

Urgent Field Safety Notice



SBN-CPS-2017-017

CPS / ClinChem fully automated

Version 2b

Apr-2019

New claim for endogenous interferences for BILT3, IGM-2, and LACT2

Product Name	BILT3 BILT3 LACT2	cobas c 111 COBAS INTEGRA® 400 PLUS COBAS INTEGRA® 400 PLUS	
Production Description / (GMMI)	Bilirubin Total Gen.3 Bilirubin Total Gen.3 Lactate Gen.2	cobas c 111 COBAS INTEGRA® 400 plus COBAS INTEGRA® 400 plus	05795648190 05795397190 03183700190
Type of Action	Field Safety Corrective Action (FSCA)		

Dear Valued Customer,

Description of Situation

We would like to inform you about selected endogenous interferences in serum/plasma, urine and CSF (cerebrospinal fluid). The interferences were assessed for their potential risk on all Roche tests for COBAS INTEGRA® 400 plus and **cobas c 111**

Additional endogenous interferences with potential medical risk were found:

- IgG: in BILT3 on COBAS INTEGRA® 400 plus and **cobas c 111**
- Ditaurobilirubin: in LACT2 CSF on COBAS INTEGRA® 400 plus

Catalogue Number	Test Short name	Analyzer	Interferent
05795397190	BILT3 (Serum, plasma)	COBAS INTEGRA® 400 plus	IgG
05795648190	BILT3 (Serum, plasma)	cobas c 111	IgG
03183700190	LACT2 (CSF)	COBAS INTEGRA® 400 plus	Ditaurobilirubin

Please note: LACT Gen.2 plasma applications are not affected by the claim update since these claims have previously been assessed.

The root cause for the interference is the direct concentration-dependent interaction of the interferent with the test system.

If discrepant high BILT3 in serum/plasma, or low LACT2 in CSF values should occur, a medical risk cannot be entirely excluded:

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- **BILT3:** An interference with **IGG** was observed for total bilirubin, leading to deviations of up to +43.5% max.: With IGG interferent concentration of 61.7 g/L at the observed sample concentration of 14.4 µmol/L a BILT3 result of 20.6 µmol/L was obtained.
- **LACT2:** An interference with **ditaurobilirubin** was observed for lactate in CSF, leading to deviations of up to -38.8 % max.: With ditaurobilirubin interferent concentration of 47 mg/dL at the observed sample concentration of 2.60 mmol/L a LACT2 result of 1.59 mmol/L was obtained.

Actions taken by Roche Diagnostics

In the *Limitations – interference* section of the instructions for use of COBAS INTEGRA® 400 plus and **cobas c 111** the following claims will be added:

BILT3:

Immunoglobulins: No significant interference from immunoglobulins up to a concentration of 28 g/L (187 µmol/L) (simulated by human immunoglobulin G).

LACT2 (CSF):

Ditaurobilirubin: No significant interference from ditaurobilirubin up to an approximate concentration of 102 µmol/L (6 mg/dL).

Please note: The CSF application is only available on COBAS INTEGRA® 400 plus and not on **cobas c 111**

The updated instructions for use (IFU) for COBAS INTEGRA® 400 plus and **cobas c 111** are expected to be available in Q2/2019.

Actions to be taken by the customer/user

For the time being until release of the new instructions for use (**cobas c** modules) or phase out of the instruments (MODULAR ANALYTICS P/D) please be aware of the updated interference claims.

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.

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<closing salutations>,

Contact Details

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