MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.

Research Use Only

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 the Xpert HemosIL® Assay 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.

Xpert FII & FV NOR/MUT Control 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 NOR/MUT Control consists of a suspension of synthetic Factor II and Factor V DNA. There are two bottles each of wild type and mutant genotypes. The Xpert FII & FV Normal Control contains wild type Factor II and Factor V DNA. The Xpert FII & FV Mutant Control contains homozygous mutant Factor II and Factor V DNA.

Best practice is to establish a quality control program for every assay performed by the laboratory.[1, 2] 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 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 thirty (30) days from the date of opening.

INSTRUCTIONS FOR USE:

Handle 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 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.

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.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for the Xpert FII & FV NOR/MUT Control in demonstrating adequate system performance.

ORDERING INFORMATION:

Xpert FII & FV NOR/MUT Control
Order Number: G11601
Kit contains: 4 x 0.5mL bottles (2 Normal & 2 Mutant)

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