

# 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

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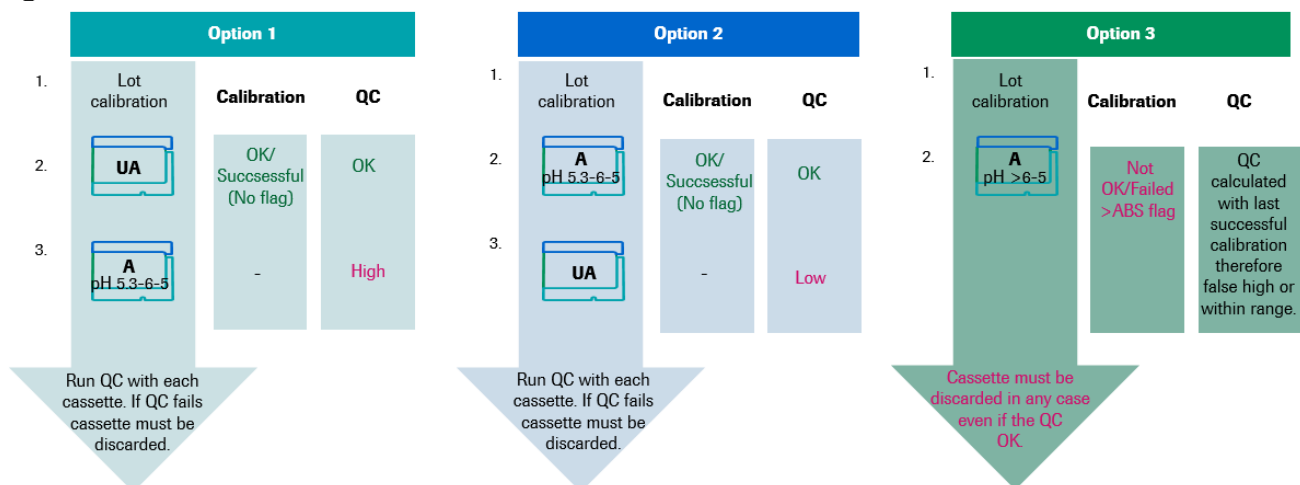


The issue can be clearly detected either by the >Abs flagged calibration result or by the control recovery.

