

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

A. 510(k) Number:

k052101

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for Glycoslyated hemoglobin (HbA1c)

D. Type of Test:

Not applicable - calibrator

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

C.f.a.s (Calibrator for Automated Systems) HbA1c

G. Regulatory Information:

1. Regulation section:

21 CFR §864.8165, Calibrator for hemoglobin or hematocrit measurement

2. Classification:

Class II

3. Product code:

KRZ

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Roche Diagnostics C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

3. Special conditions for use statement(s):

For Prescription use only.

4. Special instrument requirements:

Roche Cobas Integra 800

I. Device Description:

The Roche Diagnostic C.f.a.s HbA1c calibrator kit contains three vials of HbA1c calibrator. The vials contain freeze-dried (lyophilized) calibrator based on hemolyzed sheep blood. The concentration of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

Reactive components

Hemolyzed sheep blood, with chemical additives and material of biological origin as specified. The origin of the biological additives is as follows:

Analyte	Origin
Hemoglobin	Sheep blood
HbA1c	Human blood

Non-reactive components

Preservatives and stabilizers

The concentrations and activities of the calibrator components are lot-specific and specified in the labeling. The values are also encoded in the calibrator barcode sheets for COBAS INTEGRA analyzers. The calibrators 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.

J. Substantial Equivalence Information:1. Predicate device name(s):

Tina-Quant HbA1c reagent kit

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

k934070

3. Comparison with predicate:

The table below indicates the similarities and differences between the modified C.f.a.s. HbA1c and its predicate device Tina-Quant HbA1c test system (k934070)

Similarities		
Characteristic	New Device Roche C.f.a.s HbA1c (k052101)	Predicate Device Tina-Quant HbA1c (k934070)
Intended Use	C.f.a.s. HbA1c is for the use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet	Calibrator included in kit for calibration of the quantitative Tina-Quant HbA1c method.
Format	Lyophilized	Lyophilized
Matrix and Composition	Hemolysate derived from human and sheep blood; 0.9% TTAB (tetradecyl trimethylammonium bromide)	Hemolysate derived from human and sheep blood; 0.9% TTAB (tetradecyl trimethylammonium bromide)

Differences		
Item	New Device Roche C.f.a.s HbA1c (k052101)	Predicate Device Tina-Quant HbA1c (k934070)
Handling	Reconstituted with 2.0 mL distilled or deionized water.	Reconstituted with 1.0 mL distilled or deionized water.
Levels	Four levels	Single level
Stability	Unopened: stable up to the expiration date Reconstituted: 2 days @ 2-8° C 8 hours @ 15-25° C 3 months @ (-15 to -25) ° C	Unopened: stable up to the expiration date Reconstituted: 2 days @ 2-8° C 8 hours @ 20-25° C 3 months @ 20 ° C

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

FDA Guidance for Industry “Abbreviated 510(k) submissions for In Vitro Diagnostic Calibrators; Final”

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Deleted: See Traceability, Stability, Expected values (controls, calibrators, or methods) below.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable.

b. Linearity/assay reportable range:

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Not applicable.

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

Traceability: The sponsor states that the absolute Hemoglobin (Hb) values for the C.f.a.s. HbA1c are traceable to the CRM 522, through the use of the cyanomethemoglobin (CNMetHb) reference method. For more information see the following references:

- (1) International Committee for standardization in hematology expert panel on hemoglobinometry. Recommendations for reference method for hemoglobinometry in human blood and specifications for international haemoglobin cyanide reference preparation. Clinical & Laboratory Hematology, 9, 78-79, 1987.
- (2) Preparation and certification of a reference material of haemoglobin cyanide for standardization of blood hemoglobin measurement CRM 522; Report EUR 16101 EN European Commission bcr information reference material 1995.

The sponsor also states, that the absolute HbA1c values are traceable to the IFCC reference method through the use of the IFCC calibrator set “Los Angeles 2004”, Levels 1-8.

Value assignment – Hb values: The value assignment process for the Hb values was performed in five laboratories. Each laboratory conducted three independent runs where 30 whole blood samples were measured:

- in duplicate using CNMetHb reference method and
- in singleton using a commercially available method

Value assignment and transfer process - HbA1c values: Assigned values were verified using a commercially available assay against the IFCC Calibrator set (Levels 1-8) in five laboratories, with each lab performing three independent runs on Integra 800 analyzers.

Real-Time Shelf life stability was established by taking a set of stored calibrators (2-8° C) and assaying them after 12, 24, and 30 months. The acceptance criterion was established at $\pm 10\%$ of the initial assigned value.

Accelerated stability was established by taking C.f.a.s. HbA1c calibrator that was stored at 2-8° C and then stored for 5 days at 35° C. Five replicates of this on-test material was analyzed and compared to a reference material (fresh C.f.a.s. HbA1c). The average of the five replicates was calculated as a percentage of the reference value. The acceptance criterion is recovery of $\pm 10\%$ of the reference value.

Stability of reconstituted calibrator was established by reconstituting the C.f.a.s. calibrator according to package insert directions and then store a 30° C for 8 hours; at 4° C for 2 days; and at -20° C for 3 months. Five replicates of each on-test material were analyzed and compared to a reference material (freshly reconstituted C.f.a.s. HbA1c). The average of the five replicates was calculated as a percentage of the reference value. The acceptance criterion is recovery of $\pm 10\%$ of the reference value.

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):

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.