



## INTROL™ THROMBOSIS GENOTYPE PANEL

### INTENDED USE:

INTROL™ Thrombosis Genotype Panel is intended for *in vitro* use as a quality control to monitor analytical performance of the extraction, amplification and detection steps of test systems used in the qualitative measurement of the Factor II (Prothrombin), Factor V Leiden and Methylenetetrahydrofolate reductase (MTHFR) genes for mutations **Factor II G20210A**, **Factor V G1691A Leiden**, **MTHFR C677T** and **A1298C**. This product is intended to be extracted and analyzed routinely with each Factor II, Factor V and MTHFR test run.

INTROL Thrombosis Genotype Panel is designed to monitor the detection of mutations **Factor II G20210A**, **Factor V G1691A Leiden**, the most common genetic risk factors for thrombotic events and **MTHFR C677T** and **A1298C** which are associated with thrombosis, cancers, leukemia, neural tube defects, high homocystine levels, cardiovascular disease, schizophrenia, Alzheimer's and toxicity of anti-folate drugs like methotrexate.

INTROL Thrombosis Genotype Panel is provided for Research Use Only (RUO). It cannot be cloned, sold, or transferred without the explicit written consent of MMQCI. Patents issued.

### PRODUCT SUMMARY:

INTROL Thrombosis Genotype Panel consists of synthetic Factor II, Factor V and MTHFR DNA suspended in a non-infectious, blood-like matrix containing carrier DNA, preservatives and stabilizers. The DNA should be extracted and purified from its matrix before analysis.

There are three bottles, each containing a different genotype. Bottle a, contains wild type (normal) Factor II, Factor V and MTHFR C677T & A1298C. Bottle b, contains heterozygous Factor II, Factor V and MTHFR C677T & A1298C. Bottle c, contains mutant Factor II, Factor V and MTHFR C677T & A1298C.

Analysis of INTROL Thrombosis Genotype Panel test results can be valuable in the detection and troubleshooting of errors associated with the sample extraction, amplification, and signal measurement phases of Factor II, Factor V and MTHFR test systems.

### INGREDIENTS:

Each bottle of INTROL Thrombosis Genotype Panel contains synthetic DNA of Factor II, Factor V and MTHFR genes. Specific mutations present are described below.

Mutations:	
<b>Factor II</b>	G20210A
<b>Factor V</b>	G1691A (Leiden)
<b>MTHFR</b>	C677T
<b>MTHFR</b>	A1298C

INTROL Thrombosis Genotype Panel has been sequenced to validate the presence of mutant or wild type sequence. The base matrix for the control solution contains synthetic DNA targets, carrier DNA of a non-human species, preservatives and stabilizers.

### PRECAUTIONS AND WARNINGS:

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.

### INSTRUCTIONS FOR USE:

Extract and analyze INTROL Thrombosis Genotype Panel as you would a whole blood specimen:

1. Allow INTROL Thrombosis Genotype Panel 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. Extract INTROL Thrombosis Genotype Panel in the same manner as a whole blood clinical specimen. Use the same volume that would be used for a patient sample in your lab.

Note 1: Certain test methods may require additional processing of control material, such as dilution prior to analysis.

Note 2: The level of DNA present in the extracted control may not be detectable by certain quantitation methods and is not quantifiable by spectrophotometer measurements.

4. Analyze the extracted DNA as you would genomic DNA. If dilutions or other preparations of the extracted DNA are required as part of the testing procedure, handle the INTROL Thrombosis Genotype Panel DNA in the same manner as clinical specimens.
5. Tightly recap each bottle after use and store refrigerated (2° – 8°C).
6. Controls should be tested routinely as a matter of Good Laboratory Practice and according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. The frequency of analysis will depend on individual laboratory policies for control use and may vary according to the analyte being measured or the analytical system being used.

### STORAGE:

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

### STABILITY:

Unopened INTROL Thrombosis Genotype Panel 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.

### EXPECTED VALUES:

Analyte	Bottle a	Bottle b	Bottle c
<b>FII G20210A</b>	<b>WT</b>	<b>HET</b>	<b>MUT</b>
<b>FV G1691A (Leiden)</b>	<b>WT</b>	<b>HET</b>	<b>MUT</b>
<b>MTHFR (C677T)</b>	<b>WT</b>	<b>HET</b>	<b>MUT</b>
<b>MTHFR (A1298C)</b>	<b>WT</b>	<b>HET</b>	<b>MUT</b>

Other Factor II, Factor V and MTHFR mutations are not detected in the INTROL Thrombosis Genotype Panel.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for the INTROL Thrombosis Genotype Panel in demonstrating adequate system performance. Recoveries may vary depending on extraction method, instrumentation, cycle time / temperature, reagents, method variation, and other systematic or random errors.

### ORDERING INFORMATION:

#### INTROL Thrombosis Genotype Panel:

Order Number:

**G123-1** contains: 3 bottles, 1 milliliter each

**G123-2** contains: 3 bottles, 2 milliliters each