Section III: 510(k) Summary

K 111188

510(k) Summary

MAY 14 2012

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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Device name

Proprietary Name:

(1) **cobas® b** 123 POC System
(2) **cobas® b** 123 AutoQC Pack Tri-Level
(3) **cobas® b** 123 AutoCVC Pack
(4) Roche COMBITROL PLUS B

Common Name:

(1) Blood gas analyzer
(2) AutoQC Pack Tri-Level
(3) AutoCVC Pack
(4) COMBITROL PLUS B

Analyte	Classification Name	Regulation Section	Product Code
PCO_2, PO_2, pH	Blood gases (PCO2, PO2) and blood pH test system	21 CFR § 862.1120	CHL
Na^+ (sodium)	Sodium test system	21 CFR § 862.1665	JGS
K^+ (potassium)	Potassium test system	21 CFR § 862.1600	CEM
Ca^{2+} (Calcium)	Calcium test system	21 CFR § 862.1145	JFP
Hct (Hematocrit)	Automated hematocrit instrument	21 CFR § 864.5600	GKF
Glucose	Glucose test system	21 CFR § 862.1345	CGA
Lactate	Lactic acid test system	21 CFR § 862.1450	KHP
tHb	Whole blood hemoglobin assays (tHb)	21 CFR § 864.7500	KHG
O_2Hb	Whole blood hemoglobin assays (Oxyhemoglobin)	21 CFR § 864.7500	GGZ
HHb	Deoxyhemoglobin	21 CFR § 864.7500	GKA
MetHb	Methemoglobin	21 CFR § 864.5620	KHG
SO_2	Oxygen Saturation	870.1230 Oximeter	GLY
COHb (carboxyhemoglobin)	Carboxyhemoglobin assay	21 CFR § 864.7425	GHS
cobas b 123 AutoQC Pack Tri-Level **cobas b** 123 AutoCVC Pack Roche COMBITROL PLUS B	Quality control material (assayed and unassayed)	21 CFR § 862.1660	JJY

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Device description

(1) **cobas b** 123 POC System:

The **cobas b** 123 POC system consists of a modular analyzer incorporating a Linux-based graphical user interface with a large color touch screen interfacing the analyzer electronic, sensor, fluidic and AutoQC modules. The user interface module contains the analyzer CPU and all required electronic interfaces for external communication, data storage and data transfer.

A single electrochemical sensor system independent of the reagent delivery system that utilizes Roche thick film technology consolidates the following analytes:

- pCO_2, pH, calcium, potassium and sodium (potentiometric measurement)
- pO_2 (amperometric measurement)
- Hct (conductivity measurement)
- Glucose and Lactate enzyme reaction (amperometric measurement)

An optionally integrated oximeter module consisting of a spectrometer, measurement and calibration light source, respectively, an ultrasonic hemolyzer and thermostatic components measure SO_2, tHb, O_2Hb, HHb, COHb, and MetHb.

A disposable, self-contained sample and reagent delivery system contains:

- Liquid reagents, calibrators and waste container, stable for 42 days on-board
- Built-in safety shielded sample port
- Built-in oximeter cuvette
- Two peristaltic pump fluidics system
- Built-in air filter

The system also includes an optional integrated AutoQC module which utilizes a disposable cassette containing three levels of quality control material.

A smart memory chip is incorporated into each biosensor, reagent pack (sample and reagent delivery system) and AutoQC cassette providing the lot number, expiration date and value assignments (for QC and CVC materials). The chip also tracks and monitors sensor, reagent pack, AutoQC and AutoCVC cassette usage.

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(assayed and unassayed) (continued)

(2) **cobas b** 123 AutoQC Pack Tri-Level:

The **cobas b** 123 AutoQC pack Tri-Level contains 24 single glass ampoules of multi-analyte controls in 3 levels:

Level 1: representing concentrations of a patient's respiratory acidosis as given by low pH and high PCO_2 values, low PO_2, low values for Na^+, K^+, and tHb, normal values for glucose and high values for Hct, iCa^{2+} and lactate.

