INSTRUCTIONS FOR USE

ThromboGUARD FII FV
Kit for multiplex detection of FII / FV thrombophilia by real-time PCR

CE 0459 IVD

1. PRODUCT LIST

Trade Name	Commercial Reference	Number of reaction
ThromboGUARD FII FV	AB0023	Σ 24 (24 possible reactions, including controls)
Unique Device Identifier (UDI-DI)		
03760322820102		

2. INTENDED PURPOSE AND USE

Clinical conditions	Hereditary thrombophilia linked to Factor II Prothrombin (FII) Factor V Leiden (FV) is a genetic disorder involving the genes that code for the FII and FV proteins in the coagulation system. Mutations of these genes result in hypercoagulability and are the two most common genetic risk factors for inherited thrombophilia. Hereditary thrombophilia predisposes an individual to venous thromboembolism, a severe condition characterized by high morbidity and mortality.
Intended purpose	ThromboGUARD FII FV kit is intended to be used by laboratory professionals for the non-automated qualitative detection and genotyping of mutations of the genes encoding coagulation Factor II (prothrombin) and Factor V (factor V Leiden) in a blood sample, as an aid in the diagnosis of hereditary thrombophilia.
Test principle	Real-time Polymerase Chain Reaction (PCR), amplification of two specific regions of the human genome and detection by fluorescence-based scatter plot analysis using TaqMan™ MGB probes marked with specific fluorophores.
Target Population	Patients with suspicion of hereditary thrombophilia, within the recommendations of national health authorities of European Union population, based on the patient's clinical and biological context as well as personal and family history.
Intended users	Qualified laboratory staff trained in good laboratory practice and molecular biology techniques, in particular real-time PCR.
Environment of use	Medical biology laboratories with a structure that complies with the recommendations of the national health authority.
Required sample type	Whole blood in sterile, single-use vacuum PET blood collection tubes containing K2 EDTA anticoagulant for the collection and storage of samples for *in vitro* diagnostic use.

Manual or automated steps	- Automatic DNA extraction - Manual pipetting of samples and reagents - Manual loading of thermocycler - Automated Real-Time PCR and fluorescence detection - Automated allele discrimination by PCR software - Manual result interpretation
Analysis type	Qualitative
PCR reaction duration	45 minutes
Summary of Safety and Performance	See EUDAMED – European Database on Medical Devices on *ec.europa.eu*
Regulatory Status	*In Vitro* Diagnostic Medical Device (IVD MD) Regulation (EU) 2017/746

3. TECHNICAL SPECIFICATIONS

Validated sampling/transport medium	Whole blood in sterile, single-use vacuum PET blood collection tubes containing K2 EDTA anticoagulant for the collection and storage of samples for *in vitro* diagnostic use.
Validated extraction method	DNA extraction with magnetic beads: QIAsymphony extraction kit, DSP DNA Mini Kit (Ref: 937236, Qiagen).
Validated combinations with instrument(s)	**Instrument name** / **Manufacturer** QIAsymphony SP (Ref: 9001297) (extractor)* / Qiagen CFX Opus 96 Dx Real-Time PCR Thermocycler associated with Bio-Rad CFX Maestro Dx SE Software / Bio-Rad
Target genes	- Factor II : G20210A (gene) - Factor V : G1691A (gene)
Fluorescence channels	- Factor II Wild-type: FAM - Factor II Mutant : HEX - Factor V Wild-type: ROX - Factor V Mutant : Cy5

4. ANALYTICAL PERFORMANCES

Analytical Specificity	
Inclusivity	The oligonucleotides in ThromboGUARD FII FV kit have an inclusivity of: • *In silico* 100% • *In vitro*: - Factor II: 100% (95% CI [85%,100%]) - Factor V: 100% (95% CI [95%,100%])
Exclusivity (cross reaction)	Human genome (tested *in silico*): no cross-reactivity.

