSERVATION
8	R	1		OBR - Observation request
9	O	*		NTE - Notes and comments

6. The segments used in Seegene Viewer

6.1 MSH (Message Header)

The MSH segment defines the message's source, purpose and destination. This segment has information about Seegene Viewer application. The fields not used in this application mark "Used" column as X

SEQ	LEN	OPT	NAME	Used
1	1	R	Field Separator	O
2	4	R	Encoding Characters	O
3	180	O	Sending Application	O
4	180	O	Sending Facility	O
5	180	O	Receiving Application	O
6	180	O	Receiving Facility	O
7	26	O	Date/Time Of Message	X
8	40	O	Security	X
9	7	R	Message Type	O
10	20	R	Message Control ID	O
11	3	R	Processing ID	X
12	8	R	Version ID	O
13	15	O	Sequence Number	X
14	180	O	Continuation Pointer	X
15	2	O	Accept Acknowledgment Type	X
16	2	O	Application Acknowledgment Type	X
17	2	O	Country Code	X
18	6	O	Character Set	X
19	60	O	Principal Language Of Message	X

The MSH segment applied to Seegene Viewer data

SEQ	NAME	DATA
1	Field Separator	|
2	Encoding Characters	^~₩&
3	Sending Application	Seegene Viewer
4	Sending Facility	Seegene
6	Receiving Application	Receiving Application
7	Receiving Facility	Receiving Facility
9	Message Type	ORU^R01
12	Version ID	2.5

6.2 PID (Patient Identification)

The PID segment defines patient information. This segment is used to transmit patients ID of Seegene Viewer.

SEQ	LEN	OPT	NAME	Used
1	4	O	Set ID – Patient ID	X
2	20	O	Patient ID (External ID)	O
3	20	R	Patient ID (Internal ID)	O
4	20	O	Alternate Patient ID – PID	O
5	48	R	Patient Name	X
6	48	O	Mother's Maiden Name	X
7	26	O	Date/Time of Birth	X
8	1	O	Sex	X
9	48	O	Patient Alias	X
10	1	O	Race	X
11	106	O	Patient Address	X
12	4	R	Country Code	X
13	40	O	Phone Number – Home	X
14	40	O	Phone Number – Business	X
15	60	O	Primary Language	X
16	1	O	Marital Status	X
17	3	O	Religion	X
18	20	O	Patient Account Number	X
19	16	O	SSN Number – Patient	X
20	25	O	Driver's License Number – Patient	X
21	20	O	Mother's Identifier	X
22	3	O	Ethnic Group	X
23	60	O	Birth Place	X
24	2	O	Multiple Birth Indicator	X
25	2	O	Birth Order	X
26	4	O	Citizenship	X
27	60	O	Veterans Military Status	X
28	80	O	Nationality	X
29	26	O	Patient Death Date and Time	X
30	1	O	Patient Death Indicator	X

The PID segment applied to Seegene Viewer data.

SEQ	NAME	DATA
3	Patient ID (Internal ID)	Patient ID

6.3 OBR (Observation Request)

The OBR segment defines diagnostic result. This segment is used to transmit product information, positive/negative, auto interpretation and comments of Seegene Viewer.

SEQ	LEN	OPT	NAME	Used
1	4	C	Set ID – OBR	O
2	75	C	Placer Order Number	X
3	75	C	Filler Order Number	O
4	200	R	Universal Service ID	O
5	2	B	Priority	X
6	26	B	Requested Date/time	X
7	26	C	Observation Date/Time	X
8	26	O	Observation End Date/Time	X
9	20	O	Collection Volume	X
10	60	O	Collector Identifier	X
11	1	O	Specimen Action Code	X
12	60	O	Danger Code	X
13	300	O	Relevant Clinical Info.	X
14	26	C	Specimen Received Date/Time	X
15	300	O	Specimen Source	X
16	80	O	Ordering Provider	X
17	40	O	Order Callback Phone Number	X
18	60	O	Placer field 1	X
19	60	O	Placer field 2	X
20	60	O	Filler Field 1	X
21	60	O	Filler Field 2	X
22	26	C	Results Rpt/Status Chng – Date/Time	X
23	40	O	Charge to Practice	X

24	10	O	Diagnostic Serv Sect ID	X
25	1	C	Result Status	X
26	400	O	Parent Result	X
27	200	O	Quantity/Timing	X
28	150	O	Result Copies To	X
29	150	O	Parent	X
30	20	O	Transportation Mode	X
31	300	O	Reason for Study	X
32	200	O	Principal Result Interpreter	X
33	200	O	Assistant Result Interpreter	X
34	200	O	Technician	X
35	200	O	Transcriptionist	X
36	26	O	Scheduled Date/Time	X
37	4	O	Number of Sample Containers	X
38	60	O	Transport Logistics of Collected Sample	X
39	200	O	Collector's Comment	X
40	60	O	Transport Arrangement Responsibility	X
41	30	O	Transport Arranged	X
42	1	O	Escort Required	X
43	200	O	Planned Patient Transport Comment	X

The OBR segment applied to Seegene Viewer Data.

SEQ	NAME	DATA
1	Set ID – OBR	OBR Id
3	Filler Order Number	Well Name^Well Id
4	Universal Service ID	Product name^Auto interpretation ^Comment

The data type of Seegene Viewer

Data Type	Seegene Viewer Data
Auto Interpretation	Positive Control, Negative Control, Positive Control(Invalid), Negative Control(Invalid)

6.4 NTE (Notes and Comments)

The NTE segment defines the comments of message. This segment is used to transmit channel, target, target positive/negative, result type and result value of a well.

SEQ	LEN	OPT	NAME	Used
1	4	O	Set ID - NTE	O
2	8	O	Source of Comment	O
3	65536	O	Comment	O
4	60	O	Comment Type	X

The NTE segment applied to Seegene Viewer Data.

