



# Field Safety Notice

## SBN-CPS-2018-012

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

### Carryover on COBAS INTEGRA® 400 plus

<b>Product Name</b>	COBAS INTEGRA® 400 plus analyzer	
<b>GMMI / Device Identifier</b>	COBAS INTEGRA® 400 plus analyzer with ISE CLEAN (Cleaner Cassette, COBAS INTEGRA® 400 plus)	03245233001 20764337322
<i>Note: There may be other affected identifiers that are affected globally. Please contact the product owner if the device is obtained from an overseas dealer.</i>		
<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. 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

Affected tests (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

### 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.

### 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.

#### **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

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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
	<b>DIG</b> (20737836 322) Digoxin	Needle assignment
APOAT [0-568]	<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>DIG</b> (20737836 322) Digoxin	Needle assignment
	<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) 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, LDLC3, 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.

## Carryover on COBAS INTEGRA® 400 plus

**\*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.

### 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**

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