

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

A. 510(k) Number:

k043378

B. Purpose for Submission:

Change in product design

C. Measurand:

Glycoslyated hemoglobin (HbA1c)

D. Type of Test:

Quantitative: cation exchange chromatography in junction with gradient elution used for calibration of instruments.

E. Applicant:

Drew Scientific Ltd.

F. Proprietary and Established Names:

Drew Scientific Ltd. Glycated Haemoglobin Two Level Calibrator Kit

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIT

4. Panel:

H. Intended Use:

1. Intended use(s):

See Indications for use.

2. Indication(s) for use:

The drew Scientific Glycated Haemoglobin Two Level Calibrator Kit is intended for use with instruments for the measurement of HbA1c and is designed to allow calibration to either the American NGSP system or the International IFCC system.

3. Special conditions for use statement(s):

For Prescription use only.

4. Special instrument requirements:

DS5 Analyzer (k933287)

I. Device Description:

The Drew Scientific Glycated Haemoglobin Two Level Calibrator Kit contains four vials two levels each of HbA1c calibrator, one vial of diluent solution for each level of calibrator, and a product instruction leaflet.

The vials contain freeze-dried (lyophilized) haemolysate from human blood donor units.

The calibrators are intended for use with instruments for the measurement of HbA1c and are designed to allow calibration to either the American NGSP system or the International IFCC system.

The product has been tested and found negative by FDA accepted methods for HBV, HCV and HIV 1 and 2.

For In Vitro diagnostic use only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Primus Corporation Glycated Hemoglobin Calibrators

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

k936204

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Stability	Unopened: Lyophilized – stable at 2 - 8°C until expiration date on the label.	Unopened: Lyophilized – 2 - 8°C until expiration date on the label.
Matrix	Human whole blood	Human whole blood
Form	Lyophilized	Lyophilized

Differences		
Item	Device	Predicate
Reconstituted Volume	0.3 mL	0.4 mL
Stability	Opened: Reconstituted – stable at 2 - 8°C for 1 day	Opened: Reconstituted – stable at 2 - 8°C for 7 days.

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

Results are traceable to both the Diabetes Control and Complications Trial (DCCT) reference method and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) reference method for the measurement of HbA1c in human blood.

Certified by the National Glycohemoglobin Standardization Program (NGSP)

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable.

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: the sponsor states the DCCT/NGSP aligned values are traceable to the DCCT Designated Comparison Method (DCM). The DCM is ion-exchange HPLC using Bio-Rex 70 resin (Bio-Rad Laboratories).

IFCC aligned values are traceable to the IFCC approved reference method. Hb is cleaved enzymatically, the beta-N-terminal hexapeptides are separated from the peptide mixture by reverse phase HPLC. HbA1c is then determined by mass spectrometry or capillary electrophoresis as the ratio of glycosylated to nonglycosylated beta-N-terminal hexapeptides.

Shelf-life Stability: Shelf-life stability was established by taking a set of stored calibrators (2-8°C) and reconstituting and assaying them every few months. Acceptance criteria of a percentage change from the starting point of less than 10%.

Open vial stability was established by taking a set of calibrators, reconstituting them and storing them at 2-8°C for 24 hours. After 24 hours they were assayed and the values were then compared to the values from a fresh set of reconstituted calibrators by paired t-test. The acceptance criteria is a p value of >0.05.

Open vial stability is 1 day at 2 - 8°C

Closed vial stability is 3 years stored at 2 - 8°C

Value assignment: Values are assigned to the Drew Scientific Ltd., Glycosylated Haemoglobin Calibrators to allow alignment of HbA1c results to both DCCT and IFCC reference methods.

DCCT /NGSP assigned values are assigned to the Drew Scientific Ltd., Glycosylated Haemoglobin Calibrators through the use of 5 levels of NGSP reference material. One replicate of each level of reference material was run 3

different times on 6 different instruments. Linear regression based on the mean of the three replicates is then used to calculate a factor and offset for each instrument. Using the factor and offsets generated, values are assigned to the three replicates of each level of calibrator analysed in each run. The final DCCT/NGSP aligned target value is then the mean of 54 replicates analysed across 6 instruments.

IFCC assigned values are assigned to the Drew Scientific Ltd., Glycated Haemoglobin Calibrators through the use of 8 levels of IFCC reference material. One replicate of each level of reference material was run 5 different times on 6 different instruments. Linear regression based on the mean of the five replicates is then used to calculate a factor and offset for each instrument. Using the factor and offsets generated, values are assigned to the two replicates of each level of calibrator analysed in each run. The final IFCC aligned target value is then the mean of 60 replicates analysed across six instruments.

Validation of the value assignment is done through the IFCC Monitoring programme. A calibrated system is used to report HbA1c values on unknown samples on a fortnightly basis. From the results the calibrators are certified as being traceable to the IFCC Reference Method.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

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.