Level 2: representing concentrations of normal values for all parameters except glucose, which is low.

Level 3: representing concentrations of a patient's respiratory alkalosis as given by high pH and low PCO_2 values, high PO_2, high values for Na^+, K^+, tHb, and glucose, and low values for Hct, iCa^{2+} and lactate.

(3) **cobas® b** 123 AutoCVC Pack:

The **cobas b** 123 AutoCVC pack contains 24 single glass ampoules of multi-analyte controls in 6 levels covering the range of instrument performance. The CVC materials are an aqueous-based solution of salts, organic and carbonate buffers and metabolites equilibrated with predetermined levels of oxygen, carbon dioxide, nitrogen and dyes.

(4) Roche COMBITROL PLUS B:

COMBITROL PLUS B multi-analyte controls are available in 3 levels:

Level 1: representing concentrations of a patient's respiratory acidosis as given by low pH and high PCO_2 values, low PO_2, low values for Na^+, K^+, and tHb, normal values for glucose and high values for Hct, iCa^{2+}, urea/BUN and lactate.

Level 2: representing concentrations of normal values for all parameters except glucose, which is low.

Level 3: representing concentrations of a patient's respiratory alkalosis as given by high pH and low PCO_2 values, high PO_2, high values for Na^+, K^+, tHb, and glucose, and low values for Hct, iCa^{2+}, lactate and urea/BUN.

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Intended use

(1) **cobas b** 123 POC System:

The **cobas b** 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (BG), electrolytes Na^+, K^+, iCa^{2+} (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), and oxygen saturation (SO_2). In addition, the **cobas b** 123 POC system calculates derived parameters.

It is dedicated for use in a Point-of-Care environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option.

Depending on the equipment configuration of the instrument, the Sensor Cartridge and the Fluid Pack used, the following parameters are measured in human whole blood and QC materials (Table 1):

Table 1. Versions of the cobas b 123 POC System

Instrument Version	Measured Parameters	Optional Modules
cobas b 123 <1> System	pH, BG (pO_2, pCO_2), ISE (Na^+, K^+, Ca^{2+}), Hct, Glu, Lac	N/A
cobas b 123 <2> System	pH, BG (pO_2, pCO_2), ISE (Na^+, K^+, Ca^{2+}), Hct, Glu, Lac	AutoQC Module
cobas b 123 <3> System	pH, BG (pO_2, pCO_2), ISE (Na^+, K^+, Ca^{2+}), Hct, Glu, Lac, tHb, O_2Hb, HHb, COHb, MetHb, SO_2	Oximeter Module
cobas b 123 <4> System	pH, BG (pO_2, pCO_2), ISE (Na^+, K^+, Ca^{2+}), Hct, Glu, Lac, tHb, O_2Hb, HHb, COHb, MetHb, SO_2	AutoQC Module and Oximeter Module

(2) **cobas b** 123 AutoQC Pack Tri-Level:

The **cobas b** 123 AutoQC pack Tri-Level is a multi-analyte control intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.

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Intended use (continued)

(3) **cobas® b** 123 AutoCVC Pack:

The **cobas b** 123 AutoCVC pack is a multi-analyte control, intended for use in calibration verification of the measuring range established by the **cobas b** 123 POC system for pH, PCO_2, PO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.

(4) Roche COMBITROL PLUS B:

COMBITROL PLUS B is a multi-analyte control intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose, lactate, urea/BUN and bilirubin on Roche OMNI S or **cobas b** 221 analyzers with an oximeter module, and **cobas b** 123 analyzers (except urea/BUN, chloride, and bilirubin). COMBITROL PLUS B control material is not intended for use with analyzers from other manufacturers.

