

INTROL™ PGx 1 Control

INTENDED USE

The INTROL™ PGx 1 Control 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 nucleotide variants of Cytochrome P450 2C9 (CYP2C9) that may affect an individual's response to warfarin. This product is intended to be extracted and analyzed routinely with each CYP2C9 test run.

INTROL™ PGx 1 Control cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

SUMMARY AND PRINCIPLE

INTROL™ PGx 1 Control is synthetic Cytochrome P450 2C9 (CYP2C9), Cytochrome P450 4F2 (CYP4F2), and Vitamin K Epoxide Reductase Complex, Subunit 1 (VKORC1) DNA suspended in a non-infectious matrix with preservatives and stabilizers. The DNA should be extracted and purified from its matrix before analysis.

Specific nucleotide polymorphisms found in INTROL™ PGx 1 Control that may be associated with warfarin (Coumadin®) sensitivity are listed in the Variants Table 1.

KIT COMPONENTS

The INTROL™ PGx 1 Control kit consists of three bottles of synthetic CYP2C9/CYP4F2/VKORC1 DNA suspended in a non-infectious matrix with preservatives and stabilizers. Each bottle contains the genotypes listed in the Variants Table 1.

STORAGE AND STABILITY

INTROL™ PGx 1 Control should be stored refrigerated (2° – 8°C). It is acceptable for this material to arrive at room temperature. However, upon receipt, material should be refrigerated (2° – 8°C) immediately.

Unopened INTROL™ PGx 1 Control 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.

INSTRUCTIONS FOR USE

1. Allow INTROL™ PGx 1 Control 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™ PGx 1 Control in the same manner as a whole blood 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 according to test manufacturers' instructions.
5. Tightly recap each control bottle after use and store refrigerated (2° - 8°C).

Note: INTROL™ PGx 1 Control DNA extracts cannot be quantified by spectrophotometric methods.

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™ PGx 1 products are not intended to be frozen and are shipped with a DO NOT FREEZE label.

EXPECTED VALUES

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL™ PGx 1 in demonstrating adequate system performance. Recoveries may vary depending on extraction method, instrumentation, cycle time / temperature, reagents, method variation, and systematic or random errors. Nucleotide variants found in INTROL™ PGx 1 are listed in the Variants Table 1.

INTROL™ PGx 1 Control Variants Table 1.

Polymorphism (Allele)	Bottle b	Bottle c	Bottle d
CYP2C9			
430C>T (*2)	C/T	C/C	T/T
1075A>C (*3)	A/C	C/C	A/A
1080C>G (*5)	C/G	C/C	G/G
818delA (*6)	A/delA	A/A	delA/delA
1003C>T (*11)	C/T	C/C	T/T
374G>A (*14)	G/A	A/A	G/G
485C>A (*15)	C/A	C/C	A/A
895A>G (*16)	A/G	A/A	G/G
VKORC1 Promoter			
-1639G>A	G/A	G/G	A/A
5808 (497T>G)	T/G	T/T	G/G
6009 (698C>T)	C/T	T/T	C/C
6484 (1173C>T)	C/T	C/C	T/T
6853 (1542G>C)	G/C	G/G	C/C
7566 (2255C>T)	C/T	C/C	T/T
9041 (3730G>A)	G/A	A/A	G/G
CYP4F2			
1347G>A	G/A	G/G	A/A

ORDERING INFORMATION

INTROL™ PGx 1 Control

P/N P102-1 contains: 1 mL per bottle

3 bottles, P101b-1, P101c-1, P101d-1

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