<table>
<tr><th colspan="2">Analytical Sensibility</th></tr>
<tr><td>Limit of Detection (LoD)
Measuring range</td><td>
<table>
<tr><th>Gene concerned</th><th>Low LoD</th><th>High LoD</th></tr>
<tr><td>Factor II</td><td>0.65 ng/µL</td><td>5.0E+4 ng/µL</td></tr>
<tr><td>Factor V</td><td>0.65 ng/µL</td><td>5.0E+4 ng/µL</td></tr>
</table>
</td></tr>
<tr><th colspan="2">Fidelity</th></tr>
<tr><td>Repeatability</td><td>• Factor II: 100% agreement on the 3 genotypes; 95% CI [96%,100%]
• Factor V: 100% agreement on the 3 genotypes; 95% CI [96%,100%]</td></tr>
<tr><td>Reproducibility</td><td>• Factor II: 100% agreement on the 3 genotypes; 95% CI [98%,100%]
• Factor V: 100% agreement on the 3 genotypes; 95% CI [98%,100%]</td></tr>
<tr><th colspan="2">Other parameters</th></tr>
<tr><td>Linearity
Linearity range
Efficiency</td><td>• Validated parameter: $R^2 \geq 0.98$
• Linearity range: 1.3 ng/µL - 1.3E+3 ng/µL
• Validated parameter: 80% <Efficiency< 120%</td></tr>
</table>

- **Interfering substances**

The interference assessment was carried out in accordance with CLSI guide EP07-Ed3. The results are similar for FII and FV factors.

Interfering substances	Tested levels (qty)	Observed interferences
K2 EDTA	5.71 mg/mL	None
Heparin	14.73 IU/mL	None
Hemoglobin	300.00 mg/mL	None
Bilirubin	0.15 mg/mL	None
Cholesterol	3.15 mg/mL	None
Ethanol	5.0% v/v	None
Warfarin	32.5 µmol/L	None
Rivaroxaban	1.5 µmol/L	None
Dabigatran etexilate	0.567 µmol/L	None

5. CLINICAL PERFORMANCE

Clinical performance of the ThromboGUARD FII FV kit was established on EDTA-anticoagulated whole blood patient samples (61 heterozygous FII samples (Het), 98 homozygous wild-type FII samples, 0 homozygous FII mutant sample (Mut), 101 heterozygous FV samples (Het), 98 homozygous wild-type FV samples and 5 homozygous FV mutant samples (Mut)).

Samples were extracted using the QIAsymphony SP automated magnetic bead extraction system and QIAsymphony extraction kit DSP DNA Mini Kit

	Factor II		Factor V	
	Het	**Mut**	**Het**	**Mut**
Diagnostic sensitivity	100%; 95% CI [96%;100%]	N/A	100%; 95% CI [98%;100%]	100%; 95% CI [62%;100%]
Diagnostic specificity	100%; 95% CI [97%;100%]	N/A	100%; 95% CI [97%;100%]	100%; 95% CI [97%;100%]
Positive Predictive Value (PPV)	100%; 95% CI [96%;100%]	N/A	100%; 95% CI [98%;100%]	100%; 95% CI [62%;100%]
Negative Predictive Value (NPV)	100%; 95% CI [97%;100%]	N/A	100%; 95% CI [97%;100%]	100%; 95% CI [97%;100%]
Likelihood ratio	LR+ : infinite value LR- = 0	N/A	LR+ : infinite value LR- = 0	LR+ : infinite value LR- = 0

6. CONTENT OF THE KIT

- **Reagents list of the kit:**

Reagents	Commercial reference	Part Number « P/N »	Cap color	Content	Quantity	Volume
Mix	AB0023	F2F5MIX	Transparent	Reaction mix: - Specific primers and probes for Wild-type and Mutant alleles of the FII gene - Specific primers and probes for Wild-type and Mutant alleles of the FV gene - Enzyme Mix Polymerase Hot Start Taq - Molecular biology grade water	1 tube	480 µL
Mutant Homozygous Control	AB0023	F2F5CMut	Red	- Synthetic DNA for FII et FV Mutant alleles in a preservation solution (Tris-EDTA buffer)	1 tube	120 µL
Wild-type Homozygous Control	AB0023	F2F5CWT	Blue	- Synthetic DNA for FII et FV Wild-type alleles in a preservation solution (Tris-EDTA buffer)	1 tube	120 µL
Heterozygous Control	AB0023	F2F5CHet	Yellow	- Synthetic DNA for FII et FV Mutant and Wild-type alleles in a preservation solution (Tris-EDTA buffer)	1 tube	120 µL

Description of reagents and limitations
The substances in this kit are not classified as dangerous substances under Regulation (EC) 1272/2008.

