GeneFinder™ HLA-B*27 Real*Amp* Kit

Instructions for Use

IVD CE 2797

IFMR-08

REF **IFMR-08.02B100**

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1. INTRODUCTION

The human leukocyte antigen (HLA) is well known as genetic factor for disease sensitivities and plays a key role in transplantations, transfusions and parentage test as well[1)]. The HLA-B*27 is closely related to Ankylosing spondylitis (AS) which cause inflammation of the spondylarthritis and pericoxitis such as inflammatory rheumatic disease[2)]. The 90% of Ankylosing spondylitis patients have the HLA-B*27 genes and normal person also has that of 5 to 7%. The HLA-B*27 subtype, whose frequency in the worldwide population is extremely variable, differ from each other by one or a few amino acids, and they bind overlapping peptide repertoires. Worldwide population-based studies indicate that, among the widely distributed subtypes, HLA-B*27:02, B*27:04, and B*27:05 are strongly associated with AS[3)]. Previously cytotoxicity test or immunofluorescence test have been used as HLA-B*27 test methods, but with the recent development of molecular biological methods, HLA Typing using Real-time PCR is widely used as the latest test method.

2. INTENDED PURPOSE

GeneFinder™ HLA-B*27 Real*Amp* Kit is an in vitro diagnostic medical device to aid in the diagnosis of ankylosing spondylitis. It qualitatively analyzes the HLA-B27 allele through real-time polymerase chain reaction (RT-PCR) using genomic DNA extracted from whole blood samples of individuals suspected of having ankylosing spondylitis.
The GeneFinder™ HLA-B*27 Real*Amp* Kit is not automated product, specifically designed for use by qualified healthcare professionals who have received special training in real-time PCR and in vitro diagnostic procedures.

3. TEST PRINCIPLE

Real-time PCR is similar to the conventional PCR, but it is different from that as 'Real-time' quantitative which is monitored the amplification reaction of DNA. Generally there are various technologies to be monitored amplified DNA that probe labeled with fluorescent dye in processing. The genetic copying is increased during PCR reaction, and consequently emission intensity of the fluorescent dye is also specifically increased. Hereby reaction rate and efficiency is facilitated by the fluorescent dye.

Allele specific target DNA is amplified by a forward, reverse primer and Taq polymerase. During real-time PCR, DNA-based probe labeled with each fluorescent dye, those are 'fluorescent reporter' and 'fluorescence quencher' at each end of probe can be detected. Emission intensity of fluorescent dye is detected by laser. Monitoring of the fluorescence intensities during the PCR run allows the detection and quantitation of the accumulating product in real time. Each step of reaction is implemented by amplification with specific primers and probes (TaqMan probe) for exon-2 region of HLA-B*27 and *adenomatous polyposis coli* (APC) gene of internal control. The probe labeled with FAM is for detecting HLA-B*27 allele and probe labeled with Cy5 detects internal control.

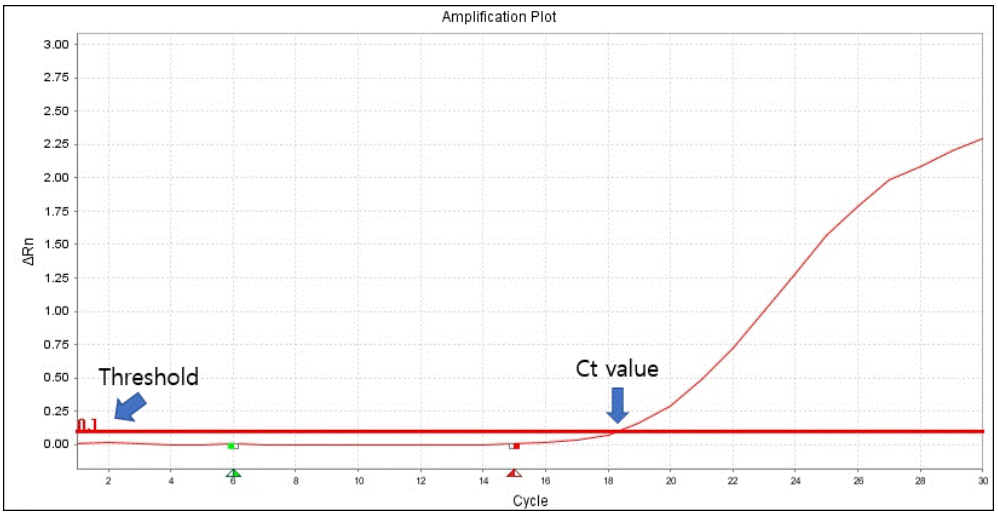


Figure 1. Graphical representation of real-time PCR data.

As shown in Figure 1., the measured fluorescence value is graphed, the Ct value is calculated. Ct (threshold cycle) is the intersection between an amplification curve and a threshold line. Using the calculated Ct value, the positive / negative of HLA-B* 27 is determined according to the RESULT INTERPRETATION.

4. REQUIRED MATERIALS

1) Materials Provided, Kit Contents

(Packaging unit: **100Tests/Kit**)

Reagents	Cap color	Description	Storage	Quantity
B27 2X *Rxn*	White	Oligonucleotides, Magnesium chloride, Deoxyribonucleotide triphosphates, ROX Passive reference dye, primers and probes	-25℃~-15℃	1 x 550 ㎕
B27 DNA pol.	Blue	*Taq* DNA polymerase	-25℃~-15℃	1 x 110 ㎕
B27 PC	Red	Plasmid DNA	-25℃~-15℃	1 x 50 ㎕
Quick Manual (Summary instructions for use)				

Description of the reagents

(1) B27 2X *Rxn*

Buffer mixture contained Rox Passive reference dye, primers and probes specific for HLA-B*27 and internal control.

Note. Contains dye-labeled oligos and should be stored in amber tube containers.

(2) B27 DNA pol.

DNA polymerase for amplification of HLA-B*27 and internal control

(3) B27 PC

HLA-B*27 and internal control plasmid DNA for confirmation of testing error

***Caution*.** Should be careful to avoid cross-contamination between other specimens when handling reagents contained positive control

- This kit is sufficient for **100 tests** including Positive control.
- This product does not contain Negative Control, please use Ultrapure Water.

2) Materials Required, But Not Provided

- Applied Biosystems® 7500 Real Time PCR Instrument System
- Bio-Rad CFX96 Real-Time PCR detection system
- Pipettes (1- 20 ㎕, 20-200 ㎕, 200-1,000 ㎕)
- Pipettes tips with aerosol barrier (RNase, DNase-free)
- Powder-free gloves (disposable)
- Vortex mixer or equivalent
- 1.5 mL tube
- Bench microcentrifuge
- DNA extraction kit
- Ultrapure Water, PCR-grade

5. STORAGE AND HANDLING REQUIREMNET

- All components of the kit should be stored at -25°C ~ -15°C and are stable until the expiry date stated on the label.
- This kit will keep approximately 12 months after manufacturing. Do not use reagents past the expiration date.
- Once opened, this kit will be stable for 12 months. Do not use opened after reagents past the expiration date.
- Repeated Freezing and thawing cycle is allowed up to 12 times. Unnecessary repeated freezing and thawing will be occurred inaccurate results.
- Remaining reagents should be stored at -25°C ~ -15°C.
- Do not use products with cracks on the tubes or box.
- Do not use damaged product.

