Urgent Field Safety Notice
SBN-RPD-2015-002

RPD / Blood Gas & Electrolytes
Version 1
17-Apr-2015

Neonatal Bilirubin: Limitations on Clinical Analysis of Bilirubin on the cobas b 123 POC System

Product Name	**cobas b** 123 < 4 > POC system
GMMI / Part No Device Identifier	05122287001
Production Identifier (Lot No./Serial No.)	all
Type of Action	Field Safety Corrective Action

Dear Valued **cobas b** 123 POC system Customer,

We regret to inform you that the bilirubin value can result in higher values in case cellular particles are present in neonatal blood samples. Detectability of this issue might be reduced if additional available parameters, total Hemoglobin (tHb) and Hematocrit (Hct), are deactivated. The necessity of these parameters for the interpretation of bilirubin values in neonatal blood samples is not explicitly stated in the current version of the Instructions for Use, version 9.0 (Operator's Manual).

Description of Situation

We have received complaints related to high bilirubin values from neonatal samples measured on the **cobas b** 123 POC system. Incorrect high bilirubin values may lead to further diagnostics and unnecessary treatment of neonates.

It was observed that on the instruments used in the related cases the tHb parameter was deactivated. This parameter can be used to interpret the homogeneity of the sample as unexpected high tHb values are decision criteria to determine if the result might be influenced by cellular particles. A further available decision criterion is the calculated mean corpuscular hemoglobin concentration (MCHC) value which can be displayed if, in addition to the tHb, the Hct parameter is activated. The measurement should then be repeated with a newly taken blood sample to confirm the results. However, it has to be noted that if parameters other than COOX and tHb are activated a minimum blood sample of 55 µL is required to perform the measurement instead of 25 µL.

Roche Diagnostics Asia Pacific Pte Ltd
8 Kallang Avenue
#10-01/09 Aperia Tower 1
Singapore 339509
Tel. +65 – 6272 7500
Fax +65 – 6371 6633

Neonatal Bilirubin:
Limitations on Clinical Analysis of Bilirubin on the cobas b 123 POC System

Actions taken by Roche Diagnostics

A revision of the Instructions for Use (IFU) will be initiated and be effective in Q4/2015. This revision will describe the required steps to increase the detectability of bilirubin results being affected by cellular particles.

Actions to be taken by the customer/user

In order to increase the detectability of neonatal bilirubin results affected by cellular particles, the following steps are required:

1. Whenever measuring bilirubin the tHb parameter and MCHC as calculated value should be activated. This parameter activation will not increase the minimum sample volume of 25 µL required for a measurement.
2. If a sample volume of ≥ 55 µL is available, the Hct parameter should be activated (required for the MCHC calculation). If the sample volume is between 25 µL and 55 µL no other parameter than COOX and tHb must be activated in order to measure bilirubin and tHb. MCHC value will then display "Base value not available".
3. If tHb or MCHC exceed their critical values (either defined locally or 22 g/dL [1] for neonatal tHb resp. see Table 1 for MCHC critical values) and bilirubin exceeds the critical value (either defined locally or 15 mg/dL [1]) the measurement should then be confirmed with a newly taken blood sample.

Table 1: Overview of reference ranges for MCHC for different ages [2]. Table is adapted.

Age	MCHC/g/dL
1st day	31.0 – 35.0
2nd – 6th day	24.0 – 36.0
7th – 13th day	NA *
14th – 23rd day	26.0 – 34.0
24th – 37th day	25.0 – 34.0

[1] Tietz, Textbook of Clinical Chemistry and Molecular Diagnostics: 5th Edition 2012, 2187

[2] Thomas, Lothar, Labor und Diagnose – Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik, 8. Auflage, TH-Books Verlagsgesellschaft mbH, Frankfurt/Main, 2012, Band 1, 822

[*] Reference values for MCHC from age 7th day to 13th day are not available in the referenced literature [2]

Neonatal Bilirubin:
Limitations on Clinical Analysis of Bilirubin on the cobas b 123 POC System

Communication of this Field Safety Notice

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

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

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com

Neonatal Bilirubin:
Limitations on Clinical Analysis of Bilirubin on the cobas b 123 POC System

ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Safety Board Advisory Notice: SBN-RPD-2015-002, dated 17-Apr-2015, regarding limitations on clinical analysis of bilirubin on the cobas b 123 POC System

Received by:

_____

Name & Signature

_____

Hospital & Stamp

_____

Date