510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k163633

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glycosylated hemoglobin (HbA1c)

D. Type of Test:

Latex agglutination inhibition

E. Applicant:

Roche Diagnostics Operations

F. Proprietary and Established Names:

cobas HbA1c Test

cobas b 101 system

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCP	Class II	21 CFR 864.7470 Glycosylated hemoglobin assay	Hematology (81)
JJE	Class I	21 CFR 862.2160 Discrete photometric chemistry analyzer	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Cobas HbA1c Test: The cobas HbA1c Test is an in vitro diagnostic test designed to quantitatively determine glycated hemoglobin (HbA1c) in capillary finger-stick or venous whole blood, collected in EDTA (K_2 or K_3) or lithium heparin tubes, on the cobas b 101 instrument. This test is intended for professional use in a clinical laboratory setting or point-of-care (PoC) locations. This test is not for screening or diagnosis of diabetes or neonatal use. Measurement of hemoglobin A1c is used to monitor long term blood glucose control in patients previously diagnosed with diabetes.

   Cobas 101 system: The cobas b 101 instrument is a multi-assay system designed to quantitatively analyze cobas reagent discs. The system is intended for professional, in vitro diagnostic use in a clinical laboratory setting or point-of-care (PoC) locations.

3. Special conditions for use statement(s):

   - This test is not for screening or diagnosis of diabetes or neonatal use
   - For clinical laboratory and point-of care use
   - Use fresh whole blood only. Do not use plasma and serum.
   - For prescription use only
   - The test is not intended for judging day-to-day glucose control and should not be used to replace daily home testing of urine or blood glucose.
   - This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, homozygous sickle cell trait, pregnancy and significant acute or chronic blood loss
   - Glycated HbF is not detected by this assay as it does not contain the glycated beta-chain that characterize HbA1c, However, HbF levels (>10%) may result in lower than expected %HbA1c values (DCCT/NGSP).

4. Special instrument requirements:

   cobas b 101 system

I. Device Description:

The cobas HbA1c test is an in vitro diagnostic test designed to measure glycated hemoglobin (HbA1c) in capillary or venous whole blood samples on the cobas b 101 instrument. The cobas b 101 system is a bench top analyzer which measures HbA1c. The system is fully automated, self-contained and utilizes a single use reagent disc. The operator applies sample to the disc and places the disc in the instrument. The disc is self-filling by capillary forces. At completion of the test, the instrument displays a quantitative result.

The cobas HbA1c Test contains 10 tests. Each test contains:

- Dilution buffer: TRIS (hydroxymethylaminomethane)
- Erythrocyte Hemolysis: Sodium Lauryl Sulfate

- Sodium Chloride
- Denaturation: Potassium ferricyanide, sucrose laurate
- HbA1c antibody‑Latex conjugate
- Agglutination: Glycopeptide‑globulin conjugate

The cobas HbA1c Control a ready to use solution based on hemolyzed human blood. The control is used for monitoring accuracy and precision of the cobas HbA1c Test. The adjusted concentrations of the control components are in the normal range (Level 1) and in the pathological range (Level 2).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens DCA Vantage

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

   k071466

3. Comparison with predicate:

Similarities / Differences		
Item	Candidate Device cobas b 101 system/cobas HbA1c Test k163633	Predicate Device Siemens DCA Vantage k071466
Intended Use	Quantitative determination of glycated hemoglobin (HbA1c) in human whole blood samples to monitor long term blood glucose control.	Same
Methodology	Latex agglutination - inhibition immunoassay	Monoclonal antibody agglutination
Sample Type	Whole blood: capillary and venous	Same
Sample Anticoagulant	EDTA(K_2 or K_3), lithium heparin	EDTA, heparin, fluoride/oxalate, citrate
Detection Method	Photometry	Same
Sample Type	Whole blood: capillary and venous	Same
Calibration method	Calibration information read from each reagent disc	Calibration read from a calibration card for each reagent lot
Traceability/Standardization	IFCC, NGSP	Same
Sample volume	2µL	1 µL
Sample Total Hemoglobin Range	6-20 g/dL	7-24 g/dL