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

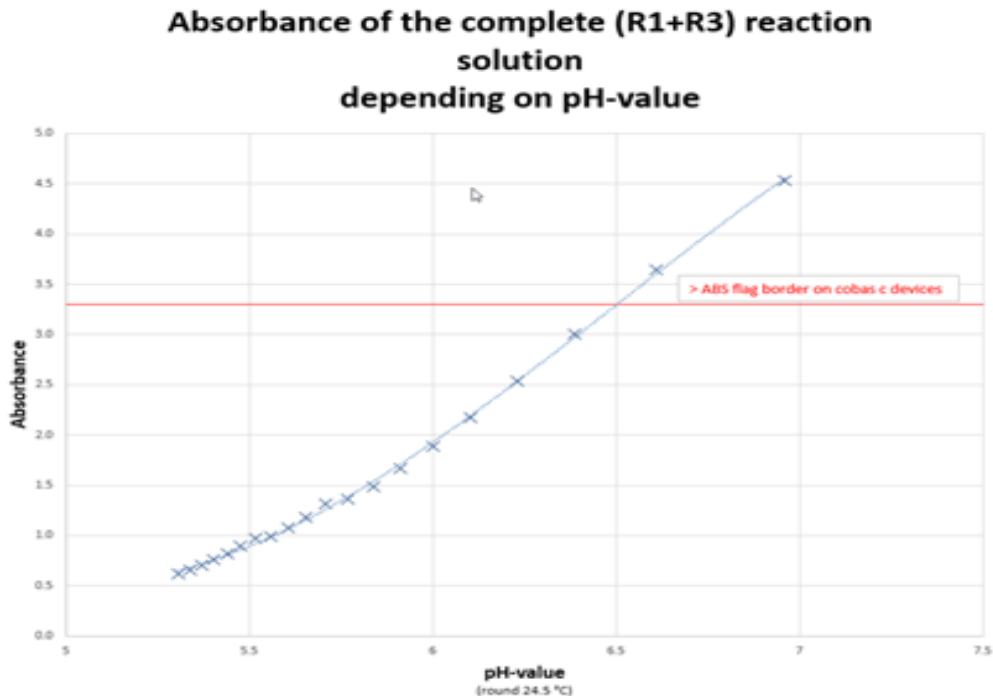
### pH of R1+R2 mixture

- "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

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

## 1. To check the sequence number of the reagent cassette that was used for calibration

### 1.1 Calibration trace print-out

- Use the **Print** window to select the report to be printed or viewed.
- Prior to printing or viewing the Calibration trace report, select the desired data on the **Calibration > Status** screen.
- Select the **Calibration Tab** and subsequently the **Calibration trace** report from the list to print the Calibration Trace report.

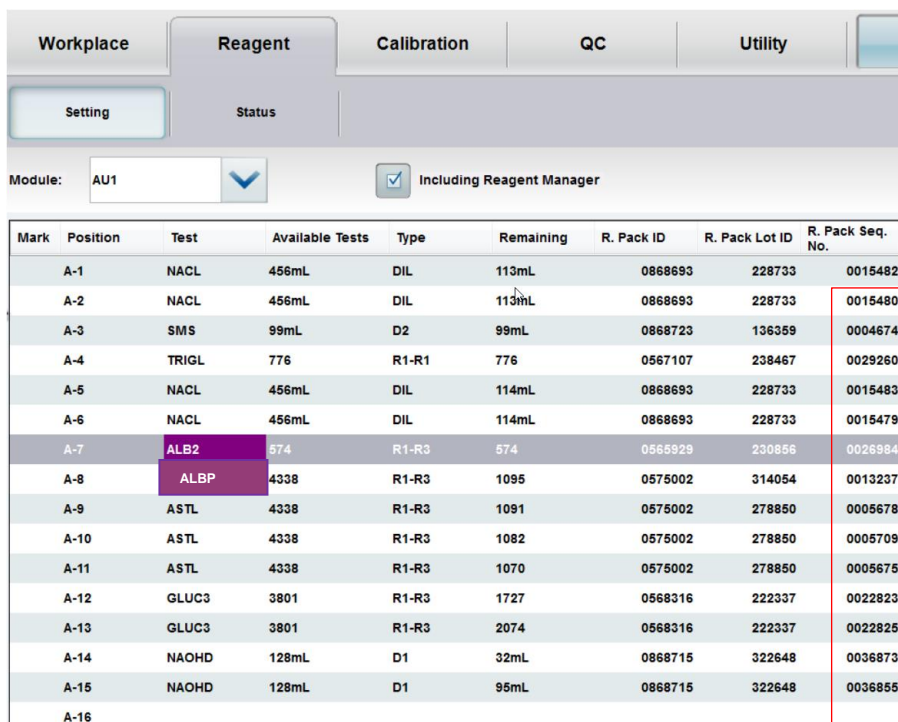
The reagent cassette sequence numbers are displayed in the last right-hand column of the Calibration trace print-out.

bmserv						R3	356514	0002493
21/11/2018	12:29	5094	999999	10078	305596	R1	356514	0002493
bmserv						R3	356514	0002493
22/11/2018	08:30	*****	999999	*****	305596	R1	356514	0012498*
bmserv		Std.E		Std.E		R3	356514	0012498*

\* (an asterisk) A reagent cassette changeover

### 1.2 Reagent setting screen

- Use the reagent setting screen to view the reagent cassette sequence number displayed in the column on the right hand site.



