K121610

510(k) Summary for cobas c 501 Tina-quant HbA1cDx Gen.3 Assay

AUG 8 2013

Introduction

Roche Diagnostics hereby submits this 510(k) to provide FDA with notification of intent to market the **cobas c** 501 Tina-quant HbA1cDx Gen.3 assay with a new intended use that includes the device as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk of developing diabetes. This submission presents data to support this new intended use.

Submitter

Susan Hollandbeck from Roche Diagnostics, U.S. Regulatory Affairs

Date prepared

The submission was originally prepared on May 31, 2012.

Device name

Proprietary name: **cobas c** 501 Tina-quant Hemoglobin A1cDx Gen.3 assay

Common names: HbA1cDx Gen.3 and TQ HbA1cDx Gen.3

Classification name: Hemoglobin A1c Test System

Product codes: PDJ

C.F.R. Section: 862.1373

Device description

Whole blood samples are placed on the analyzer. The anticoagulated whole blood is hemolyzed on board the analyzer prior to determination of HbA1c by this turbidimetric inhibition immunoassay. Liberated hemoglobin in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum and measured bichromatically. The instrument first measures hemoglobin (Hb) and glycohemoglobin (HbA1c) in terms of either g/dL or mmol/L, then calculates the % HbA1c from the HbA1c/Hb ratio according to a user-selected protocol, either IFCC or NGSP protocols.

Predicate device

The **cobas c** Tina-quant HbA1cDx Gen.3 assay is substantially equivalent to the COBAS INTEGRA 800 Tina-quant HbA1cDx Gen.2 assay that was cleared in 510(k) k121291.

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Intended use

This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. The **cobas c** 501Tina-quant HbA1cDx Gen.3 assay is an in vitro diagnostics reagent system intended for quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood on the Roche/Hitachi **cobas c** 501 clinical chemistry analyzer.

Comparison to predicate

The table compares the features of the candidate device, **cobas c** Tina-quant HbA1cDx Gen.3 assay, to the predicate device, COBAS INTEGRA 800 HbA1cDx Gen.2 that was cleared in 510(k) k121291.

Comparison Table

Feature	Candidate Device	Predicate Device
Sample Types	Anticoagulated venous or capillary blood Acceptable anticoagulants · Li-Heparin · K2-EDTA · K3-EDTA · KF/Na_2-EDTA · Na-Heparin · NaF/K-Oxalate · NaF/Na_2-EDTA	Same
Instrument Platform	**cobas c** 501	COBAS INTEGRA 800
Calibrator	C.f.a.s. HbA1c	Same
Calibration Frequency	Each lot, every 29 days, and as required following quality control procedures	Same
Calibration Mode	Hb determination uses a linear mode. HbA1c determination uses a spline mode.	Logit/Log 5
Controls	PreciControl HbA1c norm and path	Same

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Comparison to predicate (continued)

The table compares the features of the candidate device, **cobas c** Tina-quant HbA1cDx Gen.3 assay, to the predicate device, COBAS INTEGRA 800 HbA1cDx Gen.2 that was cleared in 510(k) k121291.

Comparison Table (continued)

Feature	Candidate Device	Predicate Device
Reporting Units	For the components, Hb and HbA1c: mmol/L and g/dL For the ratio: % HbA1c (DCCT/NGSP) and mmol/mol HbA1c (IFCC)	Components: g/dL Ratio: Same
Determination of HbA1c	HbA1c determination is based on the turbidimetric inhibition immunoassay for hemolyzed whole blood. Glycohemoglobin in the sample reacts with anti-HbA1c to form soluble antigen-antibody complexes. Polyhaptens react with excess anti-HbA1c to form an insoluble antibody-polyhapten complex which can be measured turbidimetrically.	Same
Determination of Hb	Liberated hemoglobin in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum which is measured bichromatically.	Same
Sample Pretreatment	Automated on-board sample pretreatment with hemolyzing reagent	Same
Measuring Range	**Hb** 2.48 – 24.8 mmol/L (4 - 40 g/dL) **HbA1c** 0.186 – 1.61 mmol/L (0.3 - 2.6 g/dL) **Ratio** 4.2 – 20.1 % HbA1c 23 – 196 mmol/mol HbA1c Note: This measuring range was established in 510(k) k102914 for the COBAS INTEGRA Tina-quant HbA1c Gen.3 assay.	**Hb** 4 - 35 g/dL **HbA1c** 0.3 - 3.4 g/dL **Ratio** 4.3 – 24.8 % HbA1c 23 – 258 mmol/mol HbA1c

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Comparison to predicate (continued)

The table compares the features of the candidate device, **cobas c** Tina-quant HbA1cDx Gen.3 assay, to the predicate device, COBAS INTEGRA 800 HbA1cDx Gen.2 that was cleared in 510(k) k121291.

