FMF-SAA1 StripAssay®

Instructions For Use

REF	Σ
4-390	20 tests
4-390-A	48 tests
4-390-TRIAL	5 tests

2°C – 8°C

IVD

CE 0123

Version: rev 1.0 / English
eIFU and other languages available at
www.viennalab.com

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REVISION HISTORY:

version	date	description
rev 1.0	2022-11	Addition of IVDR-related contents to version 2022-01.

Summary of Safety and Performance (SSP) of the StripAssay® is retrievable from the European Database on Medical Devices (EUDAMED): https://ec.europa.eu/tools/eudamed or from the manufacturer.

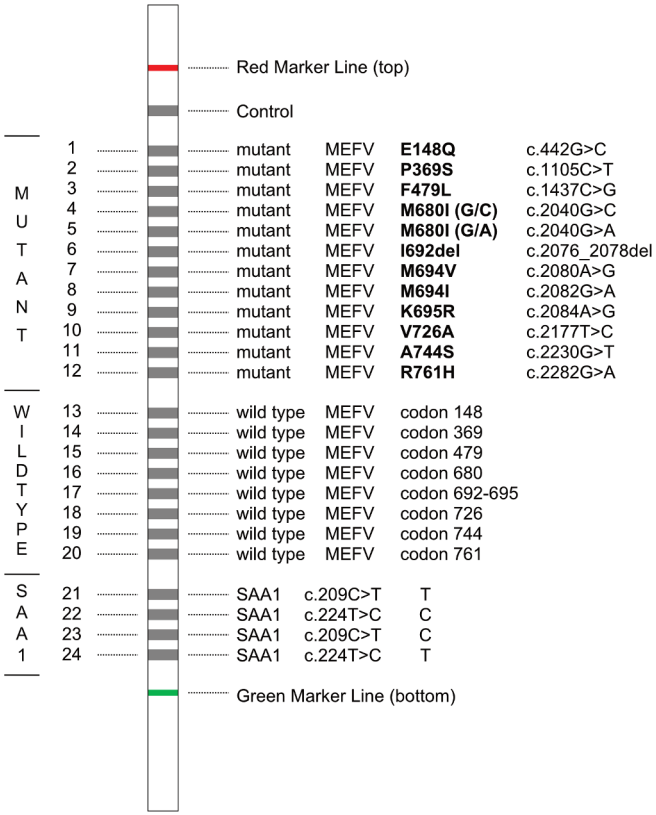

Fig. 1: Teststrip Design

Note: Teststrips are not drawn in real size and must not be used for interpretation of results!

I. INTENDED PURPOSE

The FMF-SAA1 StripAssay® is a qualitative genetic test for the targeted analysis of 12 frequent mutations in the *MEFV* gene associated with Familial Mediterranean Fever (FMF). In addition, the assay detects *SAA1* genotypes, which correlate with a higher risk for FMF patients to develop systemic reactive (AA) amyloidosis. Genomic DNA extracted from whole peripheral blood samples is used for testing. The FMF-SAA1 StripAssay® is designed to serve as aid for diagnosis of FMF in patients presenting with a clinical symptom pattern consistent with FMF, or at-risk relatives of a patient with an identified pathogenic *MEFV* mutation. The StripAssay® can be carried out either manually or semi-automated.

For human *in vitro* diagnostic use.

II. BACKGROUND

Familial Mediterranean Fever is the most common monogenic autoinflammatory disorder, which is characterized by recurrent febrile episodes, accompanied by pain in the abdomen (peritonitis), chest (pleuritis) or joints (arthritis), and erysipelas-like skin erythema. The disease has an autosomal recessive pattern of inheritance in the majority of cases and is primarily observed in patients from Mediterranean or Middle Eastern populations. Multitudinous variants within the Mediterranean fever (*MEFV*) gene have been described as the molecular defects which cause FMF. The clinical representation of FMF can be complex, thus genetic testing for *MEFV* mutations is a feasible way to corroborate diagnosis.