Note: Unnecessary repeated freezing and thawing will be occurred inaccurate results.

6. WARNINGS AND PRECAUTIONS

The GeneFinder™ HLA-B*27 Real*Amp* Kit is designed for **In vitro diagnostics.**

General warning and cautions

- This product should be **used by professionals** in the laboratory.
- Read and understand the user manual prior to using this kit.
- Use 0.1% v / v sodium hypochlorite or another disinfectant to clean and disinfect the area around the sample.
- Decontaminate and dispose of all specimens, reagents and other potentially contaminated materials in accordance with local regulations.
- Follow universal precautions when performing the assay. Handle samples as if capable of transmitting infection.
- Wear personal protective apparel, including disposable gloves, throughout the assay procedure. Thoroughly wash hands after removing gloves, and dispose of gloves as biohazardous wastes.
- The material that come into contact with the biological samples must be autoclaved for one hour at 120°C before disposal.
- Do not eat, drink, smoke, or apply cosmetics in areas where reagents of samples are handled.
- Do not pipet by mouth.
- Do not use a kit after its expiration date.
- Use aerosol-resistant pipette tips and use a new tip every time a volume is dispensed.
- Store the regents recommended temperature.

- Do not mix reagent from different lot.
- Store the kit away from any source of contaminating DNA, especially amplified nucleic acid.
- Use sterile disposable laboratory materials and do not reuse.
- Alterations in the physical appearance of kit components may indicate instability or deterioration.
- Use all pipetting devices and instruments with care and follow the manufacturer's instructions for calibration and quality control.
- Do not modify the reagent/sample volume used in the test and do not use in a wrong way which is not recommended.
- The test results provided by the product should be interpreted with clinical result. It is user's responsibility for erroneous results due to experimental method which is not recommended by the manufacturer.

7. PROCEDURE

1) Specimen preparation and storage

(1) Specimen preparation

GeneFinder™ HLA-B*27 Real*Amp* kit is used with genomic DNA extracted from whole blood collected in a tube containing anticoagulants (K2-EDTA, K3-EDTA, sodium citrate) except for Li-heparin. Blood samples must be collected according to laboratory guidelines.

(2) Storage method

It is recommended to frozen (gerate the blood sample at 2 ~ 8°C and extract DNA from fresh blood within 3 days (72hr). The stability of frozen whole blood is recommended for 6 months, and the freezing temperature condition is to store whole blood collected in a tube containing anticoagulants below -70°C. Do not use samples that are thawed and then re-frozen.

2) DNA extraction and storage

(1) DNA extraction

GeneFinder™ HLA-B*27 Real*Amp* kit is recommended using commercial DNA extraction kit such as Qiagen DSP DNA blood mini kit (Qiagen, Germany, Cat # 61104). It should be followed manufacture's user manual.

(2) Storage method

According to the reference, the stability of genomic DNA storage at -20°C was recommended. An extracted genomic DNA should be aliquots to avoid unnecessary repeated freezing and thawing. The

recommended concentration of DNA applied to this kit is approximately 50-100 ng/㎕ and A260/280 ratio of DNA is within 1.6 ~2.0.

Reference. *Nature communications (2021)12:1358_DNA stability: a central design consideration for DNA data storage systems_ www.nature.com/naturecommunications*

3) Reagent preparation

Take B27 2X *Rxn*, B27 DNA pol. and B27 PC and thaw the components thoroughly at room temperature before using it and spin down the content for 5 seconds and then test it immediately. B27 DNA pol. is added right before testing to avoid degradation of enzyme.

Note: Do not leave the kit at room temperature for a long time. It may cause incorrect results of the test.

① For a Master mixture, prepare B27 2X *Rxn* and B27 DNA pol. as the table 1 below. To avoid a pipetting error, prepare one more reaction volume.

Note: Total Master Mixture no. = n sample + 1 positive control + 1 negative control + 1 extra

Table 1. Preparation of Master mixture

Number of Reactions / Component	1 test	3 tests	5 tests	Total volume of Master Mixture
B27 2X *Rxn*	5 ㎕	15 ㎕	25 ㎕	5 x (n+3)
B27 DNA pol.	1 ㎕	3 ㎕	5 ㎕	1 x (n+3)
Total (B27 Master mixture)	6 ㎕	18 ㎕	30 ㎕	6 x (n+3)

Important: For the reliability of the results, positive control and negative control (Ultrapure Water, not provided in the kit) should be verified each testing.

② After mixing well, place 6 ㎕ of Master mixture into optical 96 well plate or PCR tube.

Note: It is recommended to use BR white plate/tube when running tests on Bio-Rad CFX96.

③ Add 4 ㎕ of extracted DNA into optical 96 well plate or PCR tube, then mix well by pipetting. Proceed in the same way with other DNA samples.

Note: Total volume of each well/tube will be 10 ㎕.

Note: Do not vortex tube or plate to avoid any bubbles.