Comparison Table (continued)

Feature	Candidate Device	Predicate Device
Antibody	Polyclonal anti-HbA1c from sheep blood	Same
Reagent Stability	**Unopened** 2-8 °C until expiration date on **cobas c** pack label **On-board in use** Refrigerated on the analyzer for 4 weeks	Same
Analytical Sensitivity	**Hb** LoB = 0.31 mmol/L (0.50 g/dL) LoD = 0.62 mmol/L (1.00 g/dL) **HbA1c** LoB = 0.12 mmol/L (0.19 g/dL) LoD = 0.18 mmol/L (0.29 g/dL)	**Hb** LoB = 0.50 g/dL LoD = 1.00 g/dL **HbA1c** LoB = 0.19 g/dL LoD = 0.29 g/dL
Analytical Specificity	**Hb fractions** At physiological concentrations, no cross reactions were found with · HbA0, · HbA1a, · HbA1b, · acetylated hemoglobin, · carbamylated hemoglobin, · glycated albumin, and · labile HbA1c. **Hb variants** This device has significant negative interference with samples containing elevated levels of HbF. The bias exceeds -7% when HbF content exceeds +7%. The negative bias with HbF is independent of % HbA1c, but is directly proportional in magnitude to the % HbF content. HbS, HbC, HbD, HbA2, and HbE do not significantly interfere.	Same Same

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Comparison to predicate (continued)

The table compares the features of the candidate device, **cobas c** Tina-quant HbA1cDx Gen.3 assay, to the predicate device, COBAS INTEGRA 800 HbA1cDx Gen.2 that was cleared in 510(k) k121291.

Comparison Table (continued)

Feature	Candidate Device	Predicate Device
Endogenous Interferences	**Icterus** No significant interference up to 60 mg/dL. **Lipemia** No significant interference up to an Intralipid concentration of 600 mg/dL. **Glycemia** No significant interference up to 1000 mg/dL. **Rheumatoid factors** No significant interference up to 750 IU/mL. **Total Protein** Up to 21 g/dL of additional protein spiked into the sample does not interfere. **Drugs** No interference was found at therapeutic concentrations using a common drug panel of 16 drugs.	**Icterus** Same **Lipemia** No significant interference up to an Intralipid concentration of 800 mg/dL. **Glycemia** Same **Rheumatoid factors** Same **Total Protein** Same **Drugs** Same
Expected Values	**Protocol 1 (IFCC)** 20 - 42 mmol/mol HbA1c **Protocol 2 (DCCT/NGSP)** 4.0 – 6.0 % HbA1c	Same

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Analytical performance The following discusses the precision of the device.

Precision

Precision was evaluated according to CLSI EP5-A2. It included evaluation of three reagent lots, three **cobas c** 501 analyzers, four native samples and two control samples, two aliquots per sample run in singlicate, two runs per day for 21 days. Results are in terms of % HbA1c.

c 501 - Analyzer 1 Precision

Mean	Repeatability		Between-run		Between-day		Between-lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Human Sample 1 (5.0 %HbA1c)	0.056	1.1	0.022	0.4	0.047	0.9	0.067	1.3	0.102	2.0
Human Sample 2 (6.4 %HbA1c)	0.062	1.0	0.035	0.5	0.051	0.8	0.095	1.5	0.129	2.0
Human Sample 3 (7.9 %HbA1c)	0.078	1.0	0.051	0.7	0.087	1.1	0.053	0.7	0.139	1.8
Human Sample 4 (11.3 %HbA1c)	0.116	1.0	0.000	0.0	0.084	0.7	0.239	2.1	0.278	2.5
PreciControl HbA1c norm (5.2 %HbA1c)	0.062	1.2	0.034	0.7	0.050	1.0	0.077	1.5	0.115	2.2
PreciControl HbA1c path (9.4 %HbA1c)	0.085	0.9	0.022	0.2	0.060	0.6	0.177	1.9	0.206	2.2

