Genematrix

INSTRUCTIONS FOR USE

NeoPlex™ GI-Virus 6 Detection Kit

REF

NG01A

GENEMATRIX INC.

CE IVD

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NeoPlex™ GI-Virus Detection Kit

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Multiplex Real-time RT-PCR Reagents for Gastrointestinal pathogens Detection
For professional *in vitro* diagnostic use only

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1. INTENDED USE

The 'NeoPlex™ GI-Virus 6 Detection Kit' is a qualitative *in vitro* test for the simultaneous detection of six gastrointestinal infection(GI)-causing pathogens including *Rotavirus A(RoV), Norovirus GI(NoV GI), Norovirus GII(NoV GII), Astrovirus(AsV), Adenovirus F (AdV) and Sapovirus(SaV)* from stool specimen using one-step based multiplex real-time RT-PCR. It is an *in vitro* diagnostic medical device for qualitative examination intended for professionals use.

2. PRINCIPLE OF ASSAY

'NeoPlex™ GI-Virus 6 Detection Kit' is based on two major proc esses, isolation of nucleic acid from specimens and multiplex real-time amplification. Respiratory disease infection-causing pathogens nucleic acid is extracted from a specimen, amplified in multiplex One-step real-time RT-PCR and detected using fluorescent reporte r dye probes specific for the pathogens nucleic acid and Internal Control.

3. KIT CONTENTS

The 'NeoPlex™ GI-Virus 6 Detection Kit' components are shown in the table below.

Contents	Volume(96T)	Storage condition	Shelf life
GI-Virus 6 Enzyme Mix	100 µL x 1 Vial	Upper limit -20 ℃	12 months (Before opening) 12 weeks (After opening)
5X GI-Virus 6 Buffer	400 µL x 1 Vial		
4X GI-Virus 6 PPM	500 µL x 1 Vial		
GI-Virus 6 Positive Control(PC)	50 µL x 1 Vial		
GI-Virus 6 Internal Control(IC)	1 mL x 1 Vial		
DW(RNase-free Water)	1 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)
- QIAamp DSP DNA Mini Kit (QIAGEN, Cat No.61304) or equivalent nucleic acid extraction kit
- Pipettes set
- Micro Centrifuge
- Disposable powder-free gloves

6. KIT STORAGE AND STABILITY

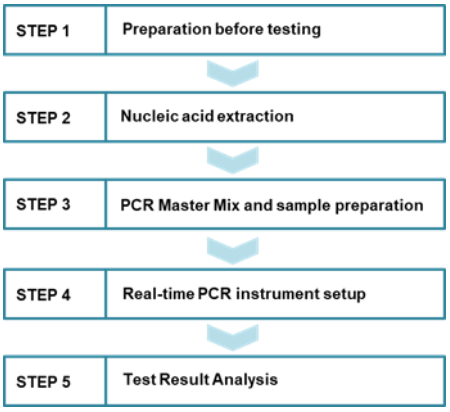
- Store the kit below -20℃(-4°F).
- Kit materials are stable until the expiration date printed on the label under un-opened condition.
- Kit's shelf life is one (1) year.
- Please use the reagents within twelve (12) weeks after opening.

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 equipments, such as gloves and lab coats when handling NeoPlex™ GI-Virus 6 Detection Kit and/or specimens.
3. Do not smoke, drink or eat while handling NeoPlex™ GI-Virus 6 Detection Kit and/or samples.
4. Please be careful when handling samples to prevent infectio ns of user and/or indirect contact to a person. Sample conta ins a risk of infections and unknown diseases.
5. Do not use reagents from different lots or from different tube s 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 four 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, Positive Control). The use of filter tips is recommended to prevent contamination of the product.
8. It is recommended that the sample or the positive control (PC, Positive Control) 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 (PC, Positive Control) into the reaction solution in a space separate 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, Positive Control) separately when using to avoid contamination.
15. Before starting the PCR, make sure the lid is closed properl y.
16. Dispose the product in accordance with local or national reg ulations.
17. Please consult with doctor about the test results.

8. TEST PROCEDURE



STEP 1. Preparation before testing

1) Preparation before testing

A. Prepare the all devices and reagent before use.
B. We recommend placing the kit on ice to dissolve the reagent at least 10 minutes before testing.
C. Vortex the dissolved reagent lightly.

⚠ Do not freeze/thaw over four (4) times.