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Predicate devices

The **cobas b** 123 POC System is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the following currently marketed products:

- **cobas b** 221 (OMNI S) Blood Gas System—K032311
- Hitachi 902 Analyzer (Glucose and Lactate)—K921661
- **cobas c** 501 Analyzer (Glucose and Lactate)—K060373/A001
- COMBITROL PLUS B / AUTOTROL PLUS B—K032453

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Substantial equivalence

The **cobas b** 123 POC System is substantially equivalent to other devices legally marketed in the United States.

The **cobas b** 123 POC System is substantially equivalent to the **cobas b** 221 (OMNI S Analyzer), cleared on K032311, for the following parameters:

- pH
- pO_2
- pCO_2
- Na^+
- K^+
- iCa^{2+}
- Hct[1]
- tHb
- O_2Hb
- HHb
- COHb
- MetHb
- SO_2

The **cobas b** 123 POC system is substantially equivalent to the Roche Gluco-Quant Glucose/HK assay on the Hitachi 902 (K921661) and the Roche Glucose HK Assay on the **cobas c** 501 analyzer (K060373/A001) for the measurement of glucose.

The **cobas b** 123 POC system is substantially equivalent to the Roche Lactate assay on the Hitachi 902 analyzer (K921661) and the Lactate Generation 2 (Gen.2) assay on the **cobas c** 501 analyzer (K060373/A001) for the measurement of lactate. Per 21 CFR 862.1450, a Lactic Acid Test System is exempt to measure lactic acid in whole blood and plasma.

The **cobas b** 123 AutoQC Pack Tri-Level, **cobas b** 123 AutoCVC Pack, and COMBITROL PLUS B materials are substantially equivalent to the Roche AUTOTROL PLUS B and Roche COMBITROL PLUS B materials cleared on K032453.

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[1] Hematocrit measurements on the **cobas b** 123 POC system were also compared to the hemofuge, which represents the gold standard (reference) method for measurement of hematocrit in blood. This analysis was performed as part of the non-clinical (internal) method comparison study and the results may be located in Section IV (Volume 2) of this Premarket Notification 510(k) submission. Hct measurements on the **cobas b** 123 POC System were compared against the predicate device, **cobas b** 221, as part of the clinical (external) study; the results may be located in Section V (Volume 3).

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Substantial equivalence comparison—similarities

Table 2 provides the similarities between the **cobas b** 123 POC System (K111188) and the **cobas b** 221 predicate device (K032311).

Table 2. Comparison of Candidate (cobas b 123) and Predicate (cobas b 221) Devices—Similarities

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device cobas b 221 (K032311)
Intended Use	The **cobas b** 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (BG), electrolytes Na^+, K^+, iCa^{2+} (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), and oxygen saturation (SO_2). In addition, the **cobas b** 123 POC system calculates derived parameters. It is dedicated for use in a Point-of-Care environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option. Depending on the equipment configuration of the instrument, the Sensor Cartridge and the Fluid Pack used, the following parameters are measured in human whole blood and QC materials. See Table 1 (page 5).	Same
Blood Gas Measurement	pH and pCO_2 by potentiometry pO_2 by amperometry	Same
Electrolyte Measurement	K^+, Na^+, iCa^{2+} by potentiometry	Same
Metabolite Measurement	Glucose and Lactate by amperometry	Same

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Substantial equivalence comparison—similarities (continued)

Table 2 provides the similarities between the **cobas b** 123 POC System (K111188) and the **cobas b** 221 predicate device (K032311).

Table 2. Comparison of Candidate (cobas b 123) and Predicate (cobas b 221) Devices—Similarities, cont.

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device cobas b 221 (K032311)
Hemoglobin Measurement	tHb, SO_2, O_2Hb, HHb, COHb, MetHb: Spectrophotometric	Same
Hematocrit Measurement	Conductivity	Same
Sensor Technology	Amperometric and potentiometric thick film microelectrode array technology for Glucose and Lactate	Same
Sample Introduction	Syringe and capillary aspiration	Same
On-Board (In-Use) Reagent Stability	Up to 42 days	Same
Reagent Tracking	Memory chip technology for identification, lot specifications, usage tracking and traceability allowing pack to be moved from one system to another	Same
QC Material	COMBITROL PLUS B (manual QC) and AUTOTROL PLUS B (automated QC)	Same
Calibration	Two-point liquid calibration	Same
Graphical User Interface	Menu-driven touch screen	Same
Additional Analyzer Hardware	Hard drive and printer	Same
Operating System Software	Linux-based	Same
System Operating Temperature	15-32°C	Same