c 501 - Analyzer 2 Precision

Mean	Repeatability		Between-run		Between-day		Between-lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Human Sample 1 (5.1 %HbA1c)	0.054	1.1	0.051	1.0	0.024	0.5	0.028	0.5	0.083	1.6
Human Sample 2 (6.4 %HbA1c)	0.072	1.1	0.055	0.9	0.032	0.5	0.043	0.7	0.105	1.6
Human Sample 3 (8.1 %HbA1c)	0.081	1.0	0.060	0.7	0.083	1.0	0.021	0.3	0.133	1.6
Human Sample 4 (11.4 %HbA1c)	0.107	0.9	0.077	0.7	0.076	0.7	0.175	1.5	0.232	2.0
PreciControl HbA1c norm (5.2 %HbA1c)	0.065	1.2	0.054	1.0	0.014	0.3	0.029	0.6	0.090	1.7
PreciControl HbA1c path (9.6 %HbA1c)	0.096	1.0	0.047	0.5	0.038	0.4	0.078	0.8	0.138	1.4

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Analytical performance (continued) The following discusses the precision of the device.

Precision results are in terms of % HbA1c.

c 501 - Analyzer 3 Precision										
Mean	Repeatability		Between-run		Between-day		Between-lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Human Sample 1 (5.0 %HbA1c)	0.062	1.2	0.026	0.5	0.020	0.4	0.075	1.5	0.103	2.0
Human Sample 2 (6.4 %HbA1c)	0.076	1.2	0.021	0.3	0.034	0.5	0.037	0.6	0.094	1.5
Human Sample 3 (8.0 %HbA1c)	0.100	1.2	0.055	0.7	0.027	0.3	0.073	0.9	0.138	1.7
Human Sample 4 (11.3 %HbA1c)	0.112	1.0	0.097	0.9	0.040	0.4	0.036	0.3	0.157	1.4
PreciControl HbA1c norm (5.2 %HbA1c)	0.076	1.5	0.000	0.0	0.029	0.6	0.133	2.6	0.156	3.0
PreciControl HbA1c path (9.5 %HbA1c)	0.121	1.3	0.044	0.5	0.000	0.0	0.116	1.2	0.174	1.8

Reproducibility – Roche/Hitachi **cobas c** 501												
Mean	Repeatability		Between-run		Between-day		Between-lot		Between-instrument		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Human Sample 1 (5.1 %HbA1c)	0.058	1.1	0.036	0.7	0.032	0.6	0.060	1.2	0.000	0.0	0.096	1.9
Human Sample 2 (6.4 %HbA1c)	0.070	1.1	0.040	0.6	0.040	0.6	0.064	1.0	0.000	0.0	0.110	1.7
Human Sample 3 (8.0 %HbA1c)	0.087	1.1	0.056	0.7	0.071	0.9	0.053	0.7	0.100	1.3	0.169	2.1
Human Sample 4 (11.3 %HbA1c)	0.112	1.0	0.067	0.6	0.069	0.6	0.172	1.5	0.000	0.0	0.227	2.0
PreciControl HbA1c norm (5.2 %HbA1c)	0.068	1.3	0.035	0.7	0.034	0.7	0.090	1.7	0.000	0.0	0.123	2.4
PreciControl HbA1c path (9.5 %HbA1c)	0.102	1.1	0.039	0.4	0.040	0.4	0.130	1.4	0.079	0.8	0.192	2.0

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Analytical performance (continued)

The following discusses the method comparison and total error.

Method Comparison

A method comparison was performed to compare sample results from the candidate method using one reagent lot on one **cobas c** 501 analyzer to sample results from Tosoh HPLC, the secondary NGSP reference laboratory method. Samples were tested in singlicate and measured over three days. 141 variant-free samples ranged from 4.7 to 12.2% HbA1c. The distribution of samples tested appears below.

Sample Distribution

% HbA1c	# sample tested	% samples tested
< 5%	5	3.5%
5-6%	21	14.9%
6-6.5%	28	19.9%
6.5-7%	33	23.4%
7-8%	27	19.1%
8-9%	15	10.6%
> 9%	12	8.5%
Total	141	100%

Total Error

The bias component from the method comparison study and the precision component from the reproducibility study are used to calculate the total error at three concentrations near the cutoff.

Total Error

Decision Level (% HbA1c)	%Bias	%CV	%TE
5.2	-1.98%	2.07%	6.0%
6.5	-1.45%	1.7%	4.7%
8.0	-1.06%	2.1%	5.1%

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Analytical performance (continued) The following discusses the endogenous interference.