2) Specimen Collection, Transportation and Storage

A. Specimens for use: Stool
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 fourty-eight (48) hours. For pro-longed storage, Freeze under -20°C (-4°F) condition.
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.
- 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, nucleic acid extraction can be done by auto mated purification system or using manual prep kits (QIAamp DS P DNA Mini Kit or equivalent).

1) Pre-treatment of the Specimen

Add sterilized 1X PBS, which is 9 times the sample, and vortex i for 15 to 30 seconds. Centrifuge the specimen at 3,000rpm for 20 minutes and Use the supernatant.

2) For nucleic acid extraction, follow the manufacturer's protocol

We recommend QIAamp DSP DNA Mini Kit or equivalent Nucleic acid extraction kit/automatic machine for nucleic acid extraction. Following the instruction for use of the nucleic acid extraction kit, extract nucleic acid from the sample.

Example: QIAamp DSP DNA Mini Kit
Elution volume: 200 µL
Sample volume: 50 µL

*** Internal control**
The Internal Control (GI-Virus 6 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.
Add 10µL of GI-Virus 6 Internal Control(IC) to the solution mixture or directly to the specimen.

⚠
- Extracted nucleic acid should be stored at -20°C
- Do not freeze/thaw the extracted nucleic acid, Repeated freezing/thawing may cause false positive or negative.

STEP 3. PCR Master Mix and sample preparation

1) Prepare the Master Mix

Contents	Volume per test
GI-Virus 6 Enzyme Mix	1 µL
5X GI-Virus 6 Buffer	4 µL
4X GI-Virus 6 PPM	5 µL
DW(RNase-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) Mix by inversion 5 times or by vortexing and centrifuging briefly.
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	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 (NC): Add 5 µL of DW(RNase-free Water) instead of nucleic acid samples to the 0.2ml PCR tube.
- Positive Control (PC): Add 5 µL of GI-Virus 6 Positive Control(PC) instead of nucleic acid samples to the 0.2ml PCR 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™ Dx System, 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	55	30 min	1
2	95	15 min	1
3	95	10 sec	40
4	63	1 min	
5	75	10 min	1
6	55	30 sec	1
7*	Melting curve 55 ℃ ~ 90 ℃ (5s/0.5℃)		

** Segment 7: Melting curve measurement*

STEP 5. Test result analysis

Test results should be interpreted according to the '9. INTERPR ETATION 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 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*)
NoV GI	FAM	68.5 ± 1℃	≥100
Nov GII	FAM	78.0 ± 1℃	≥100
SaV	HEX	68.0 ± 1℃	≥100
RoV	HEX	78.0 ± 1℃	≥100
AdV	Cal Red 610	67.5 ± 1℃	≥100
AsV	Cal Red 610	78.5 ± 1℃	≥100
IC	Quasar 670	79.0 ± 1℃	≥100

* RFU(–d(RFU)/dT): Relative fluorescence units

2. Interpretation of result

Target	IC	Result	
+	+	**Detected**	Target is detected.
+	-	**Detected**	If the nucleic acid 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
-	+	**Not detected**	Target 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 nucleic acid extraction again. IC may be mixed with 10 µL during the extraction process.

3. Application examples of clinical samples

No.	FAM		HEX		Cal Red 610		Quasar 670	Interpretation
	NoV GI	NoV GII	SaV	RoV	AdV	AsV	IC	
1	+	+	-	-	-	+	+	NoV GI, NoV GII, AsV
2	+	-	-	-	+	-	-	NoV GI, AdV
3	-	-	-	+	-	+	-	RoV, AsV
4	-	+	+	-	-	-	-	NoV GII, SaV
5	-	-	-	-	-	-	+	Not detected
6	-	-	-	-	-	-	-	Invalid

10. QUALITY CONTROL

NeoPlex™ GI-Virus 6 Detection Kit includes GI-Virus 6 Positive Control(PC) as positive control and DW(RNase-free Water) as negative control. For all runs, valid test results must be obtained for both positive and negative control. Positive control result must be "Detected (Valid)". Negative control result must be "not detected (Valid)". If the positive and negative control results are consistently invalid, contact us for technical assistance

