

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

**A. 510(k) Number:**

k060510

**B. Purpose for Submission:**

New intended use and modification of cleared materials

**C. Analyte:**

Linearity verification materials for hemoglobin A1c

**D. Type of Test:**

Not applicable

**E. Applicant:**

Drew Scientific LTD

**F. Proprietary and Established Names:**

Drew Scientific Glycated Hemoglobin 5- level Linearity Kit

**G. Regulatory Information:**

1. Regulation section:  
21 CFR 862.1660 Quality Control Material
2. Classification:  
Class I
3. Product Code:  
JJX
4. Panel:  
75 - Chemistry

**H. Intended Use:**

1. Intended use(s):  
See Indications for use below.
2. Indication(s) for use:  
For *in vitro* diagnostic use only. The Drew Scientific Glycated Hemoglobin Five Level Linearity Kit is intended to verify the linearity of HbA1c assays across the patient reportable range ( 4 to 18% NGSP aligned) using protocols established in individual laboratories.
3. Special condition for use statement(s):  
For prescription use

4. Special instrument Requirements:

The product is for use with HbA1c analyzers, in particular the Drew Scientific DS5 HbA1c analyzer (K933287), which is a low pressure, ion exchange chromatography system.

**I. Device Description:**

The device contains one vial for each of five control levels evenly spaced across the range of 4-18% HbA1c. Each vial contains a stabilized preparation of freeze-dried human whole blood, cryopreservatives, antibiotic, stabilizers, and 0.09% sodium azide.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Bio-Rad Laboratories Lypochek® Hemoglobin A1C Linearity Set.

2. Predicate K number(s):

k003030

3. Comparison with predicate:

The devices are similar in intended use, form (lyophilized), matrix (human whole blood), and stability. The reconstituted volumes and the number of levels differ between the 2 devices.

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

CLSI EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures"

**L. Test Principle**

The kit contains five levels of HbA1C to be used for linearity verification. The levels are evenly spaced. The laboratory should plot the observed results against the corresponding level number.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Not specifically addressed. See stability and linearity.

*b. Linearity/assay reportable range:*

Linearity was evaluated according to CLSI EP6-A, on three Drew Scientific DS5 Analyzers. Values obtained on the DS5 Analyzer were plotted against the target values obtained from another commercially available FDA cleared system. Additionally, a linearity set produced as intended for marketing was evaluated on the DS5 and plotted against relative concentrations (1-5).

The manufacturer accepted the data as linear if the difference between the predicted results using the best-fit polynomial and the first order equation was  $< 0.5\%$ . All difference results, calculated according to EP6-A, were within this criterion.

*c. Traceability (controls, calibrators, or method):*

**Value assignment:** Values are assigned based on the mean value of replicate analyses performed on another FDA cleared, commercially available assay system. The manufacturer's acceptance criteria for the HbA1c values are  $\pm 20\%$  of the assigned value.

**Stability:** Linearity materials were reconstituted and analyzed in triplicate on the DS5 analyzers (Drew Scientific). To evaluate reconstituted stability, controls were stored for 14 days at 2 to 8° C and then reanalyzed. Linearity was evaluated according to CLSI EP6-A. The manufacturer's criteria for linearity (given above in the linearity section) were met. Target and mean results for each level on one of the 3 instruments are shown below:

Target (%HbA1c)	Mean on Day 0 (%HbA1c)	Mean on Day 14 (%HbA1c)
3.2	3.9	4.2
5.8	6.5	6.7
8.6	9.3	9.6
12.0	12.6	13.4
16.7	17.0	18.3

Closed vial stability was determined over 160 weeks by reconstituting the linearity material and analyzing replicate determinations every 20 weeks. The manufacturer's acceptance criteria are that drift should be less than 10% for lower level material and 5% for the higher level material. All results presented in the 510(k) were well within these criteria.

*d. Detection limit:*

Not applicable for control/linearity materials

*e. Analytical specificity:*

Not applicable for control/linearity materials

*f. Assay cut-off:*

Not applicable for control/linearity materials

2. Comparison studies:

- a. *Method comparison with predicate device:*  
Not applicable for control/linearity materials
- b. *Matrix comparison:*  
Not applicable for control/linearity materials

3. Clinical studies:

- a. *Clinical sensitivity:*  
Not applicable for control/linearity materials
- b. *Clinical specificity:*  
Not applicable for control/linearity materials

4. Clinical cut-off:

Not applicable for control/linearity materials

5. Expected values/Reference range:

Not applicable for control/linearity materials

**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 substantial equivalence decision.