510(k) Summary

k131595

1. This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

2. **Submitter**

Eurotrol B.V.
Keplerlaan 20
6716 BS Ede, The Netherlands
T +31 318 695777
F +31 318 695770
E office@eurotrol.com

JUL 2 6 2013

3. **Submitter Contact**

Paul B.P. Kooijmans
Regulatory Affairs manager
Eurotrol B.V.
Keplerlaan 20
6716 BS Ede, The Netherlands
T +31 318 695777
F +31 318 695770
E pkooijmans@eurotrol.com

4. **Device identification**

Proprietary Name: Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM
Common Name: Blood gas, electrolyte and metabolite control
Classification Name: Class I, reserved
Product code: JJY; Multi-analyte controls, all kinds (assayed) (21 CFR 862.1660)

5. **Predicate Device**

Device Name: Roche Combitrol Plus B,
Manufacturer: Bionostics, Inc.,
510(k) number: k032453,
Decision Date: 08/28/2003

6. **Intended Use**

Eurotrol GAS-ISE Hct QC
Eurotrol GAS-ISE Hct QC is an assayed aqueous quality control material for professional use in the verification of the precision and accuracy of the Abbott i-STAT® POCT analyzer.
It is intended that Eurotrol GAS-ISE Hct QC should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine, TCO2 and Hematocrit.

Eurotrol GAS-ISE Hct LVM
Eurotrol GAS-ISE Hct LVM is an assayed aqueous blood gas, electrolyte and metabolite control material for professional use suitable for calibration verification of the Abbott i-STAT® POCT analyzer.
It is intended that Eurotrol GAS-ISE Hct LVM should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine, TCO2 and Hematocrit.

7. **Device description**

Eurotrol GAS-ISE Hct QC
Eurotrol GAS-ISE Hct QC quality controls are prepared using salts in an aqueous, physiologically buffered matrix. Tonometry with predetermined levels of oxygen and carbon dioxide balanced with nitrogen and different salt concentrations provides distinct levels for each parameter, simulating clinically significant ranges of acid-base and electrolyte balance, respiratory function, glucose, lactate, urea and creatinine concentrations, within the reportable range of the Abbott i-STAT POCT analyzer.
Eurotrol GAS-ISE Hct QC is a non-hazardous aqueous solution that contains no biological materials.
Eurotrol GAS-ISE Hct QC provides three (3) physiological relevant levels, each ampule containing 2.5 mL of solution.
Eurotrol GAS-ISE Hct QC is packed in a carton box containing 10 ampules of a separate level.

Eurotrol GAS-ISE Hct LVM
Eurotrol GAS-ISE Hct LVM provides five (5) physiological relevant levels, each ampule containing 2.5 mL of solution. Eurotrol GAS-ISE Hct LVM quality controls are prepared using salts in an aqueous, physiologically buffered matrix. Tonometry with predetermined levels of oxygen and carbon dioxide balanced with nitrogen and different salt concentrations provides five (5) distinct levels for each parameter, simulating clinically significant ranges of acid-base and electrolyte balance, respiratory function, glucose, lactate, urea and creatinine concentrations, within the reportable range of the Abbott i-STAT POCT analyzer.
Eurotrol GAS-ISE Hct LVM is a non-hazardous aqueous solution that contains no biological materials.
Eurotrol GAS-ISE Hct LVM provides five (5) physiological relevant levels, each ampule containing 2.5 mL of solution.
Eurotrol GAS-ISE Hct LVM is packed in a carton box containing a set of 5 ampules; one ampule of each level.

8. Special Instrument Required
For an appropriate use of Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM the use of the Abbott i-STAT System, including test cartridges, is required.

