Field Safety Notice

SBN-CPS-2018-017

CPS / ClinChem fully automated
Version 2
07-May-19

New claim for endogenous interferences for BILT3

Product Name	BILT3 BILT3	**cobas c** 111 COBAS INTEGRA® 400 PLUS
Product Description / GMMI	Bilirubin Total Gen.3 Bilirubin Total Gen.3	**cobas c** 111 05795648190 COBAS INTEGRA® 400 plus 05795397190
	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.	
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. 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

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

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 should occur, a medical risk cannot be entirely excluded.

BILT3 in serum/plasma:
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.

Roche Diagnostics Asia Pacific Pte Ltd
8 Kallang Avenue
#10-01/09 Aperia Tower 1
Singapore 339509
Tel. +65 – 6272 7500
Fax +65 – 6371 6633

New claim for endogenous interferences for BILT3

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).

The updated instructions for use (IFU) for COBAS INTEGRA® 400 plus and **cobas c** 111 are expected to be available in Q3/2019.

Actions to be taken by the customer/user

Please be aware of the updated interference claims. Revised and approved package inserts will be available by the end of Q3/2019.

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