Endogenous Interference

Six endogenous substances were evaluated for potential interference of the assay. These substances were spiked into whole blood sample pools. A separate preparation occurred for each substance. Two HbA1c levels, one near the medical decision level and one above it, were tested for each endogenous substance. Thus twelve dilution series were created.

Each sample in each dilution series was tested ten-fold for % HbA1c on a single **cobas c** 501 analyzer, using a single reagent lot.

The median value for each set of ten was calculated. The reference sample is the sample Level 0 in the dilution series; it contains no interferent. The initial value is the measured result for the reference sample. The results for all remaining samples in the dilution series are compared to the initial value. This comparison is evaluated as a percent deviation. Interference is significant when it exceeds 7% deviation from the initial value.

Endogenous Interference Summary

endogenous substance	**range tested**	**highest level tested with no significant interference**
Lipemia (Intralipid)	0-2000 mg/dL	600 mg/dL
Unconjugated Bilirubin	0-66 mg/dL	60mg/dL
Conjugated Bilirubin	0-66 mg/dL	60 mg/dL
Glucose	0-2000 mg/dL	1000 mg/dL
Rheumatoid Factor	0-1200 IU/mL	750 IU/mL
Total Protein	0-24.5 g/dL	21 g/dL

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Analytical performance The following discusses the drug interference.
(continued)

Drug Interference

Sixteen drugs were evaluated for potential interference of the assay. These drugs were spiked into whole blood samples at two concentrations, Concentration 1 is ~5 times the maximum daily dose and Concentration 2 is the maximum daily dose. A separate preparation occurred for each drug. Two HbA1c levels, one near the medical decision level and one above it, were tested for each drug. Thus, 64 samples were prepared. Also, an HbA1c sample with no drug served at the reference sample.

Each sample was tested ten-fold for % HbA1c on a single **cobas c** 501 analyzer, using a single reagent lot.

The median value for each set of ten was calculated and compared to the initial value. Percent recovery was calculated. Interference is significant when it exceeds 7% deviation from the initial value. Results show that no significant interference was observed with the following drugs up to the stated concentrations.

Drug Interference Summary

drug	highest level tested with no significant interference
Acetylcystein	150 mg/dL
Ampicillin-Na	1000 mg/dL
Ascorbic acid	300 mg/dL
Cefoxitin	2500 mg/dL
Heparin	5000 U/L
Levodopa	20 mg/dL
Methyldopa	20 mg/dL
Metronidazole	200 mg/dL
Doxycyclin	50 mg/dL
Acetylsalicylic Acid	1000 mg/dL
Rifampicin	60 mg/L
Cyclosporine	5 mg/L
Acetaminophen	200 mg/L
Ibuprofen	500 mg/L
Theophylline	100 mg/L
Phenylbutazone	400 mg/L

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Analytical performance (continued)

The following discusses cross-reactivity with hemoglobin derivatives.

Cross-Reactivity with Hemoglobin Derivatives

Six hemoglobin derivatives were evaluated for potential interference of the assay. Two HbA1c levels, one near the medical decision level and one above it, were represented in whole blood sample pools. For each HbA1c level, two whole blood pools were prepared for each derivative, one with none and one with a high concentration of derivative. From the pools, a serial dilution was prepared to yield varying concentrations of the derivative for both HbA1c levels.

Each sample was tested ten-fold for % HbA1c on a single **cobas c** 501 analyzer, using a single reagent lot.

The median value for each set of ten was calculated. The reference sample is the sample Level 0 in the dilution series; it contains no interferent. The initial value is the measured result for the reference sample. The results for all remaining samples in the dilution series are compared to the initial value. This comparison is evaluated as a percent deviation. Interference is significant when it exceeds 7% deviation from the initial value.

Cross-Reactivity with Hemoglobin Derivatives Summary

endogenous substance	range tested	highest level tested with no significant interference
HbA0	0-120 g/dL	120 g/dL
HbA1a+b	0-0.64 g/dL	0.48 g/dL
Acetylated Hb	0-2.0 g/dL	2.0 g/dL
Carbamylated Hb	0-1.0 g/dL	1.0 g/dL
Labile HbA1c	0-100 mg/dL	100 mg/dL
Glycated Albumin	0-10 g/dL	10 g/dL

There is no significant cross-reactivity with these hemoglobin derivatives at physiologically occurring concentrations.