Acceptance criteria for quality control

Quality Control	Target	Dye	Melt temp.	Cut-off (-d(RFU)/dT)
Positive Control	NoV GI	FAM	68.5 ± 1℃	≥100
	NoV GII	FAM	78.0 ± 1℃	≥100
	SaV	HEX	68.0 ± 1℃	≥100
	RoV	HEX	78.0 ± 1℃	≥100
	AdV	Cal Red 610	67.5 ± 1℃	≥100

	AsV	Cal Red 610	78.5 ± 1℃	≥100
	IC	Quasar 670	79.0 ± 1℃	≥100
Negative Control	-	-	-	Not detected

- If the Melt temperature and RFU (-d(RFU)/dT) values of positive control(PC) are out of the allowable range, invalidate the related test and retest.
- Negative Control(NC) should not cause any amplification, and if amplification is observed, identify the cause, remove it and retest.
- The internal control(IC) should always be amplified and the signal may be inhibited when there is a high concentration of positive pathogens.

11. TROUBLE SHOOTING

1 If the Internal control signals are not observed.

Potential causes	Solution
Error in specimen collection	If the both target and IC signal were not observed, recollect the specimen
Nucleic acid extraction failure	Read carefully the instruction for use of nucleic acid extraction kit and extract the nucleic acid from specimen again. IC may be mixed with 10 µl during the extraction process.
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 do 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
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 reagents should be used after homogenization and spin down reagent tube before put 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 Stool specimens.

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	LoD
NoV GI	45.7 copies/rxn
NoV GII	55.3 copies/rxn
SaV	6118 copies/rxn
RoV	91.1 U/mL
AdV 40	0.59 U/mL
AdV 41	0.92 U/mL
AsV	23.7 copies/rxn

1.2 Cut-off value

For the cut-off establishment, ΔRFU value was set to be 100 for all targets.

2. Analytical Specificity

2.1 Interference

Total six (6) substances, endogenous and exogenous source, were studied to determine their interfering effect and no interference reactions was found with the concentration as below.

No.	Interfering substance	Concentration	Remark
1	Human whole blood	40% v/v	Exogenous source
2	Hemoglobin	10% v/v	
3	Mucin	50ug/ml	
4	Ampicillin sodium salt	50mg/ml	Endogenous source
5	Fecal fat	5% w/v	
6	PBS	1x	

2.2 Cross reactivity

For analytical specificity, three (3) times of cross reactivity studies used sixty-four (64) different pathogens similar with RI-pathogens and other pathogens. As a result, PCR amplification and cross reactivity were not observed with all the pathogens as below.

No.	Strain No.	Pathogen
1	Zeptometrix 801597	Acinetobacter baumannii
2	ATCC 35654	Aeromonas hydrophila
3	ATCC 25285	Bacteroides fragilis
4	Zeptometrix 801649	Bordetella bronchiseptica
5	Zeptometrix 801464	Bordetella holmesii