Similarities / Differences		
Item	Candidate Device cobas b 101 system/cobas HbA1c Test k163633	Predicate Device Siemens DCA Vantage k071466
Sample Application	Sample collected directly to the disc or by transfer of sample using pipette or dropper.	Sample collected in capillary holder. Holder inserted into cartridge.
Application Test Time	<6 minutes	6.5 minutes
Reagent stability	16 months at 2-30 °C (36-86 °F)	3 months at room temperature
Measuring range	4-12% HbA1c	2.5-14% HbA1c
Test Platform	Single use	Same
Operating Temperature	15-32 °C (59-90 °F)	15-32 °C (61-88 °F)

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

CLSI EP05-A3- Evaluation of Precision of Quantitative Procedures; Approved Guideline

CLSI EP06-A- Evaluation of the Linearity of Quantitative Measurement Procedure: A statistical Approach; Approved Guideline

CLSI EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition

CLSI EP9-A3 – Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline

CLSI EP25A-Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

IEC 62304:2006 Medical device software - Software life cycle processes

IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements

IEC 60601-1-2 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests

L. Test Principle:

The device is based on a latex agglutination inhibition immunoassay. The blood sample is diluted and mixed with TRIS buffer to release hemoglobin from the erythrocytes. A fraction of the sample is conveyed into a reaction chamber where it is mixed with sodium lauryl sulfate (SLS). SLS is used to form the SLS‑hemoglobin complex. The concentration of total

hemoglobin is calculated by measuring SLS‑hemoglobin complex with a wavelength of 525 nm. Hemoglobin A1c (HbA1c) in another fraction of the sample is first denaturated by potassium ferricyanide and sucrose laurate. The denatured HbA1c bonds with HbA1c antibody on the latex particle. Latex agglutination inhibition reaction then occurs by reacting the agglutinator that has synthetic antigen which can bond with HbA1c antibody. The concentration of HbA1c is calculated by measuring the latex agglutination inhibition reaction with a wavelength of 625 nm. The % hemoglobin A1c value is measured using a ratio of concentrations of HbA1c to total hemoglobin.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

An internal precision study was performed according to CLSI EP05-A3 on one cobas b 101 instrument with two cobas HbA1c Test disc lots and one cobas HbA1c Control lot. Two control samples and nine K_2-EDTA venous whole blood samples were measured over 21 days. The protocol consisted of measuring the sample material in duplicate in two runs per day for 21 days producing n=84 results per sample. Samples and runs were randomized each day.

NGSP units (%HbA1c):

			Repeatability		**Between run**		**Between day**		**Total**	
Sample	N	Mean (%)	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Sample 1	84	5.2	0.14	2.8	0.00	0.0	0.04	0.8	0.15	2.9
Sample 2	84	5.5	0.10	1.8	0.03	0.6	0.05	1.0	0.12	2.1
Sample 3	84	7.8	0.13	1.7	0.00	0.0	0.04	0.5	0.14	1.7
Sample 4	84	10.3	0.11	1.1	0.00	0.0	0.06	0.5	0.13	1.2
Sample 5	84	5.0	0.08	1.7	0.00	0.0	0.05	1.0	0.10	2.0
Sample 6	84	5.6	0.07	1.2	0.02	0.3	0.04	0.7	0.08	1.5
Sample 7	84	6.9	0.11	1.6	0.00	0.0	0.05	0.8	0.12	1.8
Sample 8	84	8.2	0.10	1.2	0.02	0.3	0.03	0.4	0.11	1.3
HbA1c Control Level 1	84	5.1	0.08	1.7	0.02	0.4	0.05	0.9	0.10	1.9
HbA1c Control Level 2	84	9.3	0.10	1.0	0.04	0.5	0.13	1.3	0.16	1.8

An external precision study was performed according to CLSI EP05-A3 at three point-of-care (POC) sites. At each site, the samples were measured in duplicate two times per day for 21 days for a total of n = 168 measurements. Six cobas b 101 instruments with three reagent disc lots were used in the study. Each POC site assessed two reagent disc lots on two cobas b 101 instruments. Three lots of controls and five human sample pools were tested. Control Level 1 target range was 4.1 – 6.5 and Control Level 2 target range was 7.9-12.1. The five EDTA (K_3) venous whole blood samples expected target concentrations were WB ~ 5.0, WB1 ~ 5.7, WB3 ~ 8.0 and WBP ~ 12.0. The results are summarized in the tables below.

