

Urgent Field Safety Notice



SBN-CPS-2019-002

CPS / ClinChem fully automated substrates

Version 1

March-2019

cobas c 701/702: Albumin BCP failed calibration

Product Name	Albumin BCP (ALBP)
System	cobas c 701/702 module
GMMI / Part No	05975573190
Device Identifier	
Production Identifier (Product name/Product code)	Lot 35651401
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche has received a number of complaints regarding Albumin BCP (bromcresol purple) on the **cobas c** 701/702 modules for specific **cobas c** pack sequence numbers of reagent lot 35651401.

One affiliate complained about a particular delivery to the customer site for lot 35651401, where several reagent cassettes were failing calibration accompanied by an invalidating flag >Abs (ABS over alarm).

The calibration signals were up to 57,000 for both standard 1 and standard 2 and therefore above the threshold of >32,000 resulting in >Abs flags. The expected absorbance signals are approx. 5,000 for STD 1 and 10,000 for STD 2.

Two groups of complaints regarding the reagent lot 35651401 were identified:

Group 1: >Abs ALBP (Albumin BCP) calibration flags

Group 2: QC imprecision and elevated QC recovery

Investigations showed that affected reagent cassettes obtained from customers for investigation purposes had an elevated pH level in R1 of around 12.4 (usual pH 5.3) causing higher absorbance values when mixed with R2, resulting in >Abs alarms when performing a calibration or measuring a sample or quality control.

Not all ALBP reagent cassettes of reagent lot 35651401 are affected. Only reagent cassettes with sequence number above 12,000 from lot 35651401 may be affected.

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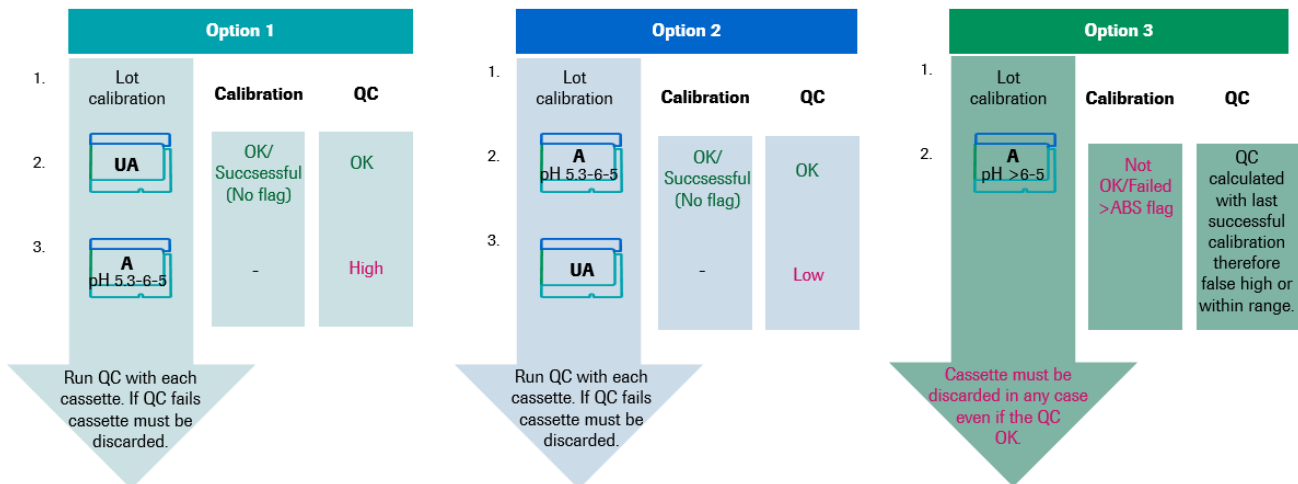


The issue can be clearly detected either by the >Abs flagged calibration result or by the control recovery.

