Genematrix

INSTRUCTIONS FOR USE

NeoPlex™ STI-14 Detection Kit

REF

NS01A / NS01B

GENEMATRIX INC.

CE 0123 IVD

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REF NS01A / NS01B

NeoPlex™ STI-14 Detection Kit

CE 0123 IVD

Multiplex Real-time PCR Reagents for 14 Sex-Transmitted Pathogens Detection
For professional *in vitro* diagnostic use only

1. INTENDED USE

The 'NeoPlexTM STI-14 Detection Kit' is a qualitative in vitro test for the simultaneous detection and confirmation of fourteen (14) sex-transmitted infection (STI)-causing pathogens including C.trach omatis(CT), N.gonorrhoeae(NG), M.hominis(MH), M.genitalium(MG), T.vaginalis(TV), U.urealyticum(UU), U.parvum(UP), C.aibicans(CA), G.vaginalis(GV), Herpes simplex virus type 1(HSV1), Herpes sim plex virus type 2(HSV2), T.pallidum(TP), Group B Streptococcus(G BS) and H.ducreyi(HD) from urine or vaginal swab specimens. It i s an in vitro diagnostic medical device for qualitative examination intended for professionals use.

2. PRINCIPLE OF ASSAY

'NeoPlex™ STI-14 Detection Kit' is based on two major processe s,isolation of DNA from specimens and multiplex real-time amplific ation. STI-causing pathogens DNA is extracted from the specimen s,amplified in multiplex real-time PCR and detected using fluoresc ent reporter dye probes specific for STIs-causing pathogens DNA and Internal Control. Internal Control(IC) serves as an amplificatio n control for each individually processed specimen and to identify possible reaction inhibition.

3. KIT CONTENTS

The 'NeoPlex™ STI-14 Detection Kit' components are shown in the table below.

1) NS01A (96 Tests)

Contents	Volume(96T)	Storage condition	Shelf life
4X NeoPlex PCR Master Mix	500 μL x 1 Vial	Upper limit -20 ℃	12 months (Before opening) 6 months (After opening)
4X STI-14 PPM	500 μL x 1 Vial		
STI-14 Positive Control(PC)	50 μL x 1 Vial		
STI-14 Internal Control(IC)	1 mL x 1 Vial		
DW(DNase-free Water)	1 mL x 1 Vial		

2) NS01B (50 Tests)

Contents	Volume(50T)	Storage condition	Shelf life
4X NeoPlex PCR Master Mix	250 μL x 1 Vial	Upper limit -20 ℃	12 months (Before opening) 6 months (After opening)
4X STI-14 PPM	250 μL x 1 Vial		
STI-14 Positive Control(PC)	25 μL x 1 Vial		
STI-14 Internal Control(IC)	0.5 mL x 1 Vial		
DW(DNase-free Water)	0.5 mL x 1 Vial		

4. COMPATIBLE INSTRUMENT

- CFX96™ Dx System (Bio-Rad, Cat No.1845097-IVD)

5. ADDITIONAL REQUIRED EQUIPMENT & MATERIALS

- CFX96™ Dx System (BioRad, Inc., Cat No. 1845097-IVD) or equivalent
- 0.2 ml 8-Tube PCR Strips without Caps, low profile, white (BioRad, Inc., Cat No. TLS0851)
- Optical Flat 8-Cap Strips for PCR Tubes (BioRad, Inc., Cat No. TCS0803)
- Multiplate™ 96-Well PCR Plates, low profile, unskirted, white (BioRad, Inc., Cat No. MLL9651)
- QIAamp DSP DNA Mini Kit (QIAGEN, Cat No.61304) or equivalent DNA extraction kit
- Pipettes set
- Micro Centrifuge
- Disposable powder-free gloves

6. KIT STORAGE AND STABILITY

- Store the kit below -20℃(-4°F).
- Kit materials are stable until the expiration date printed on the label under un-opened condition.
- Kit's shelf life is one (1) year.
- Please use the reagents within six (6) months after opening.