NGSP units (%HbA1c):

				Repeatability		**Between run**		**Between day**		**Total**	
Sample	Site	N	Mean (%)	SD	% CV	SD	% CV	SD	% CV	SD	% CV
WB	Site 1	168	5.3	0.06	1.2	0.04	0.9	0.04	0.7	0.09	1.6
	Site 2	168	5.2	0.07	1.4	0.00	0.0	0.05	0.9	0.09	1.7
	Site 3	168	5.1	0.08	1.5	0.03	0.6	0.02	0.3	0.09	1.7
	Combined	504	5.2	0.07	1.4	0.03	0.6	0.06	1.1	0.10	1.9
WB 1	Site 1	168	5.4	0.07	1.3	0.03	0.5	0.06	1.2	0.10	1.8
	Site 2	168	5.3	0.07	1.3	0.04	0.8	0.03	0.6	0.09	1.6
	Site 3	168	5.3	0.08	1.5	0.03	0.7	0.02	0.4	0.09	1.7
	Combined	504	5.3	0.07	1.4	0.04	0.7	0.06	1.1	0.10	1.9
WB 3	Site 1	168	8.0	0.13	1.6	0.13	1.6	0.00	0.0	0.18	2.3
	Site 2	168	7.9	0.10	1.3	0.04	0.5	0.06	0.7	0.12	1.5
	Site 3	168	8.0	0.24	3.0	0.08	1.0	0.16	2.0	0.30	3.8
	Combined	504	8.0	0.17	2.1	0.09	1.1	0.11	1.3	0.22	2.7
WBP	Site 1	168	10.9	0.11	1.0	0.01	0.1	0.04	0.3	0.11	1.0
	Site 2	168	10.8	0.13	1.2	0.08	0.8	0.00	0.0	0.16	1.4
	Site 3	168	10.8	0.12	1.1	0.02	0.2	0.06	0.5	0.13	1.2
	Combined	504	10.8	0.12	1.1	0.05	0.5	0.06	0.6	0.14	1.3
HbA1c Control Level 1	Site 1	168	5.2	0.10	2.0	0.09	1.8	0.17	3.2	0.22	4.2
	Site 2	168	5.1	0.09	1.8	0.05	1.0	0.17	3.4	0.20	4.0
	Site 3	168	5.2	0.13	2.5	0.00	0.0	0.07	1.3	0.14	2.8
	Combined	504	5.2	0.11	2.1	0.06	1.1	0.14	2.8	0.19	3.7
HbA1c Control Level 2	Site 1	168	10.2	0.17	1.7	0.13	1.2	0.26	2.6	0.34	3.3
	Site 2	168	10.1	0.14	1.4	0.19	1.9	0.14	1.4	0.27	2.7
	Site 3	168	9.9	0.15	1.6	0.08	0.8	0.18	1.8	0.25	2.5
	Combined	504	10.1	0.16	1.5	0.14	1.4	0.23	2.3	0.31	3.1

b. *Linearity/assay reportable range:*

The linearity study was evaluated according to CLSI-EP06-A. Linearity was verified on the cobas b 101 System using 11 dilutions of a low (3.6 % HbA1c) and high (12.9 % HbA1c) K_2-EDTA whole blood sample. Single measurements on three instruments were performed for every dilution level. The following sample concentrations were tested: 3.6, 4.8, 6.2, 7.2, 8.2, 9.0, 9.7, 10.7, 11.4, 12.1, and 12.9% HbA1c. The linearity regression results are in the table below:

NGSP units (%HbA1c):

Slope	Intercept	Pearson's R	Claimed Measuring Range
0.996	-0.014	0.9961	4 – 12% HbA1c

The linearity results support the sponsor's claims that the assay is linear across the reportable measuring range of 4 to 12% HbA1c.

