

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

A. 510(k) Number:

k103099

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for HbA1c

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

PreciControl HbA1c norm and PreciControl HbA1c path

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR 862.1660, single (specified) analyte controls (assayed and unassayed)	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

PreciControl HbA1c norm and path are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

COBAS INTEGRA and cobas c Systems analyzers: Integra 400, Integra 800, cobas c 111, c311, c501, and c 502.

I. Device Description:

PreciControl HbA1c is a quality control with two levels; one level represents HbA1c concentrations in the normal range and one in the pathological range. The two levels are sold separately as PreciControl HbA1c norm and PreciControl HbA1c path. They are liquid, ready-to-use, single-analyte controls based on hemolyzed human blood that contains the component HbA1c. Concentrations are batch-specific and adjustable to ensure that their levels fall in the appropriate ranges. The exact values are provided in the batch-specific value sheets. They are for use with COBAS INTEGRA and **cobas c** Systems analyzers.

Reagents – working solutions

Reactive components in the liquid controls:

Hemolyzed human blood, in vitro glycosylated HbA1c

The human blood products used in the manufacture of these quality control materials has been tested using FDA approved methods and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

J. Substantial Equivalence Information:

1. Predicate device name:

Roche Diagnostics HbA1c Control N and HbA1c Control P

Predicate 510(k) number(s):

k072714

2. Comparison with predicate:

Feature	Candidate Device: PreciControl HbA1c norm/PreciControl HbA1c path	Predicate Device: HbA1c Control N/HbA1c Control P
Intended Use/ Indications for Use	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.	Same
Format	Liquid	Lyophilized
Reagent Composition	<p><u>Matrix</u></p> <p>The controls are based on hemolyzed human blood.</p> <p><u>Components</u></p> <p>HbA1c is isolated from a normal patient population then glycated in vitro.</p>	<p><u>Matrix</u></p> <p>Same</p> <p><u>Components</u></p> <p>The glycated HbA1c is isolated from a diabetic patient population.</p>
Stability	<p><u>Unopened</u></p> <p>2-8°C until expiration</p> <p><u>Stability after opening</u></p> <p>2-8°C for 28 days</p> <p>(-15)-(-25)°C for 12 weeks (freeze only once)</p>	<p><u>Unopened</u></p> <p>Same</p> <p><u>Stability after reconstitution</u></p> <p>2-8°C for 4 weeks</p> <p>(-15)-(-25)°C for 3 months (only freeze once in aliquots of no less than 0.1 mL)</p>
Traceability	Traceable to IFCC standards	Same

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

None were 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):*

Traceability and Value Assignment:

The assigned values for PreciControl HbA1c norm and path are determined using the hemolysate and whole blood applications of the Roche Tinaquant Hemoglobin A1c Gen 2 and Gen 3 assays which are traceable to IFCC and transferrable to results traceable by calculation ($NGSP = [0.09148 * IFCC] + 2.152$) to DCCT/NGSP.

For lot-specific value assignment, each level of quality control is tested in singlicate in at least three separate runs on at least three separate master analyzers (Integra 800 and **cobas c** 501 analyzers). All master analyzers used in the value assignment process were calibrated using a master calibrator. The assigned target value of each control level is defined as the mean of all the runs for each assay and analyzer. The corresponding control range is calculated as the target value ± 3 standard deviations (with the standard deviation being the value obtained from several target value determinations).

Stability:

Closed Vial Stability (Real-time/ shelf-life stability)

Unopened vials of PreciControl norm and path stored at 2 to 8° C (test material) were tested against unopened vials of PreciControl norm and path stored at -80°C (reference material). Each material was tested in triplicate after timepoints of 0, 12, 18, 20, and 21 months. Percent recoveries at each timepoint were within 10% of the reference material concentration. The unopened control vials are stable until the stated expiration date (15 months) printed on the vials when stored at 2-8°C.

Opened Vial Stability

Opened and subsequently closed vials of PreciControl norm and path stored at 2-8°C and at -15°C to -25°C were tested against unopened vials of PreciControl norm and path stored at -80°C (reference material). Each material was tested in triplicate after timepoints stated in the stability protocol. Percent recoveries of each material was within 10% of the reference material concentration. Data supports the package insert's open vial stability claim of 28 days when stored at 2-8°C or 12 weeks at -15°C - (-25)°C (when frozen once).

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:

The expected values for each analyzer are presented in the labeling.

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.