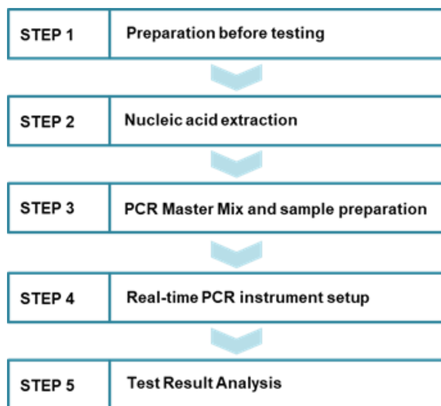
7. WARNINGS AND PRECAUTIONS

1. This device is intended for *in vitro* use only. Do not use the device for other purposes.
2. Wear personal protective equipment, such as gloves and lab coats when handling NeoPlex™ STI-14 Detection Kit and/or specimens.
3. Do not smoke, drink, or eat while handling NeoPlex™ STI-14 Detection Kit and/or samples.
4. Please be careful when handling samples to prevent infections of user and/or indirect contact to a person. Sample contains a risk of infections and unknown diseases.
5. Do not use reagents from different lots or from different tubes of the same lot.
6. If you do not frequently inspect the product, keep a kit in a refrigerator for a certain amount of time. Do not freeze/thaw over five times. Repeated frozen/thawed product may result in false negative and false positive results.
7. Be careful not to contaminate the product when extracting nucleic

acid, amplifying PCR product, using Positive Control(PC).

8. It is recommended that the sample or the Positive Control(PC) contained in the product to be frozen and stored separately from the freezer storing the product.
9. Use the sterilized consumable laboratory supplies. Do not reuse it.
10. Add the extracted nucleic acid sample and positive control Add the extracted nucleic acid sample and positive control from the PCR reaction solution preparation space.
11. Before using, read this instruction for use carefully.
12. Use calibrated measuring tools. (e.g. pipette)
13. Please check the expiration date before using the reagent.
14. Keep Positive Control(PC) separately when using to avoid contamination
15. Before starting the PCR, make sure the lid is closed properly.
16. Dispose the product in accordance with local or national regulations.
17. Please consult with doctor about the test results.

8. TEST PROCEDURE



STEP 1. Preparation before testing

1) Preparation before testing

A. Prepare all the devices and reagent before use.

B. Place the kit on ice and dissolve the reagent at least 10 minutes before testing.

Do not freeze/thaw over five (5) times.

2) Specimen Collection, Transportation and Storage

A. Specimens for use: Urine(first-catch for the day recommended) and vaginal swab.

B. It is recommended to process specimen within one (1) day after collection.

C. Store specimens at 2~8 °C (35.6~46.4°F) for no longer than one (1) week. For pro-longed storage, Freeze at -20~ -80°C (-4°F ~ -112°F). The frozen specimen can be used for one (1) year.

D. Transportation of clinical specimens must comply with local regulations for the transport of etiologic agents.

- Use only the specimen type listed in the instruction manual.
- The specimen volume should be above 1ml.
- Wear eye protection, laboratory coats and disposable gloves when handling specimens.
- Specimens should be stored under the storage conditions above. Otherwise, the wrong test results can be obtained.
- Sample information should be recorded to avoid confusion.

STEP 2. Nucleic acid extraction

After pre-treatment, DNA extraction can be done by automated p urification system or using manual prep kits (QIAamp DSP DNA Mini Kit or equivalent).

1) Pre-treatment of the Specimen

Urine	Vaginal swab
Centrifuge 1mL of urine specimen for 10 minutes at 13,000 rpm.	Centrifuge 1mL of vaginal swab specimen with PBS for 10 minutes at 13,000 rpm.
Discard the supernatant. Re-suspend 1X PBS (1mL) on the vortexing.	Discard the supernatant. Re-suspend 1X PBS (1mL) on the vortexing.
Follow the manufacturer's protocol.	Follow the manufacturer's protocol.

2) Internal control

The Internal Control (STI-14 Internal Control(IC)) is included in the kit. This allows the user to monitor the nucleic acid isolation procedure and the possibility of PCR inhibition.

Urine: Add 10μL of STI-14 Internal Control(IC) to each sample solution mixture or directly to the lysis buffer.

3) For DNA extraction, follow the manufacturer's protocol.

We recommend QIAamp DSP DNA Mini Kit or equivalent DNA extraction kit for nucleic acid extraction.

STEP 3. PCR Master Mix and sample preparation

1) Prepare the Master Mix

Contents	Volume per test
4X NeoPlex PCR Master Mix	5 μL
4X STI-14 PPM	5 μL
DW(DNase-free Water)	5 μL
Total Volume	15 μL

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

2) Vortex and briefly centrifuge the PCR Master Mix.

3) Place 15 μL aliquots of the PCR Master mix into 0.2 ml PCR tubes and close the lids.