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

Traceability

The cobas HbA1c Test has been standardized against the approved IFCC reference method for the measurement of hemoglobin A1c in human blood. The cobas b 101 instrument reports values in % hemoglobin A1c traceable to DCCT/NGSP by calculation. The cobas b 101 is certified with the National Glycohemoglobin Standardization Program (NGSP). The certification expires in one year. See NGSP website for current certification at http://www.ngsp.org.

Stability

The shelf life, out-of-pouch and disc warm up stability study protocols and acceptance criteria for the cobas b 101 HbA1c test system were reviewed and found to be acceptable to support the sponsor's following claims:

Shelf life 2-30 °C (36-86 °F) for 16 months

Out-of-pouch use disc within 20 minutes after the pouch is opened.

Disc warm up if the pouch is stored in a refrigerator, remove the pouch but do not open for at least 20 minutes.

d. *Detection limit:*

Please see linearity study above in M1b.

e. Analytical specificity:

Endogenous Interference

The effect on quantitation of HbA1c in the presence of endogenous interfering substances was determined on the cobas b 101 system using the cobas HbA1c Test. The interference study was performed according to CLSI guideline EP07-A2. The sample pool material was K_2-EDTA venous whole blood with a concentration of 4.9-5.5 % HbA1c and 8.6-9.2 % HbA1c.

To achieve the target high concentration interferent pool (high sample pool); pooled whole blood was spiked with the interferent. Another pool (low sample pool), without interferent, was created by dilution of the pooled whole blood with the same volume of diluent as the high sample pool. This pool contains no interferent and serves as the reference pool for the testing. The high and low sample pools were mixed in different ratios to yield a dilution series with varying concentrations of the interferent. The sponsor defined non-significant interference as <±10% deviation compared to the result of the reference pool. The table below summarizes the results and claims for the endogenous substances.

Endogenous Substance	**Highest Level Tested with no Significant Interference**	**Labeling Claim: no significant interference up to**
Conjugated Bilirubin	85 mg/dL	60 mg/dL
Unconjugated Bilirubin	85 mg/dL	60 mg/dL
Lipemia / Intralipid	750 mg/dL	500 mg/dL
Glucose	2800 mg/dL	2000 mg/dL
Rheumatoid Factor (RF)	1200 IU/mL	750 Iu/mL
Lipemia / NativeTriglyceride	694 mg/dL	500 mg/dL
Total Protein	126 g/L	120g/L
Albumin	77.5g/L	60g/L

Exogenous Interference

The effect on quantitation of HbA1c in the presence of exogenous interfering substances was determined on the cobas b 101 system with the cobas HbA1c Test. The interference study was performed according to CLSI guideline EP07-A2. For each substance, a separate stock solution containing the potentially interfering drug was prepared. All pools were prepared using K_2-EDTA venous whole blood with a concentration of 5.1-5.4 % HbA1c and 8.3-9.1 % HbA1c. To achieve the target concentration drug pool, pooled whole blood was spiked with the drug. Another pool, without drug, was created by dilution of the pooled whole blood with the same volume of diluent as the high concentration drug pool. This pool contains no drug and serves as the reference pool for the testing. Each sample was tested in 5 replicates and the mean value used for the assessment. No interference was found at therapeutic

concentrations using common drug panels.

Drug	Highest concentration tested with no significant interference
Acetyl Cysteine	166 mg/dL
Ampicillin-Na	100mg/dL
Ascorbic acid	30 mg/dL
Cyclosporine	0.5 mg/dL
Cefoxitin	250mg/dL
Heparin	5000 U/L
Levodopa	2 mg/dL
Methyldopa +1,5	2 mg/dL
Metronidazole	20 mg/dL
Phenylbutazone	40 mg/dL
Doxycycline	5 mg/dL
Acetylsalycilic acid	100 mg/dL
Rifampicin	6 mg/dL
Acetaminophen	20 mg/dL
Ibuprofen	50 mg/dL
Theophylline	10 mg/dL

Cross-Reactivity

The effect on quantitation of HbA1c in the presence of potential cross-reactants was determined on the cobas b 101 system with the cobas HbA1c Test. The study was performed according to CLSI guideline EP07-A2. Sample pool material was K_2-EDTA venous whole blood with a concentration of 4.9-5.5 %HbA1c and 8.0- 8.5 % HbA1c.