9. Predicate Device Comparison
Comparison of Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM to the predicate device for substantial equivalence:

	New Device	**Predicate Device**
	Eurotrol GAS-ISE Hct	**Roche Combitrol Plus B**
510(k), date		K032453, 08/28/2003
Number of levels	- Eurotrol GAS-ISE Hct QC: 3 - Eurotrol GAS-ISE Hct LVM: 5	3
Analytes	pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine, TCO2 and Hematocrit (Conductivity)	pH, blood gases, Na+, K+, iCa++ Cl-, Li+, iMg++, Glucose, Lactate, BUN, Creatinine, tHb, Hb derivatives and bilirubin
Container	Clear glass ampules	Clear glass ampules
Filling Volume	2,5 mL	1,7 mL
Color	Clear, colorless	Red
Storage temperature	2 - 8°C/35 - 46°F	2 - 8°C/35 - 46°F
Indications for Use	Verification of the precision and accuracy of the Abbott i-STAT POCT and cartridges.	To be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.
Matrix/ Materials	Eurotrol GAS-ISE Hct controls are prepared using salts in a physiologically buffered aqueous matrix. Tonometry with predetermined levels of oxygen and carbon dioxide balanced with nitrogen and different salt concentrations provide five distinct levels for each parameter.	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture
Form	Liquid	Liquid
Open Ampule Stability	30 seconds	Use immediately and only use once after opening
Values	Lot specific	Lot specific
Shelf life	24 months at 2-8°C 10 days at 20-25°C	24 months at 2-8°C 3 months at room temperature
Where used	Clinical Laboratories, Point of Care testing sites	Clinical Laboratories, Intensive Care Units (ICU), Emergency Rooms (ER), Operating rooms (OR), Remote or STAT-labs, Recovery Rooms, Neonatal Units and Renal Dialysis.

10. Standards and guidelines reference

- CLSI EP5-A2; Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition, Vol 24, No. 25, August 2004
- CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, Vol 29, No. 20, September 2009

11. Stability

Real time stability studies have been performed for Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM. The claimed stability is 24 months when the product is stored at 2-8°C, 10 days when the product is stored unopened at room temperature and 30 seconds after opening the ampules.

12. Value Assignment

Multiple replicates of test samples are measured at the beginning and end of the production run on various analyzers for metabolites and on blood gas analyzers for blood gas and pH values. Values are assigned on the Abbott i-STAT 300 System, using multiple cartridges of the latest available batches of the following cartridge types: CG4+, CG8+, EC8+, CHEM8+ and Crea. Values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot. Ranges are assigned using pre-determined intervals. Value assignment is performed for each lot of Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM and for each new software (CLEW) update of the Abbott i-STAT 300 System.

The assigned values of each batch are available on a value sheet as per the example in Annex 1. on page 4 - 7.

13. Traceability

The different levels of Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM are traceable to the reference materials as shown in the table below.

Analyte	Reference Material
pH	NIST SRM: 186 I/II, 185, 187, 191 and 192
pCO2	NIST SRM: 1674b, 2625a, 2658a and 2659a
pO2	NIST SRM: 1674b, 2625a, 2658a and 2659a
Na+	NIST SRM 956b
K+	NIST SRM 956b
Ca++	NIST SRM 956b
Cl-	NIST SRM 956b
Glucose	NIST SRM 965c
Lactate	Biomed DuoCal Multi 10260
Urea	Precipath U plus 159955 + Precinorm U plus 157249
Creatinine	NIST SRM 967a
Hematocrit (Conductivity)	Hanna Instruments Conductivity Standard 1.413 mS/cm Hanna Instruments Conductivity Standard 5.000 mS/cm Hanna Instruments Conductivity Standard 12.88 mS/cm

Table 2. Traceability of the analytes of Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM to reference materials.

14. Conclusion

Eurotrol GAS-ISE Hct QC and Eurotrol GAS-ISE Hct LVM is intended to be used for the same intended use as the predicate and performs similarly as the predicate device.