4) Add 5 μL of each nucleic acid sample to its respective tube.

Contents	1 test (Volume)
PCR Mixture Mix	15 μL
Nucleic acid sample	5 μL
Total Reaction Volume	20 μL

- It is recommended that the PCR mixture to be prepared just before use.
- Aerosol-resistant filter tips and tight gloves should be used when preparing samples.
- Take great care to avoid cross contamination.
- Defrost the reagents completely.
- Centrifuge the reagent tubes briefly to remove the drops from the inside of the lids.

5) Make the control amplification reactions.

- Negative Control: Add 5 μL of DW(DNase-free Water) instead of nucleic acid samples to the tube.
- Positive Control: Add 5 μL of STI-14 Positive Control(PC) instead of nucleic acid samples to the tube.

- Use a new pipette tip with each different sample.
- Avoid cross-contamination of PCR Master Mix and samples with Positive Control.
- For CFX 96™, do not label on the cap of the reaction tubes as fluorescence is detected through the cap.
- Centrifuge the PCR tube thoroughly for 30 seconds.

STEP 4. Real-time PCR instrument setup

1) Setting the PCR protocol.

PCR protocol should be set according to the table as below.

Segment	Tm(°C)	Time	Cycles
1	50	4 min	1
2	95	15 min	1
3	95	30 sec	40
4	63	1 min	
5	73	10 min	1
6	55	30 sec	1
7*	Melting curve 55 ℃ ~ 85 ℃ (5s/0.5℃)*		

** Segment 7: Melting curve measurement*

STEP 5. Test result analysis

Test results should be interpreted according to the '9. INTERPRETATION OF TEST RESULTS' presented as below.

9. INTERPRETATION OF TEST RESULTS

For the analysis of the test result after PCR amplification, take the melting peak result (For CFX96™ Dx System check the 'Melt Peak' tab) and interpret the according to the following interpretation table.

1. Interpretation criteria for result analysis

Target	Dye	Melt Tm	Cut-off(RFU*)
CT	FAM	80.0 ± 1 ℃	≥ 100
UP	FAM	72.5 ± 1 ℃	≥ 100
NG	HEX	80.0 ± 1 ℃	≥ 100
MH	HEX	64.5 ± 1 ℃	≥ 100
GV	Quasar 670	79.0 ± 1 ℃	≥ 100
HSV2	Cal Red 610	72.0 ± 1 ℃	≥ 100
HD	Quasar 705	66.0 ± 1 ℃	≥ 100
IC	Quasar 705	73.0 ± 1 ℃	≥ 100
MG	HEX	71.5 ± 1 ℃	≥ 100
UU	Cal Red 610	80.0 ± 1 ℃	≥ 100
TV	Quasar 670	71.0 ± 1 ℃	≥ 100
CA	FAM	64.5 ± 1 ℃	≥ 100
HSV1	Cal Red 610	64.5 ± 1 ℃	≥ 100
TP	Quasar 670	63.5 ± 1 ℃	≥ 100
GBS	Quasar 705	79.5 ± 1 ℃	≥ 100

* RFU: Relative fluorescene units

2. Interpretation of result

Target	IC	Result	
+	+	Detected	The sexually transmitted pathogen is detected
-	+	Not detected	The sexually transmitted pathogen is not detected.
-	-	Invalid	The negative (-) result of IC is the result of inhibition of PCR reaction due to the presence of a PCR inhibitor contained in the sample, and the sample is not suitable for the test. It is recommended to remove the PCR inhibitor and perform the DNA extraction again.
+	-	Invalid	If the nucleic acid DNA concentration is high in the sample, IC signal may be attenuated. Dilute the template nucleic acid in distilled water and repeat the PCR with the diluted nucleic acid

3. Application examples of clinical samples

No	FAM			HEX			Cal Red 610			Quasar 670			Quasar 705		
	CT	UP	CA	NG	MH	MG	UU	HSV 1	HSV 2	GV	TV	TP	GBS	HD	IC
Sample 1	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
Sample 2	-	-	-	+	-	-	+	-	-	-	-	-	-	-	+
Sample 3	-	+	-	-	+	-	+	-	-	-	-	-	-	-	+
Sample 4	+	+	-	+	-	-	-	-	-	-	-	-	-	-	+
Sample 5	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
Sample 6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
Sample 7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Positive Control	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Negative Control	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

No	Interpretation
Sample 1	CT detected
Sample 2	NG, UU detected
Sample 3	UP, MH, UU detected
Sample 4	CT, UP, NG detected