Systemic reactive (AA) amyloidosis represents the most important complication within FMF and other autoinflammatory syndromes, progressively leading to endstage renal failure. The homozygous condition of the serum amyloid A (SAA) variant *SAA1.1* is associated with a 3-7 fold higher risk for AA amyloidosis in FMF patients. Consequently, *SAA1* genotyping can be used for risk assessment in context of FMF.

III. METHODOLOGY

The FMF-SAA1 StripAssay® is based on polymerase chain reaction (PCR) and reverse-hybridization. The procedure includes three steps: (1) DNA isolation, (2) PCR amplification using biotinylated primers, (3) hybridization of amplification products to a Teststrip containing allele-specific oligonucleotide probes immobilized as an array of parallel lines (Fig. 1). Bound biotinylated sequences are detected using streptavidin-alkaline phosphatase and color substrates.

The FMF-SAA1 StripAssay® detects the following 12 mutations in the *MEFV* gene and two polymorphic loci in the *SAA1* gene:

	legacy name (*MEFV*)	**HGVS nomenclature (*MEFV*)**		**RefSNP**
1	E148Q	c.442G>C	g.7002G>C	rs3743930
2	P369S	c.1105C>T	g.12042C>T	rs11466023
3	F479L	c.1437C>G	g.14462C>G	rs104895083
4	M680I (G/C)	c.2040G>C	g.18181G>C	rs28940580
5	M680I (G/A)	c.2040G>A	g.18181G>A	rs28940580
6	I692del	c.2076_2078del	g.18217_18219delAAT	rs104895093
7	M694V	c.2080A>G	g.18221A>G	rs61752717
8	M694I	c.2082G>A	g.18223G>A	rs28940578
9	K695R	c.2084A>G	g.18225A>G	rs104895094
10	V726A	c.2177T>C	g.18318T>C	rs28940579
11	A744S	c.2230G>T	g.18371G>T	rs61732874
12	R761H	c.2282G>A	g.18423G>A	rs104895097

	legacy name (*SAA1*)	**HGVS nomenclature (*SAA1*)**		**RefSNP**
13	c.209 [C>T]	c.209C>T	g.8052C>T	rs1136743
14	c.224 [T>C]	c.224T>C	g.8067T>C	rs1136747

Reference Sequence (RefSeq):

NM_000243.2 (*MEFV*)
NG_007871.1 (*MEFV*)
NM_000331.4 (*SAA1*)
NG_021330.1 (*SAA1*)

The test can be carried out manually or semi-automated using instruments designed for automation of Teststrip processing (see section VI. 3.4).

IV. KIT COMPONENTS

REF

	4-390	4-390-A	4-390 -TRIAL
1. **Lysis Solution**	50 ml	---	50 ml
2. **GEN^{X}TRACT™ Resin**	5 ml	---	5 ml
3. **Amplification Mix** *(yellow cap)*	500 µl	2 x 500µl	500 µl
4. **Taq Dilution Buffer** *(transparent cap)*	500 µl	500 µl	500 µl
5. **Taq DNA Polymerase (5 U/µl)** *(red cap)*	75 U	125 U	75 U
6. **DNAT** *(blue cap)*	1.5 ml	1.5 ml	1.5 ml
⚠ Warning: DNAT contains 1.6 % NaOH H315: Causes skin irritation H319: Causes serious eye irritation P280: Wear protective gloves/protective clothing/eye protection/face protection P337 + P313: If eye irritation persists: Get medical advice/attention			
7. **Typing Trays**	3	---	1
8. **Teststrips**	20	2 x 24	5
9. **Hybridization Buffer** *(white cap)*	25 ml	65 ml	25 ml
10. **Wash Solution A** *(white cap)*	80 ml	200 ml	80 ml
11. **Conjugate Solution** *(transparent cap)*	25 ml	65 ml	25 ml
12. **Wash Solution B** *(transparent cap)*	80 ml	200 ml	80 ml
13. **Color Developer** *(brown cap)*	25 ml	65 ml	25 ml
⚠ Warning: Color Developer contains ≤0.4% maleic acid H317: May cause an allergic skin reaction P280: Wear protective gloves/protective clothing/eye protection/face protection P302 + P352: If on skin: wash with plenty of water P333 + P313: If skin irritation or rash occurs: get medical advice /attention			
14. **Instructions For Use**	1	1	1
15. **Collector™ Sheet**	1	3	1

