Urgent Field Safety Notice

SBN-CPS-2019-014

CPS / ClinChem fully automated

Version 4

October-2020

BILD2, CRPL3 and ALB2: Calibration and QC failures on cobas c 701/702

Product Name	ALB2 (Albumin Gen.2) BILD2 (Bilirubin Direct Gen. 2) CRPL3 (C-Reactive Protein Gen. 3)
System	**cobas c** 701/702 module
Product Description / GMMI	05166861190 (ALB2) **cobas c** 701/702 Lot 43031001 and 43718901 05168384190 (BILD2) **cobas c** 701/702 Lot 43907901 05172373190 (CRPL3) **cobas c** 701/702 Lot 42402301
Type of Action	Field Safety Corrective Action

Change history		
	Version 1	Initial document
	Version 2	Updated affected lot 37437301
	Version 3	Update ABL2 lots 43031001 and 43718901 and C4-2 lot 36870301, removal of expired lots from version 2.
	Version 4	Update new parameter/lot BILD2 43907901 and CRPL3 lot 42402301, removal C4-2 (expired)

Dear Valued Customer,

Description of Situation

In the versions 1, 2 and 3 of this FSN we informed about a number of complaints regarding Albumin Gen.2 (ALB2), Bilirubin Total Gen.3 (BILT3) and Tina-quant Complement C4 ver.2 (C4-2) on **cobas c** 701/702 modules alleging low control recoveries outside of the laboratory acceptable control ranges. Customers observed a low QC recovery and sometimes calibration failures for single **cobas c** pack large cassettes.
The lots listed in version 1 and 2 of the Field Safety Notification and the C4-2 lot listed in version 3 have already expired, the ALB2 lots communicated in version 3 are still in the market.

Recently we received and confirmed new customer complaints for Bilirubin Direct Gen. 2 (BILD2) reagent lot 43907901 and C-Reactive Protein Gen. 3 (CRPL3) reagent lot 42402301 with the same error pattern and root cause.

Affected Lots			
FSN Version	**Assay**	**Lot Number**	**Expiry Date**
Version 1	ALB2	33962301	31-Aug-2019
	BILT3	36133801	29-Feb-2020
Version 2	ALB2	37437301	31-Jan-2020
Version 3	C4-2	36870301	30-Sep-2020
	ALB2	43031001	30-Nov-2020

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	ALB2	43718901	31-Jan-2021
Version 4	BILD2	43907901	31-Jan-2021
	CRPL3	42402301	30-Nov-2020

Table 1: Overview of affected lots of FSN Version 1-4

The issue can be detected either by implausible low control recovery or invalid calibration of the affected reagent cassettes. This issue affects only a small number of cassettes (< 8 parts per million based on confirmed cases) from the lot numbers above; the majority of cassettes continue to perform within specification.

Due to the fact that these negative deviations can lead to an underestimation of albumin, direct bilirubin and CRP in serum/plasma, a medical risk cannot be excluded. Due to the residual medical risk associated with this issue, customers using the affected products must follow the actions as described below.

Internal investigations have shown that **cobas c** pack (**cobas c** 311/501/502, COBAS INTEGRA® 400 plus) and **cobas c** pack green (**cobas c** 503 analytical unit) are not affected.

Actions taken by Roche Diagnostics

All BILD2 cassettes of lot 43907901 and CRPL3 lot 42402301 have already been distributed.
Meanwhile the manufacturer of the cassettes corrected the welding process successfully (including process revalidation) which should prevent further incidents with cassettes produced after the correction.

Actions to be taken by the customer/user

Each cassette of reagent lots: ALB2 lots 43031001 and 43718901, BILD2 lot 43907901 and CRPL3 lot 42402301 must be calibrated and undergo QC before use (refer also to **cobas** 8000 Operator Manual). If the calibration and/or QC recovery is out of specification, the cassette must be discarded.

In this case, no general recommendations with respect to the review and follow up of previous results are given, taking into account different possible scenarios (e.g. detectability via QC might be given, failed calibration, error appearance). Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied. (If appropriate).

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.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

<closing salutations>,

Contact Details

To be completed locally:
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