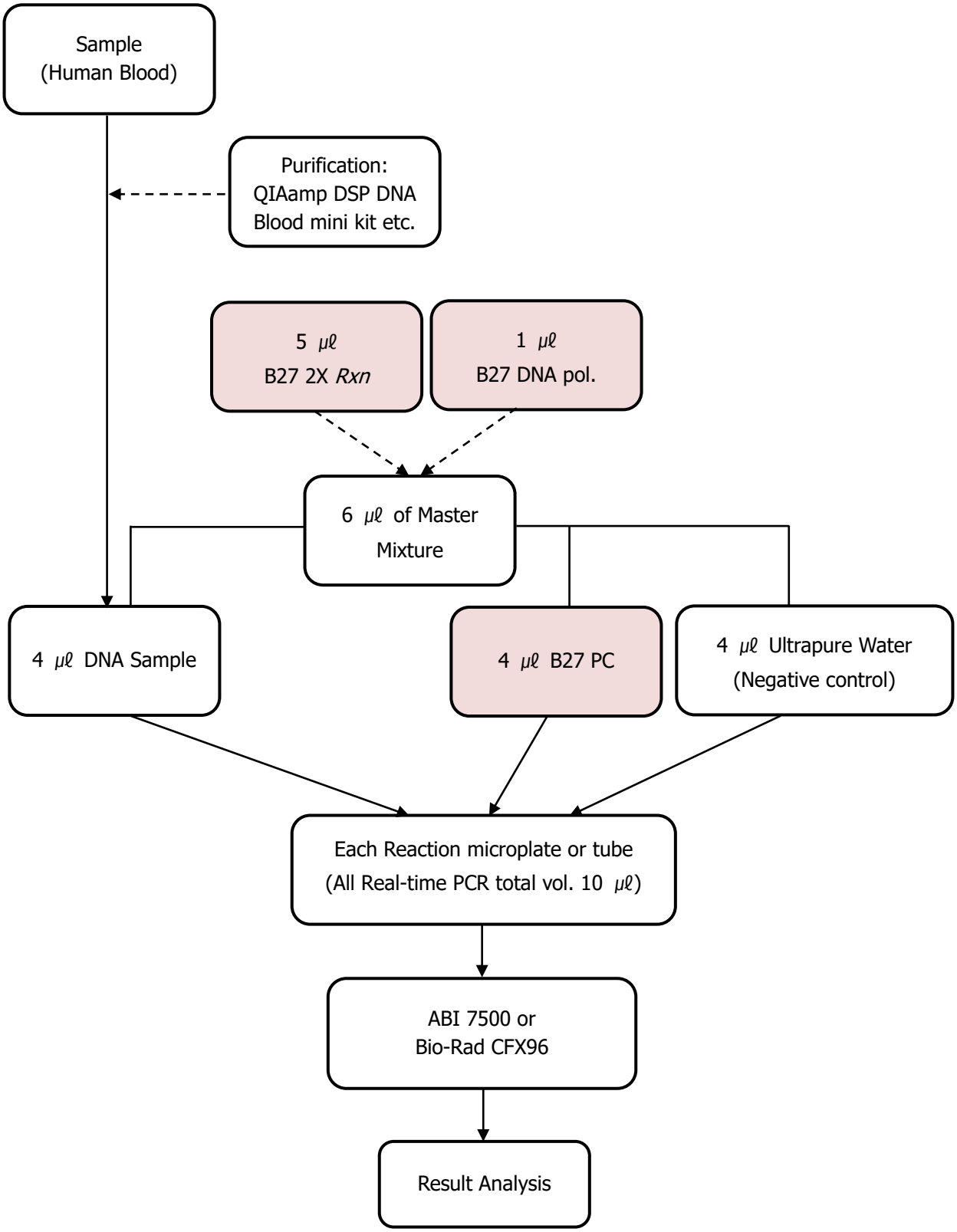
Note: Unless mix the mater mixture properly it would provide inaccurate results.

④ Add each of 4 ㎕ of positive control and negative control into the each tube/well in the same way.

⑤ Accurately close the tube with the cap or seal the plate.

⑥ Place the microplate or tubes to Real time PCR instrument for running.

Schematic Workflow for TEST



4) Real-time PCR condition setting and implementation

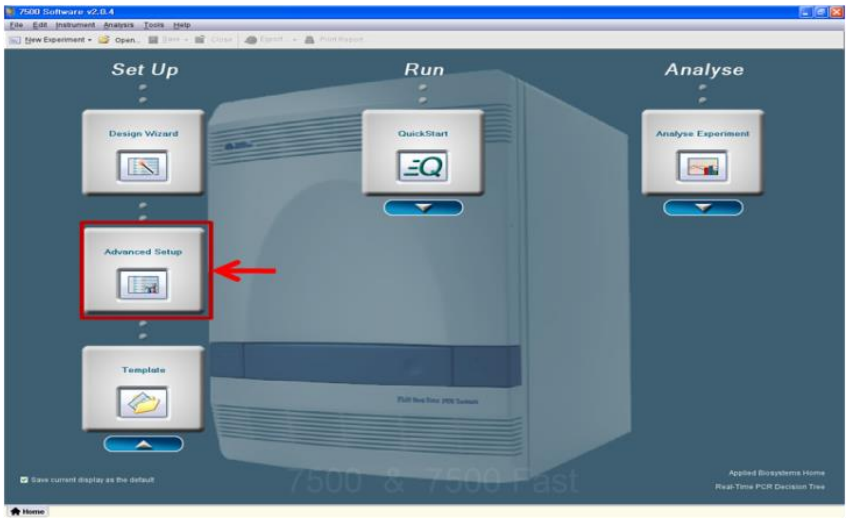
Operate PCR instrument according to the manufacturer's manual prior to amplification.

① ABI 7500

Run software of instrument

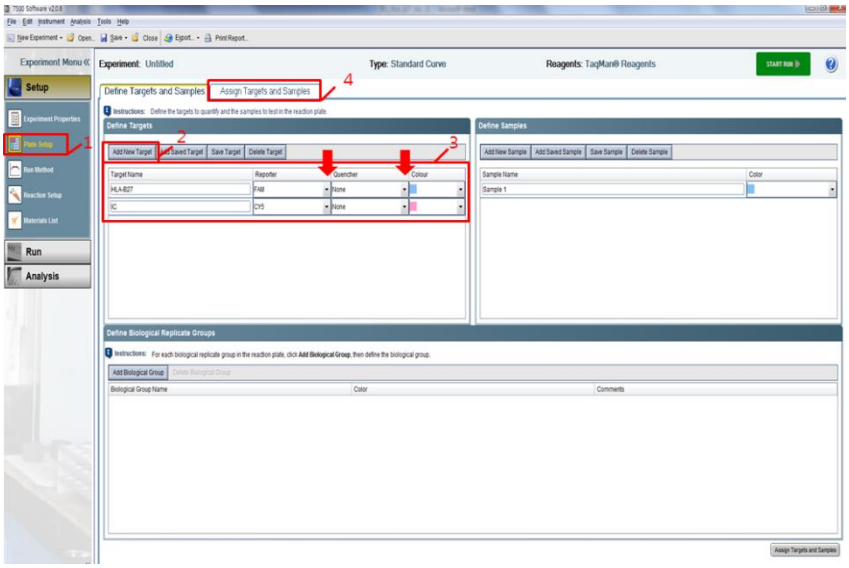
I. Template input

1> Select 'Advanced Setup' as below figure.



2> Refer to figure below, take things in order

1. Select 'Plate Setup' mode
2. Choose the 2 targets by 'Add New Target', input target names
3. Select dye for each target according to information of Reporter and Quencher
4. Move to Assign Targets and Samples



