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

A. 510(k) Number:

k061683

B. Purpose for Submission:

New device

C. Measurand:

Myoglobin

D. Type of Test:

Quantitative, immunoturbidimetric assay

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

Tina-Quant Myoglobin Gen.2 Test System and C.f.a.s. (Calibrator for automated systems) Myoglobin

G. Regulatory Information:

Product Code	**Classification**	**Regulation Section**	**Panel**
Myoglobin, Antigen, Antiserum, Control (DDR)	Class II	21 CFR 866.5680, Myoglobin immunological test system.	82 Immunology(IM)
Product Code	**Classification**	**Regulation Section**	**Panel**
Calibrator (JIT)	Class II	21 CFR 862.1150 Secondary calibrator	75 Chemistry(CH)

H. Intended Use:

1. Intended use(s):

   The Tina-Quant ® Myoglobin Gen.2 Test System is an immunoturbidimetric assay for the quantitative *in vitro* determination of myoglobin in human serum and plasma on Roche Automated Clinical Chemistry analyzers. Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.

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

2. Indication(s) for use:

   See Intended use above

3. Special conditions for use statement(s):

   Prescription use only

4. Special instrument requirements:

   Roche/Hitachi 904, 911, 912, 917, Cobas c6000 series, Modular P analyzers, and Integra family analyzers

I. Device Description:

The Tina-Quant Myoglobin Gen.2 reagent consists of a dual chambered reagent pack containing two ready-to-use-liquid reagents. R1 consists of glycine buffer and R2 consists of latex particles coated with anti-human myoglobin antibodies.

The C.f.a.s. Myoglobin is a one level liquid prepared from bovine serum albumin. This calibrator is used to calibrate Roche clinical chemistry analyzers for the quantitative measurement of Myoglobin.

J. Substantial Equivalence Information:

The Tina-Quant Myoglobin Gen.2 test system is substantially equivalent to the currently marketed Tina-quant Myoglobin test system cleared under k972513. Similarities and differences between the new device and the predicate are presented in the table below.

Items	**Tina-quant Myoglobin Gen.2 test system (New device)**	**Tina-quant Myoglobin test system (Predicate device)**
Intended Use	For the quantitative in vitro determination of myoglobin in human serum and plasma on Roche automated clinical chemistry analyzers	For the quantitative in vitro determination of myoglobin in human serum and plasma using automated clinical chemistry analyzers
Indications for use	Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease	Same
Assay principle	Immunoturbidimetry	Same
Instrument	Will be applied to Hitachi family (including cobas c6000 series) and Integra family analyzers	Hitachi family of analyzers
Sample type	Serum or plasma with Li, Na heparin, or EDTA	Same
Calibrator	C.f.a.s. Myoglobin	Provided with kit
Calibrator composition	Human myoglobin in a bovine serum albumin matrix	Same
Calibrator configuration	Provided separately from kit	Provided with kit
Calibrator levels	One level	Four levels provided
Traceability/standardization	Standardized against a selected manufacturer's measurement procedure (immunological method). Results are corrected by + 8 µg/L to maintain traceability. Performance validated using this correction.	NIBSC (National Biological Standard Board) reagents
Controls	Myoglobin Control Set	Same
Measuring range	Hitachi 902:30-580 µg/L Other Hitachi: 20-580 µg/L, 20-5800 µg/L with extended measuring range	3-560 µg/L, 3-4500 µg/L with extended measuring range
Lower Detection Limit	Hitachi 902: < 20 µg/L Other Hitachi: <15 µg/L	3 µg/L
Reference interval	Men: 23-72 µg/L Women: 19-51 µg/L	Men: 23-72 µg/L Women: 19-51 µg/L

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

STANDARDS
Title and Reference Number
Use of Anticoagulants in Diagnostic Laboratory Investigations. (WHO/DIL/LAB/99.1 Rev.2 Jan 2002)
Other Standards
None

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
None			

L. Test Principle:

In this immunoturbidimetric method, latex–bound anti-myoglobin antibodies react with antigen in the sample to form an antigen/antibody complex which after agglutination can be determined turbidimetrically.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed by measuring human samples and controls on the Hitachi 917 analyzer. Samples were run in triplicate, one run per day, for 21 days. The following results were obtained:

	Within-run			Between-run		
Sample	Mean		CV	Mean		CV
	µg/L	nmol/L	%	µg/L	nmol/L	%
Human serum I	36.3	2.07	1.1	63.1	3.60	2.0
Human serum II	—	—	—	240	13.7	1.4
Control low	60.9	3.48	0.7	62.4	3.56	1.8
Control high	252	14.4	0.3	265	15.1	1.8
Control medium	129	7.37	0.7	—	—	—

b. Linearity/assay reportable range:

Three sets of dilution series (one fresh unspiked serum, two spiked sera) diluted with saline were measured on the Hitachi 917 analyzer. Each series was measured using three lots of reagent. The linearity data support a linear range of 20-580 µg/L for the Hitachi 917.

