

# Urgent Field Safety Notice

## SB-RPD-2014-007

RPD / Blood Gas & Electrolytes  
Version 3  
02-Dec-2014

### Reference Ranges Update cobas b 221

<b>Product Name</b>	<b>cobas b 221&lt;1&gt;</b> =Roche OMNI S1 system <b>cobas b 221&lt;2&gt;</b> =Roche OMNI S2 system <b>cobas b 221&lt;3&gt;</b> =Roche OMNI S3 system <b>cobas b 221&lt;4&gt;</b> =Roche OMNI S4 system <b>cobas b 221&lt;5&gt;</b> =Roche OMNI S5 system <b>cobas b 221&lt;6&gt;</b> =Roche OMNI S6 system
<b>GMMI / Part No</b>	03337103001
<b>Device Identifier</b>	03337111001 03337120001 03337138001 03337146001 03337154001
<b>Production Identifier (Lot No./Serial No.)</b>	all
<b>Type of Action</b>	Customer information Customer action Field Implementation Mandatory

Dear Valued **cobas b 221** system/OMNI S Customer,

We regret to inform you that a typo for the lactate value was found in the scientific reference ("Tietz") leading to a correction of the reference values for lactate (see table in appendix 1).

### Description of Situation

In addition to the information already communicated in the previous version of this FSN, it was now detected that the reference ranges for lactate are incorrect. In addition, inquiries regarding editing bilirubin reference ranges were received needing some explanation.

Table 60-1 in Tietz 5th edition contains a printing error; values are shifted by one row. This typo was transcribed when using Tietz as scientific source.

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Lactate correction (new information in yellow):

Lactate Lac (mmol/L)	0.56-1.39	Whole blood, venous	0.4-2.2	0.6-1.4	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	Proposed reference range refers to venous blood at bed rest. Default value rounded to one tenth place value. Note: Table 60-1 in Tietz 5 <sup>th</sup> edition contains printing error; values are shifted by one row.
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## Actions taken by Roche Diagnostics

The actions taken by Roche Diagnostics remain unchanged when compared to previous versions.

## Actions to be taken by the customer/user

The actions taken by you as a customer/user remain unchanged when compared to previous versions.

## 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 support.

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 1

(new information is highlighted in yellow)

Please find the updated reference ranges in the following table including the information about printouts for cobas b 221

Note: The proposed reference ranges (excluding Bilirubin) are applicable to adult patients with unspecified gender and age.

Parameter	Normal range	Sample type <sup>1)</sup>	Normal range seen on printouts today	Normal range seen on printouts update	Source	Comment
<b>COHb</b> (%):	≤3.0% nonsmoker	Whole blood	0.5-2.5	0.0-3.0	Lothar Thomas, Labor und Diagnose, 8. Auflage	Upper limit refer to nonsmoker
<b>MetHb</b> (% of total Hb):	0.04-1.52	Whole blood	0.4-1.5	0.0-1.5	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	Default value rounded to one tenth place value
<b>O<sub>2</sub>Hb</b> (%O <sub>2</sub> Hb):	94.0-98.0	Arterial blood	95.0-99.0	94.0-98.0	Lothar Thomas, Labor und Diagnose, 8. Auflage	N/A
<b>SO<sub>2</sub></b> (O <sub>2</sub> Saturation;%)	94.0-98.0	Whole blood arterial	75.0-99.0	94.0-98.0	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>HHb</b> (%HHb):	<3%		1.0-5.0	0.0-2.9	Kenneth A. Wyka, Paul J. Mathews, John Rutkowski: Foundations of respiratory care	N/A
<b>tHb</b> (g/dL):	11.5-16.0 (female adult) 13.5 -17.8 (male adult)	Capillary blood	11.5-17.4	11.5-17.8	Lothar Thomas, Labor und Diagnose, 8. Auflage	Proposed reference ranges refer to lower limit for females to upper limit of males
<b>Bilirubin Bili</b> (µmol/L)	34-103 (0-1 d full term) 103-171 (1-2 d full term) 68-137 (3-5 d full term) 0-34 (adult)	Serum	51-149 51-205 51 – 850 51-149	34-171 68-137 0-34 0-34	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	The proposed reference values are given in the order: "fetal/new born", "2nd day / 1 year", "> 1 year" and "unknown". For "fetal/new born" the proposed reference range refers to lower level of 0-1 day old full-term to upper level for 1-2 days old full term. For "2nd day / 1 year"