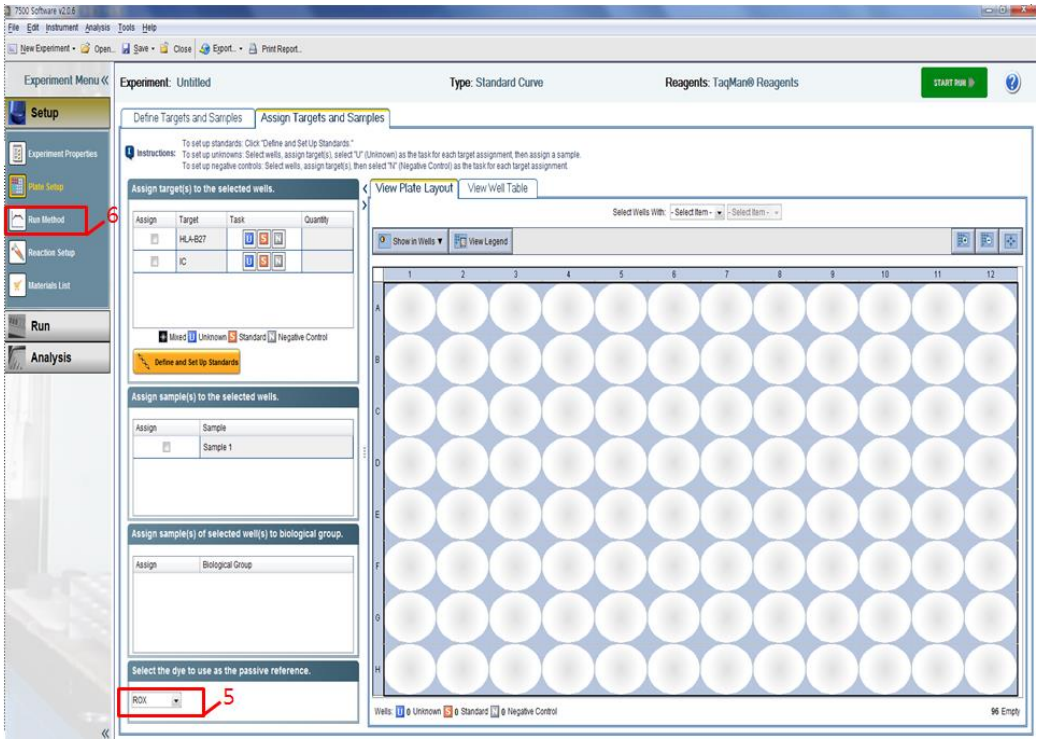
※ Fluorescence setting

Target	Reporter	Quencher
HLA-B*27	FAM	None
IC	Cy5	None
Reference Dye	ROX	

3> Refer to figure below, take things in order

5. Choose 'ROX' on screen of selection for Passive reference dye

6. Move to Run Method



4> Refer to figure below, take things in order

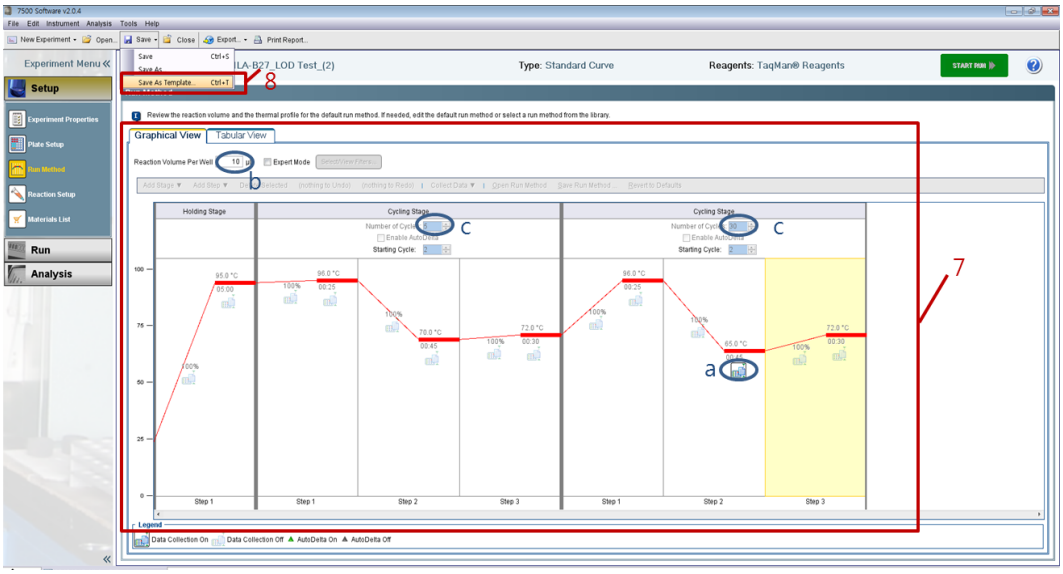
7. Input the PCR condition according to Insert

7-a. Click the data collection then 'on' mode

7-b. Input Total volume

7-c. Check the number of cycles

8. Save the PCR condition as 'Save As Template'



※ Real-Time PCR condition

Step		Temperature	Time	Cycle
1	Denaturation	96 ºC	5 min	1 cycle
2	Denaturation	96 ºC	25 sec	5 cycles
	Annealing	70 ºC	45 sec	
	Extension	72 ºC	30 sec	
3	Denaturation	96 ºC	25 sec	30 cycles
	Annealing *	65 ºC	45 sec	
	Extension	72 ºC	30 sec	

Note:* Select ON for data collection in Annealing (65 ºC) stage at Step 3.

