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.[2]

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.[1-3]

The Solution

The Xpert FII & FV 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.[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

- Improves patient management and optimizes lab workflow with fast test and accurate results that doesn'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]
- Facilitates labs and clinicians compliance with guidelines.[3]

1 Mannucci P.M et al. Classic thrombophilic gene variants. Thromb Haemost. 2015 Nov;114(5):885-9.

2 Heit J et al. The epidemiology of venous thromboembolism. J Throm Thrombolysis 2016 41: 3-14 CDC. Accessed Aug 2020 https://www.cdc.gov/ncbddd/dvt/facts.html

3 Zhang S et al. 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. Oct 2018;20(12):1489–1498.

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. 301-0590.

Xpert® FII & FV

Product Reference Sheet — US-IVD & CE-IVD

Test Reagent Kit	Xpert FII & FV	
Catalog Number	**US-IVD & CE-IVD** GXFIIFV-10	
Technology	Real-time PCR	
Targets	Factor II c.*97G>A (G20210A or 20210G>A4) 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	✓	
	GeneXpert® Dx System	**GeneXpert® Infinity**
System & Software	GeneXpert Dx software version 4.0 or higher	Xpertise software version 6.6 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	

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

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