

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

A. 510(k) Number: K032791

B. Analyte: Hemoglobin A1c

C. Type of Test: N/A

D. Applicant: Quantimetrix Corporation.

E. Proprietary and Established Names: Quantimetrix GlycoHemosure HbA1c Control

F. Regulatory Information:

1. Regulation section: 21 CFR §864.8625 Control, Hemoglobin
2. Classification: Class II
3. Product Code: GGM
4. Panel: 81

G. Intended Use:

1. Intended use(s):

The Quantimetrix GlycoHemosure controls are intended for the quality control of laboratory procedures for the quantitation of HbA1c.

2. Indication(s) for use:

The Quantimetrix GlycoHemosure is intended for the quality control of laboratory procedures for the quantitation on HbA1c.

3. Special condition for use statement(s): None

4. Special instrument Requirements: None

H. Device Description:

The Quantimetrix GlycoHemosure Controls are supplied as ready-to-use liquid requiring no reconstitution. The Quantimetrix GlycoHemosure consists of human blood components with clinically significant HbA1c levels as manufacturing

targets. Packed red blood cells from a number of non-diabetic donors is pooled, fortified with stabilizers and preservative and used as the base matrix for the formulation of controls at the specified target ranges.

I. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Laboratories, Lypocheck Diabetes Control

2. Predicate K number(s):

k831478

3. Comparison with predicate:

	Quantimetrix Corporation. GlycoHemosure	Bio-Rad Laboratories Lypocheck Diabetes Control
Indication for use	The Quantimetrix GlycoHemosure is intended for the quality control of laboratory procedures for the quantitation of HbA1c.	As a quality control lysate to monitor the precision of laboratory procedures for measurement of HbA1c and HbA1.
Type of Material	Liquid, ready-to-use control (2 levels)	Lyophilized control (2 levels)
Matrix	Human blood, stabilizers and preservative.	Human blood, preservative, stabilizers.
Analyte	HbA1c	HbA1c, HbA1
Preservative	Antibiotics	Not known
Packaging	4x2 ml (glass vial with TRISEAL cap) per kit (level 1: 2 vials, level 2: 2 vials)	6x0.5 ml (glass vial with crimp seal) per kit (level 1: 3 vials, level 2: 3 vials)
Stability claims	Stable until the expiration date when stored at 2-8° C. Once opened the material is stable for 30 days when stored at 2-8° C.	The product will be stable until the expiration date when stored unopened at 2 to 8° c. Once the control is reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 to 8° C.
Analytes	HbA1c: L1 4.0 – 6.0 % L2 9.0 – 18.0 %	HbA1c: L1 4.7 – 13.0 % L2 5.6 – 15.6 %

The predicate device and the GlycoHemosure control contain similar matrices, analyte and analyte concentration. They also have similar stability claims.

Similarities between the Quantimetrix control and the predicate device:

- both have a base matrix of human blood
- both have similar stability claims
- both cover the clinically significant HbA1c concentration ranges
- both contain preservatives

Differences between the Quantimetrix control and the predicate device:

- the predicate is lyophilized while the Quantimetrix product is liquid.
- the fill volume is higher for the Quantimetrix product (2 ml vs. 0.5 ml)
- the predicate device consists of diabetic blood while the Quantimetrix product has been glycated in vitro

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

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials”.

K. Test Principle: NA

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

- a. *Precision/Reproducibility:* NA
- b. *Linearity/assay reportable range:* NA
- c. *Traceability (controls, calibrators, or method):* Not Stated
- d. *Detection limit:* NA
- e. *Analytical specificity:* NA
- f. *Assay cut-off:* NA

2. Comparison studies:

- a. *Method comparison with predicate device:* NA
- b. *Matrix comparison:* NA

3. Clinical studies:

- a. *Clinical sensitivity:* NA
- b. *Clinical specificity:* NA
- c. *Other clinical supportive data (when a and b are not applicable):* NA

4. Clinical cut-off: NA

5. Expected values/Reference range:

The assigned ranges for these controls are based upon replicate assays of representative samples of the product by participating laboratories in accordance with established protocol. All values have been assigned with instruments and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned ranges.

Expected values may vary slightly with different reagent and/or methodologies used. Refer to the included table for values obtained for specific systems. Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters.

M. Conclusion:

Based on the information provided, I recommend that the Quantimetrix Corporation GlycoHemosure HbA1c Control is substantially equivalent to the predicate device.