

# Automated Solution for Thrombotic Mutation Diagnostics

Automated system executes the entire diagnostic workflow, including NA extraction, PCR setup, PCR amplification and automated evaluation of results.

Simplify  
Complexity

Broad portfolio of PCR tests

Flexibility

High throughput



# Why test for Thrombotic Mutations?

Urgent and growing health problem worldwide...

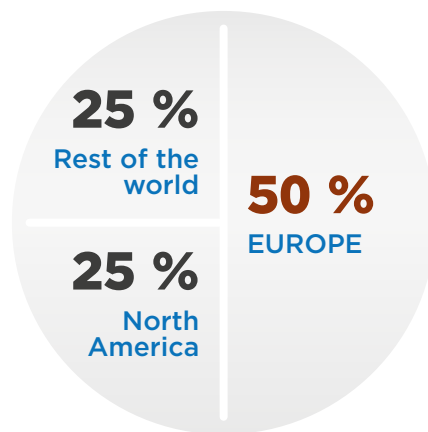
1 in 4

**PEOPLE WORLDWIDE are dying from conditions caused by thrombosis**

An estimated 10 million cases of hospitalizations due to blood clots occur each year around the globe.

There are 148 cases of deep vein thrombosis and 95 pulmonary embolism per 100,000 people every year in Europe. <sup>/1</sup>

## Testing for Thrombotic Mutations worldwide



The most frequently examined parameters FII, FV, MTHFR <sup>/2</sup>

**FII and FV, testing, followed by MTHFR and PAI-1, are covered by the reimbursement system in EU countries.**

## Why choose our automated workflow?

The GeneProof myCROBE™ Solution provides the most comprehensive range of PCR kits designed for the automated detection of Thrombotic Mutations. Furthermore, with the singleplex kit, you have the flexibility to customize your own test design and are not required to utilize all mandatory assays in a multiplex format.

Manufacturers / Tests	FII Prothrombin	FV Leiden	F XIII V 34L	MTHFR A1298C	MTHFR C677T	PAI-1
<b>GeneProof™</b>	✓	✓	✓	✓	✓	✓
Cepheid	✓*		×	×	×	×
Elitech	✓**		×	×	✓**	×
Roche	✓*		×	×	×	×

\* FII/FV Multiplex only | \*\* FII/FV/MTHFR Multiplex only

# Why

## myCROBE™ Automated Solution?



CE IVD

CERTIFIED  
DIAGNOSTIC  
TESTS

### MOST COMPREHENSIVE PORTFOLIO OF PCR TESTS

- Broadest menu of tests available on an automated platform

**FII, FV, FXIII, MTHFR CT, MTHFR AC, PAI-1**

### FLEXIBILITY

- Any combination of Thrombotic Mutation tests from one sample - run only the tests you need
- Up to 6 different tests per sample

### HIGH THROUGHPUT

- Up to 36 samples and 90 tests per run
- Up to 108 samples and 270 tests / day
- Time to first results 4 hours (then new results every 2 hours)



### 100% TRACEABILITY

- Unique barcode system
- Traceability of the entire diagnostic process
- Automated evaluation of results
- Bidirectional LIMS/LIS connectivity
- Automatic correction of human errors

### SIMPLE LABORATORY WORKFLOW

- Sample-to-result solution and walk-away system
- Reduce hands on time (approx. 1 minute per sample) and improve your lab's profitability
- Easily automates your laboratory workflow
- Suitable for labs with no experience with PCR testing



Thrombotic  
Mutations



**myCROBE™**  
GeneProof



#### TECHNICAL SPECIFICATIONS

PLATFORM	myCROBE™ Fully Automated Instrument (IVDR)
DIMENSIONS	1130 x 750 x 900 mm (compact size)
WEIGHT	189 kg
TRACEABILITY	QR codes labeling
LIMS/LIS CONNECTIVITY	Bidirectional connectivity (ASTM)
VALIDATED SPECIMEN	Whole blood
ELUATE STORAGE	Extracted DNA can be archived for subsequent analysis
SAMPLE VOLUME	500 µl
ELUTION VOLUME	100 µl
EXTERNAL QUALITY ASSESSMENT	Tested in INSTAND e.V. External Quality Assessment Panels or in Reference Institute for Bioanalytics Quality Assessment Panels - results at <a href="http://geneproof.com">geneproof.com</a>
TECHNICAL SPECIFICATION OF PCR KITS	See <a href="http://www.geneproof.com">www.geneproof.com</a>

#### ORDER INFORMATION

PRODUCT NAME	REF	
myCROBE™ Fully Automated Instrument	MC100	
GeneProof™ Factor II Prothrombin MC PCR Kit	FII/MC/200	for 180 tests
GeneProof™ Factor V Leiden MC PCR Kit	FV/MC/200	for 180 tests
GeneProof™ Factor XIII V34L MC PCR Kit	FXIII/MC/200	for 180 tests
GeneProof™ MTHFR C677T MC PCR Kit	M677/MC/200	for 180 tests
GeneProof™ MTHFR A1298C MC PCR Kit	M1298/MC/200	for 180 tests
GeneProof™ PAI-1 Genotyping MC PCR Kit	PAI1/MC/200	for 180 tests
myCROBE™/croBEE™ 2.0 Blood Pretreatment Sample tube	MC203/540	for 540 samples
myCROBE™ Genetic Control Set	MC202/15	for 15 test types
myCROBE™/croBEE™ 2.0 Universal Extraction Kit	MC200/036	for 36 samples
myCROBE™/croBEE™ 2.0 Tips	MC300/1152	1152 tips
	MC300/192	192 tips
myCROBE™ PCR pack (PCR plate, PCR seal, Waste bin)	MC401/100	for 100 runs