Note: Store all reagents at 2°C to 8°C when not in use!

name of component	composition
Lysis Solution	hypotonic solution containing $KHCO_3$, NH_4Cl, EDTA
GEN^{X}TRACT™ Resin	Chelex 100 Resin MB in a buffered solution
Amplification Mix	sequence-specific 5'-biotin labelled oligonucleotides, an equimolar mixture of deoxy ribonucleotide triphosphates (dATP, dCTP, dGTP, and dTTP), ammonium sulfate buffer, glycerol, 0.05% sodium azide
Taq Dilution Buffer	buffer for taq DNA polymerase, including $(NH_4)_2SO_4$ and $MgCl_2$, 0.05% sodium azide
Taq DNA Polymerase (5 U/µl)	taq DNA polymerase at a concentration of 5U/µl
DNAT	basic solution containing 1.6 % sodium hydroxide and a blue dye indicating a change of pH
Typing Trays	plastic tray with eight wells

name of component	composition
Teststrips	allele-specific oligonucleotide probes and a hybridization control immobilized as an array of parallel lines on a polyester-supported membrane framed by a red line on the top and a green line on the bottom
Hybridization Buffer	phosphate buffer with <2% detergent
Wash Solution A	citrate buffer with <1% detergent
Conjugate Solution	streptavidin conjugated alkaline phosphatase diluted in a saline based buffer with 0.05% sodium azide
Wash Solution B	tris buffer containing <2% detergent and 0.05% sodium azide
Color Developer	color substrate for the alkaline phosphatase contains nitro blue tetrazolium (NBT) and 5-bromo-4-chloro-3-indolyl phosphate (BCIP)
Instructions For Use	printed paper
Collector™ Sheet	printed paper

V. MATERIALS REQUIRED BUT NOT SUPPLIED

In addition to standard molecular biology laboratory equipment, the following is needed:

- Thermoblock or thermomixer for 1.5 ml reaction tubes with temperature control up to 99°C
- Adjustable microcentrifuge capable of 3,000-12,000 rpm (1,000-12,000 x g)
- Thermocycler with heated lid (for specification of ramp rates see section VIII)
- Waterbath with shaking platform, lid and adjustable temperature (45°C ± 1°C)
- Shaker (rocker or orbital shaker)

Optional:

- Vacuum aspiration apparatus
- Thermoshaker for microtiter plate format with lid and adjustable temperature (45°C ± 1°C), e.g. PST-60 HL (Biosan) or equivalent device
- Instrument for automated hybridization, adjustable to the time-temperature profile as described in section VI. 3.4, e.g. DYNABLOT Heat (Dynex) or equivalent device
- Agarose gel electrophoresis equipment (for control of amplification products)

VI. ASSAY PROCEDURE

1. Sample Preparation

Specimen: Use fresh or frozen blood with EDTA anticoagulant. Blood containing heparin or citrate has not been tested. Do not store blood for more than 3 days at ambient temperature or more than 1 week at 2°C to 8°C before use. Blood that has been kept frozen for more than one year, or gone through more than three freeze-thaw cycles shall not be used. For specimen collection and transportation follow the instructions for use of the EDTA-blood collection tube and general recommendations for blood sampling.

DNA Extraction: Bring blood samples to room temperature. Mix well by carefully inverting blood collection tubes several times. Allow Lysis Solution and GEN^{X}TRACT™ Resin to reach room temperature.

- Pipette **100 µl blood sample** into a 1.5 ml microtube with screw cap.
- Add **1 ml Lysis Solution**, close tube and mix by inverting several times.
- Let stand for **15 min.** at room temperature.
- Centrifuge for **5 min.** at **3,000 rpm** (approx. 1,000 x g) in a microcentrifuge.
- Remove and discard the upper (top) 1 ml of supernatant.
- Add **1 ml Lysis Solution**, close tube and mix by inverting several times.
- Centrifuge for **5 min.** at **12,000 rpm** (approx. 12,000 x g) in a microcentrifuge.
- Remove and discard the supernatant except for approx. 50 µl of a visible, soft pellet.
- Resuspend GEN^{X}TRACT™ Resin by swirling the bottle thoroughly.
- Add **200 µl GEN^{X}TRACT™ Resin** to the pellet. Close tube and vortex for 10 sec.

