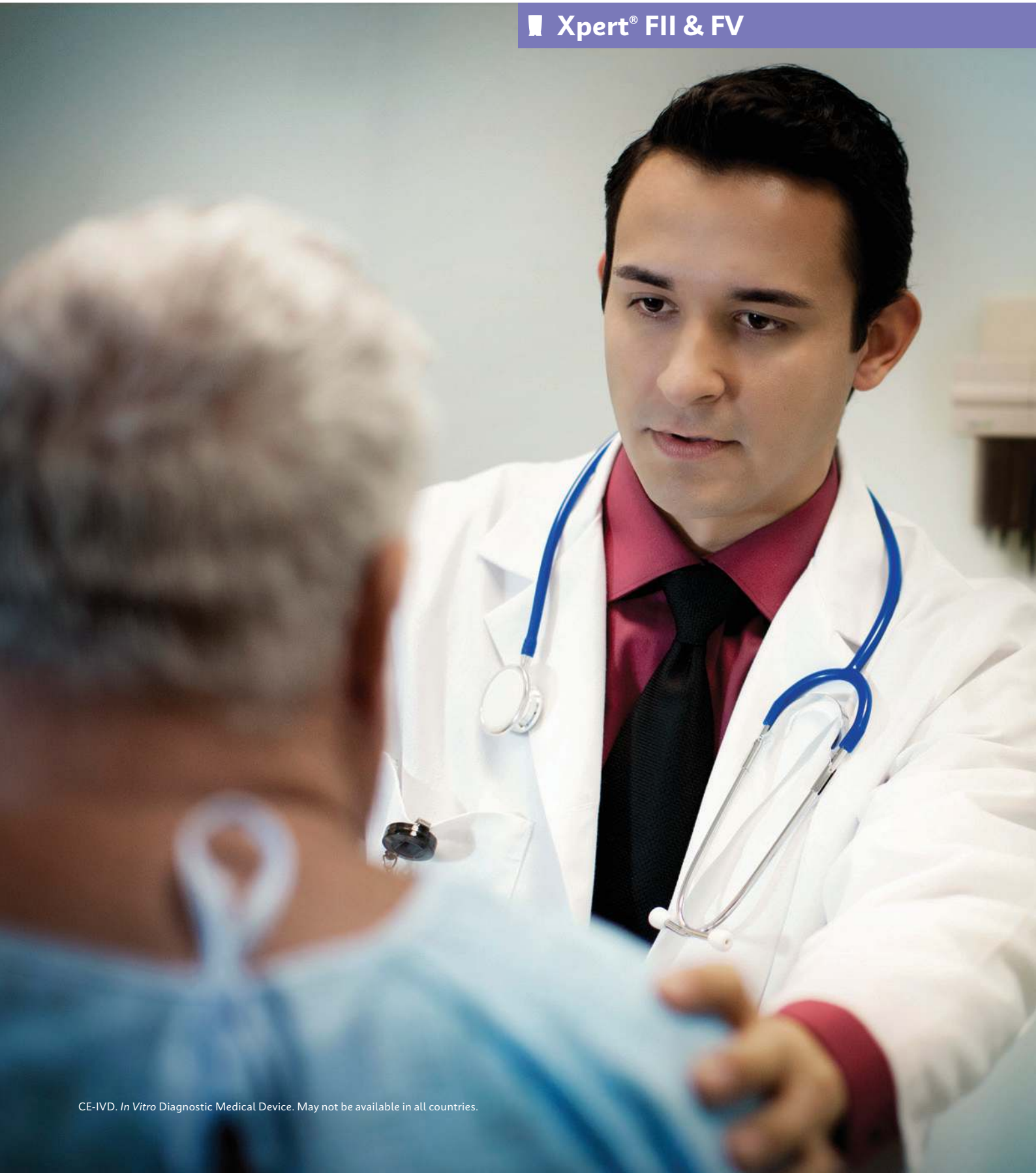
Cepheid®
A better way.

30-minute Test for Genetic Risk of Thrombosis

Xpert® FII & FV



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

“We use Xpert® FII & FV because of its simplicity. It improves the lab flow by offering a flexible approach to testing, with genotyping results in approximately 30 minutes, assisting patient management.”