Sample 5	CT detected
Sample 6	Not detected
Sample 7	Invalid
Positive Control	Positive (Valid)
Negative Control	Negative (Valid)

10. QUALITY CONTROL

NeoPlex™ STI-14 Detection Kit includes STI-14 Positive Control(PC) and DW(DNase-free Water) set. DW(DNase-free Water) is used as negative control. For all runs, valid test results must be obtained for both Positive and Negative control for NeoPlex™ STI-14 Detection Kit. Positive Control result must be Positive (Valid). Negative Control result must be Negative (Valid). If the positive and negative control results are consistently invalid, contact us for technical assistance.

11. TROUBLE SHOOTING

1. If the Internal control signal is not observed.

Potential causes	Solution
Error in specimen collection	If both target and IC signal were not observed, recollect the specimen
Nucleic acid extraction failure	Carefully read the instruction for use of nucleic acid extraction kit and extract the nucleic acid from specimen again.
Incorrect PCR setting	Repeat the detection procedure with a correct setting
Incorrect PCR cycle or machine temperature	Check the PCR conditions and repeat the PCR under the correct setting if necessary
The fluorescence for data analysis does not comply with the protocol	Select the correct fluorescence for each target listed in this Instruction guide for data analysis
Leaving reagents at room temperature for a long time or incorrect storage condition	Check the storage conditions and the expiration date of the reagents and use a new kit
Presence of inhibitor	Dilute the template nucleic acid in distilled water (10-100x) and repeat the PCR with the diluted nucleic acid (If specimen is still present, restart from nucleic acid extraction procedure)
High load of pathogen's nucleic acid	Dilute the template nucleic acid in distilled water (10-100x) and repeat the PCR with the diluted nucleic acid

2. If signals are observed at the negative control / false positive.

Potential causes	Solution
Presence of cross contamination	Decontaminate all surfaces and instruments with sodium hypochlorite or ethanol. Use filter tips during the extraction procedure. Change tips among tubes. Repeat the nucleic acid extraction with the new set of reagents

3. If no signal is observed at the positive control / false negative.

Potential causes	Solution
Error in specimen collection	Recollect the specimen and repeat the whole process. Make sure the product is stored in recommended conditions.
Incorrect storage of the specimen	Recollect the specimen and repeat the whole process. Make sure the product is stored in recommended conditions
Error in nucleic acid extraction	Re-extract the nucleic acid
Incorrect PCR setting	Repeat the PCR with corrected setting
Error in adding nucleic acid to corresponding PCR tubes	Check the sample numbers for nucleic acid containing tubes and make sure to add nucleic acid into correct PCR tubes during detection process.
Incorrect PCR mixture	Check whether all components are added or not (If you use to pre-composed premix, should be reduce sensitivity) Each reagent should be used after homogenization and spin down reagent tube before putting the real-time PCR

12. PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

1.1 Limit of Detection (LoD)

This study was conducted to determine the sensitivity by testing Liquid based cytology specimen. The proportion of positive results obtained from each concentration was subjected to 95% hit rate by probit analysis, and LoD of each target were obtained by performing 24 times of the tests.

Target	Specimen type	LoD
CT	Urine	$5.3X10^{0}$ copies/ul
	Vaginal Swab	$7.3X10^{0}$ copies/ul
NG	Urine	$7.3x10^{0}$ copies/ul
	Vaginal Swab	$7.3x10^{0}$ copies/ul
MH	Urine	$5.96\ x10^{0}$ cfu/ml
	Vaginal Swab	$5.96\ x10^{0}$ cfu/ml
MG	Urine	$7.64\ x10^{0}$ ccu/ml
	Vaginal Swab	$7.64\ x10^{0}$ ccu/ml
TV	Urine	$1.61\ x10^{1}$ cells/ml
	Vaginal Swab	$1.61\ x10^{1}$ cells/ml
UU	Urine	$7.64\ x10^{0}$ ccu/ml
	Vaginal Swab	$7.64\ x10^{0}$ ccu/ml
UP	Urine	$7.64\ x10^{0}$ ccu/ml
	Vaginal Swab	$7.64\ x10^{0}$ ccu/ml
CA	Urine	$3.44\ x10^{1}$ cfu/ml
	Vaginal Swab	$3.44\ x10^{1}$ cfu/ml
GV	Urine	$3.39\ x10^{1}$ cfu/ml
	Vaginal Swab	$3.58\ x10^{1}$ cfu/ml
HSV1	Urine	$1.10\ x10^{1}$ copies/ul
	Vaginal Swab	$1.10\ x10^{1}$ copies/ul
HSV2	Urine	$8.56\ x10^{0}$ copies/ul
	Vaginal Swab	$8.56\ x10^{0}$ copies/ul
TP	Urine	$9.17\ x10^{0}$ copies/ul
	Vaginal Swab	$9.17\ x10^{0}$ copies/ul
GBS	Urine	$4.21\ x10^{0}$ copies/ul
	Vaginal Swab	$4.13\ x10^{0}$ copies/ul
HD	Urine	$3.94\ x10^{0}$ copies/ul
	Vaginal Swab	$3.80\ x10^{0}$ copies/ul