Note: GEN^{X}TRACT™ Resin sediments quickly. Repeat resuspension each time immediately before removing another aliquot.

- Incubate for **20 min.** at **56°C**. Vortex for 10 sec.
- Incubate for **10 min.** at **98°C**. Vortex for 10 sec.
- Centrifuge for **5 min.** at **12,000 rpm** in a microcentrifuge. Cool on ice.

The resulting supernatant contains DNA template suitable for immediate use in PCR. For further storage, the supernatant should be transferred into a fresh tube and kept refrigerated (2°C to 8°C; up to one week) or frozen at -30°C to -15°C (for long term).

Use of other DNA isolation methods with the FMF-SAA1 StripAssay® has not been validated. In case other DNA extraction systems are used, concentration and purity of DNA should be within a range of 2 to 10 ng/µl and an $OD_{A260/280}$ ratio of 1.7 to 2.0, respectively. Higher DNA concentrations have to be diluted to the recommended range prior to PCR input.

2. In Vitro Amplification (PCR)

Important: Keep all PCR reagents and DNA templates refrigerated throughout.

- Freshly prepare each time an appropriate amount of working solution (1:25, final conc. 0.2 U/µl) of **Taq DNA Polymerase** (5 U/µl, red cap) in **Taq Dilution Buffer** (transparent cap) for the number of samples to be analyzed, plus the **no-template control (NTC)**.

component	per reaction	e.g. 10 reactions
Taq DNA Polymerase (5 U/µl)	0.2 µl	2 µl
Taq Dilution Buffer	4.8 µl	48 µl
working solution	5 µl	50 µl

- Prepare one reaction tube for each sample to be amplified. Place tubes on ice.
- For each sample prepare a final PCR reaction mix on ice:

  15 µl Amplification Mix (yellow cap)
  5 µl diluted Taq DNA Polymerase (1U)
  5 µl DNA template

Note: It is recommended to prepare a mastermix for all samples containing Ampification Mix and diluted Taq DNA Polymerase. First pipette 20 µl of the mastermix into each PCR tube, and then add DNA template. Include a no-template control in each run by using PCR grade water instead of DNA (or preferably the negative control of your DNA extraction).

Generally, prepare working solutions / mastermix with a 10% excess volume to compensate for pipetting inaccuracies.

- Cap tubes tightly. Preheat the thermocycler to 94°C.
- Insert reaction tubes and run the following thermocycling program:

  pre-PCR: 94°C/2 min.
  thermocycling: 94°C/15 sec. - 58°C/30 sec. - 72°C/30 sec. (35 cycles)
  final extension: 72°C/3 min.

- Store amplification products on ice or at 2°C to 8°C for further use.

Optional: Analyze amplification products by gel electrophoresis (e.g. 3% agarose gel).

Fragment lengths: 206, 236, 269, 318, 402 bp

3. Processing of Teststrips

3.1. Hybridization (manual) – 1 Teststrip per sample (45°C, shaking waterbath)

Important: Adjust the water level of the waterbath to approx. ½ of the height of the Typing Tray. Heat the waterbath to exactly 45°C. Check water temperature with a calibrated thermometer. Prewarm Hybridization Buffer and Wash Solution A to 45°C. Take care that all precipitates formed at 2°C to 8°C become completely dissolved. Allow Teststrips, DNAT, Conjugate Solution, Wash Solution B and Color Developer to reach room temperature. Prepare Typing Tray(s).

Remove one Teststrip for each sample using clean tweezers. Touch Teststrips with unpowdered gloves only! Label Teststrips outside of the marker lines with a pencil (no ballpoint pens, markers, etc.).