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Substantial equivalence comparison—similarities (continued)

Table 3 provides the similarities between the **cobas b** 123 POC System (K111188) and the following predicate devices:

- Roche Glucose HK Assays (K921661 and K060703/A001)
- Roche Lactate Assays (K921661 and K060703/A001)

Table 3. Comparison of Candidate and Predicate Devices for Glucose and Lactate Measurement—Similarities

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device Roche Hitachi Glucose HK Assays: Hitachi 902 (K921661) and cobas c 501 (K060373/A001)
Test Principle	Enzymatic	Same
Characteristic	**Candidate Device cobas b 123 POC System (K111188)**	**Predicate Device Roche Hitachi Lactate Assays: Hitachi 902 (K921661) and cobas c 501 (K060373/A001)**
Sample Type	Whole blood	Same
Test Principle	Enzymatic	Same

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Substantial equivalence comparison—similarities (continued)

Table 4 provides the similarities between the **cobas b** 123 AutoQC Pack Tri-Level quality control materials (K111188) and the predicate device, Roche AUTOTROL PLUS B (K032453).

Table 4. Comparison of Candidate and Predicate Devices (AutoQC Materials)—Similarities

Characteristic	Candidate Device cobas b 123 AutoQC Pack Tri-Level (K111188)	Predicate Device Roche AUTOTROL PLUS B (K032453)
Number of Levels	3	Same
Matrix	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Same
Technological Characteristics	The material consists of buffered aqueous electrolyte solutions with clinically relevant concentrations of the targeted analytes, tonometered with precision gas mixtures of carbon dioxide and oxygen to achieve pH and blood gas values that span the range of values typical for such products with the same intended use. A mixture of dyes is used to simulate absorbance of hemoglobin derivatives. Hematocrit is simulated by conductivity.	Same

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Substantial equivalence comparison—similarities (continued)

Table 5 provides the similarities between the modified Roche COMBITROL PLUS B quality control material (K111188) and the predicate device, Roche COMBITROL PLUS B (K032453).

Table 5. Comparison of Candidate and Predicate Devices (COMBITROL PLUS B)—Similarities

Characteristic	Candidate Device Modified COMBITROL PLUS B (K111188)	Predicate Device Roche COMBITROL PLUS B (K032453)
Number of Levels	3	Same
Fill Volume	1.7 mL	Same
Matrix	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Same
Technological Characteristics	The material consists of buffered aqueous electrolyte solutions with clinically relevant concentrations of the targeted analytes, tonometered with precision gas mixtures of carbon dioxide and oxygen to achieve pH and blood gas values that span the range of values typical for such products with the same intended use. A mixture of dyes is used to simulate absorbance of hemoglobin derivatives. Hematocrit is simulated by conductivity.	Same

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Substantial equivalence comparison—similarities (continued)

Table 6 provides the similarities between the **cobas b** 123 AutoCVC Pack (K111188) and the predicate device, Roche AUTOTROL PLUS B (K032453).

Table 6. Comparison of Candidate and Predicate Devices (CVC Materials)—Similarities

Characteristic	Candidate Device cobas b 123 AutoCVC Pack (K111188)	Predicate Device Roche AUTOTROL PLUS B (K032453)
Matrix	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Same.
Technological Characteristics	The material consists of buffered aqueous electrolyte solutions with clinically relevant concentrations of the targeted analytes, tonometered with precision gas mixtures of carbon dioxide and oxygen to achieve pH and blood gas values that span the range of values typical for such products with the same intended use. A mixture of dyes is used to simulate absorbance of hemoglobin derivatives. Hematocrit is simulated by conductivity.	Same

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Substantial equivalence comparison—differences

Table 7 provides the differences between the **cobas b** 123 POC System (K111188) and the **cobas b** 221 predicate device (K032311).