1.2 Cut-off value

For the cut-off establishment, ΔRFU value was set to be 100 for all of our target and specimens.

2. Analytical Specificity

2.1 Interference

Total thirteen (13) substances, endogenous and exogenous source, were studied to determine their interfering effect and no interference reactions was found with the concentration as below.
The test concentration was selected referring the competitor devices on the market.

No	Same Type	Interfering substance	Concentration	Remark
1	Urine	Urea	10mg/dL	Endogenous source
2		Glucose	10mg/dL	Endogenous source
3		pH (acid)	pH4	Endogenous source
4		pH (alkaline)	pH9	Endogenous source
5		Blood	5%	Endogenous source
6		Bovine Serum Albumin (BSA)	10mg/dL	Endogenous source
7		Phosphate-buffered saline (PBS)	1%	Sample treatment media
8	Vaginal swab	Phosphate-buffered saline (PBS)	1%	Sample treatment media
9		Blood	5%	Endogenous source
10		Human genomic DNA	1ng	Endogenous source
11		Canesten Cream	0.5%	Exogenous source
12		NOBASON Cream	0.5%	Exogenous source
13		GYNO-BETADINE	0.5%	Exogenous source

2.2 Cross reactivity

For analytical specificity, three (3) times of cross reactivity studies using seven (7) different pathogens similar with STI-pathogens pathogens were performed. Additionally, total twenty-nine (29) other pathogens were studied. As a result, PCR amplification and cross reactivity were not observed with all the pathogens as below.

No	Strain No	Pathogen
1	ATCC 49145D-5	*Gardnerella vaginalis*
2	ATCC 700724D-5	*Haemophilus ducreyi*
3	ATCC 10231D-5	*Candida albicans*
4	ATCC VR-540	*Human herpesvirus 2*
5	ATCC VR-539	*Human herpesvirus 1*
6	ATCC 4357D-5	*Lactobacillus acidophilus*
7	ATCC 700669D-5	*Streptococcus pneumoniae*
8	ATCC 700928D-5	*Escherichia coli*
9	ATCC 25285D-5	*Bacteroides fragilis*
10	ATCC 13047D-5	*Enterobacter cloacae*
11	ATCC 700698D-5	*Staphylococcus aureus*
12	ATCC 12453D	*Proteus mirabilis*
13	ATCC 700802D-5	*Enterococcus faecalis*
14	ATCC 12228D-5	*Staphylococcus epidermidis*
15	HPKTCC B3204	*Neisseria meningitidis*
16	HPKTCC B1834	*Neisseria sicca*
17	ATCC VR-97	Influenza A virus (H1N1), A/FM/1/47
18	ATCC VR-95	Influenza A virus (H1N1), A/PR/8/34
19	ATCC VR-897	Influenza A virus (H1N1), A/New Jersey/8/76
20	ATCC VR-546	Influenza A virus (H1N1), A/Denver/1/57
21	ATCC VR-219	Influenza A virus (H1N1), A/NWS/33
22	ATCC VR-823	Influenza B virus, B/Hong Kong/5/72
23	ATCC VR-26	Human respiratory syncytial virus A, Long
24	ATCC VR-955	Human respiratory syncytial virus B, 9320
25	ATCC VR-3250SD	Quantitative Synthetic Human metapneumovirus (hMPV) RNA
26	ATCC VR-94	Human parainfluenza virus 1 HPIV-1, C35
27	ATCC VR-1602	Human adeovirus 50
28	ATCC VR-284	*Human Rhinovirus 14*
29	ATCC VR-850	*Human Coxsackievirus A 21*
30	KBPV-VR-45	*Parainfluenza virus 2*
31	KBPV-VR-19	*Echovirus 6*
32	VIRCELL MBC090	*Human coronavirus*
33	ATCC 15531	*Mycoplasma pneumoniae*
34	VIRCELL MBC007	*Bordetella parapertussis*
35	VIRCELL MBC117	*Moraxella catarrhalis*
36	VIRCELL MBC031	*Legionella pneumophila*