- Pipette **10 µl DNAT** (blue cap) into the lower corner of each lane to be used in the Typing Trays (one lane per sample).
- Add **10 µl amplification product** into the corresponding drop of DNAT.
- Mix thoroughly with a pipette. (The solution will remain blue.)
- Let stand for **5 min.** at room temperature.
- Add **1 ml Hybridization Buffer** (prewarmed to 45°C) into each lane.
  Gently agitate tray. (The blue color will disappear.)
- Insert **Teststrip** with marked side up (lines visible!) into the respective lanes. Submerge completely.
- Incubate for **30 min.** at **45°C** on the shaking platform of the waterbath.

Set moderate shaking frequency (approx. 50 rpm) to avoid spilling. Keep the cover of the waterbath closed to avoid variations in temperature.

- At the end of incubation remove hybridization solutions by vacuum aspiration or pipetting.

Proceed immediately. Do not allow Teststrips to run dry during the entire procedure.

3.2. Stringent Wash (45°C, shaking waterbath)

- Add **1 ml Wash Solution A** (prewarmed to 45°C). Rinse briefly (10 sec.).
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Wash Solution A** (45°C).
- Incubate for **15 min.** at **45°C** in the shaking waterbath.
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Wash Solution A** (45°C).
- Incubate for **15 min.** at **45°C** in the shaking waterbath.
  Remove liquids by vacuum aspiration or pipetting.

3.3. Colorimetric Detection (room temperature, 22°C ± 3°C)

- Add **1 ml Conjugate Solution**.
- Incubate for **15 min.** at **room temperature** on a rocker or orbital shaker.
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Wash Solution B**. Rinse briefly (10 sec.).
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Wash Solution B**.
- Incubate for **5 min.** at **room temperature** on a rocker or orbital shaker.
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Wash Solution B**.
- Incubate for **5 min.** at **room temperature** on a rocker or orbital shaker.
  Remove liquids by vacuum aspiration or pipetting.
- Add **1 ml Color Developer**.
- Incubate for **15 min.** at **room temperature** in the dark on a rocker or orbital shaker.
  A purple staining will appear upon positive reaction.
- Wash Teststrips several times with distilled water.
  Let strips dry in the dark on absorbent paper.

Do not expose Teststrips to intense light after Color Development.

3.4. Hybridization (automated) - optional instead of waterbath and shaker

An instrument for the automated processing of Teststrips shall meet the following requirements:

- Programmable temperature and time profile according to section 3.1 to 3.3 of the StripAssay® procedure.
- Integrated preheating station for Hybridization Buffer and Wash Solution A.
- Temperature control of trays during Hybridization and Stringent Wash steps at 45°C ± 1°C.
- Active cooling system for the tray to ensure rapid temperature decrease for Colorimetric Detection steps at room temperature.
- Shaking capability for tray.
- Heated lid for the tray to avoid evaporation of reagents during incubation.
- Dispensation of defined reagent volumes.
- Aspiration of reagents.
- Depending on the instrument used and the number of samples processed in one run, additional reagents may be required. Separate StripAssay® Detection Reagents are available for 20 tests (REF CS-012) and 48 tests (REF CS-017).

VII. INTERPRETATION OF RESULTS

The genotype of a sample is determined using the enclosed Collector™ sheet. Place the processed Teststrip into one of the designated fields, align it to the schematic drawing using the red marker line (top) and the green marker line (bottom), and fix them with adhesive tape.

A positive reaction of the uppermost Control line indicates the correct function of Conjugate Solution and Color Developer. This line should always stain positive.

For each polymorphic position, one of the following staining patterns (Fig. 2) should be obtained:

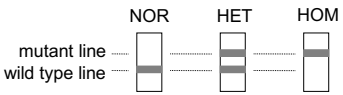

Fig. 2: Genotypes – staining patterns on the Teststrip

	wild type line	mutant line	genotype
NOR	**positive**	negative	normal
HET	**positive**	**positive**	heterozygous
HOM	negative	**positive**	homozygous mutant

Note: Staining intensities of positive lines may vary. This is of no significance for the result.

