Field Safety Notice

SBN-CPS-2016-011

CPS / Blood Gas & Electrolytes
Version 1
12-JUL-2016

cobas b 123: Neonatal Bilirubin – Erroneously low results

Product Name	**cobas b** 123 < 3 > POC system **cobas b** 123 < 4 > POC system
GMMI / Part No **Device Identifier**	05122279001 05122287001
Production Identifier (Lot No./Serial No.)	All
Type of Action	Field Safety Corrective Action (FSCA)

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

We would like to re-emphasise the importance of following the recommended Instructions for Use manual to avoid erroneously low results for neonatal bilirubin on **cobas b** 123 systems in rare cases. In addition, we have identified temporary measures that reduce the occurrence and ensure the detectability of the issue until a final solution will be provided with SW Version 4.8 in Q4/2016.

Description of Situation

We have become aware of an issue that may lead to erroneously low results for neonatal bilirubin on **cobas b** 123 systems in rare cases. The issue was detected in one customer site globally. Nonetheless, we have identified measures to reduce the occurrence of the issue and to ensure that measurements that may have yielded erroneously low results can be identified by customers.

The measures are twofold:

- Mandatory use of a clot catcher for neonatal samples
- Assessment of tHb, O_2Hb and MCHC according to a set of rules for neonatal samples

They are described in detail below.

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Actions to be taken by the customer/user

1. For measurement of neonatal bilirubin from capillaries a clot catcher (03112012180 CLOT CATCHER (250 PCS)) **must be used**.).

Note:

The **cobas b** 123 Instructions for Use V.10 already contains the following recommendation (p 188):

Sample collection container accessories

The use of a clot catcher is recommended to prevent clogging of the sample path during measurement of critical blood, for example, when sampling blood of newborns from earlobes or heels.

Clot Catcher The Clot Catcher, which is placed on top of the capillary or **Roche MICROSAMPLER PROTECT**, prevents blood clots and tissue particles from entering the **cobas b** 123 POC system.

Using the Clot Catcher is suitable for the capillary mode of the **cobas b** 123 POC system only.

WARNING

- The Clot Catcher is not suitable for the **cobas b** 123 POC system syringe mode.

For measurement of neonatal bilirubin from syringes a clot catcher (05689856001 CLOT CATCHER PRO (100 PCS)) **must be used.**

Clot Catcher PRO The Clot Catcher PRO, which is placed on top of a syringe, prevents blood clots and tissue particles from entering the **cobas b** 123 POC system.

Using the Clot Catcher PRO is suitable for the **capillary mode** of the **cobas b** 123 POC system only.

WARNING

- The Clot Catcher PRO is not suitable for syringe mode of the **cobas b** 123 POC system.

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2. Whenever measuring neonatal bilirubin, the parameters **tHb**, **O_2Hb** and **MCHC** must be activated to be shown on the measurement report and printout. **tHb** needs to be active in the parameter panel.

For configuration of these parameters on the measurement report refer to **cobas b** 123 IFU, section "**Results view"**.

For the activation of parameters in the parameter panel see **cobas b** 123 IFU, section **"Edit panels".**

For the measurement to yield MCHC results, **Hct** needs to be active in the parameter panel and the minimum sample volume needs to be **55 µL**.

The following two rules must be applied to all measurements of neonatal bilirubin:

A) If either the result of tHb is below 4 g/dL or O_2Hb is flagged with "sample error". The bilirubin value is unreliable and the measurement must be re-run with a fresh sample.

B) If the MCHC value of the measurement is below the range given in Table 1, the bilirubin value is unreliable and the measurement must be re-run with a fresh sample.

Table 1: Overview of reference ranges for MCHC for different ages [1]. 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] *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 ages 7th day to 13th day are not available in the referenced literature.*

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Relation to Field Safety Notice "SB-RPD-2015-008 Neonatal Bilirubin: Limitations on Clinical Analysis of Bilirubin on the **cobas b** 123 POC System" and associated SBN:

The assessment of tHb, and, if available, MCHC for measurements of neonatal bilirubin is already required by SB-RPD-2015-008 and associated SBN, concerning **elevated** Bilirubin results due to the presence of cellular particles. The associated instructions and rule set have also been included in the **cobas b** 123 IFU, V10.

Those instructions and rule set remain valid and continue to be applicable.

The analytical limitations described in SB-RPD-2015-008 lead to violations of the *upper* limit of the given ranges.

This Field Safety Notice SB-CPS-2016-011 now temporarily **extends the rule set** to allow identification of erroneously **low** Bilirubin results due to a delayed or incomplete aspiration of the sample to the cuvette. These additional rules are only required until a solution is implemented with SW Version 4.8 in Q4/2016.

Actions taken by Roche Diagnostics

Software Version where the issue is solved will be made available Q4/2016.

Communication of this Field Safety Notice

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

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

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