K072714

APR 18 2008

510(k) Summary – Tina-Quant® Hemoglobin A1c Gen.2

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Tracy Bush

Date prepared: Oct 15, 2007

Submission Purpose and History

The Tina-Quant Hemoglobin A1c Gen.2 assay was originally cleared for use as K052464. The purpose of this submission is to modify the device by extending the labeled measuring range for the HbA1c portion of the %HbA1c measurement in the application for Integra 800 analyzers.

Since the clearance of K052464, a number of changes have taken place to the device, for which an additional filing was not deemed necessary. We hereby provide notification of these changes:

- Inclusion of additional anticoagulant type (potassium fluoride/ Na2-EDTA) in the Specimen Collection and Preparation section of the labeling (supported via internally documented data)

Device Name

Proprietary name: Tina-Quant® Hemoglobin A1c Gen.2 test

Common name: Hemoglobin A1c test

Classification name: Glycosylated hemoglobin assay

Device Description

With the Tina-Quant Hemoglobin A1c Gen.2 test system, the anticoagulated whole blood specimen is hemolyzed prior to determination of HbA1c by an turbidimetric inhibition immunoassay (TINIA). Liberated hemoglobin (Hb) in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum and measured bichromatically. The instrument calculates the % HbA1c from the HbA1c/ Hb ratio according to a user selected protocol.

Intended use

The Tina-Quant Hemoglobin A1c Gen.2 test is in vitro diagnostic reagent system intended for use on the COBAS INTEGRA 800 analyzers for the quantitative determination of percent hemoglobin A1c in hemolysate or whole blood. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Predicate Device

We claim substantial equivalence to the Tina-Quant ® Hemoglobin A1c Gen.2 cleared as K052464.

Substantial equivalency – Similarities

The table below indicates the similarities between the modified Tina-Quant ® Hemoglobin A1c Gen.2 test and its predicate device (original Tina-Quant ® Hemoglobin A1c Gen.2, K052464).

Feature	Predicate: Tina-Quant ® Hemoglobin A1c Gen.2 (K052464)	Modified device: Tina-Quant HbA1c Gen.2
General		
Intended Use/ Indications for Use	For the quantitative determination of percent hemoglobin A1c in whole blood (or hemolysate derived from whole blood) on COBAS Integra 800 anlayzers. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.	For the quantitative determination of percent hemoglobin A1c in whole blood (or hemolysate derived from whole blood) on Roche clinical chemistry analyzers.
Indications for Use	HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.	HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Specimen type	Anticoagulated venous or capillary blood. Acceptable anticoagulants in clude Li-heparin, K2-EDTA, K3-EDTA	Anticoagulated venous or capillary blood. Acceptable anticoagulants in clude Li-heparin, K2-EDTA, K3-EDTA and potassium fluoride/Na2-EDTA
Instrument platform	Integra 800 analyzer	Integra family including Integra 400/400 plus, 800, 800 CTS (Closed Tube Sampling), **cobas** c111; also **cobas** c501
Test principle		
Determination of HbA1c	Turbidimetric immunoinhibition (TINIA). Antigen-antibody complexes are formed and excess Ab aggregate with polyhapten to form insoluble complexes.	Same
Determination of Hb	Bichromatic photometric determination after conversion to a colored derivative. Hb is measured in same channel during preincubation phase of HbA1c determination (sample + R1).	Same.
Calculation of % HbA1c	% HbA1c is calculated automatically by instrument according to user-selected protocol	Same
Pretreatment	Two options for pretreatment: Hemolysate application: same (Manual pretreatment with hemolyzing reagent) Whole blood application: automated on-board sample pretreatment with hemolyzing reagent	Same
Reagent information		
Antibody	Polyclonal anti-HbA1c from sheep blood	Same.
Calibrator	Hemolysate derived from human blood and sheep blood; TTAB detergent; stabilizer.	Same
Quality control	Precinorm HbA1c Precipath HbA1c	Same
R1	Buffer: 25 mM MES/ 15 mM TRIS pH 6.2 Antibody; stabilizers	Same

