

# Field Safety Notice

## SBN-CPS-2018-017

CPS / ClinChem fully automated  
Version 1  
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### New claim for endogenous interferences for BILT3, IGM-2, and LACT2

<b>Product Name</b>	BILT3	<b>cobas c</b> 311/501/502/701/702	
	LACT2	<b>cobas c</b> 311/501/502/701/702	
	IgM-2	<b>cobas c</b> 311/501/502/701/702	
<b>Product Description / GMMI</b>	Bilirubin Total Gen.3	<b>cobas c</b> 311/501/502	05795397190
	Bilirubin Total Gen.3	<b>cobas c</b> 701/702	05795419190
	Lactate Gen.2	<b>cobas c</b> 311/501/502	03183700190 (only CSF application is affected)
	Lactate Gen.2	<b>cobas c</b> 701/702	05171881190 (only CSF application is affected)
	Tina-quant IgM Gen.2	<b>cobas c</b> 311/ 501/502	03507190190 (No affected customers using sensitive application in Singapore. cobas c311 / 501: ACN: 274 cobas c502: ACN: 8274)
	Tina-quant IgM Gen.2	<b>cobas c</b> 701/702	05220726190 (No affected customers using sensitive application in Singapore. cobas c702: ACN: 8274)
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)		

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

Dear Valued Customer,

## Description of Situation

In preparation for the introduction of a new analyzer, endogenous drug interferences in serum/plasma, urine and cerebrospinal fluid (CSF) were conducted to assess for potential risk on all Roche tests and platforms.

During the investigation, new endogenous interference claims for three tests with potential medical risk were found:

- BIL-T Gen. 3 (BILT3) in serum/plasma
- LACT Gen. 2 in CSF
- IGM Gen. 2 sensitive application (IGMP2) in serum/plasma

**Please note:** LACT Gen. 2 plasma and IGM Gen. 2 standard applications are not affected.

The findings were:

### **BILT3 in serum/plasma:**

An interference with **IGG** was observed for total bilirubin, leading to deviations of up to + 43.5% max.: 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 in CSF:**

An interference with **ditaurobilirubin** was observed for lactate in CSF, leading to deviations of up to -38.8 % max.: 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.

### **IGMP2 (sensitive application) in serum/plasma:**

An interference with **hemolysis** was observed for IGMP2, leading to deviations of up to +33.7 % max.: H-Index of 970 at an IGMP2 concentration of 0.0223 g/L, a result of 0.0298 g/L was obtained.

An interference with **lipemia** was observed for IGMP2, leading to deviations of up to -41.3 % max. For instance, L index of 832 at an IGMP2 concentration of 0.0230 g/L, a result of 0.0135 g/L was obtained.

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

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

## Actions taken by Roche Diagnostics

The *Limitations – interference* section of respective package inserts will be updated as follows:

### 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).*

### IGMP2 (Sensitive application):

*Hemolysis: No significant interference up to an H index of 600 (approximate hemoglobin concentration: 373 µmol/L or 600 mg/dL).*

*Lipemia (Intralipid): No significant interference up to an L index of 600.*

The updated package inserts will be available and sent to you by the end of Q1 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 Q1 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](mailto:sg.regulatory@roche.com)