

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K053031

B. Purpose for Submission:

New Device

C. Measurand:

Hemoglobin A, F, S, C

D. Type of Test:

Quantitative

E. Applicant:

Canterbury Scientific Ltd

F. Proprietary and Established Names:

extend SURE™ HbFASC Variant Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7415 Abnormal Hemoglobin Assay

2. Classification:

Class II

3. Product code:

JCM

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

The Hematology FASC Variant Control is intended as a position marker for hemoglobin variant analysis methods such as ion exchange HPLC, capillary electrophoresis, cellulose acetate and agar/agarose gel electrophoresis. The Hematology FASC Variant Control will assist in defining the elution time on HPLC or capillary electrophoresis or migration distance on electrophoresis. In this way the common hemoglobin variants can be identified and rare variants that elute close to these can be distinguished for further characterization.

2. Indication(s) for use:

The Hematology FASC Variant Control is intended as a position marker for hemoglobin variant analysis methods such as ion exchange HPLC, capillary electrophoresis, cellulose acetate and agar/agarose gel electrophoresis. The Hematology FASC Variant Control will assist in defining the elution time on HPLC or capillary electrophoresis or migration distance on electrophoresis. In this way the common hemoglobin variants can be identified and rare variants that elute close to these can be distinguished for further characterization.

3. Special conditions for use statement(s):

Not applicable (N/A).

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Hematology FASC Variant Control kit contains HbA, HbF, HbS and HbC. The levels are HbF 20-30%, HbA 40-50%, HbS 15-20% and HbC 5-10%. The control contains stabilizers and preservative to maintain stability of the hemoglobin variants. The product is provided in a lyophilized form and is reconstituted with 1.0 mL of reconstitution fluid (0.09% sodium azide) prior to use. Both the control and reconstitution fluid are supplied in vials with screw top caps.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Helena Laboratories, AFSC Hemo Control

Canterbury Health Laboratories, Hemoglobin F & A2 Control

2. Predicate 510(k) number(s):

K933086

K011389

3. Comparison with predicate:

| Similarities | | | |
|---------------------|--|------------------------------|---------------------------------|
| Item | Device | Predicate | |
| | <i>Hemoglobin FASC Variant Control</i> | <i>AFSC Hemo Control</i> | <i>HbF & A2 Control</i> |

| Differences | | |
|--------------------|--------|-----------|
| Item | Device | Predicate |
| | | |

K. Standard/Guidance Document Referenced (if applicable):

N/A

L. Test Principle:

The hemoglobin variants are prepared from blood obtained from individuals who are heterozygous (or homozygous, HbSS, HbCC, or mixed heterozygous, HbSC) for the variant. They are blended to give a product containing HbFASC and can be used to calibrate elution times or migration distance of each specific hemoglobin. They can be used on their own alongside, before, or after a patient sample, or a portion may be added to a patient sample to serve as an internal marker to assist in the identification of an observed hemoglobin variant.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

N/A

- b. *Linearity/assay reportable range:*
N/A
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

d. *Detection limit:*
N/A
 - e. *Analytical specificity:*
N/A
 - f. *Assay cut-off:*
N/A
2. Comparison studies:
- a. *Method comparison with predicate device:*
N/A
 - b. *Matrix comparison:*
N/A
3. Clinical studies:
- a. *Clinical Sensitivity:*
N/A
 - b. *Clinical specificity:*
N/A
 - c. *Other clinical supportive data (when a. and b. are not applicable):*
N/A
4. Clinical cut-off:

N/A

5. Expected values/Reference range:

The Hematology FASC Variant Control will enable elution times and migration distances to be determined for HbF, HbA, HbS, and HbC. These values should be established for each individual instrument for each lot of reagent and buffers.

The levels are HbF 20-30%, HbA 40-50%, HbS 15-20% and HbC 5-10%. The control should be included within each batch run of patient samples. For ion-exchange HPLC and capillary electrophoresis methods individual laboratories should chart the elution times of the HbFASC components and in this way establish their own control limits from day-to-day use of the test. Any result that falls outside the limits established by your laboratory should be investigated.

Due to variations amongst separation and integration systems specific value are not provided for each method platform. However as a guide the values obtained on the BioRad Variant Classic using the β -thalassemia short program is provided with each control kit.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.