7. KIT TRANSPORT, STORAGE AND STABILITY

Steps	Conditions details
Transport	- The kit must be transported between -80°C and -15°C (dry ice).
Storage/Conservation	- Reagents should be stored in a dark, dry place. - Storage temperatures should be between -25 °C and -15 °C. - Unopened shelf life: refer to the expiry date on the product label.
Shelf life following the first opening of tubes Stability in use	- Mix should be used out of direct sunlight. - Do not leave the kit at room temperature (between +15°C and +25°C) for more than 24 hours. - Do not exceed 10 freeze/thaw cycles. - Do not use after expiry date.

8. REQUIRED EQUIPMENTS AND ACCESSORIES BUT NOT SUPPLIED WITH THE KIT

Steps	Equipment type
Laboratory Equipment	Freezer -20°C, Refrigerator +4°C Powder-free disposable gloves Laboratory coat Benchtop centrifuge for 1.5-mL and 2.0-mL tubes and/or rack Plate centrifuge (optional) Benchtop vortexer Adjustable micropipettes P10, P20, P200 Sterile filter cones for 10 µL, 20 µL, 200 µL 1.5 mL Eppendorf microtubes or equivalent Microtubes, strips or opaque 96-well 0.2 mL PCR plates compatible with CFX Opus 96 Dx thermal cycler (Bio-Rad) Specific optical films for PCR (or caps if strips are used) Microbiological Safety Cabinet (MSC) for handling class I or II pathogens Cold rack or crushed ice
Extraction	QIAsymphony, DSP DNA Mini Kit Kit (Ref: 937236, Qiagen) QIAsymphony SP (Ref: 9001297, Qiagen) (extractor)
PCR Amplification	CFX Opus 96 Dx Real-Time PCR associated to Bio-Rad CFX Maestro Dx SE software (Bio-Rad)
Other Reagents	Molecular biology grade water DNA-RNA decontamination product

9. SAMPLE COLLECTION PROCEDURE

Samples for DNA extraction must be collected and transported following professional guidelines.
Samples for DNA extraction must be transported and processed by the laboratory as soon as possible.

Whole blood specimens should be collected in sterile, single-use vacuum PET blood collection tubes containing K2 EDTA anticoagulant and transported at room temperature (between +15°C and +25°C) within 24 hours. Whole blood specimens can be stored at +4°C for up to 5 days or at -20°C for 4 months after collection.

10. USE PROTOCOL

10.1 NUCLEIC ACID EXTRACTION

If necessary, thaw the sample at room temperature.

- DNA extraction with magnetic beads: please refer to the instructions of the QIAsymphony, DSP DNA Mini Kit (Ref: 937236, Qiagen) and the QIAsymphony SP automated magnetic bead reference system (Ref: 9001297) from Qiagen.
- Control of DNA purity and quantity after extraction: follow recommendations linked to the method. The following parameters are recommended for the spectrophotometer: A260/A280 (ratio of absorbance at 260 nm to absorbance at 280 nm) between 1.7 and 1.9. The minimum concentration required for PCR reaction is 0.65 ng/µL.

It is recommended to follow the recommendations given in the instructions for use of the kits and extraction systems selected.

The extracted DNA can be stored between +2 and +8°C for a maximum of 5 days. For long-term storage, we recommend keeping it at -20°C.

10.2 REAL TIME AMPLIFICATION

1. Thaw reagents on cold block at 4° C for 15-25 minutes, according to lab environment.
2. Establish a technical roadmap (plate plan) specifying patient and control identity, preferably using CFX Maestro software.
3. For each real-time PCR run, plan the number of reactions as follows:
    - 1 reaction for each extracted DNA sample (patient) to be tested
    - 1 reaction for the Mutant Control ("Mut" = Mutant)
    - 1 reaction for the Wild-Type Control ("WT" = Wild-Type)
    - 1 reaction for Heterozygous Control ("HET" = heterozygous)
    - 1 reaction for NTC (No Template Control / molecular biology quality water). Use of this control is strongly recommended.
4. Use a cold block (+4 °C) to dispense the mix and samples.
5. Briefly vortex all kit tubes and homogenize samples.
6. Centrifuge all kit tubes until the liquid has sunk to the bottom of the tube.
7. Dispense reaction mixtures according to **Table 1:**
    a. Dispense 20 µL of amplification mix into each PCR well according to the number of patient samples and controls.
    b. Add 5 µL of each extracted DNA patient sample, according to the plate plan.
    c. Add 5 µL of Wild type Control to the corresponding control well.
    d. Add 5 µL of Mutant Control to the corresponding control well.
    e. Add 5 µL of Heterozygous Control to the corresponding control well.
    f. Add 5 µL of NTC according to plate plan.
    g. Seal plate with optical adhesive film. It is also recommended to centrifuge briefly.
    h. Briefly centrifuge the PCR plate to remove any air bubbles that may form at the bottom of the wells and interfere with the reading of the fluorescent signal.
    i. Place the plate in the thermal cycler in the right direction.
    j. Finalize the thermocycler parameters in CFX Maestro software:
        - *Select detection channels FAM, HEX, ROX and Cy5*
        - *Set reaction volume: 25 µL*

