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

A. 510(k) Number:

k051592

B. Purpose for Submission:

Addition of arterial blood as a sample type to previously cleared Accu-Chek Go System. No changes have been made to the Accu-Chek Go System meter.

C. Measurand:

Glucose

D. Type of Test:

Quantitative

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Accu-Chek Go test system

G. Regulatory Information:

1. Regulation section:

   862.1345 Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, LFR

4. Panel:

Clinical Chemistry -75

H. Intended Use:

1. Intended use(s):

   The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

   Professionals may use the test strips to test capillary, venous and arterial blood samples; lay use is limited to capillary whole blood testing.

2. Indication(s) for use:

   See Intended Use above

3. Special conditions for use statement(s):

   Over-the-counter and professional use

4. Special instrument requirements:

   Accu-Chek Go meter

I. Device Description:

The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood. The meter's software converts the test results into a value that correlates to the plasma glucose concentration. The test system retail package includes a meter, test strips, and control materials. A lancet device is provided within the kit as well.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Accu-Chek Go System

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

   k040796

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test principle	similar	similar
Reportable range	10-600 mg/dL	similar
Hematocrit range	25-65%	similar
Reagent composition for test strips	similar	similar

Differences		
Item	Device	Predicate
Intended Use	The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous and arterial blood samples; lay use is limited to capillary whole blood testing.	The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing.
Acceptable sample types	Capillary whole blood from a finger stick or AST site. Venous and arterial blood may also be used only if drawn from health care professionals.	Capillary whole blood from a finger stick or AST site. Venous blood may also be used only if drawn from health care professionals.

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

None referenced

L. Test Principle:

The test principle is a glucose dye oxidoreductase mediator reaction. In step one, glucose is oxidized by the Pyrroloquinoline quinine (PQQ) dependent enzyme glucoe-dye-oxidoreductase (EC.1.1.99.17) to gluconolactate and the reduction equivalents are transferred to the enzyme-bound PQQ to give $PQQH_2$. In step two, the enzyme transfers the reduction equivalents from $PQQH_2$ to the oxidized form of the mediator Bis-(2-hydroxyethyl)-(4-hydroxyiminocyclohexa-2,5-dienylidene)-ammonium chloride. In step three the reduced form of the mediator reduces the indicator 2,18-phosphomolybdic acid to produce the color heteropolyblue.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Previously established for predicate device

   b. *Linearity/assay reportable range:*

   Previously established for predicate device

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

   The hexokinase/glucose-6-phosphate dehydrogenase method used as the reference method for the arterial sample testing was credentialed by the National Reference System for the Clinical laboratory (NRSCL) Council on 18 January 1979 according to the criteria established for the acceptance of a reference method as explained in NRSCL13-P, The reference System for the Clinical Laboratory: Criteria for Development and credentialing of Methods and Materials for harmonization of results; Proposed Guideline.

   d. *Detection limit:*

   Previously established for predicate device

   e. *Analytical specificity:*

   Previously established for predicate device

   f. *Assay cut-off:*

   Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Previously established for predicate device

b. *Matrix comparison:*

In this submission, arterial blood was added as a sample type. A study was performed to evaluate the extent to which results obtained from the Accu-Chek Go system correlate to whole blood glucose reference that has been converted to a plasma-like result, using arterial whole blood. The clinical data demonstrates that the performance of the Accu-Chek Go correlates with the laboratory plasma glucose reference test method, glucose hexokinase.

In the study, arterial samples tested using the Accu-Chek Go meter were compared to results obtained from a reference method, the hexokinase/glucose-6-phosphate dehydrogenase method. The study utilized two external sites and four test strip lots. Arterial blood from 233 patients was transferred to lithium heparin tubes. The blood was then transferred directly to the test strips. The sample was also deproteinized and tested with the reference method. The following regression formula was obtained from the study: $y = 1.045x + 0.3$, $r = 0.992$. In addition, 98.3% of the results were within ± 15 mg/dL for results less than or equal to 100 mg/dL and ± 15 % for results greater than 100 mg/dL. This exceeds Roche's acceptance criteria that 95 % of the results be within this range.

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:

Expected values were previously established for the predicate device. The fasting adult blood glucose range for a non-diabetic is between 74 mg/dL and less than 106 mg/dL.

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.