Rapid and Accurate. *It's About Time.*

Xpert® FII & FV

30 Minute Test for Genetic Risk of Thrombosis.

CE IVD In Vitro Diagnostic Medical Device

Cepheid®
A better way.

"The GeneXpert® System is an important new development in the field of molecular diagnostics. The test is moderately complex, but the assay is simple enough to be performed reliably by individuals without a background in nucleic acid diagnostics."

Gessoni, et al.
Clinica Chimica Acta, January 2012

The Need

Thrombophilia is defined as an increased risk or tendency to develop blood clots as a consequence of predisposing factors that may be inherited or acquired. A thrombus may form in either the venous or arterial vascular system. Venous thrombophilia is usually related to an abnormality of the coagulation system and may result in deep venous thrombosis (DVT) or pulmonary embolism (PE).

Historically, laboratory analysis for thrombophilia has consisted primarily of detecting deficiencies of Antithrombin, Protein C and Protein S, and testing for dysfibrinogenemia and antiphospholid antibodies/ lupus anticoagulants.

In the last decade it has been shown that venous thromboembolism is a complex pathology that is reliant upon the interaction of both acquired and genetic factors. In this regard, FII and FV Leiden mutations play an important role in the pathogenesis of DVT in combination with acquired factors such as age.

The Solution

Xpert® FII & FV is a qualitative genotyping test for the rapid detection of Factor II (FII) and Factor V (FV) alleles. Performed on the Cepheid GeneXpert System, the test is intended to provide rapid results for FII (G20210A) and FV Leiden (G1691A) mutations as an aid in the diagnosis of suspected thrombophilia.

Simple
- Molecular lab in a cartridge: DNA Extraction, amplification and detection in one cartridge
- 24/7 availability: Run daily, or on-demand, with a simplified workflow

Clinically Validated
- Proven accuracy: Multi-site study verified over 1,000 patient samples with results comparable to those obtained with bi-directional sequencing

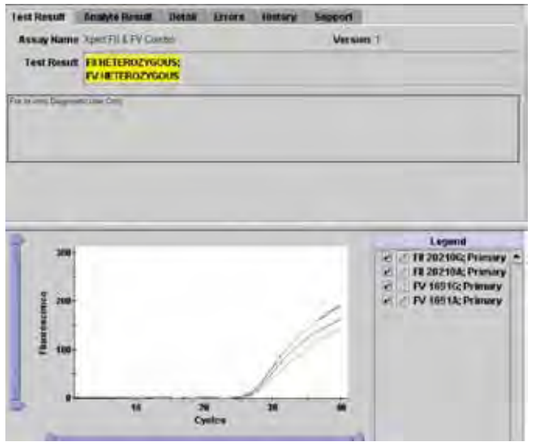
Fast
- On-demand: 30 minute FII and FV genotyping
- Actionable: No added wait time to obtain complete thrombophilia work-up

Cost-efficient
- Avoids expensive 'send-outs' to reference labs
- Optimize labor resources: No specialized personnel or lab facilities required

Cepheid's Xpert FII & FV test provides on-demand results you can trust and empowers your clinical team to better manage patients.

Technology

- Sample preparation reagents on-board with complete integration of Factor II/Factor V in a single cartridge means a streamlined procedure with no risk of contamination
- GeneXpert Software allows the user to report out FII and FV together or individually if ordered separately
- Each cartridge contains freeze-dried beads with all necessary components for PCR: DNA polymerase, nucleotides, primers and scorpions
- Through the PCR cycles, the specific binding of the scorpion sequence to the target mutation is detected by the system in real-time



GeneXpert software interprets amplification curves and delivers genotyping results..

Performance

In an FDA-reviewed multi-center study, more than 1,000 samples were tested with Xpert® FII & FV and results compared with the gold standard, bi-directional sequencing. Both FV Leiden and FII G20210A mutations demonstrated 99.3% overall accuracy relative to bi-directional sequencing (no discordant results).

Additional Performance Studies
Xpert FII & FV was evaluated in comparison to an alternate molecular platform evaluating 109 samples from consecutive patients suspected of thrombophilia (Morelli et al, 2008). In this study, both FV Leiden and FII G20210A mutations demonstrated 100% agreement when compared to an alternate molecular platform.

Rapid and Accurate.
Xpert® FII & FV

- Fully integrated sample preparation reduces chances of laboratory contamination
- Fully automated process reduces handling time to just minutes
- Random access for flexibility and workflow optimization
- Fully integrated reagent and instrument system for accuracy and reproducibility
- Versatile software reporting adds convenience and flexibility

WORKFLOW:

2 Easy Steps
Total hands-on time: <1 Minute

1

Pipette sample into cartridge

2

Insert cartridge and start assay

ORDERING INFORMATION

Xpert FII & FV Combined Kit (10 Cartridges with reagents) .....Catalog No. GXFIIFV-10

FII & FV Heterozygous DNA Control*.....Catalog No. G108-2H

FII & FV Genotype Panel* (verification panel) ..... Catalog No. G109

* Available from Maine Molecular Quality Controls (MMQCI). www.mmqci.com. Not available in all countries.

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Morelli et al. An automation experience in molecular biology: the GeneXpert Dx System for FV Leiden and FII G2010A mutations detection.Siset (Italian Society for the study of Hemostasis and Thrombosis, Florence, Italy, September 25-28, 2008)

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