See examples of StripAssay® results on page 18 (Fig. 4).

Some of the mutations covered by the FMF-SAA1 StripAssay® are located within a few nucleotides on the *MEFV* gene. On the Teststrips these are represented by a common wild type probe, so that the 12 mutations are covered by 8 wild type probes only:

line	wild type probe	mutation
13	codon 148	E148Q
14	codon 369	P369S
15	codon 479	F479L
16	codon 680	M680I (G/C), M680I (G/A)
17	codon 692-695	I692del, M694V, M694I, K695R
18	codon 726	V726A
19	codon 744	A744S
20	codon 761	R761H

Samples that are compound heterozygous for two of these mutations (e.g. M694V + M694I, M694V + K695R) will be lacking the common wild type signal (see examples I and J, page 18).

For the three SAA1 isoforms 1.1 (α), 1.3 (γ) and 1.5 (β) the following staining patterns are obtained:

1.1 or α (52: Val, 57: Ala)	lines (21) + (22)
1.3 or γ (52: Ala, 57: Ala)	lines (22) + (23)
1.5 or β (52: Ala, 57: Val)	lines (23) + (24)

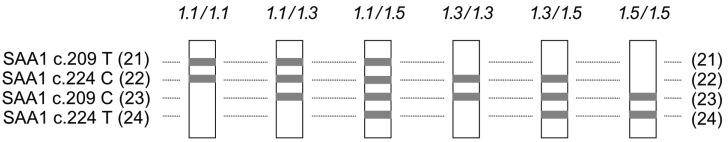

Fig. 3: *SAA 1* Genotypes – staining patterns on the Teststrip

The six possible homozygous and heterozygous *SAA1* genotypes (*1.1/1.1, 1.1/1.3, 1.1/1.5, 1.3/1.3, 1.3/1.5, 1.5/1.5*) will result in a combination of the respective individual isoforms (Fig. 3).

As with any diagnostic test, results of the FMF-SAA1 StripAssay® shall be interpreted in the context of the patient's overall clinical phenotype and other medical investigations available to the physician. ViennaLab Diagnostics GmbH is not responsible for any clinical decisions that are taken.

VIII. PERFORMANCE EVALUATION

Accuracy of the FMF-SAA1 StripAssay® was determined by analysing 254 pretyped genomic DNA samples. Results were completely concordant with the reference method (Sanger sequencing, denaturing gradient gel electrophoresis (DGGE) and restriction fragment length polymorphism (RFLP). The assay correctly detected 311 mutant alleles (= 100% Positive Percent Agreement) and 197 wild type alleles (= 100% Negative Percent Agreement).

Precision of the FMF-SAA1 StripAssay® was assessed as variability between replicates, operators, days, reagent lots, thermocyclers and hybridization devices (manual and semi-automated hybridization). In a total of 106 test replicates carried out under the investigated parameters, all tests showed the expected genotyping results. Only negligible differences in staining intensity of Teststrips were visible, and no background staining was observed. The FMF-SAA1 StripAssay® was validated on the AB GeneAmp® PCR System 2700, AB GeneAmp® PCR System 9700, AB Veriti and MJ Research PTC-200, which represent a heating and cooling rate in the range of 1.7 to 4.2°C/sec and 1.4 to 3.7°C/sec, respectively.

Use of other thermocyclers must be verified by the user.

Analytical Specificity is first and foremost ensured by the selection of the gene-specific primers and the allele-specific capture probes, as well as the selection of stringent reaction conditions. The primers and probes were checked for possible homologies to all sequences published in gene databases by sequence comparison analysis. Thereby, the detectability of all relevant genotypes has been ensured. Potential cross-reactivity between capture probes was verified by synthetic DNA harboring the respective gene fragment. No cross-reactivity was observed.

Clinical Performance: Assessment of the clinical performance of FMF StripAssays® in order to support clinical evidence comprised a systematic review of available data and applicable elements. As a result of the literature search, 22 publications were identified as pertaining to the safety and performance of the FMF StripAssays®, which demonstrate the clinical utility of the FMF-SAA1 StripAssay®. No adverse events or deviations have been identified within method comparison studies. In summary, the clinical performance, the benefits, and the safety of the FMF-SAA1 StripAssay® are confirmed when the device is used as intended for diagnosis of Familial Mediterranean Fever.

