

Field Safety Notice

SBN-CPS-2018-017

CPS / ClinChem fully automated

Version 2

27-May-19

New claim for endogenous interference for Lactate Gen.2

Product Name	Lactate Gen.2	COBAS INTEGRA® 400 PLUS
Product Description / GMMI	Lactate Gen.2	COBAS INTEGRA® 400 plus 03183700190
	Affected lots are not available in Singapore	
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.

Additional endogenous interferences with potential medical risk were found:

- Ditaurobilirubin: in LACT2 CSF on COBAS INTEGRA® 400 plus

Catalogue Number	Test Short name	Analyzer	Interferent
03183700190	LACT2 (CSF)	COBAS INTEGRA® 400 plus	Ditaurobilirubin

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

If discrepant low LACT2 in CSF values should occur, a medical risk cannot be entirely excluded.

LACT2 in CSF:

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.

New claim for endogenous interferences for Lactate Gen.2

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:

LACT2 (CSF):

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

The updated instructions for use (IFU) for COBAS INTEGRA® 400 plus is 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