Labile A1c interference:

To prepare the high sample pool, pooled whole blood was spiked with glucose. The low sample pool, without glucose, was created by dilution of the pooled whole blood with the same volume of diluent as the high sample pool. This pool contains no cross-reactant and serves as the reference pool for the testing. The high and low sample pools were mixed in different ratios to yield a 3 level dilution series with the following concentrations: 1000, 2000 and 3000 mg/dL. Each dilution level was tested in singlicate on three cobas b 101 instruments. The sponsor defined non-significant interference as $\leq \pm$ 10% deviation compared to the result of the reference pool. The study supports the sponsor's claim of no labile A1c cross-reactivity found up to 3000 mg/dL.

Carbamylated hemoglobin interference:
To prepare the high sample pool, pooled whole blood was spiked with the cross-reactant Sodium Cyanate. The low sample pool, without Sodium Cyanate, was created by dilution of the pooled whole blood with the same volume of diluent as the high sample pool. This pool contains no cross-reactant and serves as the reference pool for the testing. The high and low sample pools were mixed in different ratios to yield a three level dilution series with the following concentrations: 1000, 2000 and 3000 mg/dL. Each dilution level was tested in singlicate on three cobas b 101 instruments. The sponsor defined non-significant interference as ≤ ± 10% deviation compared to the result of the reference pool. The results support the sponsor's claim no carbamylated hemoglobin cross-reactivity was found up to 3000 mg/dL.

Acetylated hemoglobin interference:

To prepare the high sample pool, pooled whole blood was spiked with Acetylsalicylic Acid. The low sample pool, without Acetylsalicylic Acid, was created by dilution of the pooled whole blood with the same volume of diluent as the high sample pool. This pool contains no cross-reactant and serves as the reference pool for the testing. The high and low sample pools were mixed in different ratios to yield a three level dilution series with the following concentrations: 1000, 2000 and 3000 mg/dL. Each dilution level was tested in singlicate on three cobas b 101 instruments. The sponsor defined non-significant interference as ≤ ± 10% deviation compared to the result of the reference pool. The results support the sponsor's claim no acetylated hemoglobin cross-reactivity was found up to 3000 mg/dL.

Hemoglobin variant interference

Hemoglobin variant testing was conducted to determine if there is any significant interference with the major hemoglobin variants and the cobas HbA1c Test.

The study was performed using a total of 130 whole blood samples (HbS n=20, HbC n=20, HbD n=20, HbE n=20, elevated HbF n=20, and elevated HbA2 n=10). Each sample was tested once in one run on one cobas b 101 instrument. Results obtained were compared to those obtained with a comparator method shown to be free of interference from the hemoglobin variant tested (Tina-quant HbA1c Gen.3 (k121610) on cobas 501 for HbS, HbC, HbD, HbE, and HbA2; Tosoh G8 (k071132) for HbF).

Mean relative bias against the comparator method was calculated separately for each variant type. The sponsor defines no significant interference as the % recovery as ≤ ±10% deviation from the comparator method at 6% and 9% HbA1c.

The labeling contains the following limitation: Heterozygous presence of the most common hemoglobin variants (HbS, HbC, HbD, HbE, and Hb2) does not interfere. Testing results indicate that there is no significant interference for HbS (≤41%), HbC (36%), HbD (42%), HbE (27%) and HbA2 (6.2%).

