K113072



MAY 14 2012

# 510(k) Summary

**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.

**Submitter name, address, contact**

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Date Prepared: October 4, 2011

**Device Name**

Proprietary names: Tina-Quant Albumin Gen. 2

Common names: Albumin Gen. 2 – **cobas c** 311 urine assay

Regulation: 21 CFR 866.5040

Classification names: Albumin Immunological Test System

Product codes: DCF

**Device Description**

The Tina-quant Albumin Gen. 2 – **cobas c** 311 urine assay employs an immunoturbidimetric test in which anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination are determined turbidimetrically.

**Intended use**

Immunoturbidimetric assay for the quantitative, in vitro determination of albumin in human urine on the Roche/Hitachi **cobas c** 311 analyzers.

**Indications for Use**

The Tina-quant Albumin Gen. 2 – **cobas c** 311 urine assay is an immunoturbidimetric assay intended for the quantitative determination of albumin in urine on the Roche/Hitachi **cobas c** 311analyzers. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

**Substantial equivalence**

The Tina-quant Albumin Gen. 2 – **cobas** c 311 urine assay is substantially equivalent to the Tina-quant Albumin Gen.2 – **cobas c** 501 urine assay. The **cobas c** 501 Tina-quant Albumin Gen. 2 assay was cleared under K101203.

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**Substantial equivalence – comparison**

| Feature | Tina-quant Albumin Gen. 2 – cobas c 311 urine Assay | Tina-quant Albumin Gen. 2 – cobas c 501 urine Assay Predicate device – K101203 |
|---|---|---|
| Intended Use | For **cobas c** 311: In vitro test for the quantitative determination of albumin in human urine. | In vitro test for the quantitative determination of albumin in human urine, serum, plasma and CSF on Roche/Hitachi **cobas c** systems. |
| Assay Protocol | Immunoturbidimetric | Same |
| Sample Type | Urine | Same |
| Labeled Instrument Platform | Roche/Hitachi **cobas c** systems – **cobas c** 311 | Roche/Hitachi **cobas c** systems – **cobas c** 501 |
| Calibrator | C.f.a.s. PUC | Same |
| Calibration Frequency | - after reagent lot change<br>- as required following quality control procedures | Same |
| Controls | Urine<br>Precinorm PUC and Precipath PUC<br>In addition, other suitable control material can be used. | Same |
| Reagent Stability | On-board in use: 12 weeks at 2-8° C | Same |
| Measuring Range | 12-200 mg/L | 12-400 mg/L |

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|---|---|---|
| Precision | Repeatability (Within-run) (mg/L):<br>Mean = 32.0, SD = 0.2, CV = 0.7%<br>Mean = 101, SD = 1, CV = 1.2%<br>Mean = 10.7, SD = 0.2, CV = 2.2%<br>Mean = 132, SD = 2, CV = 1.9%<br><br>Intermediate Precision (Total) (mg/L):<br>Mean = 31.3, SD = 0.6, CV = 1.9%<br>Mean = 97.9, SD = 0.7, CV = 0.7%<br>Mean = 13.6, SD = 0.4, CV = 2.9%<br>Mean = 63.7, SD = 0.7, CV = 1.1% | Repeatability (Within-run) (mg/L):<br>Mean = 30.7, SD = 0.2, CV = 0.8%<br>Mean = 108, SD = 1, CV = 0.7%<br>Mean = 14.3, SD = 0.2, CV = 1.6%<br>Mean = 252, SD = 4, CV = 1.6%<br><br>Intermediate Precision (Total) (mg/L):<br>Mean = 31.2, SD = 0.5, CV = 1.7%<br>Mean = 105, SD = 1, CV = 1.2%<br>Mean = 13.6, SD = 0.4, CV = 2.8%<br>Mean = 60.6, SD = 1.4, CV = 2.3% |
| Analytical Sensitivity | Limit of Blank (LoB) =2 mg/L<br>Limit of Detection (LoD) =3 mg/L<br>Limit of Quantitation (LoQ) =12 mg/L | Same |
| Analytical Specificity | No interference was found at therapeutic concentrations using common drug panels.<br><br>High dose hook-effect: Using the prozone check, no false result without a flag was observed up to an albumin concentration of 40000 mg/L | Same |
| Interferences | Criterion: Recovery within ± 10%<br><br>Icterus: no significant interference up to a conjugated bilirubin concentration of 50 mg/dL.<br><br>Hemolysis: No significant interference up to a hemoglobin concentration of 400 mg/dL.<br><br>No interference by acetone ≤ 60 mmol/L, ammonia chloride ≤0.11 mol/L, calcium ≤40 mmol/L, Creatinine ≤0.18 mol/L, γ-globulin ≤500 mg/L, glucose ≤0.19 mol/L, urea ≤0.8 mol/L, uric acid ≤5.95 mmol/L and urobilinogen ≤378 µmol/L. | Same |

| | | |
|---|---|---|
| Expected Values | 2nd morning urine:<br>Adults:<br><20 mg albumin/g creatinine or <2.26 g albumin/mol creatinine<br><br>Children (3-5 years):<br><20 mg/L albumin<br><37 mg albumin/g creatinine<br><br>24 hour urine:<br><20 mg/L<br><30 mg/24 h | Same |
| Method Comparisons | A comparison of the Roche Tina-quant Albumin Gen. 2 assay on the **c** 501 analyzer (K101203) (x) with the Roche Tina-quant Albumin Gen. 2 assay on the c 311 analyzer (y) for human urine samples gave the following correlation:<br><br>Passing Bablock: $y = 1.036x + 0.415$ mg/L, $\tau = 0.972$<br>Linear Regression: $y = 1.038x - 1.066$ mg/L, $r = 0.999$<br><br>n = 69<br>Sample concentrations were between 13.0 and 189.6 mg/L | |

***End of Document***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Roche Diagnostics
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MAY 14 2012

Re: k113072
Trade Name: Tina-quant Albumin Gen.2
Regulation Number: 21 CFR §866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Codes: DCF
Dated: March 29, 2012
Received: April 2, 2012

Dear Mr. Stimart:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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 (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k113072

Device Name: Tina-quant Albumin Gen.2

Indications For Use:

The Tina-quant Albumin Gen.2 assay is an immunoturbidimetric assay intended for the quantitative determination of albumin in human urine on Roche/Hitachi cobas c systems. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

Prescription Use __X__ (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)

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

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