2.3 Carry-over & Cross-contamination

This study was performed to evaluate the carry-over and potential cross contamination effect. High concentrated positive sample and negative control sample were cross tested using same PCR instrument, and 100% negative results (140/140) (95% CI: 97.3%-100%) for each negative specimen were determined, respectively.

3. Precision

3.1 Repeatability

To evaluate the repeatability of NeoPlex™ STI-14 Detection Kit, Repeatability test was performed two runs per day, three replicates per run, during consecutive twenty days under same test conditions. Samples were tested using high, medium, low concentrations of positive samples and negative control. We confirmed that every test results are met the acceptance criteria: within 10% of CV, 100% agreement and the repeatability of NeoPlex™ STI-14 Detection Kit is acceptable

3.2 Reproducibility

To The reproducibility study was performed with four different conditions: for Between-lot (3 lots), Between-tester (3 testers), Between-instrument (3 instruments), and Between-site (3 sites). All results showed 100% agreements.

4. Clinical Evaluation

The clinical performance study was performed in the clinical laboratory, Samkwang Medical Laboratories, Seoul, Korea with the specimen collected from various sources, Such a hospitals, clinics and health centers (medical check-up). The comparable CE-marked product already available on EU market was used as reference test.

For clinical sensitivity and specificity, the test results were analyzed with 2x2 table, and summarized as below:

4.1 Clinical Accuracy (Clinical Sensitivity & Specificity)

Target	Specimen type	Clinical sensitivity	Clinical specificity
CT	Vaginal swab	99.18% [95% CI:95.5-99.86]	100% [95% CI:99.33-100]
	Urine	99.22% [95% CI:95.71-99.86]	100% [95% CI:99.36-100]
	Total	99.2% [95% CI:97.13-99.78]	100% [95% CI:99.67-100]
NG	Vaginal swab	100% [95% CI:97.78-100]	100% [95% CI:99.27-100]
	Urine	99.41% [95% CI:96.72-99.90]	100% [95% CI:99.31-100]
	Total	99.70% [95% CI:98.34-99.95]	100% [95% CI:99.64-100]
MH	Vaginal swab	98.71% [95% CI:96.27-99.56]	100% [95% CI:99.17-100]
	Urine	99.21% [95% CI:95.65-99.86]	100% [95% CI:99.36-100]
	Total	98.88% [95% CI:97.16-99.56]	100% [95% CI:99.64-100]
MG	Vaginal swab	98.94% [95% CI:94.22-99.81]	100% [95% CI:99.36-100]