Glycated HbF is not detected by the assay as it does not contain the glycated beta-chain that characterizes HbA1c. However, HbF is measured in the total Hb assay and as a consequence, specimens containing high amounts of HbF (> 10 %) may result in lower than expected % HbA1c values (DCCT/NGSP)

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison of the cobas b 101 HbA1c assay was performed according to CLSI EP09-A3 at three POC sites. Capillary finger-stick whole blood and venous whole blood (K_2-EDTA and Li-Heparin) from prospective blood sampling (n=379)) were measured on the cobas b 101 in singlicate and compared to matched venous K_2-EDTA whole blood measured on the Tosoh G8 HPLC Analyzer at a NGSP secondary reference laboratory. For capillary finger-stick whole blood, the range tested was 4.3-11.6 % HbA1c. For K_2-EDTA venous whole blood, the range tested was 4.4-12.9% HbA1c. For lithium heparin whole blood, the range tested was 4.3-11.6 % HbA1c. Each site utilized three cobas b 101 instruments with four study operators at each site. Each site received a different lot of the cobas b 101 HbA1c reagent disc. Passing-Bablok regression analysis results in NGSP units (%HbA1c) are listed in the tables below.

Capillary Fingerstick

Site	N	Regression Line	Pearson's r
1	125	y = 1.00x – 0.10	0.99
2	133	y = 1.00x – 0.10	0.99
3	121	y = 1.00x – 0.20	0.99

K_2-EDTA

Site	N	Regression Line	Pearson's r
1	125	y = 1.00x – 0.20	0.99
2	133	y = 1.00x – 0.20	0.99
3	121	y = 0.97x – 0.04	0.99

Lithium Heparin

Site	N	Regression Line	Pearson's r
1	125	y = 1.00x – 0.20	0.99
2	130	y = 1.00x – 0.20	0.99
3	117	y = 1.00x – 0.20	0.99

b. Matrix comparison:

A matrix study was performed using 91 matched K2-EDTA venous whole blood (reference) and K_3-EDTA venous whole blood samples ranging from 4.3 to 11.8% HbA1c. Samples were collected and tested in singlicate with one reagent lot on the cobas b 101 system. No samples were contrived. The Passing Bablok regression results are shown in the table below:

NGSP units (%HbA1c):

N	Regression Line	Pearson's r
91	y = 1.03x – 0.00	0.99

Capillary finger-stick whole blood, venous whole blood, collected in EDTA (K_2 or K_3) and lithium heparin have been shown to be acceptable for use with the cobas b 101 system.

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The sponsor states the following in the labeling:
In 2016, the American Diabetes Association (ADA) recommended a reasonable A1c goal for many non-pregnant adults is < 7 % (53 mmol/mol). Providers might reasonably suggest more stringent A1C goals (such as 6.5 % [48 mmol/mol]) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, type 2 diabetes treated with lifestyle or metformin only, long life expectancy, or no significant cardiovascular disease. Less stringent A1C goals (such as 8 % [64 mmol/mol]) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications,

extensive comorbid conditions, or longstanding diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin.

Reference:
American Diabetes Association. Standards of Medical Care in Diabetes-2016. Diabetes Care. 2016 Jan; 39 Suppl. 1: S1-S112.

N. Instrument Name:

cobas b 101 system

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes __X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___ _____ or No ____X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   A barcode reader or keyboard may be used to enter patient information. Results are displayed on the screen and can be printed out by using an optional external printer.

4. Specimen Sampling and Handling:

   Sample is applied directly from the fingerstick or via a pipette when testing venous whole blood. The operator applies sample to the disc and places the disc in the instrument. There are no pre-analytics needed as the disc is self-filling by capillary forces.

5. Calibration:

   Calibration information is contained on each disc and is specific to each lot of reagent. The instrument automatically reads in the lot-specific calibration data from the barcode information printed on the cobas HbA1c Test disc. There is no calibration needed by the user. The calibration is traceable to the International Federation of Clinical Chemistry (IFCC) and the device is certified with the NGSP standardization program.

6. Quality Control:

   Two levels of controls are provided which are below and above the respective thresholds. Controls are used to check the system performance. The controls are liquid ready to use and include a dropper for easy application of the control liquid to the disc. The HbA1c control is a whole blood based matrix. Target ranges will be assigned per each control lot and checked with each disc lot. The mean value shall meet a defined target range to reflect a normal or pathologic value respectively based on cut-off points which are recommended e.g. by American Diabetes Association (ADA).

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Postmarket information for this device and device type was considered during the review of this submission.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.