Annex 1. Value sheet example

Eurotrol
Your Global Reference Point for Quality Control

Eurotrol GAS-ISE Hct QC

Expected values for Abbott i-STAT®

LOT 17401215

17401215

Level 1

2014-09

CLEW: A26/C26/H26/J26

All cartridge types, all lot numbers

	Units	$\bar{X}$ (Mean)	*R (Range)*
pH	*1*	**6.973**	6.893 - 7.054
pCO_2	*mmHg*	**73.0**	58.6 - 87.4
	kPa	**9.71**	7.80 - 11.62
pO_2	*mmHg*	**66**	46 - 86
	kPa	**8.7**	6.1 - 11.4
Na^+	*mmol/L, mEq/L*	**119**	115 - 124
K^+	*mmol/L, mEq/L*	**2.7**	2.3 - 3.1
iCa^{++}	*mmol/L*	**1.40**	1.29 - 1.51
	mEq/L	**2.8**	2.6 - 3.0
	mg/dL	**5.6**	5.2 - 6.0
Cl^-	*mmol/L, mEq/L*	**83**	77 - 88
tCO_2	*mmol/L, mEq/L*	**19**	10 - 28
Glucose/ Glu	*mg/dL*	**303**	257 - 349
	g/L	**3.03**	2.57 - 3.49
	mmol/L	**16.8**	14.2 - 19.4
Lactate/ Lac	*mmol/L*	**8.49**	7.57 - 9.41
	mg/dL	**76.5**	68.2 - 84.8
	g/L	**0.765**	0.682 - 0.848
BUN	*mg/dL*	**61**	54 - 69
Urea	*mmol/L*	**21.9**	19.4 - 24.5
	mg/dL	**132**	116 - 147
	g/L	**1.32**	1.16 - 1.47
Creatinine/ Crea	*µmol/L*	**324**	248 - 400
	mg/dL	**3.7**	2.8 - 4.5
Hct	*%PCV*	**17**	14 - 20

VAS 174.03-RI-20130517

Eurotrol B.V. Postbus 722 6710 BS Ede, Keesterlaan 20 6716 BS Ede, The Netherlands, T +31 318 695777 F +31 318 695770 office@eurotrol.com www.eurotrol.com

Eurotrol
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Eurotrol GAS-ISE Hct QC

Expected values for Abbott i-STAT®

LOT 17401215

17401215

Level 1

⌛ **2014-09**

CLEW: A26/C26/H26/J26

EC8+, 6+, EC4+, E3+ & G
LOT F, G, H, J or K

	Units	X̄ (Mean)	R (Range)
pH	1	6.943	6.893 - 6.993
pCO_2	mmHg	77.4	67.4 - 87.4
	kPa	10.29	8.96 - 11.62
Na^+	mmol/L, mEq/L	119	115 - 123
K^+	mmol/L, mEq/L	2.7	2.3 - 3.1
Cl^-	mmol/L, mEq/L	83	78 - 88
Glucose/ Glu	mg/dL	307	265 - 349
	g/L	3.07	2.65 - 3.49
	mmol/L	17.1	14.7 - 19.4
BUN	mg/dL	61	54 - 68
Urea	mmol/L	21.9	19.4 - 24.4
	mg/dL	131	116 - 146
	g/L	1.31	1.16 - 1.46
Hct	%PCV	17	14 - 20

Eurotrol B.V. Postbus 722 6710 BS Ede Keplerlaan 20 6716 BS Ede The Netherlands T +31 318 695777 F +31 318 695770 office@eurotrol.com www.eurotrol.com