순서	NAME	DATA
1	Set ID - NTE	NTE id
2	Source of Comment	P
4	Comment	Dye~Target~Decision~Result type~ResultValue

7. The segment structure of Seegene Viewer

NTE segments are repeated as many as the number of targets for a channel.

The message structure transmitted from Seegene Viewer is like below

Message	ORU^R01
MSH	Message Header
PID	Patient Id
OBR	Product Information
NTE	Target1 result
NTE	Target2 result
NTE	Target3 result
NTE	Target4 result
NTE	Target5 result
NTE	Target6 result

The example of the product of Anyplex™ II STI-5 Detection(96 plate)

```
MSH|^~₩&|Seegene Viewer|Seegene|||20171012132900.586+0900||ORU^R01^ORU_R01|1101|P|2.5
OBR|1||15027611^A01|Anyplex™ II STI-5 Detection(96 plate)^-
NTE|1|P|FAM~UU~-~Result~N/A
NTE|2|P|FAM~UP~-~Result~N/A
NTE|3|P|HEX~MG~-~Result~N/A
NTE|4|P|HEX~MH~-~Result~N/A
NTE|5|P|Cal Red 610~TV~-~Result~N/A
NTE|6|P|Quasar 670~IC~++~Result~194.57
```

8. Message Transmission Control

There are two types of Acknowledgement message used in HL7

1. Original Mode Acknowledgement: A "received" 95% of ACK used in HL7 communications: indicates that a message has been received but no processed yet.

2. Enhanced Mode Acknowledgement: An "Application" that is a resultant status return rather than a communication response

Acknowledgement message mode used in Seegene Viewer is original mode.

8.1 Transmission control

When Seegene Viewer received ACK message from LIS, MSH-10, 15 and 16 fields are used to control transmission.

* MSH-10 contains a unique identifier for the message. Acknowledgement must refer to this Id

* MSH-15 is set to AL, which means that the message require an accept acknowledgement.

* MSH-16 is set to AL, which means that the message require an application acknowledgement and not NE.

In Seegene Viewer, MSH-10 uses Control Id to identify ACK message and MSH-10 and 15 fields for Enhanced Mode Acknowledgement are not used.

8.2 ACK Message Type

The MSA segment is used to transmit information about whether message from Seegene Viewer is transmitted successfully to LIS server or not.

SEQ	LEN	OPT	NAME	Description
1	2	R	Acknowledgement code	Acknowledgement code
2	20	R	Message Control Id	Acknowledgement code
3	80	O	Text Message	Text Message
4	15	O	Expected Sequence Number	X
5	1	O	Delayed Acknowledgement Type	X
6	100	O	Error Condition	X

The MSA segment applied to Seegene Viewer data

SEQ	NAME	DATA
1	Acknowledgement code	Acknowledgement code
2	Message Control Id	Message Control Id
3	Text Message	Text Message

Acknowledgement Code

Acknowledge Status	Description
AA	Original mode: Application Accept.
AE	Original mode: Application Error.
AR	Original mode: Application Reject.

8.3 The example of ACK message

Acknowledge Status: AA

```
MSH|^~₩&|Sending Application|Sending Facility|Seegene Viewer|Seegene|199807311532||ORU^R30|3629|P|2.5|
MSA|AA|ZZ9380|A01|
```

Acknowledge Status: AE

```
MSH|^~₩&|Sending Application|Sending Facility|Seegene Viewer|Seegene|199807311532||ORU^R30|3629|P|2.5|
MSA|AE|ZZ9380|A01|
```

Acknowledge Status: AR

```
MSH|^~₩&|Sending Application|Sending Facility|Seegene Viewer|Seegene|199807311532||ORU^R30|3629|P|2.5|
MSA|AR|ZZ9380|A01|
```

8.4 Transmission Diagram

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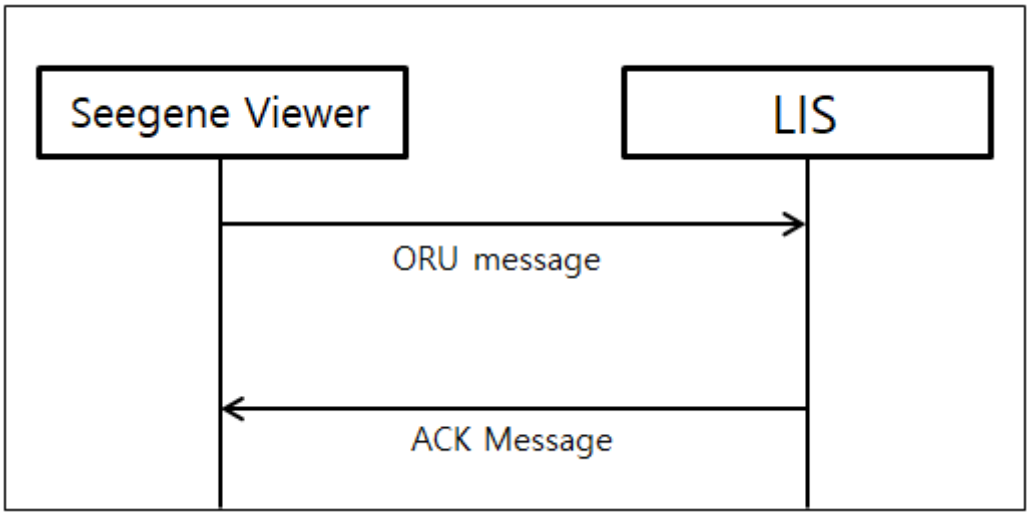
1. ACK message is transmitted from LIS to Seegene Viewer.



2. ACK message is not transmitted from LIS to Seegene Viewer.