- *Other parameters if any*
- *Set the thermal amplification profile as number of cycles, temperature and time* (**Table 2**)

k. Start PCR.

Table 1: VOLUMES TO BE DISTRIBUTED PER PCR WELL

Product	Volume/well Sample	Volume/well Wild-type control	Volume/well Mutant Control	Volume/well Heterozygous Control	Volume/well NTC
F2F5 Mix	20 µL	20 µL	20 µL	20 µL	20 µL
DNA extracted from patient	5 µL	-	-	-	-
Wild Control	-	5 µL	-	-	-
Mutant Control	-	-	5 µL	-	-
Heterozygous Control	-	-	-	5 µL	-
NTC (molecular biology quality water)	-	-	-	-	5 µL
Total reaction volume	**25 µL**	**25 µL**	**25 µL**	**25 µL**	**25 µL**

In this kit, 4 control reactions are required per run.

Table 2 : THERMAL AMPLIFICATION PROGRAM

Steps	Process	Program		Cycles	Fluorescence acquisition
		Time	Temperature		
1	*Taq* polymerase activation	2 min	95 °C	1	Not applicable
2	DNA denaturation	10 s	95 °C	40	Not applicable
3	Amplification	15 s	62 °C		FAM/HEX/ROX/Cy5

11. RESULTS INTERPRETATION

11.1 QUALITY CONTROL

At the end of the run, set the following parameters in the thermal cycler's Maestro DX (Opus) software:

1. Go to the Allelic discrimination tab (**Figure 1)**
2. The NTC point must be as close as possible to fluorescence 0 (FAM/HEX/ROX/Cy5).
3. Set the NTC point in the software as follows:
   - Plate Setup: View/Edit Plate; Sample Type = NTC (**Figure 1** and **Figure 2**)
4. Select fluorophores X: FAM and Y: HEX to check that Factor II (**Figure 1**) controls are correctly identified as follows (**Figure 3** and **Figure 4** below):

- Wild: round/orange, bottom right
- Heterozygous: triangle/green, in the middle
- Mutant: square/blue, top left
- NTC: rhombus/black, bottom left

5. Repeat step 4. with Factor V, selecting fluorophore parameters X: ROX and Y: Cy5 (position and identification of points are identical to Factor II).
6. If the controls and NTC are correct, the PCR is validated.

Once the above parameters have been set, the thermal cycler software automatically outputs the results. Results to be obtained for controls and NTCs are presented in **Figure 3** and **Figure 4** below:

