



Xpert®
FII & FV

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 antiphospholipid 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.



THE IMPACT



Speed and single-test confidence to make the most efficient use of your highly-trained resources. Accelerate your laboratory's workflow with on-demand, random-access flexibility. Combine performance with the ability to run other tests (such as GBS, MRSA, *C. difficile*, and Flu) on the GeneXpert® System to achieve proven increase in overall laboratory level service.

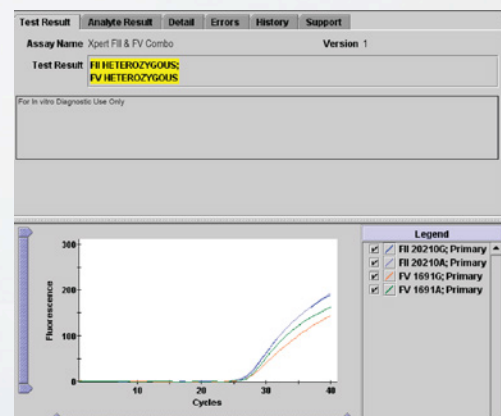
Shift your lab from reactive to proactive

- Achieve same-day containment and improve patient management
- Deliver same-day results to clinicians with a 30 minute, on-demand test
- Notify patient faster
- Help more patients live healthier lives



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



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.



WORKFLOW:

2 EASY STEPS

Total hands-on time: <1 Minute

1

Pipette* sample into cartridge

2

Insert cartridge and start assay

* Pipette not included in kit



➤ **Xpert® FII & FV is a qualitative real-time PCR test for automated detection and genotyping of the FII and FV alleles directly from whole blood with results in about 30 minutes.**

CATALOG NUMBER

Xpert FII & FV Combined Kit (10 tests)	GXFIFV-10
FII & FV Heterozygous DNA Control [^]	G108-2H
FII & FV Genotype Panel* (verification panel)	G109

[^] Available from Maine Molecular Quality Controls (MMQC). www.mmqi.com. Not available in all countries.

References:

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3. De Stefano et al. Screening for inherited thrombophilia: indications and therapeutic use. *Haematologica* 2002; 87:1095-1108.
4. Caprini et al. Laboratory markers in the diagnosis of venous thromboembolism. *Circulation* 2004; 109(suppl 1):I-4-I-8.
5. ACMG Standards and Guidelines. Technical standards and guidelines: venous thromboembolism (Factor V Leiden and prothrombin 20210G>A testing): a disease-specific supplement to the standards and guidelines for clinical genetics laboratories. July/August 2005.
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7. Cooper et al. An overview of methods for detection of Factor V Leiden and the prothrombin G20210A mutations. *Int J Lab Hematology* 2007; 29: 153-162.
8. 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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