6	ATCC 18804	Candida albicans
7	ATCC 2001	Candida glabrata
8	ATCC 22019	Candida parapsilosis
9	ATCC 750	Candida tropicalis
10	ATCC VR-571B	Chlamydia trachomatis Serovar A
11	ATCC VR-573	Chlamydia trachomatis Serovar B
12	ATCC VR-347	Chlamydia trachomatis Serovar Ba
13	ATCC VR-1477	Chlamydia trachomatis Serovar C
14	ATCC VR-885	Chlamydia trachomatis Serovar D
15	ATCC VR-348B	Chlamydia trachomatis Serovar E
16	ATCC VR-346	Chlamydia trachomatis Serovar F
17	ATCC VR-878	Chlamydia trachnomatis Serovar G
18	ATCC VR-879	Chlamydia trachomatis Serovar H
19	ATCC VR-880	Chlamydia trachomatis Serovar I
20	ATCC VR-886	Chlamydia trachomatis Serovar J
21	ATCC VR-887	Chlamydia trachomatis Serovar K
22	ATCC 13047D-5	Enterobacter cloacae
23	BEI NR-49129	Enterovirus D68
24	ATCC 700928D-5	Escherichia coli
25	ATCC 700724D-5	Haemophilus ducreyi
26	ATCC VR-1	Human adenovirus 1
27	KBPV VR-58	Human adenovirus 2
28	KBPV VR-60	Human adenovirus 5
29	KBPV VR-3	Human adenovirus 8
30	Zeptometrix 0810229CF	Human coronavrius 229E
31	Zeptometrix 0810024CF	Human coronavrius OC43
32	ATCC VR-168	Human Coxsackievirus A10
33	Zeptometrix 0810107CF	Human Coxsackievirus A16
34	ATCC VR-850	Human Coxsackievirus A21
35	ATCC VR-260	Human herpesvirus 1
36	ATCC VR-734	Human herpesvirus 2
37	ATCC VR-807	Human herpesvirus 5
38	ATCC VR-26	Human respiratory syncytial virus A
39	ATCC VR-955	Human respiratory syncytial virus B
40	ATCC VR-1559	Human rhinovirus 1A
41	ATCC VR-1645	Human rhinovirus 1B
42	ATCC VR-284	Human Rhinovirus B
43	ATCC VR-822	Influenza A virus (H3N2)
44	BEI VR-13658	Influenza virus A/2009 (H1N1)pdm09
45	Zeptometrix 801506	Klebsiella pneumoniae
46	ATCC 4357D-5	Lactobacillus acidophilus
47	ATCC 35292D-5	Legionella anisa
48	Zeptometrix 801577	Legionella longbeachae
49	ATCC 33530	Mycoplasma genitalium
50	ATCC 14027	Mycoplasma hominis
51	ATCC 15531	Mycoplasma pneumoniae
52	ATCC13090	Neisseria meningitidis serogroup b
53	ATCC 12453D	Proteus mirabilis
54	Zeptometrix 801908	Pseudomonas aeruginosa
55	ATCC 43975D-5	Salmonella bongori
56	ATCC 12228D-5	Staphylococcus epidermidis
57	Zeptometrix 804146	Streptococcus anginosus
58	Zeptometrix 804015	Streptococcus bovis
59	Zeptometrix 801695	Streptococcus mitis
60	Zeptometrix 804293	Streptococcus oralis
61	ATCC 700669D-5	Streptococcus pneumoniae
62	Zeptometrix 801512	Streptococcus pyogenes
63	ATCC 30238	Trichomonas vaginalis
64	ATCC 27618	Ureaplasma urealyticum

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 (48/48) (95% CI: 92.60%-100%) for each negative specimen were determined, respectively.

3. Precision

3.1 Repeatability

Repeatability was assessed by testing for twenty (20) different days, two (2) runs per day, two (2) cycles per run. Targets were set in three (3) levels of concentration, and 100% agreement was found determining the repeatability. The CV criteria, 10%, was met for all test results.

3.2 Reproducibility

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 with the specimen collected from various sources, such a hospitals or clinics. 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)

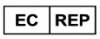
Target	Specimen type	Clinical sensitivity	Clinical specificity
NoV GI	NPS	100% [95% CI:94.50-100]	99.85% [95% CI:99.18-99.97]
NoV GII	NPS	100% [95% CI:96.50-100]	99.69% [95% CI:98.88-99.92]
SaV	NPS	100% [95% CI:92.44-100]	100% [95% CI:99.46-100]
RoV	NPS	98.72% [95% CI:93.09-99.77]	99.85% [95% CI:99.17-99.97]
AdV	NPS	99.22% [95% CI:95.71-99.86]	99.54% [95% CI:98.65-99.84]
AsV	NPS	98.81% [95% CI:93.56-99.79]	100% [95% CI:99.43-100]

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. GI-Virus 6 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

				
Catalogue number	Batch code	Date of manufacture	Use-by date	Distributor
				
In vitro diagnostic medical device	Upper limit of temperature	Caution	Consult instruction for use	Importer
				
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,
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CE IVD

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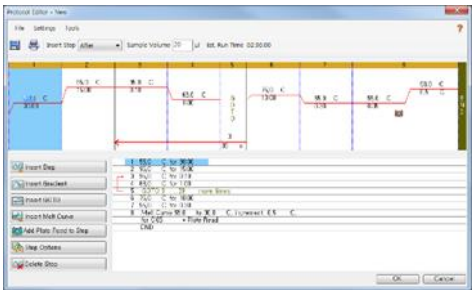
Appendix. PCR Instrument Operation

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.