Table 7. Comparison of Candidate (cobas b 123) and Predicate (cobas b 221) Devices—Differences

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device cobas b 221 (K032311)
Sample Volume	123 µl	210 µl
Electrochemical sensors	pH, PO_2, PCO_2, K^+, Na^+, iCa^{2+}, Glucose, Reference microelectrode array sensor with up to 28 days in-use life **Note:** Sensors with Lactate are stable up to 21 days.	pH, PO_2, PCO_2, K^+, Na^+, Cl^-, iCa^{2+} Reference electrodes with 6 to 16 months in-use life, depending on the electrode type.
Electrochemical sensor storage stability	Sensor: 2°C – 8°C for 4 months	Sensor: 25°C for 18 or 24 months, depending on electrode type
Auto QC Module	AutoQC Module holds one AutoQC Pack, which is comprised of 24 AUTOTROL PLUS B tri-level ampoules.	QC module holds 120 AUTOTROL PLUS B tri-level ampoules.

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Substantial equivalence comparison—differences (continued)

Table 8 provides the differences between the **cobas b** 123 POC System (K111188) and the Roche Glucose HK Assay predicate devices (K921661 and K060703/A001).

Table 8. Comparison of Candidate and Predicate Devices for Glucose Measurement—Differences

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device Roche Hitachi Glucose HK Assays: Hitachi 902 (K921661) and cobas c 501 (K060373/A001)
Intended Use	The **cobas b** 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (BG), electrolytes Na^+, K^+, iCa^{2+} (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), and oxygen saturation (SO_2). In addition, the **cobas b** 123 POC system calculates derived parameters. It is dedicated for use in a Point-of-Care environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option. Depending on the equipment configuration of the instrument, the Sensor Cartridge and the Fluid Pack used, the following parameters are measured in human whole blood and QC materials. See Table 1 (page 5).	Gluco-quant Glucose/HK Assay (Hitachi 902): Enzymatic in vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF on Roche automated clinical chemistry analyzers. Glucose HK Assay (**cobas c** 501): In vitro test for the quantitative determination of glucose in human serum, plasma, urine, CSF and hemolysate on Roche/Hitachi **cobas c** systems.
Sample Type	Whole Blood	Serum, plasma, urine, CSF and hemolysate

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Substantial equivalence comparison—differences (continued)

Table 8 provides the differences between the **cobas b** 123 POC System (K111188) and the Roche Glucose HK Assay predicate devices (K921661 and K060703/A001).

Table 8. Comparison of Candidate and Predicate Devices for Glucose Measurement—Differences, cont.

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device Roche Hitachi Glucose HK Assays: Hitachi 902 (K921661) and cobas c 501 (K060373/A001)
Measurement Principle	Amperometric measurement of the detectable product (H_2O_2) under a polarization voltage of 350 mV.	UV photometric measurement of the detectable product (NADPH) at 340 nm.

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510(k) Summary, Continued

Substantial equivalence comparison—differences (continued)

Table 9 provides the differences between the **cobas b** 123 POC System (K111188) and the Roche Lactate Assay predicate devices (K921661 and K060703/A001).

Table 9. Comparison of Candidate and Predicate Devices for Lactate Measurement—Differences

