INTROL™ 2C19 Panel P110

INTENDED USE:

The INTROL™ 2C19 Panel P110 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 10 most common mutations of Cytochrome P450 2C19 (CYP2C19) affecting drug metabolism. This product is intended to be extracted and analyzed routinely with each CYP2C19 test run.

INTROL™ 2C19 Panel P110 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

PRODUCT SUMMARY and PRINCIPLE:

INTROL™ 2C19 Panel P110 is synthetic Cytochrome P450 2C19 (CYP2C19) DNA suspended in a non-infectious matrix with 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™ 2C19 Panel P110 consists of two bottles of synthetic CYP2C19 DNA suspended in a non-infectious matrix with preservatives and stabilizers. Each bottle contains the genotypes listed in the Expected Results Table.

STORAGE and STABILITY:

INTROL™ 2C19 Panel P110 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™ 2C19 Panel P110 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™ 2C19 Panel P110 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™ 2C19 Panel P110 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. If dilutions or other preparations of the extracted DNA are required as part of the testing procedure, handle the INTROL™ 2C19 Panel P110 DNA in the same manner as clinical specimens.
5. Tightly recap each control bottle after use and store refrigerated (2° - 8°C).

Note: INTROL™ 2C19 Panel P110 DNA extracts cannot be quantified by spectrophotometric methods. Use the same volume of control extract for analysis as patient extract.

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™ 2C19 Panel P110 is not intended to be frozen and is shipped with a DO NOT FREEZE label.
- This product has been tested in several extraction and test methods but not all. Please contact MMQCI for information on using the control for your assay system.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for INTROL™ 2C19 Panel P110 in demonstrating adequate system performance. 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™ 2C19 Panel P110 Expected Results Table 1

Allele	Nucleotide Change	P10601	P10801
CYP2C19			
*2	c.681G>A	*2 Homozygous (A/A)	*2 Heterozygous (G/A)
*3	c.636G>A	*3 Homozygous (A/A)	*3 Heterozygous (G/A)
*4	c.1A>G	*4 Homozygous (G/G)	*4 Heterozygous (A/G)
*5	c.1297C>T	*5 Homozygous (T/T)	*5 Heterozygous (C/T)
*6	c.395G>A	*6 Homozygous (A/A)	*6 Heterozygous (G/A)
*7	IVS5+2T>A	*1 Wild Type (T/T)	*1 Wild Type (T/T)
*8	c.358T>C	*1 Wild Type (T/T)	*1 Wild Type (T/T)
*9	c.431G>A	*1 Wild Type (G/G)	*1 Wild Type (G/G)
*10	c.680C>T	*1 Wild Type (C/C)	*1 Wild Type (C/C)
*17	-806C>T	*17 Homozygous (T/T)	*17 Heterozygous (C/T)

NOTE 1: *1 is the wild type allele

NOTE 2: Check http://www.cypalleles.ki.se/cyp2c19.htm for latest nomenclature.

NOTE 3: *7 is also referred to as 19294T>A

ORDERING INFORMATION:

INTROL™ 2C19 Panel P110
Order Number: P110-1
Kit Contains: 2 bottles x 1mL each, P10601, P10801

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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