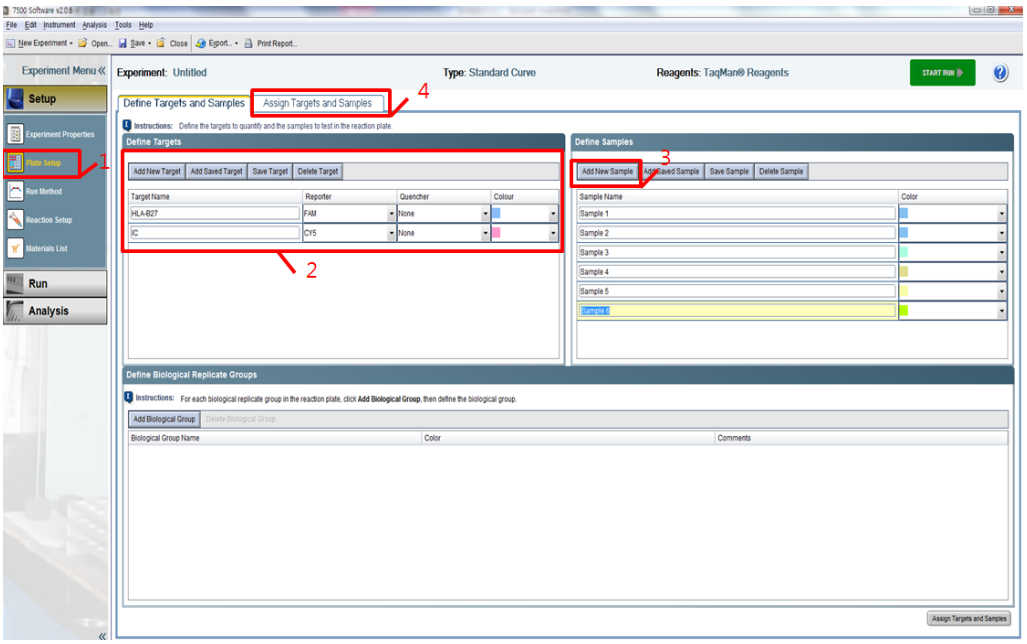
II. Saved Template Importing

1> Select 'Template' as figure below

2> Start program with saved template

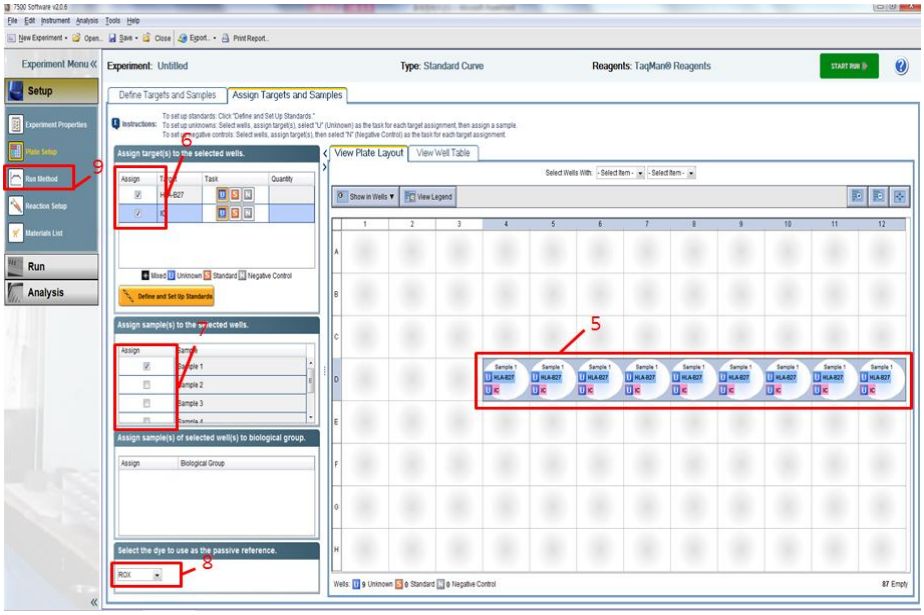
3> Refer to figure below, take things in order

1. Select 'Plate Setup' mode
2. Confirm existing input data
3. Input a sample name after check 'Add New Sample' according to number of samples
4. Move to Assign Targets and Samples



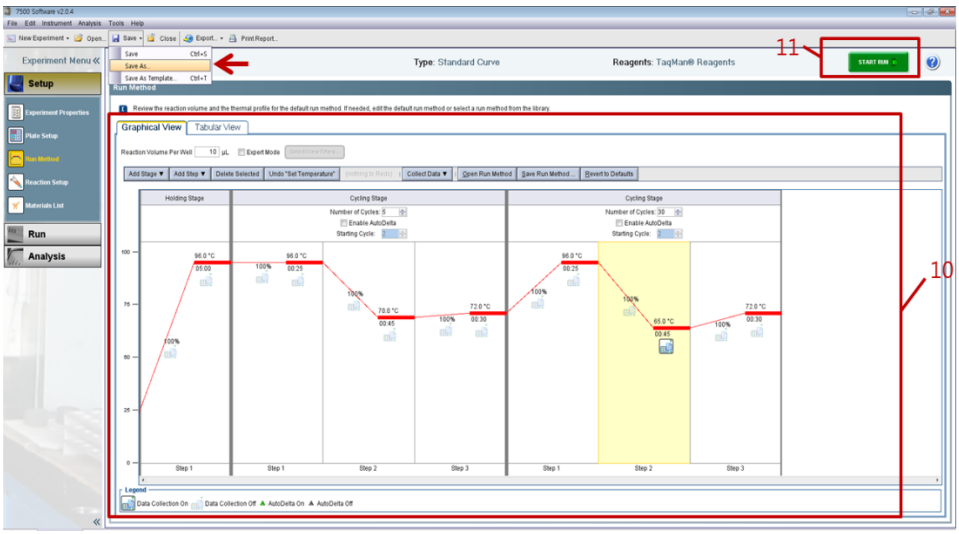
4> Refer to figure below, take things in order

5. Choose the sample position of the plate
6. Select all targets of 'Assign'
7. **Choose the plate well position** of each sample, then **check the Assign** according to samples.
8. Select 'ROX' for passive reference dye
9. Move to next stage through 'Run Method'



5> Refer to figure below, take things in order

10. Confirm again saved PCR condition
11. Save the data with 'START RUN' in the upper right of the screen, if the 'START RUN' button is not active, save the data by clicking 'Save as' of the menu then click the 'START RUN' again



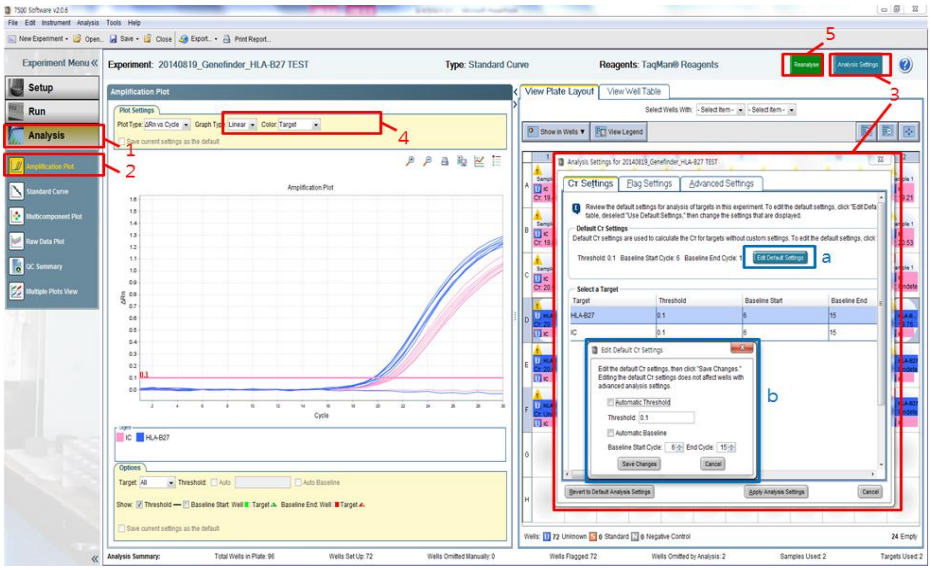
III. Data analysis

1. Choose the analysis mode
2. Select the Amplification Plot
3. In analysis setting, check the 'Edit Default Setting' (Blue box-a) and clear the 'Automatic Threshold' (Blue box-b) after that input the threshold value according to manual

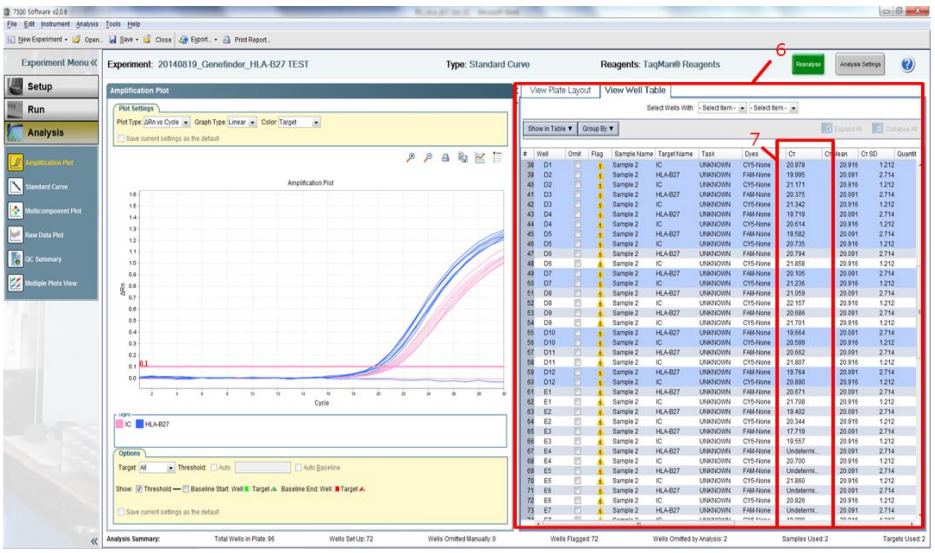
※ Edit Default Settings

Real Time PCR	Threshold	Baseline	
		Start cycle	End cycle
ABI 7500	0.1	**6**	**15**