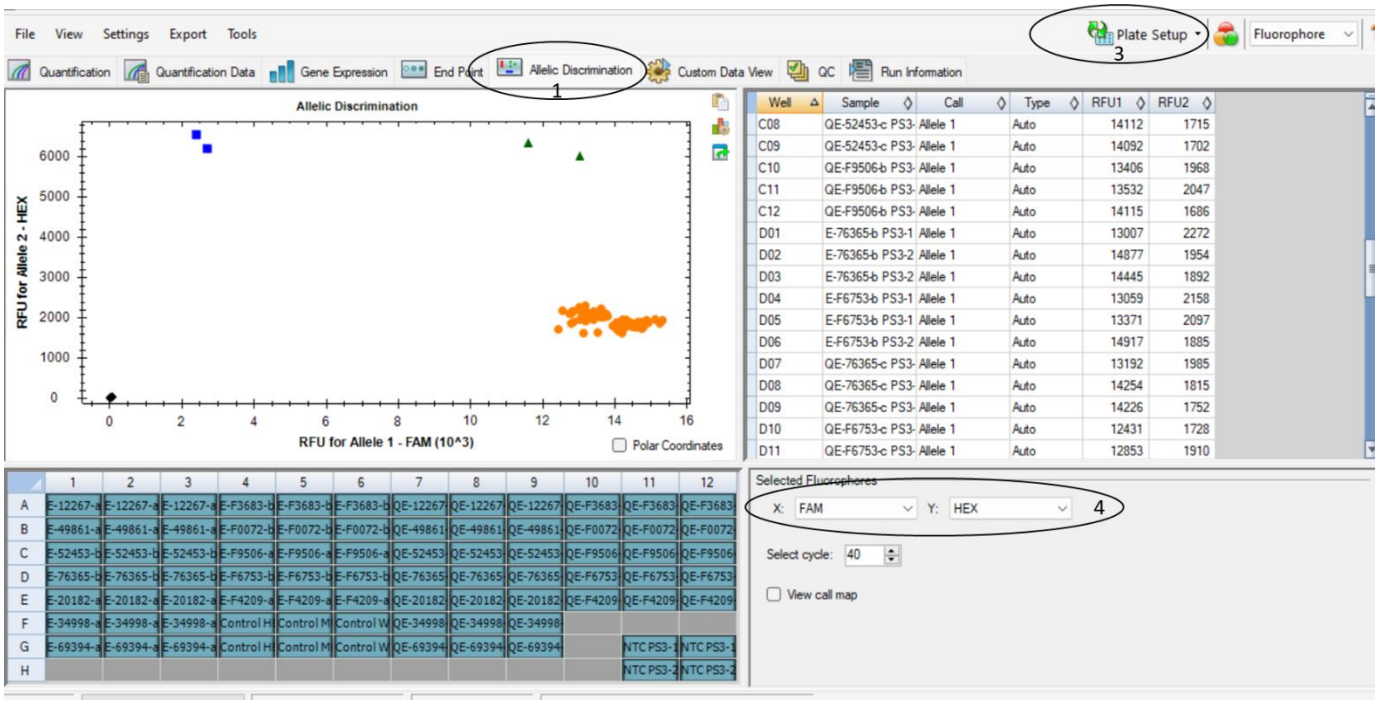

Figure 1: EXAMPLE TO GO TO ALLELIC DISCRIMINATION TAB (1) PLATE SET UP B (3) AND SELECTION OF FLUOROPHORE (4) HERE FOR FACTOR II FAM ET HEX

