

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

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

**k031296**

**B. Purpose for Submission:**

New Device

**C. Analyte:**

Glycosylated hemoglobin

**D. Type of Test:**

Quantitative immunoturbidimetric assay

**E. Applicant:**

BioDiagnostic International

**F. Proprietary and Established Names:**

Liqui-Heme Glycohemoglobin A1c Assay

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.7470, Assay, glycosylated hemoglobin

21 CFR §862.8165, Calibrator for hemoglobin or hematocrit measurement

21 CFR §862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II

3. Product Code:

LCP Glycosylated hemoglobin assay

KRZ Calibrator for hemoglobin or hematocrit measurement

JJX Quality control material (assayed and unassayed)

4. Panel:

Hematology (71)

**H. Intended Use:**

1. Intended use(s):

See below.

2. Indication(s) for use:

“The BioDiagnostic International LIQUI-HEME Glycohemoglobin A1c Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of glycohemoglobin A1c (HbA1c) in the human whole blood. The method is an immunological assay. Both the concentration of HbA1c and the concentration of total hemoglobin are measured. The reported HbA1c result is calculated as a percentage of the total hemoglobin concentration.

Measurements of percentage HbA1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

This application sheet has been developed for the Hitachi instrument of clinical chemistry analyzer and must be used by suitably qualified personnel under appropriate clinical laboratory conditions.

Further, this test kit also includes a set of six calibrators and bilevel (Human) Low and High controls, which are optional.”

3. Special condition for use statement(s):  
This product is for prescription use only.
4. Special instrument Requirements:  
This reagent assay is only intended for the Hitachi 911 analyzer.

**I. Device Description:**

The device consists of the following liquid components: denaturant reagent (porcine pepsin), total hemoglobin reagent (alkaline detergents), anti-HbA1c antibody reagent (polyclonal goat antibodies on latex particles), HbA1c agglutination reagent, two levels of controls derived from human whole blood that should be processed like samples before use, and six levels of ready-to-use calibrators. Human source material from which this product has been derived has been tested at donor level, with FDA approved or licensed methods, for the HIV 1 and HIV 2 antibodies, Hepatitis B Surface antigen (HBsAG), and HCV antibodies and found to be negative.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Randox Hemoglobin A1c Assay
2. Predicate K number(s):  
k021897
3. Comparison with predicate:  
The two products are identical in manufacturer, intended use, format, and methodology.

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

None referenced in this submission.

**L. Test Principle:**

Hemoglobin is lysed from erythrocytes then digested with pepsin to release  $\beta$ -N-terminal fragments of hemoglobin. These fragments are then bound to an excess of anti-hemoglobin polyclonal antibody; remaining free antibodies are agglutinated with a synthetic polymer carrying various HbA1c  $\beta$ -N-terminal fragments. The presence of HbA1c in the sample will slow the rate of the agglutination as it competes with the A1c agglutinate for antibody binding sites on the latex. Hence, the increase in absorbance is inversely proportional to the concentration of HbA1c in the sample. Absorbance at 600 nm is measured, and a six-point calibration curve is used to calculate percent HbA1c.

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:

Analytical performance of the Glycohemoglobin A1c Assay was established in k021897.

*a. Precision/Reproducibility:*

See above.

*b. Linearity/assay reportable range:*

See above.

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

See above.

*d. Detection limit:*

See above.

*e. Analytical specificity:*

See above.

*f. Assay cut-off:*

See above.

2. Comparison studies:*a. Method comparison with predicate device:*

The Liqui-Heme Glycohemoglobin A1c Assay, run on the Hitachi 911 analyzer, was compared to BioRad's Variant II Total GHb, another clinical chemistry lab based method, using 54 patient samples. Sample values ranged from 4.3% to 17.2% HbA1c. Below are the parameters of the regression analysis:

Parameter	Value
Slope	0.96
Y-intercept	0.45
$r^2$	0.95
n =	54

These parameters were within the sponsor's acceptance criteria.

*b. Matrix comparison:*

Not applicable. This assay is to be performed only in venous whole blood collected with anticoagulants (EDTA, sodium citrate, or oxalate/fluoride).

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:

The normal range for HbA1c in non-diabetic people is 4 to 6% according to the literature referenced. The American Diabetes Association recommends a goal of <7% for effective management of diabetes and to minimize long-term diabetic complications. A level above 7% suggests that more intensive diabetes management should be considered.

**N. Conclusion:**

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