	Urine	98.96% [95% CI:94.33-99.82]	100% [95% CI:99.39-100]
	Total	98.95% [95% CI:96.24-99.71]	100% [95% CI:99.69-100]
TV	Vaginal swab	100% [95% CI:95.77-100]	100% [95% CI:99.37-100]
	Urine	100% [95% CI:95.19-100]	100% [95% CI:99.41-100]
	Total	100% [95% CI:97.70-100]	100% [95% CI:99.69-100]
UU	Vaginal swab	99.09% [95% CI:94.56-99.58]	100% [95% CI:99.19-100]
	Urine	98.83% [95% CI:95.84-99.68]	100% [95% CI:99.31-100]
	Total	98.98% [95% CI:97.40-99.60]	100% [95% CI:99.63-100]
UP	Vaginal swab	100% [95% CI:98.96-100]	100% [95% CI:98.85-100]
	Urine	98.89% [95% CI:96.04-99.69]	100% [95% CI:99.30-100]
	Total	99.63% [95% CI:98.67-99.90]	100% [95% CI:99.56-100]
CA	Vaginal swab	99.21% [95% CI:95.67-99.86]	100% [95% CI:99.33-100]
	Urine	98.77% [95% CI:93.33-99.78]	100% [95% CI:99.41-100]
	Total	99.04% [95% CI:96.56-99.74]	100% [95% CI:99.68-100]
GV	Vaginal swab	99.37% [95% CI:98.15-99.78]	100% [95% CI:98.28-100]
	Urine	98.83% [95% CI:96.62-99.60]	100% [95% CI:99.18-100]
	Total	99.18% [95% CI:98.22-99.62]	100% [95% CI:99.44-100]
HSV1	Vaginal swab	98.59% [95% CI:92.44-99.75]	100% [95% CI:99.39-100]
	Urine	98.25% [95% CI:90.71-99.69]	100% [95% CI:99.43-100]
	Total	98.44% [95% CI:94.48-99.57]	100% [95% CI:99.70-100]
HSV2	Vaginal swab	100% [95% CI:95.55-100]	100% [95% CI:99.38-100]
	Urine	100% [95% CI:94.42-100]	100% [95% CI:99.42-100]
	Total	100% [95% CI:97.45-100]	100% [95% CI:99.70-100]
TP	Vaginal swab	100% [95% CI:92.87-100]	100% [95% CI:99.41-100]
	Urine	100% [95% CI:92.87-100]	100% [95% CI:99.43-100]
	Total	100% [95% CI:96.30-100]	100% [95% CI:99.71-100]
GBS	Vaginal swab	98.73% [95% CI:95.50-99.65]	100% [95% CI:99.29-100]
	Urine	99.02% [95% CI:94.65-99.83]	100% [95% CI:99.39-100]
	Total	98.85% [95% CI:96.66-99.61]	100% [95% CI:99.67-100]
HD	Vaginal swab	100% [95% CI:92.13-100]	100% [95% CI:99.41-100]
	Urine	97.83% [95% CI:88.66-99.62]	100% [95% CI:99.44-100]
	Total	98.90% [95% CI:94.04-99.81]	100% [95% CI:99.71-100]

13. LIMITATION OF TEST

1) Results from this test must be correlated with the clinical history, epidemiological data, and other data of the patient available to the clinician.
2) If you do not use the samples and other specimens described in this manual, you may get inaccurate results.
3) Although the results of this test are negative, it is not advisable to exclude the possibility that the infection is actually present.
4) It is not excluded that this kit shows false positive results due to the presence of cross-contamination.
5) False negative results may occur due to polymerase inhibition. STI-14 Internal Control(IC) may help to identify any substance existing in the specimens interfering with nucleic acid isolation and PCR amplification.
6) This kit is for professional use only. Only trained healthcare provider can use this kit.

14. SYMBOLS

REF	LOT			
Catalogue number	Batch code	Date of manufacture	Use-by date	Distributor
IVD				
In vitro diagnostic medical device	Upper limit of temperature	Caution	Consult instruction for use	Importer
	<n>	EC REP	CE	UDI
Manufacturer	Contains sufficient for <n> tests	Authorized representative in the European Community	Conformity to European Directive 98/79/EC	Unique Device Identification

GeneMatrix Inc.
Manufacturing site
7F, #B, Korea Bio Park, 700, Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488
REPUBLIC OF KOREA
Tel: +82-31-628-2045 Fax: +82-31-628-2002

EC REP **MT Promedt Consulting GmbH**
Ernst-Heckel-Straße 7
66386 St. Ingbert, Germany
Tel: +49-6894-581020, Fax: +49-6894-581021

CE 0123 IVD

Issue date: 2022.07

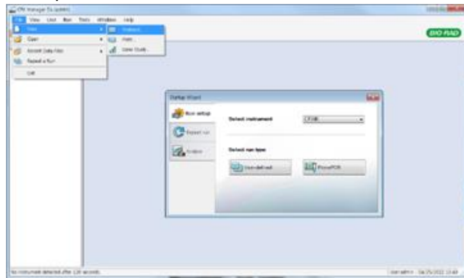
Appendix. PCR Instrument Operation

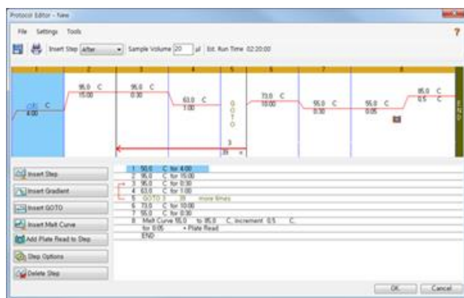
1) CFX96™ Dx System (Bio-Rad)

1. Protocol Setup

① Click File -> Protocol, Create a Protocol editor for PCR setup.

② The PCR condition is set as follows, and the sample volume set the 20 μL.