4. Set the data form such as graph type or color etc.
5. Click the Reanalyze button in order to analyze with applied changes



6. Move to 'View Well Table'
7. Result analysis with Ct value



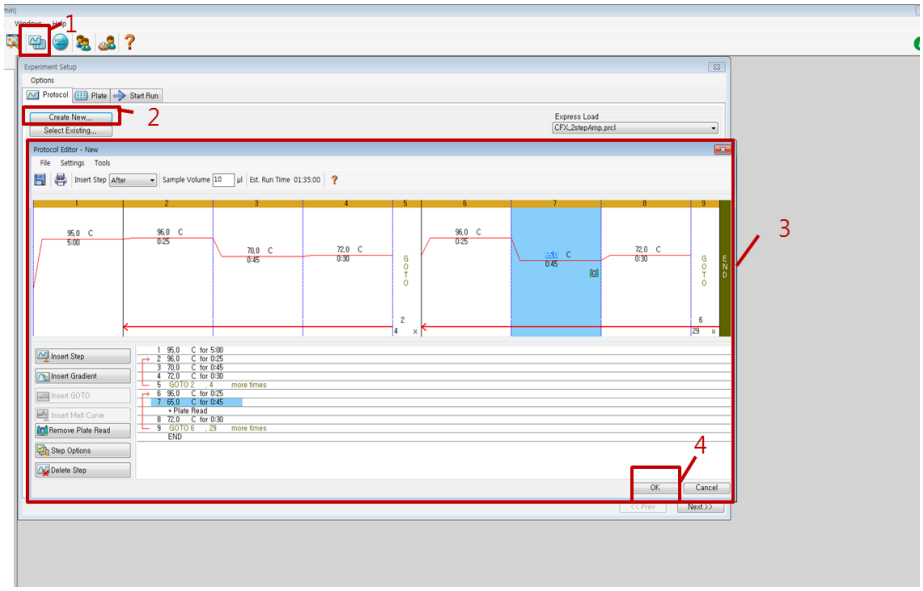
② Bio-Rad CFX96

Run instrument software

I. Template input method

1> Refer to the figure below, take things in order

1. Start Experiment setup, "Protocol" is open.
2. Open a new window by 'Create new'
3. Input the PCR condition
4. Click OK to save the test condition



※ Real-Time PCR condition

Step		Temperature	Time	Cycle
1	Denaturation	96 ºC	5 min	1 cycle
2	Denaturation	96 ºC	25 sec	5 cycles
	Annealing	70 ºC	45 sec	
	Extension	72 ºC	30 sec	
3	Denaturation	96 ºC	25 sec	30 cycles
	Annealing *	65 ºC	45 sec	
	Extension	72 ºC	30 sec	

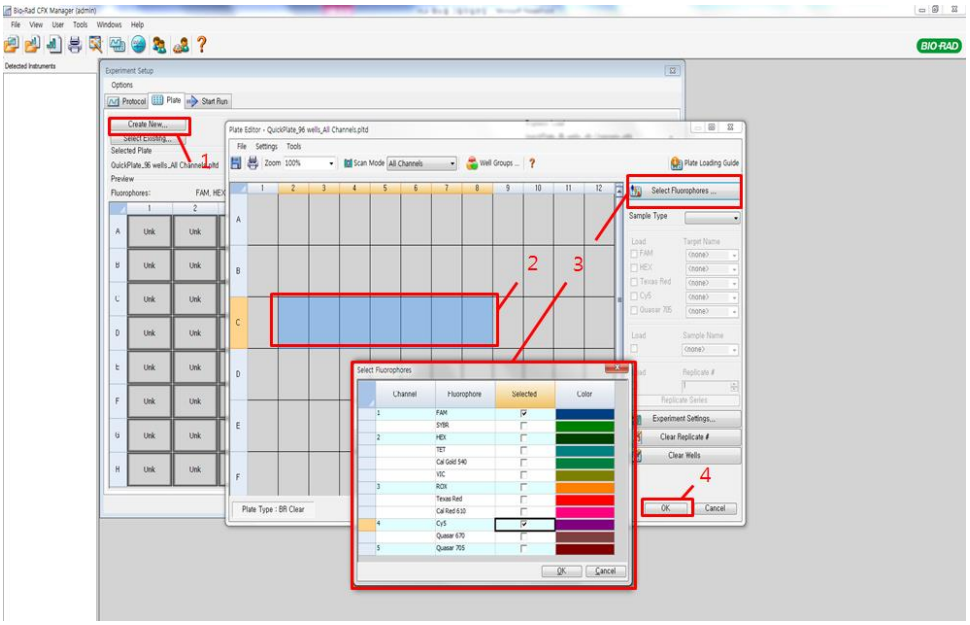
Note. * Select 'Add plate Read to Step' in Annealing stage (65 ºC) at Step 3

2> Save the condition then click Next >>

II. Plate setup and PCR Run

1> Refer to the figure below, take things in order

1. Click 'Create New' button to open a new window.
2. Choose the tube positios by drag.
3. Click "Select Flurophores" button to check dyes for each target.
4. Click OK to save the test condition



※ Fluorescence setting

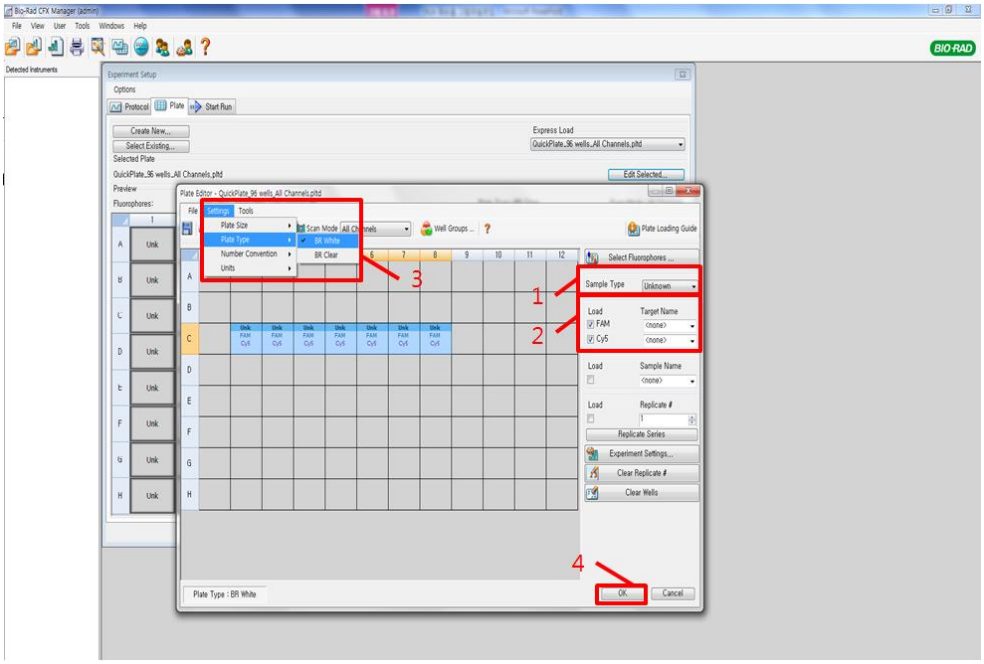
Target	Selected
HLA-B*27	FAM
IC	Cy5

Note: It is unnecessary to select Reference Dye for Bio-Rad CFX96.