R2	Buffer: 25 mM MES/15mM Tris, ph 6.2; Polyhapten modified with aminodextran AD500; concentration > 8ug/mL; Stabilizers	Same
Hemolyzing reagent	Different concentrations used Hemolysate application: Uses separate hemolyzing reagent with 20 mM EDTA Whole blood application: Uses Hemolyzing reagent Gen.2 – fourfold increase in concentration	Same
Reagent stability	2-8 °C until expiration date On-board: 28 days	Same
Performance characteristics (Integra)		
Precision	Whole blood application: Within run: 0.8 % @ 5.4% HbA1c 0.9% @ 10.2% HbA1c Between day: 1.3% @ 5.3% HbA1c 1.0% @ 10.3% HbA1c Hemolysate application Within run: 1.0 % @ 55% HbA1c 0.6% @ 10.6% HbA1c Between day: 1.0% @ 5.3% HbA1c 0.8% @ 10.7% HbA1c	Same
Lower detection limit	0.02 g/dL HbA1c 0.09 g/dL Hb	Same
Endogenous interferences	Whole blood application: No significant interference from: Icterus Lipemia: up to 800 mg/dL Intralipid Rheumatoid factor: up to 750 IU/mL Glycemia: up to 1000 mg/dL glucose	Same

Expected values	2.9-4.2% HbA1c Based on study done with IFCC standardization	Same
Specificity	No cross reaction with HbAo, HbA1a, HbA1b, acetylated hemoglobin, carbamylated hemoglobin, glycated albumin and labile HbA1c were found for the anti-HbA1c antibodies used in this kit. Specimens containing high amounts of HbF (>10%) may yield lower than expected HbA1c results.	Same

Substantial equivalency – Differences

The table below indicates the differences between the modified Tina-Quant ® Hemoglobin A1c Gen.2 test and its predicate device (original Tina-Quant ® Hemoglobin A1c Gen.2, K052464).

Feature	Predicate: Tina-Quant ® Hemoglobin A1c Gen.2 (K052464)	Modified device: Tina-Quant HbA1c Gen.2
General		
Specimen type	Anticoagulated venous or capillary blood. Acceptable anticoagulants in clude Li-heparin, K2-EDTA, K3-EDTA	Anticoagulated venous or capillary blood. Acceptable anticoagulants in clude Li-heparin, K2-EDTA, K3-EDTA and potassium fluoride/Na2-EDTA
Instrument platform	Integra 800 analyzer	Integra family including Integra 400/400 plus, 800, 800 CTS (Closed Tube Sampling), **cobas c**111; also **cobas c501**
Performance Characteristics (Integra)		
Measuring Range	0.3-2.6 g/dL HbA1c* 4-35 g/dL Hb *Based on concentration of the highest standard	Integra 400/400 plus: same Integra 800/ 800 CTS: 0.3 – 3.4 g/dL HbA1c 4-35 g/dL Hb

Endogenous interferences (whole blood application only)	Analyte recovery in presence of interfering agent. Tested for: • Lipemia (Intralipid) • Bilirubin (conjugated and unconjugated) • Rheumatoid Factor • Glucose	No significant interference (bias within ± 10%) up to: • 800 mg/dL Intralipd • 30 mg/dL Bilirubin/ ditaurobilirubin • 350 IU/mL RF • 1000 mg/dL Glucose
Anticoagulant	Testing of ≥ 50 paired samples (i.e. serum/plasma)	Both reagent-specific and general criteria apply (based on NGSP values) Reagent-specific criteria • Mean deviation of all samples: </= 0.2% HbA1c • Maximum deviation of single sample: </= 0.75% HbA1c General criteria for unlimited acceptance of anticoagulant type: • Median deviation of recovery against reference for all sample pairs </= 5% recovery • Maximum deviation of recovery of 80% of all sample pairs </= 10% recovery (up to 20% of samples can be within 10-15% recovery vs reference)
Specificity	Testing not required provided antibody does not change and reagent/sample ratio remains similar	Specificity claims transferred from predicate Tina-Quant HbA1c device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Theresa A. Bush, Ph.D.
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

APR 18 2008

Re: k072714
Trade/Device Name: Tina-Quant® Hemoglobin A1c Gen.2 Test System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay.
Regulatory Class: Class II
Product Code: LCP
Dated: March 19, 2008
Received: March 20, 2008

Dear Dr. Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Tina-Quant® Hemoglobin A1c Gen.2 Test System**

Indication For Use:

For the quantitative determination of percent hemoglobin A1c in whole blood (or hemolysate derived from whole blood) on Roche clinical chemistry analyzers.

HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072714