Characteristic	Candidate Device cobas b 123 POC System (K111188)	Predicate Device Roche Hitachi Lactate Assays: Hitachi 902 (K921661) and cobas c 501 (K060373/A001)
Intended Use	The **cobas b** 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (BG), electrolytes Na^+, K^+, iCa^{2+} (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), and oxygen saturation (SO_2). In addition, the **cobas b** 123 POC system calculates derived parameters. It is dedicated for use in a Point-of-Care environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option. Depending on the equipment configuration of the instrument, the Sensor Cartridge and the Fluid Pack used, the following parameters are measured in human whole blood and QC materials. See Table 1 (page 5).	Lactate Assay (Hitachi 902): For the quantitative determination of L-Lactate in plasma, cerebrospinal fluid or whole blood on Roche/Hitachi automated clinical chemistry analyzers. L-Lactate levels that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis. Lactate Gen. 2 Assay (**cobas c** 501): In vitro test for the quantitative determination of lactate in human plasma and CSF on Roche/Hitachi **cobas c** systems.
Measurement Principle	Amperometric measurement of the detectable product (H_2O_2) under a polarization voltage of 350 mV.	UV photometric measurement of the detectable product (chromogen) at 340 nm.

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Substantial equivalence comparison—differences (continued)

Table 10 provides the differences between the **cobas b** 123 AutoQC Pack Tri-Level quality control materials (K111188) and the predicate device, Roche AUTOTROL PLUS B (K032453).

Table 10. Comparison of Candidate and Predicate Devices (AutoQC Materials)—Differences

Characteristic	Candidate Device cobas b 123 AutoQC Pack Tri-Level (K111188)	Predicate Device Roche AUTOTROL PLUS B (K032453)
Intended Use	The **cobas b** 123 AutoQC pack Tri-Level is a multi-analyte control intended for use as control material to monitor the measurement of pH, pCO_2, pO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.	AUTOTROL PLUS B, a Multi-analyte control, is intended for use as a control material to monitor the measurement of pH, pCO_2, pO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as Glucose, Lactate, Urea/BUN and Bilirubin on Roche OMNI S and **cobas b** 221 analyzers with an oximeter module. This control material is packaged for use with the AutoQC module, an option to the Roche OMNI S and **cobas b** 221 analyzers. AUTO-TROL PLUS B control material is not intended to be used with analyzers from other manufacturers.
Auto QC Pack	The AutoQC Pack is comprised of 24 AUTOTROL PLUS B tri-level ampoules. The AutoQC Pack also contains a smart memory chip for tracking and traceability, allowing the pack to be moved from one system to another.	The QC Pack holds 120 AUTOTROL PLUS B tri-level ampoules. The QC Pack does not contain a smart memory chip.
Fill Volume	1.0 mL	1.7 mL

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510(k) Summary, Continued

Substantial equivalence comparison—differences (continued)

Table 11 provides the differences between the modified Roche COMBITROL PLUS B quality control material (K111188) and the predicate device, Roche COMBITROL PLUS B (K032453).

Table 11. Comparison of Candidate and Predicate Devices (COMBITROL PLUS B)—Differences

Characteristic	Candidate Device Modified COMBITROL PLUS B (K111188)	Predicate Device Roche COMBITROL PLUS B (K032453)
Intended Use	COMBITROL PLUS B is a multi-analyte control intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose, lactate, urea/BUN and bilirubin on Roche OMNI S or **cobas b** 221 analyzers with an oximeter module, and **cobas b** 123 analyzers (except urea/BUN, chloride, and bilirubin). COMBITROL PLUS B control material is not intended for use with analyzers from other manufacturers.	COMBITROL PLUS B, a Multi-analyte control, is intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose, lactate, urea/BUN and bilirubin on Roche OMNI S or **cobas b** 221 analyzers with an oximeter module.. COMBITROL PLUS B control material is not intended for use with analyzers from other manufacturers.

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510(k) Summary, Continued

Substantial equivalence comparison—differences (continued)

Table 12 provides the differences between the **cobas b** 123 AutoCVC Pack (K111188) and the predicate device, Roche AUTOTROL PLUS B (K032453).

