

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...

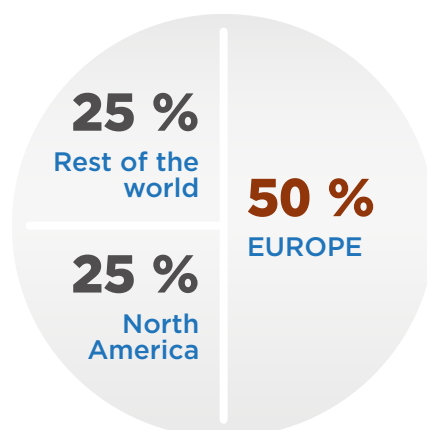
1 in 4

**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. ^{/1}

Testing for Thrombotic Mutations worldwide



The most frequently examined parameters
FII, FV, MTHFR ^{/2}

**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
GeneProof	✓	✓	✓	✓	✓	✓
Cepheid	✓ *		×	×	×	×
Elitech	✓ **		×	×	✓ **	×
Roche	✓ *		×	×	×	×

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

Why myCROBE[®] Automated Solution?

MOST COMPREHENSIVE PORTFOLIO OF PCR TESTS

- Broadest menu of tests available on an automated platform



CERTIFIED
DIAGNOSTIC
TESTS

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



TECHNICAL SUPPORT



Professional customer support
and remote troubleshooting

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 geneproof.com
TECHNICAL SPECIFICATION OF PCR KITS	See www.geneproof.com

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