



## XPert FII & FV HET

### INTENDED USE:

Xpert FII & FV HET is intended for *in vitro* use as a quality control to monitor analytical performance of FII & FV detection on the GeneXpert® System. Xpert FII & FV HET is formulated to monitor the detection of mutations Factor II G20210A and Factor V Leiden G1691A, the most common genetic risk factors for thrombotic events.

Xpert FII & FV HET is provided for Research Use Only (RUO). It cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

### PRODUCT SUMMARY and PRINCIPLE:

Xpert FII & FV HET consists of a suspension of synthetic Factor II and Factor V DNA in a proprietary matrix with preservatives. The kit is comprised of two bottles of Xpert FII & FV Heterozygous Control which contain heterozygous DNA for both Factor II and Factor V.

Best practice is to establish a quality control program for every assay performed by the laboratory.<sup>1, 2</sup> Routine use of quality controls that are consistent lot to lot and monitor the entire assay assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

### COMPOSITION:

Xpert FII & FV HET is comprised of two bottles containing 0.5mL each of synthetic Factor II and Factor V DNA suspended in a non-infectious matrix with carrier DNA, preservatives and stabilizers.

Specific mutations present are described below.

Analyte:	Mutation:
FII	G20210A (c.*97G>A)
FV Leiden	G1691A (c.1601G>A)

### STORAGE AND STABILITY:

Upon receipt and after opening, the material should be stored at 2° – 8°C. Do not freeze.

Unopened Xpert FII & FV HET material is stable through the expiration date printed on each bottle when stored refrigerated (2° – 8°C).

Opened material tightly capped and returned to the refrigerator (2° – 8°C) shortly after use is stable for thirty (30) days from the date of opening.

### INSTRUCTIONS FOR USE:

Process Xpert FII & FV HET as you would a whole blood specimen:

1. Allow Xpert FII & FV HET to come to room temperature (18° – 25°C).
2. Thoroughly mix the solution prior to opening by inverting the bottle several times or placing on an automated mixer immediately before use.
3. Follow manufacturer's test instructions for clinical specimens.
4. Tightly recap each bottle after use and store refrigerated (2° - 8°C).
5. Controls should be tested routinely as a matter of Good Laboratory Practice (GLP) and according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

### PRECAUTIONS AND WARNINGS:

Xpert FII & FV HET is for use on the GeneXpert® System only. Please contact MMQCI for controls to be used for other test systems that detect mutations Factor II G20210A and Factor V Leiden G1691A.

This product contains 23% ethanol (v/v) and could be flammable. Keep away from open flames.

This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures. This product does not contain any biological material of human origin and is non-infectious.

### EXPECTED VALUES:

Analyte	G10801 FII & FV Heterozygous Control Genotype
FII G20210A	FII HET
FV Leiden G1691A	FV HET

Other Factor II and Factor V mutations are not detected in the Xpert FII & FV HET.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for the Xpert FII & FV HET in demonstrating adequate system performance.

### ORDERING INFORMATION:

Xpert FII & FV HET

**Order Number: G108-2H**

Kit contains: 2 x 0.5mL bottles of G10801

1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000