



## Research Use Only

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### Birlinn® HH Panel G203

#### INTENDED USE:

The Birlinn® HH Panel G203 is intended for *in vitro* use as an external unassayed quality control to monitor the analytical performance of test systems used in the qualitative detection of the *HFE* H63D, S65C and C282Y variants most commonly associated with hereditary hemochromatosis (HH). HH is an autosomal recessive iron-storage disorder characterized by the inappropriate 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.

#### PRODUCT SUMMARY and PRINCIPLE:

The Birlinn HH Panel G203 consists of synthetic *HFE* DNA encompassing H63D, S65C and C282Y variants mixed with wildtype (WT) DNA, suspended in a non-infectious buffer with stabilizers to create genotypes associated with HH. The Birlinn HH Panel G203 is provided as a non-extractable control with copy numbers of *HFE* DNA similar to that of extracted human whole blood samples.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system such as failing reagents, malfunctioning equipment, or environmental contamination. Early investigation can prevent failed assay runs and incorrect patient test results.

#### COMPOSITION:

Birlinn HH Panel G203 is comprised of 6 tubes, each containing 30µL of synthetic *HFE* DNA suspended in a non-infectious buffer with stabilizers and preservatives. Three (3) of the tubes contain *HFE* genotypes H63D HET, S65C WT, C282Y HET. The other 3 tubes contain *HFE* genotypes H63D WT, S65C MUT, C282Y WT. Birlinn HH Panel G203 DNA has been bi-directionally sequenced to validate the presence of mutant or wild type *HFE* sequence.

#### STORAGE and STABILITY:

Upon receipt, Birlinn HH Panel G203 should be stored at -25°C to -15°C. Unopened Birlinn HH Panel G203 is stable through the expiration date printed on each tube when consistently stored frozen (-25°C to -15°C). Once opened, material should be tightly capped and returned to the freezer (-25°C to -15°C) immediately after use. The material is stable for five freeze/thaw cycles.

#### PRECAUTIONS, WARNINGS and LIMITATIONS:

- Birlinn HH Panel G203 can NOT be quantitated by routine spectrophotometric measurements.
- If a dilution is required for your test system, pipette a minimum of 5µL of control into TE or molecular grade water in high quality polypropylene tubes, such as Eppendorf LoBind.
- Do not freeze/thaw more than 5 times.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for diagnostic procedures.
- Appearance: Clear
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.

#### PRECAUTIONS, WARNINGS and LIMITATIONS cont'd:

- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- Birlinn HH Panel G203 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.
- It is recommended to dispose of unused product, spilled substance and waste in normal disposal containers. Please ensure that you follow local regulations.
- Degradation may not be visible.
- Do not use controls after expiration date or if stored outside of specified conditions.

#### MEASURES TO BE TAKEN:

- Investigate any performance issues by reviewing procedures, test system information, and internal workflow.
- If a quality issue with the product is suspected, contact MMQCI and do not report patient results until acceptable control performance is confirmed.

#### INSTRUCTIONS FOR USE:

Analyze Birlinn HH Panel G203 as you would for extracted DNA from a patient sample.

1. Allow the control(s) to be tested to come completely to room temperature (18°C to 25°C), **15-30 minutes**.
2. Prior to opening, thoroughly mix the control by inverting the tube several times, followed by a quick vortex and quick spin to remove droplets from the cap.
3. Pipette required volume of control into an amplification reaction, just as you would for extracted genomic DNA.
4. If the test system is sensitive to DNA overload, a dilution may be required to obtain the correct genotypes. Pipette a minimum of 5µL of control into TE or molecular grade water in high quality polypropylene tubes, such as Eppendorf LoBind, and mix well.
5. Continue with the amplification set-up and analysis.

#### EXPECTED VALUES:

| Tube    | Genotype                     |
|---------|------------------------------|
| pG20010 | H63D HET; S65C WT; C282Y HET |
| pG20013 | H63D WT; S65C MUT; C282Y WT  |

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for the Birlinn HH Panel G203 in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, cycle time/temperature, reagents, method variation, and other system specifications.

#### ORDERING INFORMATION:

Birlinn HH Panel G203:  
Part Number: G203  
Kit contains: 6 tubes x 30µL  
3 each of pG20010 & pG20013