



Xpert FII & FV NOR/MUT Control

INTENDED USE:

Xpert FII & FV NOR/MUT Control 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 NOR/MUT Control 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.

PRODUCT SUMMARY and PRINCIPLE:

Xpert FII & FV NOR/MUT Control consists of a suspension of synthetic Factor II and Factor V DNA in a proprietary matrix with preservatives. The kit is comprised of four bottles. Two bottles of Xpert FII & FV Normal Control contain wild type Factor II and Factor V DNA. Two bottles of Xpert FII & FV Mutant Control contain homozygous mutant Factor II and Factor V DNA.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs¹.

COMPOSITION:

Xpert FII & FV NOR/MUT Control is comprised of four 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 NOR/MUT Control 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 sixty (60) days from the date of opening.

1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.

INSTRUCTIONS FOR USE:

Process Xpert FII & FV NOR/MUT Control as you would a whole blood specimen:

1. Allow Xpert FII & FV NOR/MUT Control 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 NOR/MUT Control 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 is intended for *in vitro* analytical testing and is provided for Research Use only, not for use in diagnostic procedures.
- This product contains 23% ethanol (v/v) and could be flammable. Keep away from open flames.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Xpert FII & FV NOR/MUT Control in demonstrating adequate system performance.

EXPECTED VALUES:

Analyte	G116a01 Normal Control Genotype	G116b01 Mutant Control Genotype
FII G20210A	FII NORMAL	FII HOMOZYGOUS
FV Leiden G1691A	FV NORMAL	FV HOMOZYGOUS

Other Factor II and Factor V mutations are not detected in the Xpert FII & FV NOR/MUT Control.

ORDERING INFORMATION:

Xpert FII & FV NOR/MUT Control

Part Number: G11601

Kit contains: 4 x 0.5mL bottles (2 Normal & 2 Mutant)