

Urgent Field Safety Notice

SB-RPD-2014-007

RPD / Blood Gas & Electrolytes
Version 1 Update
01-Sep-2014

Reference Ranges Update cobas b 121

Product Name	cobas b 121 <BGE> system cobas b 121=Roche OMNI C system without AQC cobas b 121=Roche OMNI C system with AQC
GMMI / Part No	03143554001
Device Identifier	03143562001 03143597001
Production Identifier (Lot No./Serial No.)	All
Type of Action	Customer information Customer action Field Implementation Mandatory

Dear Valued **cobas b 121** system/OMNI C Customer,

We regret to inform you that the default Reference ranges on print outs and in Instructions for Use (Operator Manuals) refer to different sources and are inconsistent between different **cobas b 121**, 123 POC and 221 systems.

Description of Situation

We have received a complaint related to different default reference ranges between **cobas b 123** POC and **cobas b 221** systems. Early investigation identified that the default reference ranges of several parameters differ in comparison with each other on different systems (**cobas b 121**, **cobas b 221** and **cobas b 123** POC) and do not fit to the corresponding manuals. The different reference ranges show up on the instrument's display and on the printout of results, if they were not adapted by the customer. The results of tests are flagged accordingly.

The Instructions for Use (Operator Manual) provide an extensive overview of results depending on age, gender, blood type and clinical conditions.

Further investigation revealed that for the default reference ranges an update is required in this regard.

The purpose of this FSN is to provide updated values with according sources until revised Instructions for Use (Operator Manuals) are available.

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Reference ranges are intended as an additional help for users to identify results out of normal range. The Hb derivatives COHb (%COHb), MetHb (% of total Hb), O₂Hb (%O₂Hb), SO₂ (%Saturation), HHb (%HHb), tHb (g/dL), pCO₂ (mmHg), pO₂ (mmHg) and Hct (%) refer to several scientific sources with slight differences in the reference range.

The reference range for SO₂ combines arterial and venous range (lower limit venous reference range, upper limit arterial reference range). As clinical status of patients is directly related to SO₂ the detectability is certain. Nevertheless the reference range for SO₂ will be split in arterial and venous reference ranges to prevent confusion.

Reference ranges for other parameters related to a medical risk depend strongly on the individual patient population. Those parameters need special attention.

The detectability is certain as physicians and care workers know reference ranges by memory.

Actions taken by Roche Diagnostics

A new revision of the Instruction for Use is planned by Q4 2015.

Customers are able to enter individual reference ranges manually (see **cobas b 121** systems Reference Manual, Vers. 16).

Nevertheless, we would like to reiterate (according to Instruction for Use):

Reference intervals, although useful as guideline for clinicians, should not be used as absolute indicators of health and disease. The reference intervals presented in this FSN are for general information purposes only. Individual laboratories should generate their own set of reference intervals.

Actions to be taken by the customer/user

Customers must check their current set of reference values and if appropriate amend the reference ranges accordingly.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and your support.

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Yours faithfully,

Roche Diagnostics GmbH

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

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Appendix

Table 1 Updated reference ranges

Parameter	Reference range ¹	Sample type	Source
COHb (%):	<3% nonsmoker	Whole blood (EDTA)	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1
MethHb (% of total Hb):	0.04-1.52	Whole blood (EDTA, heparinized or ACD)	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
O₂Hb (%O ₂ Hb):	94.0-98.0	Arterial blood, Mixed venous blood	Lothar Thomas, Labor und Diagnose, 8. Auflage
SO₂ (O ₂ Saturation;%)	94-98	Whole blood, arterial	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
HHb (%HHb):	<3%		Kenneth A. Wyka, Paul J. Mathews, John Rutkowski: Foundations of respiratory care
tHb (g/dL):	F 11.5-16.0 M 13.5 -17.8	Capillary blood	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1 p. 827
Bilirubin (µmol/L)	0 – 2.0 mg/dL 0 - 34.2 µmol/L	Serum	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pH	7.350-7.450	Whole blood, arterial	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pCO₂ (mmHg)	F 32-45 M 35-48	Whole blood, arterial (heparinized)	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pO₂ (mmHg)	83-108 (2d - 60y)	Arterial whole blood	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Na⁺ (mmol/L)	136-145	Serum	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
K⁺ (mmol/L)	3.5 – 5.1	Serum	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Ca²⁺ (mmol/L)	1.15 – 1.33	Serum, Plasma	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Cl⁻ (mmol/L)	98-107 (Adult)	Serum	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012

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Parameter	Reference range ¹	Sample type	Source
Hct (%)	Caucasian F 36-48 Caucasian M 40-53 Black F 34-43 Black M 34-48 Athletes F 37-45 Athletes M 40-50	Whole blood	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1
Glu (mmol/L)	3.5 – 5.3	Whole blood, heparinized	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Lac (mmol/L)	0.36 – 0.75	Whole blood, venous	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Urea (mmol/L)	2.1 – 7.1	Serum	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012

¹ A new revision of the Instructions for Use is planned until Q4 2015. Currently no new software version is planned. Therefore the default references ranges displayed on the printouts will not change.