



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Ref No: CFSN Albumin BCP SBN-CPS-2019-002
Date: 06/03/2019
Type of Action: Field Safety Corrective Action (FSCA)

Product Affected: Albumin BCP (ALBP)

System Affected: cobas c 701
cobas c 702

Software Version: N/A

Product Name	Material No	Lot No
Albumin BCP (ALBP)	05975573190	35651401

Summary of Issue

Albumin BCP failed calibration.

Reason for Notice

Dear Valued Customer,

Description of Situation

Roche has received a number of complaints regarding Albumin BCP (bromocresol 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).

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

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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.

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:

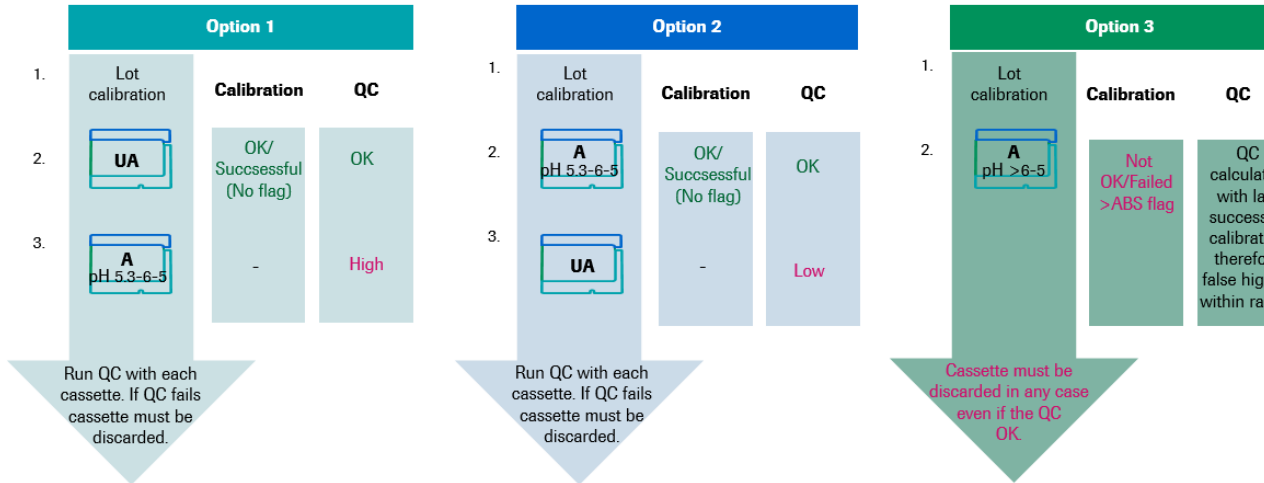
1. "Unaffected" cassette (sequence number $\leq 12,000$) is lot calibrated. "Affected" cassette (sequence number $> 12,000$) is subsequently loaded without further calibration (lot calibration is applicable to the "affected" cassette):
=> QC/samples would recover too high
2. A) "Affected" cassette is 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

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3 possible situations



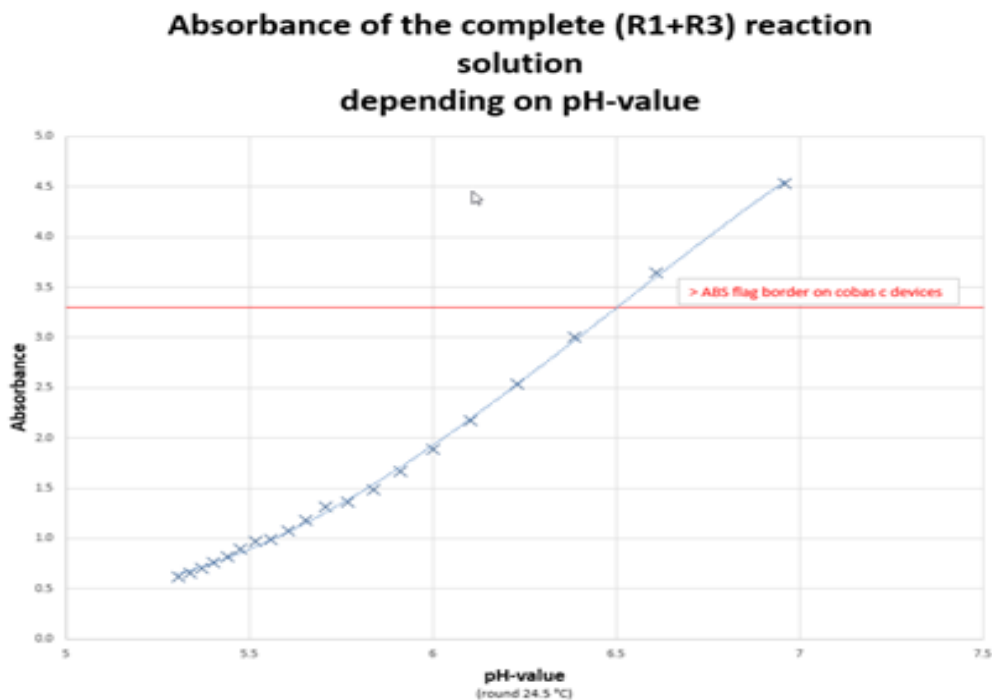
A = affected cassette
UA = unaffected cassette

pH of R1+R2 mixture

"Unaffected" reagent cassette: pH < 5.3

"Affected" reagent cassette: pH ≥ 5.3 - 6.5 or pH > 6.5

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



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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.