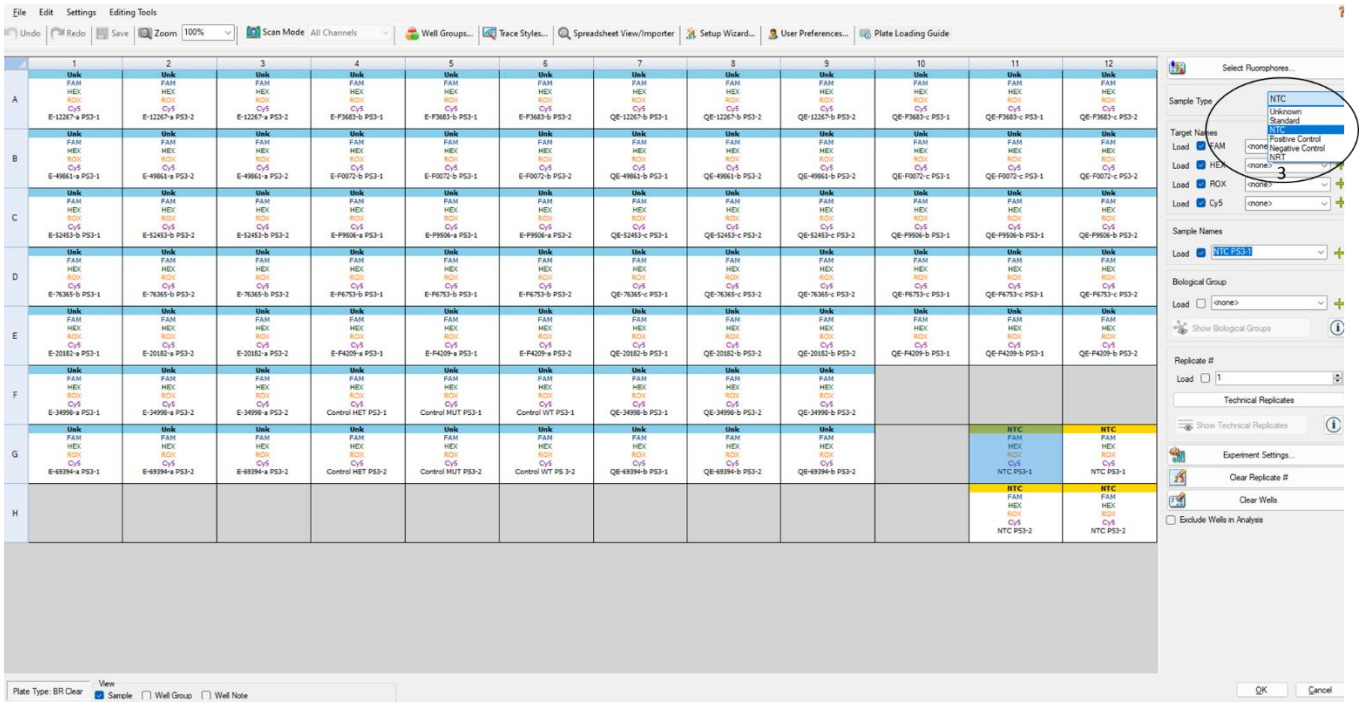

Figure 2: EXAMPLE OF PLATE SET UP TAB TO SET THE NTC (3)

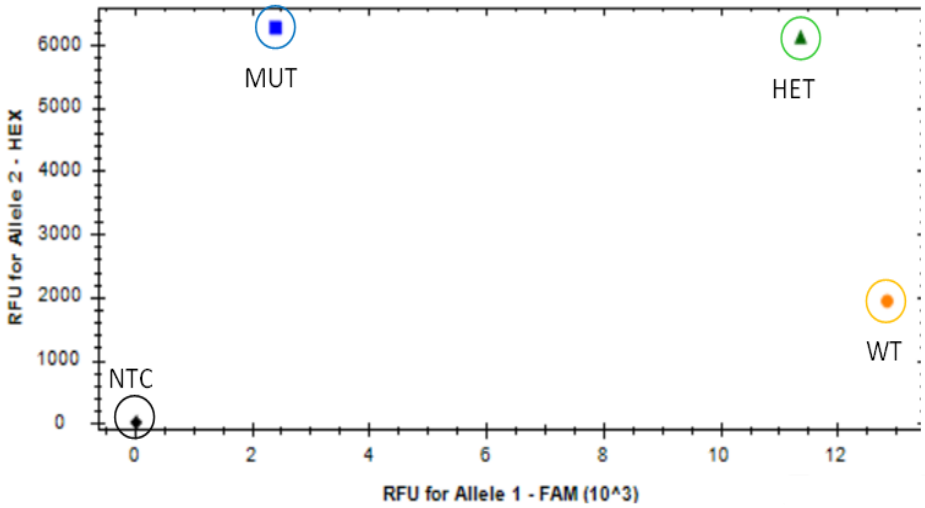

Figure 3: EXAMPLE OF RESULTS TO BE OBTAINED FOR CONTROLS AND NTC (VALID IN FACTOR FII FAM-HEX CONFIGURATION)

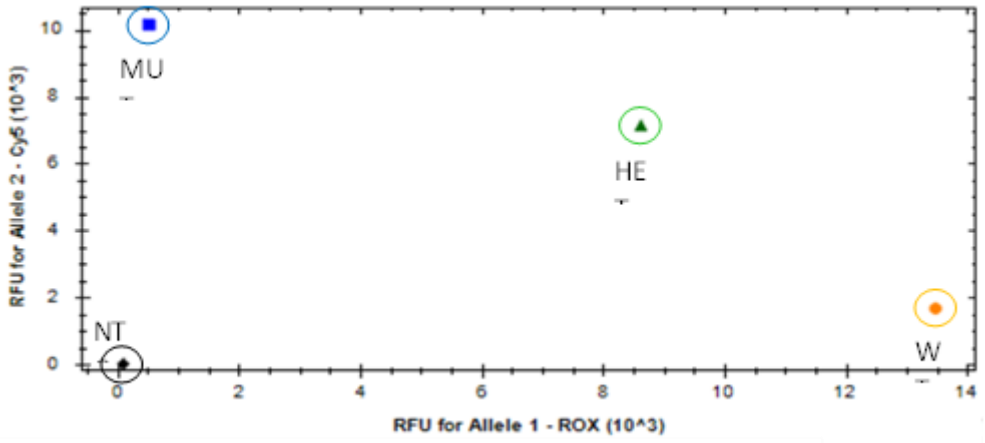

Figure 4: EXAMPLE OF RESULTS TO BE OBTAINED FOR CONTROLS AND NTC (VALID IN FACTOR V ROX-Cy5 CONFIGURATION)

11.2 SAMPLE RESULTS INTERPRETATION

In the Allelic discrimination tab of Maestro DX (Opus) software

Factor II:

Select fluorophores: X: FAM & Y: HEX then analyze the plate as indicated in **Table 3**.

