VIENNA LAB
ESTABLISHED INNOVATIONS IN DIAGNOSTICS

FMF StripAssays®

Testing for Familial Mediterranean Fever and Risk Factors for Amyloidosis

Familial Mediterranean Fever (FMF) is the most common inherited inflammatory disorder.

Recurrent bouts of fever and painful inflammation in the abdomen, chest or joints, typically lasting 12 to 72 hours, characterize the condition.

The most severe complication of FMF is amyloidosis, a build-up of protein deposits that ultimately leads to kidney failure.

Prophylactic treatment with colchicine can prevent this and allow a normal life.

FMF is caused by mutations in the *MEFV* gene, which encodes a protein known as pyrin or marenostrin. The spectrum of mutations varies between different ethnic groups and affects the severity of FMF, as well as the risk of developing systemic reactive (AA) amyloidosis.

The homozygous condition of the serum amyloid A (SAA) isotype SAA1.1 is significantly associated with AA amyloidosis and clinical severity in patients with FMF and rheumatoid arthritis (RA).

The FMF StripAssays® identify the most frequent mutations in the *MEFV* gene and risk factors for Amyloidosis

Gene	Cellular Function	Status	Therapy	Quality of Life
MEFV	Control of inflammation	wildtype		+++
		mutated	✓	++
SAA1	Response to Inflammation & Tissue Injury	Status	Effect in FMF Patients	
		SAA1.1	Risk of Amyloidosis / Clinical Severity	
		SAA1.3		
		SAA1.5		

The Assay

ESTABLISHED INNOVATIONS IN DIAGNOSTICS

ViennaLab FMF StripAssays®

- Simple protocol for complex diagnostic questions
- Manual or automated processing
- No expensive lab equipment
- Ready-to-use reagents
- CE/IVD-labeled kits including DNA extraction

FMF StripAssay®	Mutations											
	E148Q	P369S	F479L	M680I (G >C)	M680I (G >A)	I692 del	M694V	M694I	K695R	V726A	A744S	R761H
4-230	x	x	x	x	x	x	x	x	x	x	x	x

FMF-SAA1 StripAssay®	Mutations & Isotypes														
	E148Q	P369S	F479L	M680I (G >C)	M680I (G >A)	I692 del	M694V	M694I	K695R	V726A	A744S	R761H	SAA 1.1	SAA 1.3	SAA 1.5
4-390	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

FMF StripAssays®

- are based on reverse-hybridization of biotinylated PCR products
- combine probes for variants and controls in a parallel array of allele-specific oligonucleotides
- work with immobilized oligos on a teststrip
- generate test results by enzymatic color reaction easily visible to the naked eye

The three steps of the StripAssays®

Step	Requirement
1. Amplification: Multiplex PCR. Simultaneous biotin-labeling	Thermocycler
2. Hybridization: Directly on the StripAssay® teststrips	Incubator
3. Identification: Labeled products detected by streptavidin-alkaline phosphatase	Naked eye or scanner & software

Cat.no.:

FMF StripAssay® 4-230 (20 tests/kit)

FMF-SAA1 StripAssay® 4-390 (20 tests/kit)

ViennaLab offers StripAssays® for a wide range of diagnostic applications. Visit www.viennalab.com

Distributor:

Manufacturer:
ViennaLab Diagnostics GmbH
Gaudenzdorfer Guertel 43–45, A-1120 Vienna, Austria
Phone: (+43-1) 8120156-0
Fax: (+43-1) 8120156-19
info@viennalab.com
www.viennalab.com

CE IVD

More details available at www.viennalab.com

July 2016 • ISO 9001 • ISO 13485