2> Save the condition then click Next >>

3> Refer to figure below, take things in order

1. Select Unknown by clicking Sample Type button.
2. Check dye for each target.
3. Choose "BR White" of Plate Type by settings.
4. Press OK button to save the test condition.



4> After then, press the icon Next >>

5> Check that "Run Status" is Idle.

6> Click "Start Run" for the test

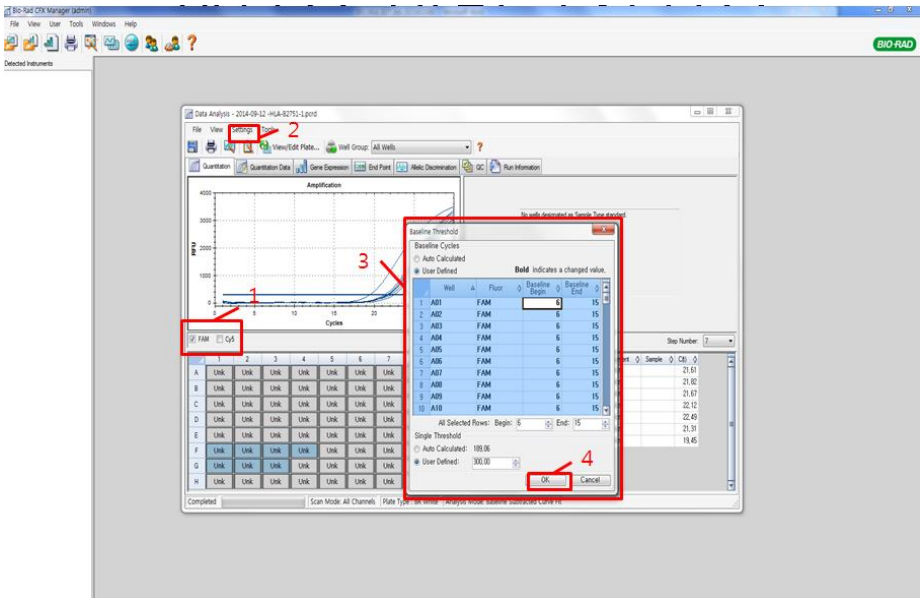
III. Data analysis

1. Import the test result then the window appears as below. Click dyes on a box for each target.
2. Check the "Baseline Threshold" of the Settings.
3. Select "User Defined" then Check the "Baseline Threshold" as below.

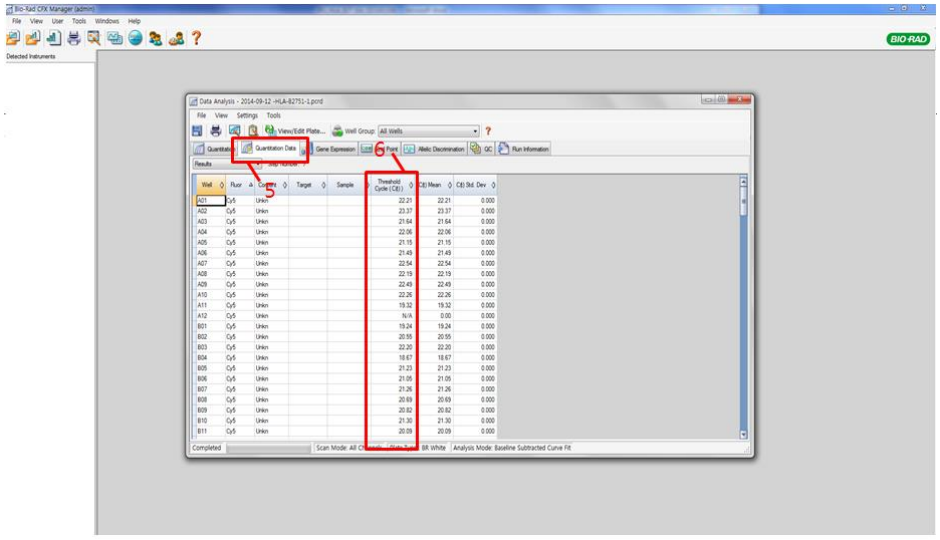
※ Edit Default Settings

Real Time PCR	Single Threshold		Baseline Cycles	
	HLA-B*27 (FAM)	IC (Cy5)	Start	End
Bio-Rad CFX96	500	300	6	15

4. Click OK for analysis.



5. Move to "Quantitation Data" tab.
6. Check the Ct values of the targets from data.



5) Analysis setting

Instrument	Threshold setting		Baseline
	HLA-B*27 (FAM)	IC (Cy5)	
ABI 7500	0.1	0.1	6-15
Bio-Rad CFX96	500	300	

8. RESULT INTERPRETATION

1) Sample

Ct value		Result	REMARK
HLA-B*27 (FAM)	IC (Cy5)		
16-26	≤ 28	B27 positive	-
16-26	> 28 or Undetermined	B27 positive	If Ct value of IC is out range of criteria and target Ct value is within the criteria, a sample is positive for B27 allele.
Undetermined	≤ 28	B27 negative	-
Undetermined	Undetermined	Invalid	Repeat the test from DNA extraction step.

2) Positive control (provided in the kit)

Instrument	Ct value	
	HLA-B*27 (FAM)	IC (Cy5)
ABI 7500	18±3	18±3
Bio-Rad CFX96	18±3	18±3

3) Negative control (Ultrapure Water, not provided in the kit)

Instrument	Ct value	
	HLA-B*27 (FAM)	IC (Cy5)
ABI 7500	Undetermined	
Bio-Rad CFX96	Not applicable	

9. QUALITY CONTROL

GeneFinder™ HLA-B*27 Real*Amp* kit is recommended for quality control evaluation by using negative and positive control or a calibrated reference material from DNA extraction to PCR amplification.