VAS 174 031 R6 2013-06/7.2

Eurotrol

Your Global Reference Point for Quality Control

Eurotrol GAS-ISE Hct QC

LOT 17401215

17401215

Level 1

Expected values for Abbott i-STAT®

2014-09

CLEW: A26/C26/H26/J26

CG8+, EG7+, EG6+, G3+, Crea & CG4+
LOT K, L, N, U, W or Y

	Units	X̄ (Mean)	R (Range)
pH	1	7.004	6.954 - 7.054
pCO_2	mmHg	66.6	58.6 - 74.6
	kPa	8.86	7.80 - 9.93
pO_2	mmHg	66	51 - 81
	kPa	8.7	6.7 - 10.7
Na^+	mmol/L, mEq/L	120	116 - 124
K^+	mmol/L, mEq/L	2.7	2.3 - 3.1
iCa^{++}	mmol/L	1.40	1.29 - 1.51
	mEq/L	2.8	2.6 - 3.0
	mg/dL	5.6	5.2 - 6.0
Glucose/ Glu	mg/dL	301	259 - 343
	g/L	3.01	2.59 - 3.43
	mmol/L	16.7	14.4 - 19.1
Creatinine/ Crea	µmol/L	319	248 - 389
	mg/dL	3.6	2.8 - 4.4
Lactate/ Lac	mmol/L	8.49	7.57 - 9.41
	mg/dL	76.5	68.2 - 84.8
	g/L	0.765	0.682 - 0.848
Hct	%PCV	17	14 - 20

VAS 174 021 R6 20130917.3

Eurotrol B.V. Postbus 722, 6710 BS Ede Keplerlaan 20, 6716 BS Ede, The Netherlands T +31 318 695777 F +31 318 695770 office@eurotrol.com www.eurotrol.com

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Your Global Reference Point for Quality Control

Eurotrol GAS-ISE Hct QC

LOT 17401215

17401215

Level 1

Expected values for Abbott i-STAT®

2014-09

CLEW: A26/C26/H26/J26

Chem8+

LOT J

	Units	X̄ (Mean)	R (Range)
Na^+	mmol/L, mEq/L	119	115 - 123
K^+	mmol/L, mEq/L	2.7	2.3 - 3.1
Cl^-	mmol/L, mEq/L	82	77 - 87
iCa^{++}	mmol/L	1.40	1.29 - 1.51
	mEq/L	2.8	2.6 - 3.0
	mg/dL	5.6	5.2 - 6.0
Glucose/ Glu	mg/dL	299	257 - 341
	g/L	2.99	2.57 - 3.41
	mmol/L	16.6	14.2 - 18.9
tCO_2	mmol/L, mEq/L	19	10 - 28
Creatinine/	µmol/L	329	258 - 400
Crea	mg/dL	3.7	2.9 - 4.5
BUN	mg/dL	62	55 - 69
Urea	mmol/L	22.0	19.5 - 24.5
	mg/dL	132	117 - 147
	g/L	1.32	1.17 - 1.47
Hct	%PCV	17	14 - 20

VAS 171.002 R6 2013/05/14

Eurotrol B.V. Postbus 722 6710 BS Ede, Keplerlaan 20 6716 BS Ede, The Netherlands T +31 318 695777 F +31 318 695770 office@eurotrol.com www.eurotrol.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Eurotrol B.V.
C/O Paul B.P. Kooijmans
Keplerlaan 20
6716 BS Ede, The Netherlands

Re: K131595
Trade/Device Name: Eurotrol GAS-ISE Hct QC
Eurotrol GAS-ISE Hct LVM
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: 1 Reserved
Product Code: JJY
Dated: June 20, 2013
Received: June 21, 2013

Dear Mr. Kooijmans:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

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): k131595

Device Name: Eurotrol GAS-ISE Hct QC
Eurotrol GAS-ISE Hct LVM

Indications for Use:

Eurotrol GAS-ISE Hct QC
Eurotrol GAS-ISE Hct QC is an assayed aqueous quality control material for professional use in the verification of the precision and accuracy of the Abbott i-STAT® POCT analyzer.
It is intended that Eurotrol GAS-ISE Hct QC should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine, TCO2 and Hematocrit.
Eurotrol GAS-ISE Hct QC is for in vitro diagnostic use only.

Eurotrol GAS-ISE Hct LVM
Eurotrol GAS-ISE Hct LVM is an assayed aqueous blood gas, electrolyte and metabolite control material for professional use suitable for calibration verification of the Abbott i-STAT® POCT analyzer.
It is intended that Eurotrol GAS-ISE Hct LVM should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine, TCO2 and Hematocrit.
Eurotrol GAS-ISE Hct LVM is for in vitro diagnostic use only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Denise Johnson-Iyles -S
2013.07.26 11:42:59 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) k131595