Three scenarios are possible at customer site:

1. "Unaffected" cassette (sequence number $\leq 12,000$) is lot calibrated. "Affected" cassette (sequence number $> 12,000$) is subsequently loaded without further calibration (lot calibration is applicable to the "affected" cassette):
=> QC/samples would recover too high
2. A) "Affected" cassette is lot calibrated without >Abs flag
=> QC/samples for this "affected" cassette would recover normal
B) In case afterwards another "Unaffected" cassette is using this lot calibration
=> QC/samples would recover too low
3. "Affected" cassette with $\text{pH} > 6.5$ is calibrated
=> Abs flag is triggered

3 possible situations



A = affected cassette
UA = unaffected cassette

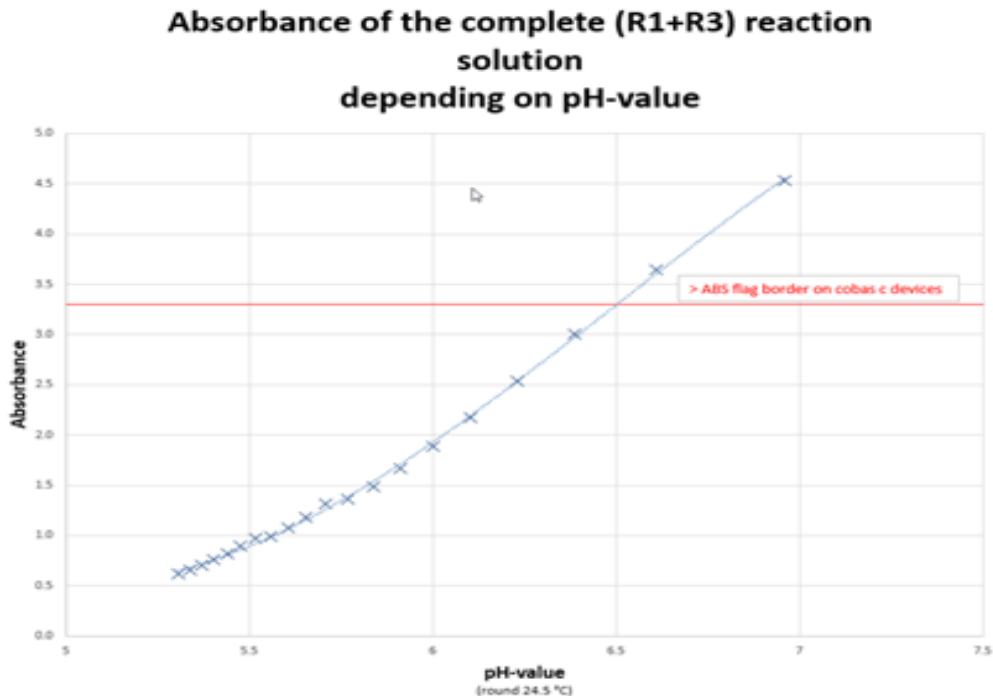
pH of R1+R2 mixture

- "Unaffected" reagent cassette: $\text{pH} < 5.3$
- "Affected" reagent cassette: $\text{pH} \geq 5.3 - 6.5$ or $\text{pH} > 6.5$

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Absorbance of the complete (R1+R3) reaction solution depending on pH-value



Considering the unreliable detectability of the issue and extent of possible deviation (calculated to be > 200%, based on pH-deviation), medical risk for the population at the greatest risk cannot be entirely excluded.

Actions taken by Roche Diagnostics

The root cause of the elevated pH in some cassettes has been identified as a sporadic issue within the production process which has now been resolved.

Actions to be taken by the customer/user

Workaround

If high or low ALBP control results are obtained, the sequence number of the reagent cassette must be checked.

The sequence number of potentially affected cobas c packs is above 12,000.

Please follow the following ALBP QC performance procedure:

1) For reagent cassettes with a **sequence number \leq 12,000:**

=> No action is required. The reagent cassette can be used without any further action.

2) For reagent cassettes with a **sequence number $>$ 12,000:**

=> **The QC must be checked for every cassette**

If the QC recovery is out of specification the cassette must be discarded.

To perform QC for every reagent cassette, the Stand by Bottle QC can be used.

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Please refer also to the attached document, "**Detailed workaround to identify the reagent cassette sequence number and to request QC for Standby reagents**".

Important Information:

A calibration must not be performed on a reagent cassette showing out of specification ALBP QC results. In this case the control results would be detected falsely low.

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>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com