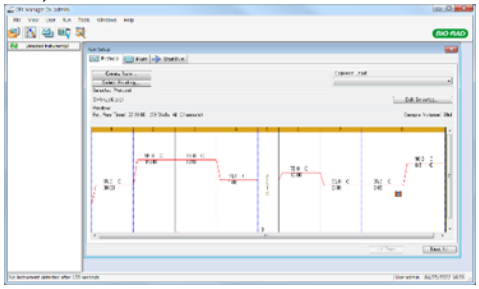


Segment	Tm(°C)	Time	Cycles
1	55	30 min	1
2	95	15 min	1
3	95	10 sec	40
4	63	1 min	
5	75	10 min	1
6	55	30 sec	1
7*	Melting curve 55 ℃ ~ 90 ℃ (5s /0.5℃)		

* Segment 7 : Melting curve measurement

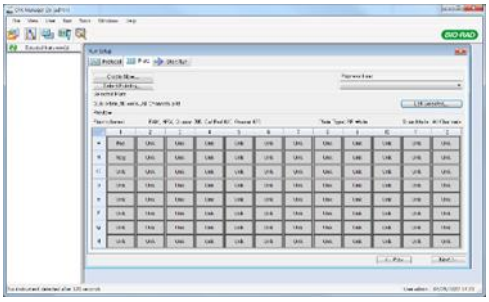
** Segment 7: Melting curve measurement*

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)

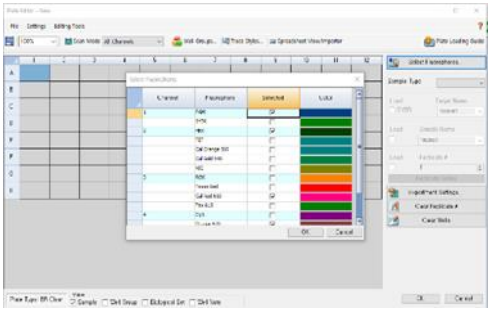


2. Protocol Setup

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



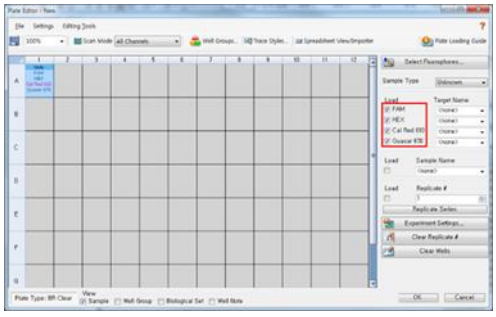
② Click the “Select Fluorophores”. Select the check box (FAM, HEX, Cal Red 610, Quasar 670) for the fluorescent substance used for the experiment and click the OK button.



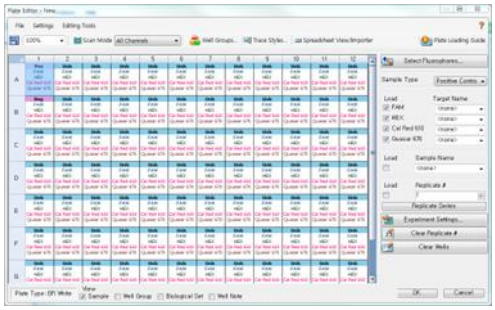
③ Select wells and select Sample Type from the drop-down menu.

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) of the selected well.

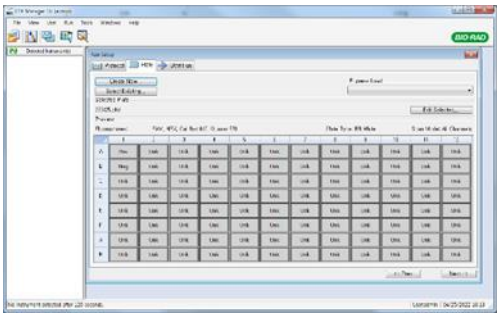


⑤ Click the “Settings” to set the plate type. (Settings -> Plate Type -> BR white)



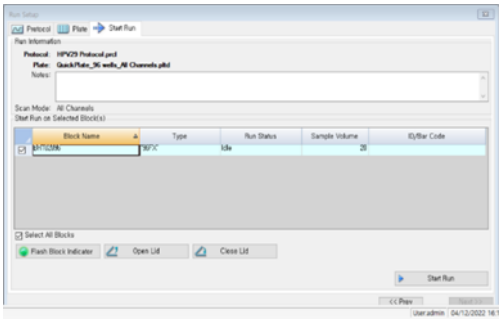
⑥ Click the “OK” and save a new Plate set-up file.

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) and set the threshold bar of Melt Peak to "0".