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						<p>the proposed reference range refers to the reference value for 3-5 days old full term. For "&gt; 1 year" and "unknown" the proposed value refers to the one of adults. The default reference value <math>\leq 34 \mu\text{mol/L}</math> is set in future software versions (e.g. b 221 SW V8.0 onwards).</p> <p>Because of the lower end of the measuring range for Bilirubin (<math>51 \mu\text{mol/L}</math>), it cannot be edited by the user. The user can only edit values within the measuring range.</p> <p>However, it will be possible to set the new reference values for the age specific reference ranges once cobas b 221 SW V8.0 is available.</p>
<b>pH</b>	7.35-7.45	Whole blood arterial	7.350-7.450	7.350-7.450	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>pCO<sub>2</sub></b> (mmHg)	32-45 (female adult) 35-48 (male adult)	Whole blood, arterial	35.0-45.0	32.0-48.0	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	Proposed reference ranges refer to lower limit for females to upper limit of males
<b>pO<sub>2</sub></b> (mmHg)	83-108	Whole blood arterial	80.0-100.0	83.0-108.0	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>Sodium Na<sup>+</sup></b> (mmol/L)	136-145	Serum, plasma	135.0-148.0	136.0-145.0	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>Potassium K<sup>+</sup></b> (mmol/L)	3.5-5.1	Serum	3.50-4.50	3.50-5.10	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>Ionized Calcium Ca<sup>2+</sup></b> (mmol/L)	1.15 – 1.33	Serum, plasma	1.120-1.320	1.150-1.330	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>Chloride Cl<sup>-</sup></b> (mmol/L)	98-107	Serum, plasma	98.0-107.0	98.0-107.0	Tietz Textbook of clinical chemistry and molecular	N/A

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					diagnostics 5th edition 2012	
<b>Hematocrit HCT (%)</b>	36-48 (Caucasian female) 40-53 (Caucasian male)	Whole blood, Capillary blood	35.0-50.0	36.0-53.0	Lothar Thomas, Labor und Diagnose, 8. Auflage	Proposed reference range refers to lower limit for Caucasian females to upper limit of Caucasian males
<b>Glucose Glu (mmol/L)</b>	3.5-5.3	Whole blood	3.3-6.1	3.5-5.3	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A
<b>Lactate Lac (mmol/L)</b>	0.56-1.39	Whole blood, venous	0.4-2.2	0.6-1.4	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	Proposed reference range refers to venous blood at bed rest. Default value rounded to one tenth place value. Note: Table 60-1 in Tietz 5 <sup>th</sup> edition contains printing error; values are shifted by one row.
<b>Urea (mmol/L)</b>	2.1-7.1	Serum	2.5-6.4	2.1-7.1	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012	N/A

<sup>1)</sup> Sample type refers to corresponding source for the normal range. Anticoagulants are not listed in this table.

Note: The availability of parameters depends on the configuration:

- cobas b 221<1> system BG, pH, tHb/SO<sub>2</sub> (no longer manufactured or offered)
- cobas b 221<2> system BG, pH, COOX, Bili
- cobas b 221<3> system BG, pH, ISE, Hct, tHb/SO<sub>2</sub> (no longer manufactured or offered)
- cobas b 221<4> system BG, pH, ISE, Hct, COOX, Bili
- cobas b 221<5> system BG, pH, ISE, Hct, MSS, tHb/SO<sub>2</sub> (no longer manufactured or offered)
- cobas b 221<6> system BG, pH, ISE, Hct, MSS, COOX, Bili

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## Appendix 2

(new information is highlighted in yellow)

Instructions to enter individual reference ranges on cobas b 221 systems

### Ref./crit. ranges

Press the following button:

☰ Setup > Parameters > Ref./crit. ranges

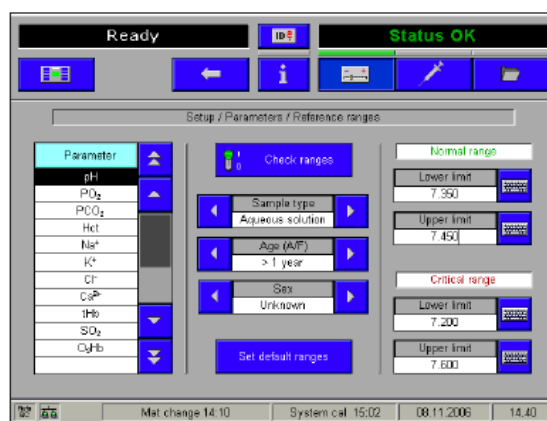


Figure C-2

In this menu the upper and lower limits of the reference and critical ranges can be entered.

Select the parameter from the overview list and then make the following additional settings, for which the set reference areas of the selected parameter are valid:

- Sample type      Blood, aqueous solution, serum/plasma, bicarbonate, acetate, unknown (unknown sample type - not specified)
- Age (A/F)        > 1 year, fetal/new born, 2nd day / 1 year, unknown
- Sex                Female, male, unknown
- Normal range    Enter the upper and lower limits of the normal range.
- Critical range    Enter the upper and lower limits of the critical range.

*[Check ranges]* Limit monitoring during measurement is activated (green) or deactivated (red). If one of the defined limits is exceeded or undershot, an appropriate note is output in the measurement report.

- (-) (+)              outside the normal range
- (--) (++)            inside critical range

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Please note the following addition regarding the parameter Bilirubin:

The default reference value  $\leq 34 \mu\text{mol/L}$  is set in future software versions (e.g. cobas b 221 SW V8.0 onwards). Because of the lower end of the measuring range for Bilirubin ( $51 \mu\text{mol/L}$ ), it cannot be edited by the user. The user can only edit values within the measuring range. However, it will be possible to set the new reference values for the age specific reference range once cobas b 221 SW V8.0 is available.

### General note:

Normal values depend among others on the patient, age, gender, lifestyle habits (e.g. smoking), underlying disease (e.g. asthma), therapy (e.g. state after an infusion). This especially applies to "critical values", as these are based on the normal values.

Therefore "critical values" can be only approximately defined and need to be checked and adapted according to individual laboratory provisions and patient population.