10. LIMITATION OF PROCEDURE

- This kit must be performed by well-trained and authorized laboratory staff.
- Any diagnostic result generated must be interpreted in conjunction with other clinical or laboratory findings. It is the user's responsibility to validated system performance for any procedures used in their laboratory which are not covered by the OSANG Healthcare performance studies.
- This kit should be used the biological samples such as human genomic DNA extracted by appropriate methods.
- Do not use contaminated DNA which can cause invalid results. The optimal conditions for DNA ratio (A260/280) and DNA concentration is within 1.6 ~2.0 and 50-100 ng/㎕ for test, respectively.
- This kit does not provide inhibition effect data obtained by medicines.
- Do not use the heparin which can interfere severely with PCR reaction.
- This kit is not a companion diagnostic device.
- If a serious incident occurs related to this device, contact the legal manufacturer and the Competent Authority.

11. TRACEABILITY OF CALIBRATOR

The B27 PC used as a quality control material for this kit is a plasmid DNA cloned by recombination of exon-2 region of HLA-B*27 and *Adenomatous polyposis coli* (APC) gene of Internal control with reference to UCLA Reference DNA.

12. TROUBLE SHOOTING

Problems	Possible Causes	Recommendation
No fluorescent signal is detected in all samples including positive control	Error in Master mixture preparation	Check the dispensing volume during preparation of master mixture
	Inhibitors added	Take care when DNA is extracted and repeat the extraction step with new sample
	Probe degradation	Use a new 2x *Rxn* reagent
	Positive control degradation	Use a new Positive control
	Omitted components	Verify each component, repeat the PCR mixture preparation
	Instrument setting error	Check the position settings for the positive control on instruments. Check the thermal cycle settings on instruments.
Non-specific fluorescent signal is detected in negative control	Carry-over contamination	Beware when dispensing sample, ultrapure water and positive control
	Microplate/ tube error	Beware of spilling the contents of the plate or tube
	Tube cap/ sealing film error	Check the condition of closure for cap or sealing film
	Reagent contamination	Repeat the test with new dispensing reagent
	Contamination of extraction/amplification area	Clean the instrument with disinfectant and replace with tubes and tips
Weak or no fluorescent signal in samples only	Poor DNA quality	Use recommended kit for DNA extraction and store extracted DNA at -20°C
	Insufficient volume of DNA	Repeat PCR reaction with correct volume of DNA
Weak or no fluorescent signal in positive control only	Positive control degradation	Use a new Positive control
Diverse intensity of fluorescent signals appear	Pipetting error	Make sure that the equal volume of reactants are added in each tube or plate
	Contamination in the outer surface of PCR tubes or plate	Wear gloves during the experiment

Note: If any issues with the product are found, please contact us immediately by referring to 16. CONTACT INFORMATION.

13. PERFORMANCE CHARACTERISTICS

1) Analytical sensitivity : Limit of Detection (LoD)

GeneFinder™ HLA-B*27 Real*Amp* kit was performed for analytical sensitivity using UCLA DNA Reference Panel (UCLA Immunogenetics Center, USA). On the basis of the test results, 100% of positive Limit of Detection was determined at a concentration of 2 ng/㎕.

2) Analytical specificity : Cross Reactivity

GeneFinder™ HLA-B*27 Real*Amp* kit was performed with 131 different reference materials for Locus A, B, and C for cross reactivity. There was no cross-reaction since all tests showed negative results.

3) Analytical specificity : Interference

GeneFinder™ HLA-B*27 Real*Amp* kit was performed with 7 interference panels for interfering test were spiked with positive DNA reference panel and blood samples were extracted for test. On the basis of the test results, 6 substances that might interfere with the assay were tested and the following concentrations were shown to have no detrimental effect on the results:

Interference factor	**Test concentration**
Hemoglobin	26.24 ug/dL
Bilirubin	99 umol/L
Triglycerides	417 mg/dL
K3 EDTA	1.6 mg/ml
K2 EDTA	1.6 mg/ml
Sodium citrate	0.106 mol/L

However, PCR amplification was clearly interfered with when Li-heparin was spiked blood samples used as a source of template DNA.

Interference factor	Test concentration
Li-heparin	16 IU/ml

4) Repeatability

GeneFinder™ HLA-B*27 Real*Amp* kit was performed on one lot using 4 types of HLA-B*27 reference materials (each low, medium and high concentrations) for the total 80 replications (2 replicates * 2 runs/day * 20 days). The results showed 100% repeatability for HLA-B*27 alleles.

5) Reproducibility

· Lot-to-Lot

GeneFinder™ HLA-B*27 Real*Amp* kit was performed on 3 different lots using 4 types of HLA-B*27 reference materials (each low, medium and high concentrations) for with 5 replicates of each sample per run and tested for 5 days. The results showed 100% reproducibility between Lot for HLA-B*27 alleles.

· Between the operators

GeneFinder™ HLA-B*27 Real*Amp* kit was performed on 3 different operators using 4 types of HLA-B*27 reference materials (each low, medium and high concentrations) for with 5 replicates of each sample per run and tested for 5 days. The results showed 100% reproducibility between the operators for HLA-B*27 alleles.

· Between the operation places

GeneFinder™ HLA-B*27 Real*Amp* kit was performed on 3 different operation places using 4 types of HLA-B*27 reference materials (each low, medium and high concentrations) for with 5 replicates of each sample per run and tested for 5 days. The results showed 100% reproducibility between the operation places for HLA-B*27 alleles.

6) Clinical Sensitivity and Specificity

GeneFinder™ HLA-B*27 Real*Amp* kit was performed using 200 positive samples and 598 negative samples for B*27 alleles to verify Clinical sensitivity and specificity. The GeneFinder™ HLA-B*27 Real*Amp* Kit had a clinical sensitivity of 98.5% and a clinical specificity of 99.8%.

7) Summary of Safety and Performance(SSP)

The SSP of GeneFinder™ HLA-B*27 Real*Amp* Kit is located at the following https://ec.europa.eu/tools/eudamed/#/screen/certificates (European Database on Medical Devices, EUDAMED)

14. SYMBOLS USED ON LABELS

CE	This product fulfills the requirements of IVDR (EU) 2017/746 on in-vitro diagnostic medical devices	EC REP	Authorized Representatives in European Community
IVD	In Vitro Diagnostic Medical Device	Σ	Contains sufficient for <n> tests
#	Model Number	⚠	Caution
LOT	Batch code		Storage temperature limits
REF	Catalogue number		Use-by date
	Consult Instruction For Use		Manufacturer

15. REFERENCES

1) Dausset J., The major histocompatibility complex in man, Science, 1981 25; 213(4515):1469-74.
2) Khan MA. Ankylosing spondylitis and related spondyloarthropathies: The dramatic advances in the last decade. Rheumatol. 2011;50:637-9.
3) Khan MA. Mathieu A. Sorrentino R. Akkoc N., The pathogenetic role of HLA-B27 and its subtypes, Autoimmun Rev. 2007; 6(3):183-9

16. CUSTOMER SERVICE CONTACT INFORMATION

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17. REVISION HISTORY

REVISION	DATE (YYYY-MM)	CHANGES
0	2023-07	New Issue for IVDR Regulation (UE) 2017/746 compliance
1	2024-01	Change packaging material number Revision of Intended Purpose Specimen storage method of freezing temperature condition Additional 10. LIMITATION OF PROCEDURE Additional 13. PERFORMANCE CHARACTERISTICS