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

Traceability:

The C.f.a.s. Myoglobin values are traceable to an immunological method. Results are corrected by an additive factor (+8 µg/L) to maintain traceability. Performance was validated using this correction.

Stability:

A real-time stability study was performed on three lots of C.f.a.s. Myoglobin. Testing interval was done at 21, 23 or 24 months and the calibrator was stored at 2-8^{0}C. At the end of the storage period, the stored C.f.a.s. Myoglobin is compared to values originally obtained using the fresh reference material at the zero time-point. The recovery is calculated as a percentage of the reference value. The average percent recovery is 97%. The open-vial stability was done at 1,3,5,7 weeks interval with bottles opened and closed once a week; and for 1,2,4,6 hrs interval with calibrator opened on the instrument (Hitachi 911). At the end of the respective storage period, the stored controls are compared to the reference material (C.f.a.s. Myoglobin stored at 2-8^{0}C). All measurements were performed in triplicate and the recovery is calculated as a percentage of the reference value. The applicant's acceptance criterion is 90-110 % recovery compared to the reference value.

d. *Detection limit:*

20 µg/L

Limit of the blank was determined by running 21 replicates of the 0 calibrator on the Hitachi 917. The limit of the blank represents the lowest measurable myoglobin concentration that can be distinguished from zero. It is calculated as the concentration at three standard deviations above that of the lowest standard (0 µg/L).

e. *Analytical specificity:*

The anti-myoglobin antibody is specific for the myoglobin protein.

Interference and Limitations:

The applicant claims no significant interference up to	• I index of 60 (Conjugated and unconjugated bilirubin up to 60 mg/dL) • H index of 500 (Hemoglobin up to 500 mg/dL) • L index of 500 (Intralipid)

- Rheumatoid factors up to 100 IU/mL

The applicant claims no interference from 18 commonly used pharmaceuticals.

(All substances tested are defined by the applicant as no significant interference if the % recovery exceeded or equal to ± 10 % of the expected 100% recovery. For drugs interference, the applicant defined no significant interference if the % recovery exceeded or equal to ± 10 % of the expected 100% recovery from the reference value for the lower drug concentration tested.)

In rare cases gammopathy, in particular type IgM, may cause unreliable results.

A high-dose hook effect may occur at myoglobin concentrations >10,000 µg/L.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A comparison of the Myoglobin determination using serum on the Roche Tina-Quant Myoglobin Gen.2 assay (y) with the Roche Tina-Quant assay (x) using the Hitachi 917 gave the following correlation: y=1.014x + 3.4, r= 0.996, n=48; samples used ranged from 31.5 µg/L to 522.7 µg/L.

Another comparison study between the Roche Tina-Quant Myoglobin Gen.2 assay (y) with the Roche Elecsys Myoglobin STAT assay (x) gave the following correlation: y=0.924x + 4.5, r= 0.991, n=58; samples used ranged from 26.1 µg/L to 347 µg/L.

b. Matrix comparison:

The matrix studies were performed using the following reference: " Use of Anticoagulants in Diagnostic Laboratory Investigations".WHO/DIL/LAB/99.1 Rev.2 Jan 2002. Paired serum and plasma samples were collected and analyzed using the Hitachi 917 and results were evaluated by linear regression analysis. Additional sample type tested were Li or Na Heparin; K2- or K3-EDTA plasma. The samples used ranged from 23µg/L to 527µg/L All linear regression analysis of the sample types were considered acceptable by the applicant if the slope is 0.9 to 1.10; the intercept is < ± 10 µg/L; and the r

>0.98. All correlations met the applicant's stated criteria.

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):

None

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected values for Myoglobin are as follows: Men: 23-72 µg/L; Women: 19-51 µg/L. These data are from a multi-center evaluation using Tina-Quant Myoglobin (the predicate device). The applicant stated that because the predicate device and this device showed similar performance characteristics and met acceptance criteria for method comparison studies, this reference range can be applied to the Myoglobin Gen.2 Test System.

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.