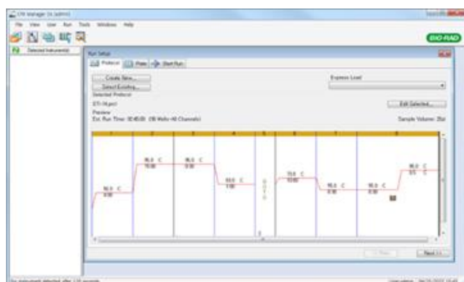




Segment	Tm(°C)	Time	Cycles
1	50	4 min	1
2	95	15 min	1
3	95	30 sec	40
4	63	1 min	
5	73	10 min	1
6	55	30 sec	1
7*	Melting curve 55 ℃ ~ 85 ℃ (5s /0.5℃)		

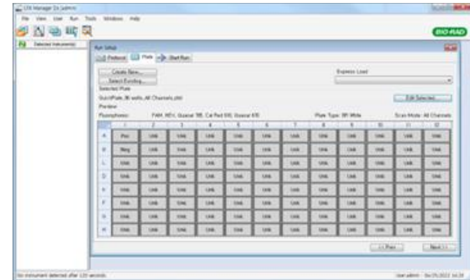
** Segment 7: Melting curve measurement*

③ After setting the PCR protocol, an Experiment Setup screen is created. Check the PCR protocol and click the “Next”.(Or click the “Plate” tab)

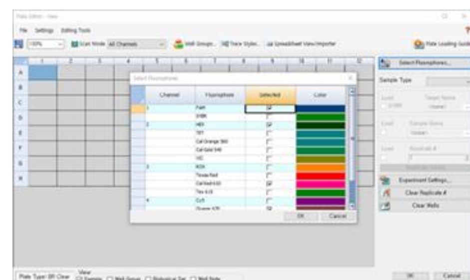


2. Plate Setup

① Click the “Create New” (or click the “Select Existing” load and existing plate for the experiment)



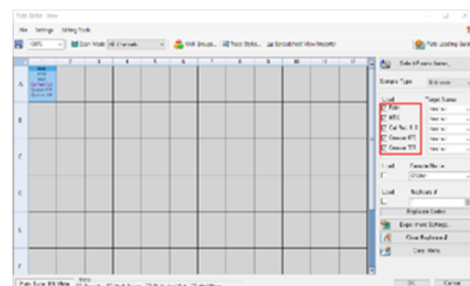
② Click the “Select Fluorophores”. Select the check box (FAM, HEX, Cal Red 610, Quasar 670, Quasar 705) for the fluorescent substance used for the experiment and click the OK button.



③ Select wells and select Sample Type from the drop-down Menu

Sample Type
‘Unknown’ : Clinical samples
‘Negative control’
‘Positive control’

④ Click the check box for the fluorescent substance (FAM, HEX, Cal Red 610, Quasar 670, Quasar 705) of the selected well.

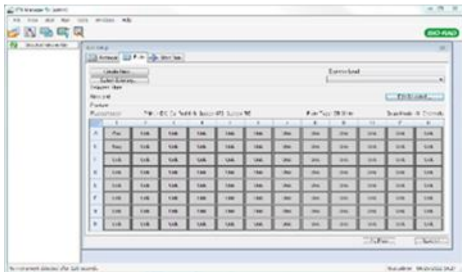


⑤ Click the “Settings” to set the plate type.

(Settings -> Plate Type -> BR white)

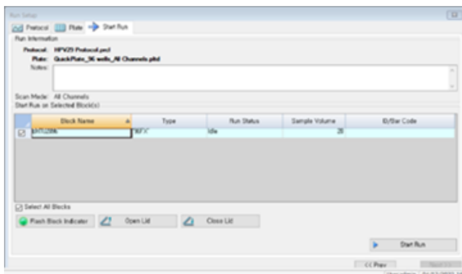
⑥ Click the “OK” and save a new Plate set-up file.

⑦ The Experimental Setup screen opens and checks the set plate.
Click the “Next” (Or click the “Start Run” tab)



3. Start Run

① In the Experiment Setup Start Run Tab screen, click the “Close Lid” to close the lid of the equipment. (If the lid is closed, skip the step)



② Click the “Start Run”.

③ The operating file is stored in the user's designated folder, and the equipment begins to operate.

4. Pre-setting for Data analysis

① After the test, select the Melt curve to check the Melt Peak results.

② Select each analytical fluorescent substance (FAM, HEX, Cal Red 610, Quasar 670, Quasar 705) and set the threshold bar of Melt Peak to "0".