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## URGENT FIELD SAFETY NOTICE

### IMMEDIATE ACTION REQUIRED

**Field Safety Notice Ref No: BFSN\_01\_16 cobas b 123: Neonatal Bilirubin –  
Erroneously Low results SB-CPS-2016-011**

**Document Date: 15/07/2016**

**Type of Action: Field Corrective Action**

**System Affected: cobas b 123**

**Summary of Issue: Erroneously low results**

#### Details of Affected

##### Devices:

**Material No:** 05122279001  
05122287001

#### Reason for Notice:

Roche would like to re-emphasise to customers 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 Quarter 4/2016.

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<sub>2</sub>Hb and MCHC according to a set of rules for neonatal samples

They are described in detail below.

Roche Diagnostics  
Charles Avenue  
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Registered No 571546

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## Actions taken by Roche Diagnostics

Software Version where the issue is solved will be made available Quarter 4/2016.

### Action Required:

## Actions to be taken by the customer

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 (IFU) 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

#### 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

#### WARNING

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

2. Whenever measuring neonatal bilirubin, the parameters **tHb**, **O<sub>2</sub>Hb** 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

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**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<sub>2</sub>Hb 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<sup>1</sup>. Table is adapted.**

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

<sup>1</sup> *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 7<sup>th</sup> day to 13<sup>th</sup> day are not available in the referenced literature.*

Relation to Field Safety Notice “BFSN\_01\_15 Neonatal Bilirubin SB-RPD-2015-008 Neonatal Bilirubin: Limitations on Clinical Analysis of Bilirubin on the **cobas b 123** POC System” and associated SBN:

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The assessment of tHb, and, if available, MCHC for measurements of neonatal bilirubin is already required by BFSN\_01\_15 Neonatal Bilirubin SB-RPD-2015-008, 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 BFSN\_01\_15 Neonatal Bilirubin SB-RPD-2015-008, lead to violations of the *upper* limit of the given ranges. This Field Safety Notice BFSN\_01\_16 cobas b 123: Neonatal Bilirubin – Erroneously Low results 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 Quarter 4/2016.

Kindly complete the attached Fax Back form and return by no later than 28<sup>th</sup> July 2016 by fax or email.

Please accept our apologies for any inconvenience caused by this issue.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

**Attachments:** BFSN\_01\_16 cobas b 123: Neonatal Bilirubin – Erroneously Low results SB-CPS-2016-011 Fax Back

**This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.**

*\* Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. \**

**If you require any further information please contact our Professional Services Department / Technical Support Hotline on:  
UK: 0808 100 19 20  
Ireland : 1800 40 9 564**

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**A copy of this notice can also be found on [www.cobas-roche.co.uk](http://www.cobas-roche.co.uk)**

**To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.**

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