



INTROL[®] TRC GENOTYPE CONTROL

INTENDED USE:

INTROL[®] Thrombotic Risk (TRC) Genotype Control is intended for *in vitro* use as a control product to monitor the analytical performance of extraction, amplification and detection of test systems used in the qualitative measurement of the Factor II (Prothrombin) and Factor V genes for mutations Factor II G20210A and Factor V Leiden. This product is intended to be extracted and analyzed routinely with each Factor II and Factor V test run.

The INTROL[®] TRC Genotype Control is designed to monitor the presence of mutations Factor II G20210A and Factor V Leiden, the most common genetic risk factors for thrombotic events.

PRODUCT SUMMARY and PRINCIPLE:

INTROL[®] TRC Genotype Control is synthetic Factor II and V DNA suspended in a non-infectious, blood-like matrix. The DNA should be extracted and purified from its matrix before analysis.

There are three bottles, each containing a different genotype. INTROL[®] TRC Wild Type, contains wild type (normal) Factor II and Factor V DNA. INTROL[®] TRC Heterozygous, contains DNA heterozygous for G20210A and G1691A (Leiden). INTROL[®] TRC Mutant, contains Factor II and V DNA homozygous for mutations G20210A and G1691A (Leiden), respectively.

Analysis of INTROL[®] TRC Genotype Control 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 and Factor V test systems.

COMPOSITION:

Each bottle of INTROL[®] TRC Genotype Control contains synthetic DNA of Factor II and V genes. Specific mutations present are described below. All other sequence is wild type (normal).

Mutations:

Factor II	G20210A
Factor V	G1691A (Leiden)

INTROL[®] TRC Genotype Control DNA 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.

STORAGE and STABILITY:

INTROL[®] TRC Genotype Control should be stored refrigerated (2°C – 8°C). It is acceptable for this material to arrive at room temperature. However, upon receipt, material should be refrigerated (2°C – 8°C) immediately. Prior to use, allow the control to come to room temperature. After use, return INTROL[®] TRC Genotype Control to the refrigerator (2°C - 8°C).

Unopened INTROL[®] TRC Genotype Control material is stable through the expiration date printed on each bottle when consistently stored refrigerated (2°C – 8°C). Opened material returned to the refrigerator (2°C – 8°C) shortly 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.
- The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL[®] TRC Genotype Control in demonstrating adequate system performance.
- INTROL[®] TRC Genotype Control is protected by patents. It cannot be cloned, sold, or transferred to other laboratories without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

Extract and analyze the INTROL[®] TRC Genotype Control as you would a whole blood specimen:

1. Allow the INTROL[®] TRC Genotype Control to come to room temperature (18°C – 25°C).
2. Thoroughly mix the solution prior to opening by inverting the bottle several times immediately before use.
3. Extract the INTROL[®] TRC Genotype Control in the same manner as a whole blood clinical specimen. Use the same volume of INTROL[®] TRC Genotype Control that would be used for a patient sample in your lab.
Note 1: Certain extraction methods may require additional processing of control material, such as dilution prior to analysis.
Note 2: The level of INTROL[®] TRC Genotype Control DNA present in the extracted control may not be detectable with certain quantitation methods and is not quantifiable by spectrophotometer measurements.
4. Analyze the extracted INTROL[®] TRC Genotype Control 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[®] TRC Genotype Control DNA according to the test manufacturer's instructions for clinical specimens.
5. Tightly recap each bottle after use and store refrigerated (2°C - 8°C). 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.

EXPECTED VALUES:

The INTROL[®] TRC Wild Type tests wild type (normal) for Factor II G20210A and Factor V Leiden. INTROL[®] TRC Heterozygous tests heterozygous for mutations Factor II G20210A and Factor V Leiden. INTROL[®] TRC Mutant will test homozygous positive for mutations Factor II G20210A and Factor V Leiden. Other Factor II and Factor V mutations are not detected in the INTROL[®] TRC Genotype Control.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for the INTROL[®] TRC Genotype Control 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:

Product Name: INTROL[®] TRC Genotype Control
Part Numbers:

G104-1 contains: 3 bottles x 1mL
G104 contains: 3 bottles x 2mL