Lab Manager
Italy

The Need

Thrombophilia is defined as an increased risk or tendency to develop blood clots (thrombi) in veins, arteries or both. Venous thrombophilia may result in deep venous thrombosis (DVT) or pulmonary embolism (PE) and is the result of either inherited or acquired defects (or an interaction between the 2) in the coagulation system. The most commonly associated genetic mutations for inherited thrombophilia are mutations in the genes for Factor V Leiden and Factor II (prothrombin).[1]

Genetic risk factors predispose to thrombophilia and play the most important etiopathogenic role in venous thromboembolism (VTE) in people younger than 50 years old. At least one inherited risk factor could be found in about half of the cases with a first episode of idiopathic VTE.[2]

There is a high incidence of venous thrombo-embolism (VTE) in hospitalized patients and they are a major cause of sudden death in this patient population. VTE recurs frequently; about 30% of patients develop recurrence within the next 10 years and 10% to 30% of people die within one month of diagnosis.[3]

The Solution

Xpert FII & FV is a qualitative genotyping test for the fast detection of Factor II and Factor V alleles. Performed on the Cepheid GeneXpert systems, the test is intended to provide rapid results for Factor II mutation c.*97G>A (formally 20210G>A) and Factor V Leiden c.1601G>A (R506Q) mutations as an aid in the diagnosis of suspected thrombophilia.

Simple

- Molecular **Lab in a Cartridge™** — DNA Extraction, amplification, detection and controls 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[4]

Fast Actionable Results

- Detection of FII c.*97G>A, Factor V Leiden in 30 minutes

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

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

The Impact

Actionable: Avoid costly 'send out' testing, and associated wait for results. Improve patient management with fast test answers on-demand.

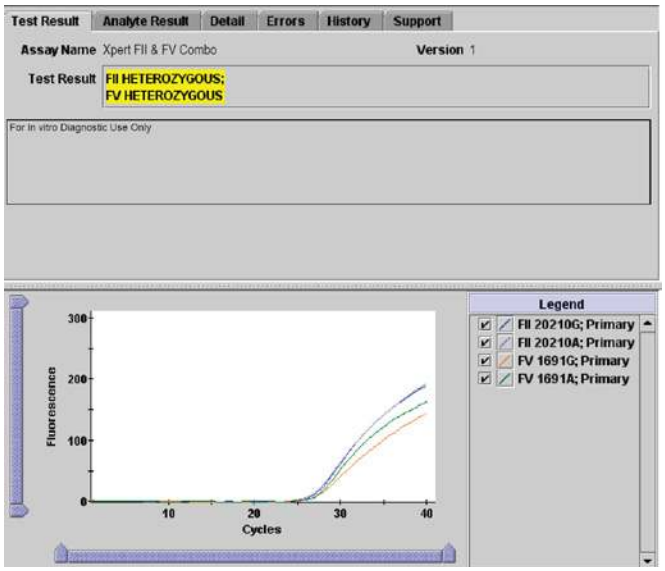
Optimized: Cartridge-based testing system, for either or both mutations, removing the risk of non-optimal reagent use associated with batch testing.

Efficient: No requirement for specialized lab personnel or facilities. Just insert the cartridge with the blood sample into a GeneXpert system and get results in 30 minutes.

Shift your lab from reactive to proactive with same-day results for clinicians.

Advanced Technology

- All reagents required to run the test are inside the cartridge, including PCR controls, giving a simple, streamline procedure.
- GeneXpert software offers color coded, easy result interpretation, with the flexibility to report out FII and FV together or individually if ordered separately
- No additional reagents or associated waste
- Accurate real time answers are provided using scorpion primer technology



GeneXpert software interprets amplification curves and delivers genotyping results.

Proven 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. Xpert FII & FV demonstrated 99.3% overall accuracy relative to bi-directional sequencing (no discordant results).[4]

Additional Performance Studies

Xpert FII & FV was evaluated in comparison to an alternate molecular platforms by both Gessoni et al and Saquilayan et al. Both studies resulted in 100% agreement with the alternative molecular platform.[5,6]

Workflow: 3 Easy Steps

1 Simply take 50 uL EDTA or sodium citrate whole blood

2 Pipette* sample into cartridge

3 Insert cartridge and start test

Results available in 30 minutes

PN0018-01

Catalog Information

Xpert® FII & FV	10 tests	GXFIIFV-10

Leverage an expanding menu of **>30 CE-IVD cleared tests** that can run simultaneously on the scalable family of GeneXpert® systems.

Scan QR code with your mobile device to **discover more.**

* Pipette not included in kit.

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