

# Field Safety Notice

## SBN-CPS-2018-012

CPS / ClinChem fully automated Application  
Version 1  
12-Dec-2018

### Carryover on cobas c 111 analyzer

<b>Product Name</b>	cobas c 111 analyzer	
<b>GMMI / Device Identifier</b>	cobas c 111 with ISE	04777433001
	cobas c 111 without ISE	04528778001
	CLEAN cobas c 111	04774248190
<b>Production Identifier (Lot No./Serial No.)</b>	Not applicable	
<b>SW Version</b>	Not applicable	
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

#### Description of Situation

Newly generated measurements at Roche Diagnostics revealed additional carryover for some tests on the **cobas c 111** analyzer. In case of carry over, it cannot be excluded that incorrect high results were generated. A medical risk cannot be excluded. The recommended wash steps needed to be updated.

Affected tests (also identified as victims) are listed in the following table:

Material Number	Test	Instrument
05 401 470 190	CREP2* (Creatinine plus ver.2)	<b>cobas c 111</b>
04 657 594 190	TRIGL (Triglycerides)	<b>cobas c 111</b>

\*Serum/plasma application only. The urine application is not affected by carryover.

# Carryover on cobas c111 analyzer

## Actions taken by Roche Diagnostics

The observed carryover will be averted by additional extra wash cycles (EWC).

The updated EWC list for **cobas c 111** is part of the updated Instructions for Use (IFU) for the Cleaner (V 6.0), that will be published in Q1/2019.

## Actions to be taken by the customer/user

Customers running one or more of the tests described in the table below need to install the required carryover evasions until extra wash cycle list is updated. For customers not running the affected tests, no action is required.

Offender Test name (Mat.Nr.)	Affected test (Victim) Application name [ACN]	Planned solution
<b>CHOL2</b> (04718917 190) Cholesterol Gen.2	CRE2 [652]**	Extra Wash Cycle
<b>CHOL2</b> (04718917 190) Cholesterol Gen.2	TRIGL [781]**	Extra Wash Cycle

### Extra Wash Cycles (EWCs):

The following EWCs have to be set up for all affected customers manually:

Test combination in use		Extra wash cycle configuration					
		Action	Trigger Bottle Code	Pipetting type	Active	Cleaner Bottle Code	Volume [µL]
CHO2I	CRE2	after	798	R1	on	947	150
CHO2I	TRIGL	after	798	R1	on	947	150
CHO2A	CRE2	after	798	R1	on	947	150
CHO2A	TRIGL	after	798	R1	on	947	150

Secondary carry-over to TRIGL or CRE2 occurs only if a dextran sulfate containing assay is performed before CHOL2.

Hence, these EWCs are only mandatory in case one of the following tests is also installed on the analyzer: HDLC4, HDLC3 or LDLC3.



# Carryover on cobas c111 analyzer

## Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

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

Sincerely,

**Roche Diagnostics Asia Pacific Pte Ltd**

Email: [sg.regulatory@roche.com](mailto:sg.regulatory@roche.com)



# Carryover on cobas c111 analyzer

## ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Field Safety Notice Reference No. SBN-CPS-2018-012 dated 12 Dec 2018, regarding an issue with the carryover on cobas c111 analyzer.

We will manually setup Extra Wash Cycles (workaround solution) for our cobas c 111, if we are using the affected tests.

Received by:

\_\_\_\_\_  
Name & Signature

\_\_\_\_\_  
Facility Stamp

\_\_\_\_\_  
Date