

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

A. 510(k) Number:

k052010

B. Purpose for Submission:

Marketing of a laboratory control

Measurand:

Quality Control for Hemoglobin A1c

D. Type of Test:

Quality Control

E. Applicant:

Cone Bioproducts

F. Proprietary and Established Names:

HbA1c Linearity Set

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660

2. Classification:

Class I, reserved

3. Product code:

JJX

4. Panel:

75- Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

Hemoglobin A1c Linearity is intended for use as quality control material to demonstrate linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) for immunoassay and HPLC test methods using protocols established by individual laboratories.

3. Special conditions for use statement(s):

For Prescription Use Only

For *In vitro* diagnostic use

4. Special instrument requirements:

Immunoassay and HPLC analyzers

I. Device Description:

Cone Bioproducts' Hemoglobin A1c Linearity Set is provided in liquid form and is prepared from human blood to which stabilizers are added. The product consists of four levels that are manufactured to include target ranges that are of clinical significance and test the dynamic range of Hemoglobin A1c Immunoassay and HPLC determination methods.

Levels 1 and 4 are prepared so that Level 1 meets the lower limit of the instrument manufacturer's claimed linearity and Level 4 the upper limit. Admixtures of levels 1 and 4 are made to create levels 2 and 3. All levels of the product are run in triplicate on the Immunoassay or HPLC test method for which the product is designed.

Each donor unit used in the manufacturing of this product was tested by FDA approved methods and found to be non-reactive for Human Immunodeficient Virus (HIV-1, HIV-2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV) antibody.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cliniq LiniCAL Enzyme Calibration Verifiers

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

k040535

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Hemoglobin A1c Linearity is intended for use as quality control material to demonstrate linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) for immunoassay and HPLC test methods using protocols established by individual laboratories.	Intended for use in the clinical laboratory to verify calibration and/or assess linearity for the Beckman Protein Systems.
Format	Liquid	Same

Differences		
Item	Device	Predicate
Constituents	Hemoglobin A1c	Alkaline Phosphatase, Alanine Aminotransferase, Amylase, Aspartate Aminotransferase, Cholinesterase, Creatine Kinase, Creatine Kinase MB, Lactate Dehydrogenase, Lipase, Gamma Glutamyl Transpeptidase, and Pancreatic Amylase
Levels	Four	Five

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

None referenced

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):

This product is certified by National Glycohemoglobin Standardization Program for traceability to the Diabetes Control and Complications Trial Reference method. The assigned values are traceable to a commercially available HbA1c Calibrator Set.

Each level is assayed in triplicate on the Immunoassay or HPLC test method for which the product is designed. The sponsor defines acceptance criterion as values being within 10% of the target concentration.

Accelerated stability studies are conducted to determine closed vial stability for the product. Vials are stored at -20°C and 25°C and one sample of each level is tested by HPLC at 0, 6, 24, and 30 hours. The sponsor defines acceptance criterion as results falling within $\pm 20\%$ from the initial value. The sponsor has determined that the Hemoglobin A1c Linearity Set is stable for 2 years when stored at -20°C.

Real time stability studies are conducted to determine the open vial stability for the product. Vials are stored at 2-8°C and tested by HPLC at 0, 7, 14, 21, 27 and 35 days. The sponsor defines acceptance criterion as results falling within $\pm 20\%$ of the initial value. The sponsor has determined that the Hemoglobin A1c Linearity Set is stable for 14 days when stored at 2-8°C in tightly closed containers.

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.