INTROL™ HH Panel II

INTENDED USE:

INTROL™ HH Panel II 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 **H63D, S65C** and **C282Y,** the mutations most commonly associated with hereditary hemochromatosis. Hereditary hemochromatosis is an autosomal recessive iron-storage disorder characterized by inappropriately high absorption of iron by the gastrointestinal mucosa, leading to excessive storage of iron (particularly in the liver, skin, pancreas, heart, joints and testes) and ultimately resulting in impaired organ structure and function.[1]

INTROL HH Panel II is designed to monitor the detection of H63D, S65C and C282Y mutations, genetic risk factors associated with hereditary hemochromatosis. This product is intended to be extracted and analyzed routinely with each HH test run.

INTROL HH Panel II 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 HH Panel II consists of synthetic H63D, S65C and C282Y 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.

The Panel is comprised of three bottles, each containing a different genotype. Analysis of **INTROL HH Panel II** test results can be valuable in the detection and troubleshooting of errors associated with the sample extraction, amplification, and signal measurement phases of HH test systems.

INGREDIENTS:

Each bottle of **INTROL HH Panel II** contains synthetic HFE gene segments.

Bottle	Genotype
G20010-1	H63D HET; S65C WT; C282Y HET
G20011-1	H63D WT; S65C WT; C282Y MUT
G20013-1	H63D WT; S65C MUT; C282Y WT

INTROL HH Panel II 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.

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.

STABILITY:

Unopened **INTROL HH Panel II Control** 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.

STORAGE:

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

INSTRUCTIONS FOR USE:

Extract and analyze **INTROL HH Panel II** as you would a whole blood specimen:

1. Allow **INTROL HH Panel II** to come to room temperature (18° – 25°C).
2. Thoroughly mix the solution prior to opening by inverting the bottle several times immediately before use or by placing on an automated mixer alongside patient whole blood samples.
3. Extract **INTROL HH Panel II** in the same manner as a whole blood 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 HH Panel II** 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.

EXPECTED VALUES:

G20010-1: H63D HET; S65C WT; C282Y HET

G20011-1: H63D WT; S65C WT; C282Y MUT

G20013-1: H63D WT; S65C MUT; C282Y WT

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for **INTROL HH Panel II** 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 HH Panel II:
Order Number:
G201-1 contains: 3 bottles, 1 milliliter each

1. King, C.; Barton, D.E. Best practice guidelines for the molecular genetic diagnosis of Type I (HFE-related) hereditary haemochromatosis. BMC Medical Genetics 2006, 7:81