



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 Methylene tetrahydrofolate 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.

PRODUCT SUMMARY and PRINCIPLE:

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.

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:

The INTROL® Thrombosis Genotype Panel consists of three bottles of synthetic DNA of Factor II, Factor V and MTHFR genes suspended in a non-infectious blood-like matrix containing carrier DNA, preservatives and stabilizers. Each bottle contains the genotypes listed in the Expected Results Table 1. Specific mutations present are described below.

Mutations:	
Factor II	G20210A
Factor V	G1691A (Leiden)
MTHFR	C677T
MTHFR	A1298C

STORAGE and STABILITY:

INTROL® Thrombosis Genotype Panel should be stored refrigerated (2° – 8°C). Do not freeze. It is acceptable for this material to arrive at room temperature. However, upon receipt, material should be refrigerated (2° – 8°C) immediately.

Unopened INTROL® Thrombosis Genotype Panel material is stable through the expiration date printed on each bottle when stored refrigerated (2° – 8°C). Opened material returned to the refrigerator (2° – 8°C) immediately after use is stable for thirty (30) days from the date of opening.

PRECAUTIONS and WARNINGS:

- 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 origin.
- INTROL® Thrombosis Genotype Panel is not intended to be frozen and is shipped with a DO NOT FREEZE label.
- The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL® Thrombosis Genotype Panel in demonstrating adequate system performance.
- INTROL® Thrombosis Genotype Panel is protected by patents. It cannot be cloned, sold, or transferred to other laboratories without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

1. Allow INTROL® Thrombosis Genotype Panel to come to room temperature (18° – 25°C).
2. Thoroughly mix the controls prior to opening by inverting the bottles several times immediately before use, or by placing on an automated mixer.
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.
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).

Note: INTROL® Thrombosis Genotype Panel DNA extracts cannot be quantified by spectrophotometric methods.

EXPECTED VALUES:

Recoveries may vary depending on extraction method, instrumentation, cycle time / temperature, reagents, method variation, and systematic or random errors. The genotypes expected when the control is analyzed are listed in the Expected Results Table 1.

INTROL® Thrombosis Genotype Panel Expected Results Table 1

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

ORDERING INFORMATION:

Product Name: INTROL® Thrombosis Genotype Panel

Product Numbers:

G123-1 contains: 3 bottles x 1mL

G123-2 contains: 3 bottles x 2mL

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