Table 12. Comparison of Candidate and Predicate Devices (CVC Materials)—Differences

Characteristic	Candidate Device cobas b 123 AutoCVC Pack (K111188)	Predicate Device Roche AUTOTROL PLUS B (K032453)
Intended Use	The **cobas b** 123 AutoCVC pack is a multi-analyte control, intended for use in calibration verification of the measuring range established by the **cobas b** 123 POC system for pH, PCO_2, PO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.	AUTOTROL PLUS B, a Multi-analyte control, is intended for use as a control material to monitor the measurement of pH, pCO_2, pO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as Glucose, Lactate, Urea/BUN and Bilirubin on Roche OMNI S and **cobas b** 221 analyzers with an oximeter module. This control material is packaged for use with the AutoQC module, an option to the Roche OMNI S and **cobas b** 221 analyzers. AUTOTROL PLUS B control material is not intended to be used with analyzers from other manufacturers.
Indications for Use	The cobas b 123 AutoCVC Pack is an assayed control for use in calibration verification of the measuring range established by the **cobas b** 123 POC system for analytes listed in the package insert.	COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.
Fill Volume	1.0 mL	1.7 mL

Conclusion

The information provided in this Premarket Notification [510(k)] will support a determination of substantial equivalence for the **cobas b** 123 POC System.

End of document

Roche Diagnostics Corporation
c/o Sarah Baumann
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MAY 14 2012

Re: k111188
Trade Name: Cobas® b 123 POC System, Cobas® b 123 AutoQC Pack Tri-Level
Cobas® b 123 AutoCVC Pack, Roche COMBITROL PLUS B
Regulation Number:21 CFR §862.1120
Regulation Name: Blood gases (PC02, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, GKF, CGA, KHP, KHG, GGZ, GKA, GLY, GHS, JJY
Dated May 9, 2012
Received: May 10, 2012

Dear Ms. Baumann:

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 Form

510(k) Number (if known): K111188

Device Name: cobas® b 123 POC System

Indications for Use:

The **cobas b** 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (BG), electrolytes Na^+, K^+, iCa^{2+} (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), and oxygen saturation (SO_2). In addition, the **cobas b** 123 POC system calculates derived parameters.

It is dedicated for use in a Point-of-Care environment and laboratory. The integrated AutoQC module and the oximeter module are available as an option.

pH, pO_2 and pCO_2 : pH, pO_2 and pCO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium (Na^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Potassium (K^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Calcium (Ca^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) K111188

Indications for Use Form

510(k) Number (if known): K111188

Device Name: cobas® b 123 POC System

Indications for Use, continued:

Hematocrit (Hct): hematocrit measurements are used to distinguish normal from abnormal states of whole blood, such as anemia and erythrocytosis (an increase in the number of red cells).

Glucose (Glu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (Lac): Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (tHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

O_2Hb: oxyhemoglobin as a fraction of total hemoglobin.

COHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

MetHb: methemoglobin as a fraction of total hemoglobin.

HHb: reduced hemoglobin as a fraction of total hemoglobin.

SO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K111188

Indications for Use Form

510(k) Number (if known): K111188

Device Name: cobas® b 123 AutoQC Pack Tri-Level

Indications for Use:

The **cobas b** 123 AutoQC pack Tri-Level is a multi-analyte control intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.

Device Name: cobas® b 123 AutoCVC Pack

Indications for Use:

The **cobas b** 123 AutoCVC Pack is a multi-analyte control, intended for use in calibration verification of the measuring range established by the **cobas b** 123 POC system for pH, PCO_2, PO_2, SO_2, Na^+, K^+, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose and lactate on **cobas b** 123 systems with an AutoQC module.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Evaluation and Safety

510(k) K111188

Indications for Use Form

510(k) Number (if known): K111188

Device Name: Roche COMBITROL PLUS B

Indications for Use:

COMBITROL PLUS B is a multi-analyte control intended for use as control material to monitor the measurement of pH, PCO_2, PO_2, SO_2, Na^+, K^+, Cl^-, iCa^{2+}, Hct, tHb and Hb derivatives as well as glucose, lactate, urea/BUN and bilirubin on Roche OMNI S or **cobas b** 221 analyzers with an oximeter module, and **cobas b** 123 analyzers (except urea/BUN, chloride, and bilirubin). COMBITROL PLUS B control material is not intended for use with analyzers from other manufacturers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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