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Analytical performance (continued) The following discusses the interference with hemoglobin variants.

Hemoglobin Variants Interference

A hemoglobin variant interference study was performed using a total of 116 samples that contain one of six common hemoglobin variants. This table summarizes the sample profile.

Representation of Hemoglobin Variants

Hemoglobin	Quantity of Samples	Range of % Content of Variant	Range of Concentration in % HbA1c
S	20	31 – 42% S	4.60 – 13.0
C	19	33 – 44% C	4.68 – 13.0
E	20	27 – 33% E	5.00 - 9.68
D	20	34 – 42% D	4.79 – 9.78
F	20	2 – 28% F	5.83 – 10.1
A2	17	4 – 7% A2	4.90 - 8.56
Total	**116**		

Testing was performed on the candidate device and with an NGSP reference method that is known to be free from the hemoglobin interference being tested. This table categorizes results for the variants as they are impacted by % HbA1c concentration. The results reflect bias between actual sample results. Interference > 7% deviation from the reference method is significant.

Hemoglobin Variant Study Results Summary

	Percent Relative Bias from Reference Method at Low and High Concentrations of HbA1c Samples	
Hb Variant	6.0 % HbA1c	9.0 % HbA1c
C	-3.07	-0.35
S	2.17	3.42
E	-1.58	3.46
D	-2.30	3.35
A2	-5.73	-4.12
F	Bias exceeds -7% when HbF content exceeds + 7%.[1]	

[1] **A negative bias with HbF is independent of % HbA1c but is directly proportional in magnitude to the % HbF content.**

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Analytical performance (continued) The following discusses the lower limits of detection and linearity.

Lower Limits of Detection

LoB (Limit of Blank) and LoD (Limit of Detection) were determined according to CLSI EP17-A.

LoB was determined using one analyte-free sample tested in five replicates on two **cobas c** 501 analyzers. LoD was determined using five low-analyte samples tested in singlicate on two cobas c 501 analyzers. Both LoB and LoD were evaluated for Hb and HbA1c (g/dL). The tests were performed in two runs per day for three days per reagent batch with a total of three reagent batches.

LoB and LoD

	Hb (g/dL)		HbA1c (g/dL)	
Reagent Batch	LoB	LoD	LoB	LoD
1	0.0380	0.0948	0.0097	0.0239
2	0.0210	0.0594	0.0079	0.0197
3	0.0445	0.1133	0.0163	0.0315

Linearity

Linearity was performed according to CLSI EP6-A for this submission and for 510(k) k102914. For this submission, a dilution series was prepared using a high analyte concentration sample pool and an analyte-free pool. The pools were mixed in different ratios to yield a 20-level dilution series with varying concentrations of Hb and HbA1c. Values were measured in triplicate for each level. The median values were compared to the theoretical values and regressed.

The linearity results from this study and from the one included in 510(k) k102914 support the claimed reportable range.

Linearity Summary

	Unit of Measure	Linear Range
Glycohemoglobin	mmol/L HbA1c	0.186-1.61
	g/dL HbA1c	0.30-02.6
Hemoglobin	mmol/L Hb	2.48 – 24.8
	g/dL Hb	4-40
Ratio	% HbA1c (DCCT/NGSP)	4.2 – 20.1
	mmol/mol HbA1c (IFCC)	23 – 196

Conclusion- based on the performance characteristics stated above, this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 8, 2013

Roche Diagnostics
c/o Ms. Susan Hollandbeck
Regulatory Affairs Consultant
9115 Hague Road
INDIANAPOLIS IN 46256

Re: k121610
Trade/Device Name: cobas c 501 Tina-quant HbA1cDx Gen.3 Assay
Regulation Number: 21 CFR §862.1373
Regulation Name: Hemoglobin A1c Test System
Regulatory Class: Class II
Product Code: PDJ
Dated: July 26, 2013
Received: July 29, 2013

Dear Ms. Hollandbeck:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson -S for

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

Enclosure

Indications for Use

510(k) Number (if known): k121610

Device Name: **cobas c** 501 Tina-quant HbA1cDx Gen.3

Indications for Use:

This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. The **cobas c** 501 Tina-quant HbA1cDx Gen.3 assay is an in vitro diagnostics reagent system intended for quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood on the Roche/Hitachi **cobas c** 501 clinical chemistry analyzer.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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 Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k121610