Xpert® FII & FV

30-minute test for genetic risk of thrombosis



The Need

Thrombophilia is as an increased risk or tendency to develop blood clots (thrombi) in veins, arteries or both due to either inherited or acquired defects.[1]

The high incidence of venous thrombo-embolism (VTE) in hospitalized patients is a major cause of sudden death.[1]

Factor II and V are the two most common genetic variants associated with VTE and testing for these variants is the most common referral in clinical genetics laboratories.[2]

The Solution

The Xpert FII & FV is intended to provide results for Factor II mutation c.*97G>A (formally G20210A or 20210G>A) and Factor V Leiden c.1601G>A (p.Arg534Gln) (formally G1691A or Arg506Gln) as an aid in the diagnosis of suspected thrombophilia.[5]

The test is a qualitative genotyping test for fast and simultaneous detection of Factor II and Factor V alleles in approximately 30 minutes.[5]

The Impact

- Potential to improve patient management and optimize lab workflow with fast test and accurate results that don't require specialized lab personnel or facilities.[4]
- Delivers fast answers on the two main factors involved in VTE enabling timely clinical management.[1–3]
- Enables laboratories and clinicians to adhere to professional standards.[2]

1 Heit J et al. The epidemiology of venous thromboembolism. J Throm Thrombolysis 2016 41: 3-14

2 Zhang S, Taylor AK, Huang X, Luo B, Spector EB, Fang P, Richards CS; ACMG Laboratory Quality Assurance Committee. Venous thromboembolism laboratory testing (factor V Leiden and factor II c.*97G>A), 2018 update: a technical standard of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2018 Dec;20(12):1489-1498. doi: 10.1038/s41436-018-0322-z. Epub 2018 Oct 5. PMID: 30297698.

3 CDC. Accessed Jan 2026 https://www.cdc.gov/blood-clots/about/?CDC_AAref_Val=https://www.cdc.gov/ncbddd/dvt/facts.html

4 Saquilayan M et al. Detection of genetic thrombophilia (Fa V Leiden & PT20210 mutation) using GeneXpert technology with IQCP implementation. Natural Sciences and Mathematics | Clinical Laboratory Sciences Culminating Projects. 2019. https://doi.org/10.33015/dominican.edu/2019.CLS.04

5 Xpert® Factor II & Factor V Kit Instructions for Use.

Xpert® FII & FV

Product Reference Sheet — US-IVD

Test Reagent Kit	Xpert FII & FV		
Catalog Number	GXFIIFV-US-10		
Technology	Real-time PCR		
Targets	Factor II c.*97G>A (G20210A or 20210G) and Factor V c.1601G>A (p.Arg534Gln) (G1691A or Arg506Gln)		
Batch or On-Demand	On-Demand		
Minimum Batch Size	1		
Sample Type	Whole blood collected in EDTA or sodium citrate anticoagulant tubes		
Sample Volume	50 µL		
Sample Extraction	Automated/integrated		
Precision Pipetting	Not Required		
Off-board Sample Preparation Time	Approximately 5 minutes		
TAT	Approximately 30 minutes		
Internal Assay Controls	✓		
System & Software	**GeneXpert® Dx System** GeneXpert Dx software version 4.0 or higher	**GeneXpert® Infinity** Xpertise software version 6.6 or higher	**GeneXpert® Touch Screen** Cepheid OS software version 2.0 or higher
Sample Stability	Up to 24 hours when stored at room temperature (22–28 °C) Up to 15 days when stored at 2–8 °C Up to 3 months when stored at -20 °C or -80 °C		
Kit Storage	2–28 °C		
Commercial Controls	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support		

US-IVD. *In Vitro* Diagnostic Medical Device.

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