IX. INTERFERING SUBSTANCES

Five interfering substances (hemoglobin, immunoglobin G, traces of blood, ethanol and EDTA) potentially being present in EDTA-blood derived DNA preparations have been tested. Their effects on PCR were evaluated in three purified DNA samples spiked with various concentrations of substances and compared to their controls without addition of any interfering substances. All samples were analyzed in triplicate.

A final concentration of <10 µM hemoglobin, 0.1 µM immunoglobulin G, <1% peripheral blood, 1.25% ethanol or 0.1 mM EDTA in the reaction did not interfere with StripAssay® performance.

X. LIMITATIONS OF THE ASSAY

The FMF-SAA1 StripAssay® is exclusively designed for the diagnosis of 14 known mutations and polymorphisms as listed in section III, which are represented by allele-specific capture probes on the Teststrips. Other *MEFV* mutations or *SAA1* variants that may be present in a patient's sample cannot be detected.

Rare or private variants within primers and probes binding sites may lead to amplification failure and missing signals on Teststrips.

The FMF-SAA1 StripAssay® can detect the common alleles *SAA1.1, SAA1.3* and *SAA1.5*. However, the rare alleles *SAA1.2* and *SAA1.4* cannot be distinguished from *SAA1.5*, and staining patterns of these alleles are identical.

DNA samples obtained by methods other than the reagents and protocol provided with the FMF-SAA1 StripAssay® may in some cases show weak or missing signals for wild type and mutant E148Q. The effect is due to impairment of PCR efficiency for this particular fragment, and has been observed with several popular DNA extraction kits. Pre-heating such DNA samples to 98°C for 10 min, immediately followed by cooling down on ice or in a cold block before setting up the PCR, can completely restore normal PCR yields.

The FMF-SAA1 StripAssay® is intended for laboratory professional use only.

XI. QUALITY CONSIDERATIONS

- A thorough understanding of the procedure outlined here, as well as standard laboratory techniques and appropriate equipment are required to obtain reliable results.
- Do not use StripAssay® kits beyond their expiration date.
- After first opening of the primary container, StripAssay® reagents are stable until the expiry date printed on the outer label of the kit when stored properly at 2°C to 8°C.
- Use sterile disposable pipette tips with filters to avoid microbial contamination and cross-contamination of reagents or samples. Do not interchange bottle caps.
- Single use only.

XII. SAFETY

- Do not drink, eat, smoke, or apply cosmetics in designated work areas. Wear laboratory coats and disposable gloves when handling specimens and kit reagents. Wash hands thoroughly afterwards.
- Handle specimens as if capable of transmitting infectious agents. Thoroughly clean and disinfect all materials and surfaces that have been in contact with specimens. Discard all waste associated with clinical specimens in a biohazard waste container.
- Avoid contact of DNAT and Color Developer with skin, eyes, or mucous membranes. If contact does occur, immediately wash with large amounts of water. If spilled, dilute with water before wiping dry.
- Adhere to all local and federal safety and environmental regulations which may apply.

XIII. TECHNICAL SUPPORT

Technical support may be obtained by:

- the local ViennaLab Diagnostics distributor (www.viennalab.com/distribution)
- Video Tutorials (www.viennalab.com/support)
- the StripAssay® Manual (www.viennalab.com/support)
- the StripAssay® Troubleshooting Guide (www.viennalab.com/support)
- contacting techhelp@viennalab.com

XIV. REFERENCES

- OMIM Online Mendelian Inheritance in Man (www.omim.org)
- Infevers database (https://infevers.umai-montpellier.fr/web)
- ISSAID (www.issaid.org)

XV. FEEDBACK TO THE MANUFACTURER

Any serious incident that has occurred in relation to the StripAssay® must be reported to the competent authority of the country and to the manufacturer.