Factor V:

Select fluorophores X: ROX & Y: Cy5 then analyze the plate as indicated in **Table 3**.

Table 3: RESULTS READING

	Factor II		Factor V	
Fluorophore parameters	X : FAM Y : HEX		X : ROX Y : Cy5	
Scatter Plot Identification	**Software Call**	**Interpretation**	**Software Call**	**Interpretation**
● Round/Orange	Allele 1	Homozygous wild-type	Allele 1	Homozygous wild-type
▲ Triangle/Green	Heterozygous	Heterozygous	Heterozygous	Heterozygous
■ Square/Blue	Allele 2	Homozygous Mutant	Allele 2	Homozygous Mutant
✖ Cross/Red	Unspecified	Invalid result	Unspecified	Invalid result

NB: The FII and FV genes are present in all human DNA. A result for Factor II and Factor V is systematically expected.

If the results are invalid, we recommend that you repeat the analysis; if the result remains invalid, repeat the analysis with a new sample. If the results remain the same, we advise you to repeat the analysis with another CE-marked technique, taking account the patient's clinical picture.

12. TROUBLESHOOTING

Problem	Possible Causes	Solutions
Invalid results (sample and/or control)	Alteration of the amplification mix	• Avoid more than 10 freeze/thaw cycles. • Use a cold block (+4 °C) when distributing Mix and samples. • Taq polymerase enzymes are sensitive to temperature variations. Do not leave at room temperature beyond kit handling time. • Protect from light. • Check the expiration date of the batch used.
Invalid sample result	Non-compliance with sample collection, transport and storage conditions	• Follow instructions for sample preparation, transport, and storage. • Check the time between sample collection and PCR analysis.
Invalid sample result	Problems during nucleic acid extraction	• Check that samples are homogenized before extraction. • Check the protocol and equipment used to extract samples. • Always carry out preventive maintenance on extraction equipment in accordance with the manufacturer's recommendations.
Incorrect control result or Invalid results	Reagent or sample distribution error Plate inverted	• Draw up a plate plan to limit the risk of dispensing errors. • Place the plate in the thermal cycler in the right direction. • Check the calibration of pipettes, which should be subject to regular metrological control. • Ensure that amplification solution, controls and samples are homogenized before distribution to PCR plate wells.
Incorrect control result or Invalid results	Thermocycler programming or loading error	• Check that the thermal cycler used is compatible with the one validated with the kit. • Check the correct direction of the PCR plate. • Check all thermocycler programming parameters (detection channel and mode, number of cycles, temperature, time, reaction volume, etc.).
Invalid results	Amplification problem	• Check Peltier block performance according to manufacturer's recommendations. • Perform preventive maintenance on PCR equipment according to manufacturer's recommendations. • Check that the PCR plate is compatible and properly sealed with the optical film. • Check that the plastic consumables used are those recommended for the instrument (half-skirt plate, low-profile tubes/plates, etc.).

Problem	Possible Causes	Solutions
Incorrect control results: Discrepancy between sample replicate results Higher proportion of heterozygous or mutant homozygous genotypes than usual.	Wrong channel allocation/selection Results analysis error Misinterpretation of results	• Set up the NTC correctly. • Analyze the Scatter Plot corresponding to each factor for each patient. • Check presence of control points. • Select channels as explained in 11.2 SAMPLE RESULTS INTERPRETATION • Check that the run validation criteria have been met as described in §11.1 QUALITY CONTROL. • Check that the thermocycler and software used are the ones recommended with the kit.
Incorrect control results Invalid results	Incorrect control result Invalid results	• Decontaminate all small equipment and laboratory instruments with products suitable for removing nucleic acids. • Change products used (water, PCR reagent, etc.). • Decontaminate thermal cycler according to manufacturer's recommendations • Change pipette tip for each sample and for each control and use filter tips to avoid carryover.
Incorrect control result	NTC incorrect: a fluorescent signal is detected, indicating contamination	• Change water to molecular biology grade. • Repeat the experiment.