Action Required

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.

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.

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Please complete and return the **Acknowledgement Form** which accompanies this **Field Safety Notice** by 20th March 2019.

Please bring this notice to the attention of all personnel in your hospital or 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 notice to them.

Attachments

CFSN Albumin BCP SBN-CPS-2019-002 Attachment 1

CFSN Albumin BCP SBN-CPS-2019-002 Acknowledgement Form

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.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Field Safety Notice Ref No: CFSN Albumin BCP SBN-CPS-2019-002 Acknowledgement Form

Date: 06/03/2019

Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before 20th March 2019.

Product Catalogue No:	05975573190
System:	cobas c 701/702 module
Customer Name & Dept:	
Address:	

Are the above contact details correct? (Please circle) Yes No (If no please insert correct details below)

Contact Name:	
Department:	
Telephone:	
	If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:
Email:	
	Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice .
	Please bring this notice to the attention of all personnel in your hospital or healthcare 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 notice to them.



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Date: 06/03/2019

Type of Action: Field Safety Corrective Action (FSCA)

I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

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Detailed workaround to identify the reagent cassette sequence number and to request QC for Standby reagents

2. Request Stand By QC reagent cassettes

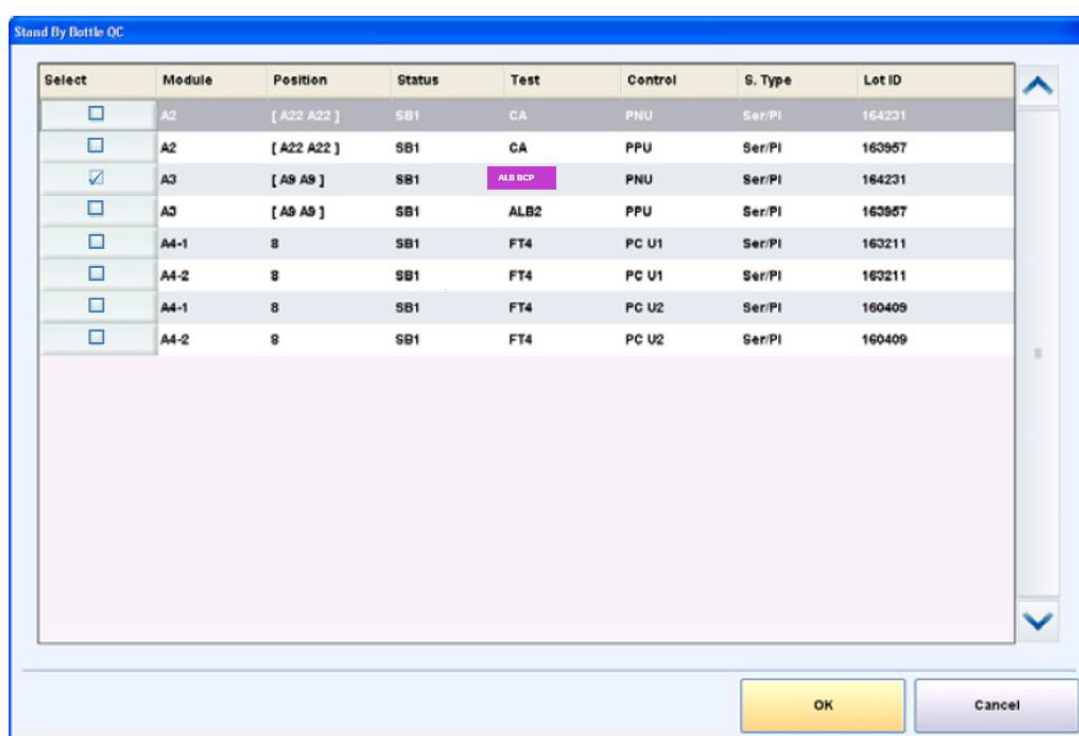
On QC > Status, choose the Stand By Bottle QC button to open the window

QC > Status > Stand By Bottle QC to select individual reagent cassettes on the module for standby QC.

This list displays information for all standby reagent cassettes currently loaded on the modules.

In the Select column, select the row containing the desired module, test ALBP and QC material. You can select multiple rows.

To request the selected QC material for measurement, choose the OK button.



Select	Module	Position	Status	Test	Control	S. Type	Lot ID
<input type="checkbox"/>	A2	[A22 A22]	SB1	CA	PNU	Ser/Pl	164231
<input type="checkbox"/>	A2	[A22 A22]	SB1	CA	PPU	Ser/Pl	163957
<input checked="" type="checkbox"/>	A3	[A9 A9]	SB1	ALB BCP	PNU	Ser/Pl	164231
<input type="checkbox"/>	A3	[A9 A9]	SB1	ALB2	PPU	Ser/Pl	163957
<input type="checkbox"/>	A4-1	8	SB1	FT4	PC U1	Ser/Pl	163211
<input type="checkbox"/>	A4-2	8	SB1	FT4	PC U1	Ser/Pl	163211
<input type="checkbox"/>	A4-1	8	SB1	FT4	PC U2	Ser/Pl	160409
<input type="checkbox"/>	A4-2	8	SB1	FT4	PC U2	Ser/Pl	160409

The sequence number of the Stand By Bottle QC reagent cassette can be found in the QC Routine component of the data manager by using the filter option Standby bottle from the QC type drop-down list and the using the mouse over function on the QC graph.

The sequence number is written as the Bottle Count No at the right end of the table.

Important note:

The screenshots are for example use only.