XVI. SYMBOLS

REF	Catalog number
LOT	Batch code
IVD	*In vitro* diagnostic medical device
CE 0123	Compliant with European IVD Regulation 2017/746 Identification number of notified body
Σ	Sufficient for <n> tests
	Storage temperature limits
	Use by
	Caution
	Manufacturer
	Date of manufacture
	Consult Instructions For Use

XVII. EXAMPLES OF TEST RESULTS

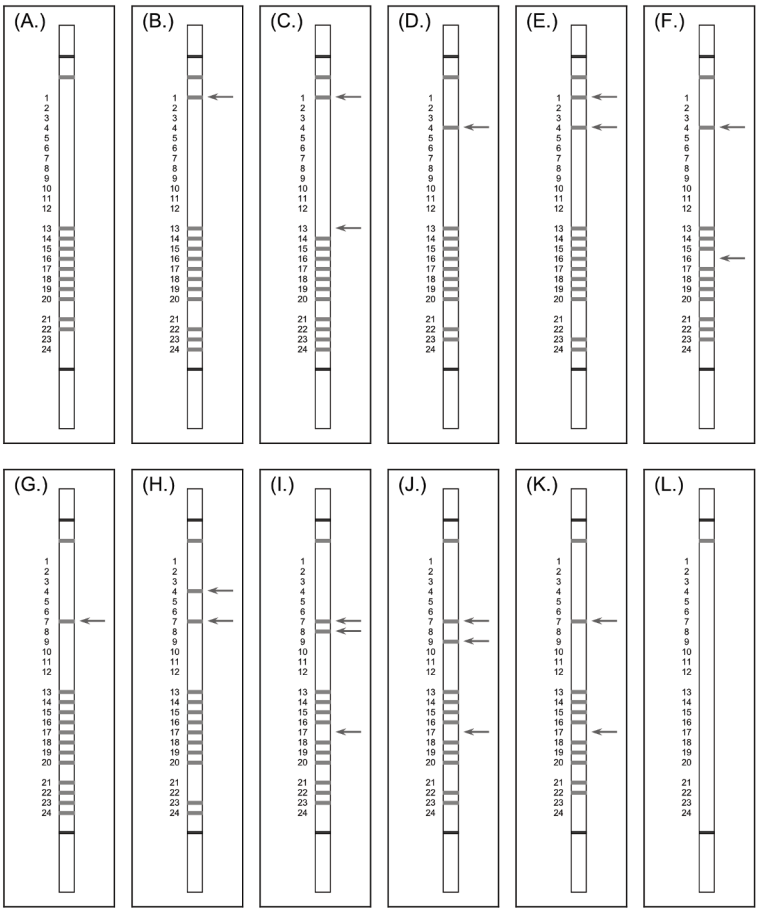

Fig. 4: Examples of results obtained with the FMF-SAA1 StripAssay®

	MEFV	*SAA1*
(A.)	normal	*1.1/1.1*
(B.)	E148Q heterozygous	*1.3/1.5*
(C.)	E148Q homozygous	*1.1/1.5*
(D.)	M680I (G/C) heterozygous	*1.3/1.3*
(E.)	E148Q - M680I (G/C)	*1.5/1.5*
(F.)	M680I (G/C) homozygous	*1.1/1.3*

	MEFV	*SAA1*
(G.)	M694V heterozygous	*1.1/1.5*
(H.)	M680I (G/C) - M694V	*1.5/1.5*
(I.)	M694V - M694I heterozygous	*1.1/1.3*
(J.)	M694V - K695R heterozygous	*1.3/1.3*
(K.)	M694V homozygous	*1.1/1.1*
(L.)	negative control or PCR failure	

NOTES

XVIII. RELATED PRODUCTS

REF		Σ
4-230	FMF StripAssay®	20 tests
4-390	FMF-SAA1 StripAssay®	20 tests
CS-012	StripAssay® Detection Reagents	20 tests
CS-017	StripAssay® Detection Reagents 48	48 tests
2-014	GENXTRACT™ Blood DNA Extraction System	100 extractions
2-020	Spin Micro DNA Extraction Kit	20 extractions
6-080	Typing Trays	5

Distributor:

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