Urgent Field Safety Notice

SBN-CPS-2019-014

CPS / ClinChem fully automated

Version 3

August-2020

ALB2 and C4-2: Calibration and QC failures on cobas c 701/702

Product Name	ALB2 (Albumin Gen.2) C4-2 (Tina-quant Complement C4 ver.2)
System	**cobas c** 701/702 module
Product Description / GMMI	05166861190 (ALB2) **cobas c** 701/702 Lot 43031001 and 43718901 05991994190 (C4-2) **cobas c** 701/702 Lot 36870301
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.

Dear Valued Customer,

Description of Situation

In versions 1 and 2 of the FSN-CPS-2019-014, Roche communicated information about a number of complaints regarding Albumin Gen.2 (ALB2) and Bilirubin Total Gen.3 (BILT3) on **cobas c** 701/702 modules alleging control recovery below 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 have already expired.

Recently we received and confirmed new customer complaints for C4-2 reagent lot 36870301 and ALB2 reagent lots 43031001 and 43718901 with the same error pattern and root cause.

Affected Lots			
SBN 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	ALB2	43031001	30-Nov-2020
	ALB2	43718901	31-Jan-2021
	C4-2	36870301	30-Sep-2020

Table 1: Overview of affected lots of SBN Version 1-3

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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 (< 7 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 and C4-2 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 ALB2 cassettes of lots 43031001 and 43718901 and C4-2 lot 36870301 have already been distributed out of global warehouses.
Meanwhile the manufacturer of the cassettes corrected the welding process successfully (including process revalidation) which should prevent further incidents in the future.

Actions to be taken by the customer/user

Each cassette of reagent lots: ALB2 lots 43031001 and 43718901 and C4-2 lot 36870301 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:

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>,

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Contact Details

To be completed locally:
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