

# Urgent Field Safety Notice

## SBN-CPS-2018-012

CPS / ClinChem fully automated Application  
Version 1  
Nov-2018

### Carryover on COBAS INTEGRA® 400 plus and cobas c 111 analyzer

<b>Product Name</b>	COBAS INTEGRA® 400 plus analyzer <b>cobas c</b> 111 analyzer	
<b>GMMI / Device Identifier</b>	COBAS INTEGRA® 400 plus analyzer with ISE	03245233001
	COBAS INTEGRA® 400 plus analyzer without ISE	04922859001
	<b>cobas c</b> 111 with ISE	04777433001
	<b>cobas c</b> 111 without ISE	04528778001
	CLEAN (Cleaner Cassette, COBAS INTEGRA® 400 plus)	20764337322
	CLEAN (Cleaner- Special Wash Requirements, cobas c111)	04774248190
<b>Production Identifier (Lot No./Serial No.)</b>	n/a	
<b>SW Version</b>	n/a	
<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 several tests on the COBAS INTEGRA® 400 plus and **cobas c** 111 analyzer. The internal findings for a number of tests show that the product specifications were not met. The recommended wash steps were either insufficient or missing altogether.

In case of carry over, it cannot be excluded that incorrect high results were generated. A medical risk cannot be excluded.

# Carryover on COBAS INTEGRA® 400 plus and cobas c111 analyzer

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

Material Number	Test	Instrument
06 750 052 190	A1MG (Tina-quant α1-Microglobulin Gen.2)	COBAS INTEGRA® 400 plus
03 032 566 122	APOAT (Tina-quant Apolipoprotein A-1 ver.2)	COBAS INTEGRA® 400 plus
04 469 658 190	ALBT2 (Tina-quant Albumin Gen.2)	COBAS INTEGRA® 400 plus
03 263 991 190	CREP2* (Creatinine plus ver.2)	COBAS INTEGRA® 400 plus
20 767 107 322	TRIGL (Triglycerides)	COBAS INTEGRA® 400 plus
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.

## Actions taken by Roche Diagnostics

The observed carryover will be averted by additional extra wash cycles. For some test combinations a needle assignment\* is applicable (see table below victim/offender).

\**Needle assignment* means, that dedicated tests will only be pipetted by a specific probe to exclude an interaction of a victim and offender combination and the resulting carryover. This assignment is part of the software (TAS = Test application software) and cannot be implemented manually.

For **COBAS INTEGRA® 400 plus** relevant changes are included in the upcoming TAS, solving the primary and secondary carry-overs; the update is planned for end of December 2018.

The updated extra wash cycle (EWC) List is part of the updated Instructions for Use (IFU) for the Cleaner Cassette (V 8.0), which will be available in Q1/2019.

**Please note:** 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 offenders in combination with the affected victim applications (as described in the table below) need to install the required carryover evasions until the TAS and extra wash cycle lists are updated.

For customers not running the affected tests no action is required.

# Carryover on COBAS INTEGRA® 400 plus and cobas c111 analyzer

## COBAS INTEGRA® 400 plus:

Customers have to install the following EWCs as described in detail in **attachment “Detailed workarounds”**

Affected test (Victim) Application name [test ID]	Offender Test name (Mat.Nr.)	Planned solution
A1MG2 [0-291]	<b>HDLC3</b> (04399803 190) HDL-Cholesterol plus 3 <sup>rd</sup> generation	Extra Wash Cycle
	<b>MDNII</b> (03046702 190) ONLINE DAT Methadone II	Extra Wash Cycle
	<b>OPI</b> (20767158 122) ONLINE DAT Opiates 300/2000	Batch mode
	<b>THCII</b> (03046753 190) ONLINE DAT Cannabinoids II	Batch mode
ALBS2 [0-172] ALBU2 [0-171] ALBC2 [0-170]	<b>HDLC3</b> (04399803 190) HDL-Cholesterol plus 3 <sup>rd</sup> generation	Extra Wash Cycle
	<b>FERR2</b> (03528995 190) Ferritin Gen. 2	Extra Wash Cycle
	<b>IGA</b> (20737755 322) Immunoglobulin A	Extra Wash Cycle
	<b>RF-II</b> (20764574 322) Rheumatoid Factors II	Extra Wash Cycle
	<b>MDNII</b> (03046702 190) ONLINE DAT Methadone II	Extra Wash Cycle
	<b>OPI</b> (20767158 122) ONLINE DAT Opiates 300/2000	Extra Wash Cycle
	<b>PCP</b> (20738042 122) Abuscreen OnLine Phencyclidine	Extra Wash Cycle
	<b>THCII</b> (03046753 190) ONLINE DAT Cannabinoids II	Extra Wash Cycle
APOAT [0-568]	<b>DIG</b> (20737836 322) Digoxin	Needle assignment
	<b>HDLC3</b> (04399803 190) HDL-Cholesterol plus 3 <sup>rd</sup> generation	Extra Wash Cycle
	<b>FERR2</b> (03528995 190) Ferritin Gen. 2	Extra Wash Cycle
	<b>RF-II</b> (20764574 322) Rheumatoid Factors II	Extra Wash Cycle
	<b>MDNII</b> (03046702 190) ONLINE DAT Methadone II	Needle assignment
	<b>OPI</b> (20767158 122) ONLINE DAT Opiates 300/2000	Needle assignment
	<b>PCP</b> (20738042 122) Abuscreen OnLine Phencyclidine	Extra Wash Cycle
	<b>THCII</b> (03046753 190) ONLINE DAT Cannabinoids II	Needle assignment
CRE2 [0-612]**	<b>CHOL2</b> (03039773 190) Cholesterol Gen.2	Extra Wash Cycle
TRIGL [0-010]**	<b>CHOL2</b> (03039773 190)	Extra Wash Cycle

# Carryover on COBAS INTEGRA® 400 plus and cobas c111 analyzer

Affected test (Victim) Application name [test ID]	Offender Test name (Mat.Nr.)	Planned solution
	Cholesterol Gen.2	

\*\* 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, LDL3, PPXS, PPXQL, PPXQC, PCPS, PCPQL, PCPQC, MTQLS, MTQQL, MTQQC, HCYS, DIGM or any TDM test using SDR II.

For all carry-over evasions which require needle assignment the only possible workaround for the customers is running the applications in batches (batch mode) until the TAS is released.

**[COUNTRY ACTION: You are allowed to modify the local availability according to your local release schedules]**

**\*Please note:** The manual set-up of the EWCs as well as the batch mode are only required until the TAS is available. However, the observed carryover of the test combinations of A1MG with OPI or THCI cannot be overcome with EWCs or needle assignment. Therefore, these test combinations must not be measured at the same time (batch mode required) even after the TAS has been published.

## **cobas c 111:**

Customers have to install the following EWCs as described in detail in **attachment 'Detailed overview about the required workarounds'**

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

\*\* 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 LDL3.

## **Communication of this Field Safety Notice (if appropriate)**

*<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:*

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

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

**The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:**

# Carryover on COBAS INTEGRA® 400 plus and cobas c111 analyzer

*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

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Email name@roche.com