Mark	Position	Test	Available Tests	Type	Remaining	R. Pack ID	R. Pack Lot ID	R. Pack Seq. No.
A-1		NACL	456mL	DIL	113mL	0868693	228733	0015482
A-2		NACL	456mL	DIL	113mL	0868693	228733	0015480
A-3		SMS	99mL	D2	99mL	0868723	136359	0004674
A-4		TRIGL	776	R1-R1	776	0567107	238467	0029260
A-5		NACL	456mL	DIL	114mL	0868693	228733	0015483
A-6		NACL	456mL	DIL	114mL	0868693	228733	0015479
A-7		ALB2	574	R1-R3	574	0565929	230856	0026984
A-8		ALBP	4338	R1-R3	1095	0575002	314054	0013237
A-9		ASTL	4338	R1-R3	1091	0575002	278850	0005678
A-10		ASTL	4338	R1-R3	1082	0575002	278850	0005709
A-11		ASTL	4338	R1-R3	1070	0575002	278850	0005675
A-12		GLUC3	3801	R1-R3	1727	0568316	222337	0022823
A-13		GLUC3	3801	R1-R3	2074	0568316	222337	0022825
A-14		NAOHD	128mL	D1	32mL	0868715	322648	0036873
A-15		NAOHD	128mL	D1	95mL	0868715	322648	0036855
A-16								

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

### 2. Request Stand By QC reagent cassettes

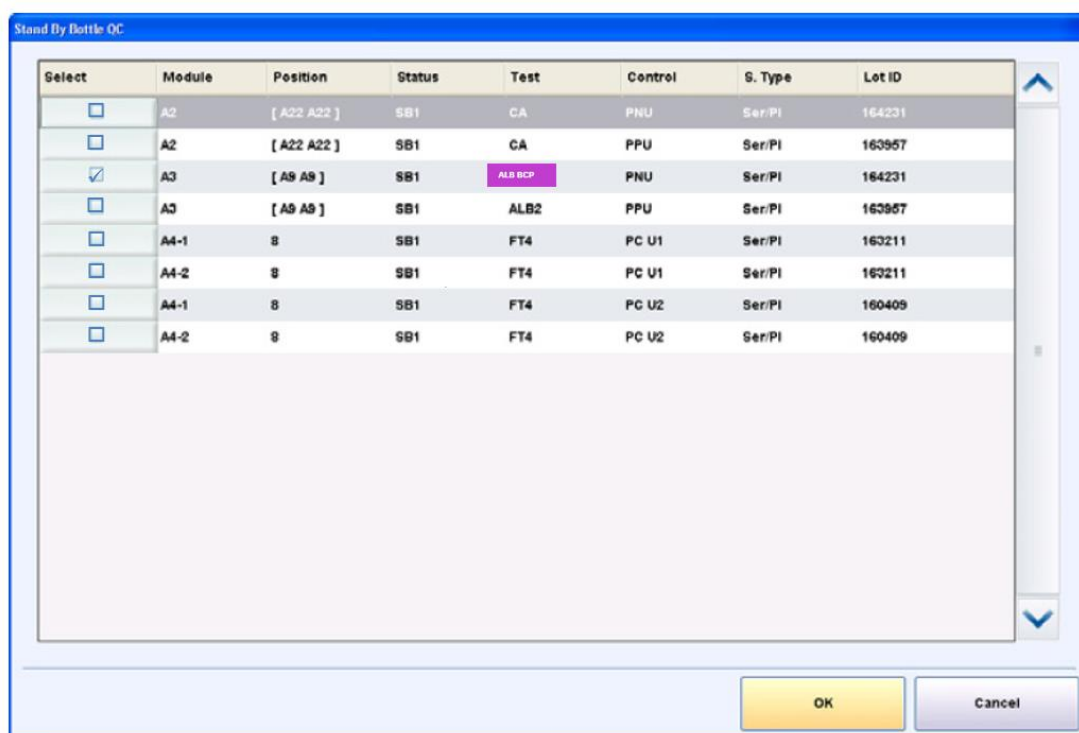
On QC > Status, choose the Stand By Bottle QC button to open the window

**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 mouseover 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 the exemplary use only.