13. PRECAUTIONS FOR USE AND LIMITATIONS

- *Pre-use precautions for the kit:*

- Read all instructions for use carefully before use. Failure to follow the IFU may lead to incorrect results.
- This kit must be used by personnel trained in good laboratory practice and competent in molecular biology.
- Please consult the Safety Data Sheet (SDS) on the company's website (The substances in this kit are not classified as dangerous substances under Regulation (EC) 1272/2008).
- Check packaging and device integrity before use (no leaks/breakage, correct number of tubes, correct volumes, etc.). Do not use product if damage is visible.
- Do not use the device if signs of contamination are present (presence of foreign bodies in tubes).
- Do not use the device after the indicated expiration date.
- Compliance with sample collection procedures (collection, transport, storage) is essential for optimum performance of this test, to avoid erroneous results.
- Do not use this kit with any type of sample or equipment other than those recommended in the IFU, as this may lead to erroneous results.
- Nucleic acid extraction and amplification must be carried out using the equipment and methods listed in the IFU. For any other equipment not listed, we recommend assessing its effectiveness by an internal laboratory validation procedure.

- Inappropriate sampling, sample processing, transport and storage conditions may lead to erroneous results.
- For equipment not supplied but to be used in conjunction with this product, please refer to the product's IFU before use.

- *Precautions when using the kit:*
- Caution: protect the mix from light exposure
- Use all necessary protective equipment (disposable protective gloves, lab coat and goggles) when handling samples and kit reagents to avoid contamination.
- Use separate workstations for sample preparation / nucleic acid extraction and amplification reactions. Never introduce amplified product into the reagent preparation and/or nucleic acid extraction area (sample preparation).
- Avoid microbial contamination of reagents during handling.
- Prepare samples under a microbiological safety cabinet (MSC).
- Use only RNase- and DNase-free filter pipette tips.
- Use new tips for each pipetting step.
- Close kit component tubes immediately after use and never interchange caps.
- Do not pool reagents from different batches or different tubes within the same batch in one tube.
- Do not substitute reagents between batches.
- Avoid skin contact with kit reagents. In case of skin contact, wash immediately with plenty of water.

- *Post-use precaution/limitations :*
- In case of a doubtful/undetermined result, please repeat the procedure.
- Patient management decisions should never be based solely on the results of this test. Other clinical and laboratory factors must also be considered when making clinical decisions.

14. CONTRAINDICATIONS

To date, Appolon Bioteck has not identified any contraindications for this device.

15. ADVERSE EVENTS

Any serious incident involving the device will be reported to Appolon Bioteck and to the competent health authority of the Member State in which the incident occurred.

Before contacting Appolon Bioteck technical support, please collect the following information:
- Product name,
- Batch number,
- Error message (if any).

Please keep the thermocycler raw data of the "runs" (raw .pcrd file, Excel export and screenshots of the software tab “Allelic discrimination" showing fluorescence values and allelic determination) to enable the manufacturer to identify the incident encountered with the device.

16. DISPOSAL OF THE DEVICE

For disposal of this device, please refer to current national and/or international regulations governing the disposal of hazardous, biological, or infectious waste.
Unused kit reagents can be considered non-hazardous and be disposed of in accordance with normal laboratory procedures.

17. DISCLAIMER

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Appolon Bioteck reserves the right to modify its products and services at any time. Appolon Bioteck accepts no liability for errors or omissions or for any damages arising from the application or use of this information.
The printed version of this manual is available on request.

18. SYMBOLS AND LOGOS USED

Symbol	Indication	Symbol	Indication
	Manufacturer		Catalogue number
	Batch code		Unique device identifier
	In vitro diagnostic medical device		European Conformity, Under Regulation (EU) 2017/746
	Use-by date		Do not use if package is damaged and consult instruction for use
	Consult instruction for use or consult electronic instructions for use		Storage temperature limit
	Caution		Keep dry
	Keep away from sunlight	 *n*	Sufficient content for <n> reactions
CONTROL	Control	P/N	« Part number », component identification
X/2	Medical device configuration in two X numbered boxes	MIX	Tube containing the mix solution

19. HISTORY OF CHANGES TO THE INSTRUCTION FOR USE

Version date	Change
2025-07	First release of document

20. CUSTOMER CONTACT

If you have any questions about additional documentation (Safety Data Sheets, Certificates of analysis, etc.), please contact Appolon Bioteck by phone or e-mail:

- Phone: +33 (0)4 37 57 00 54
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- eIFU / SDS / Summary of safety and performance:
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