Urgent Field Safety Notice

CPS / ClinChem fully automated
Version 2a
Apr-2019

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

Product Name	BILT3	**cobas c** 311/501/502/701/702
	BILT3	**MODULAR** P/D
	LACT2	**cobas c** 311/501/502/701/702
	Lactate	**MODULAR** P
	IgM-2	**cobas c** 311/501/502/701/702
	IgM-2	**MODULAR** P

Product Description / GMMI	Bilirubin Total Gen.3	**MODULAR** P	05795320190
	Bilirubin Total Gen.3	**MODULAR** P, D (R1)	05795338190
	Bilirubin Total Gen.3	**MODULAR** P, D (R2)	05795346190
	Bilirubin Total Gen.3	**cobas c** 311/501/502	05795397190
	Bilirubin Total Gen.3	**cobas c** 701/702	05795419190
	Lactate	**MODULAR** P	11822837190
	Lactate Gen.2	**cobas c** 311/501/502	03183700190
	Lactate Gen.2	**cobas c** 701/702	05171881190
	Tina-quant IgM Gen.2	**MODULAR** P	03507041190
	Tina-quant IgM Gen.2	**MODULAR** P	03507149190
	Tina-quant IgM Gen.2	**cobas c** 311/ 501/502	03507190190
	Tina-quant IgM Gen.2	**cobas c** 701/702	05220726190

Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

In readiness for the introduction of a new analyzer, selected endogenous drug interferences in serum/plasma, urine and CSF (cerebrospinal fluid) were assessed for their potential risk on all Roche tests and corresponding platforms. The root cause for the interference is the direct concentration-dependent interaction of the interferent with the test system.

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New endogenous interference claims for three tests with potential medical risk were found:

- BIL-T Gen.3
- IGM Gen2 (IGMP2 sensitive application) in serum/plasma
- LACT Gen.2 in CSF

If discrepant high (BILT3, IGMP2/hemolysis) or low (IGMP2/lipemia, LACT2 in CSF) values should occur, a medical risk cannot be entirely excluded:

- 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.

- IGMP2: An interference with **hemolysis** was observed for IGMP2, leading to deviations of up to +33.7 % max.: With H-Index of 970 at an IgMP2 concentration of 0.0223 g/L a result of 0.0298 g/L was obtained.

- IGMP2: An interference with **lipemia** was observed for IGMP, leading to deviations of up to -41.3 % max.: With L index of 832 at an IgMP2 concentration of 0.0230 g/L a result of 0.0135 g/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.

Please note: the IGM Gen.2 (IGM-2) standard and LACT Gen.2 plasma applications are not affected by the claim update since these claims were still implemented by former interference assessments.

Actions taken by Roche Diagnostics

In the *Limitations – interference* section of the instruction for use of **cobas c** 311/501/502/701/702 the following claims are newly added (BILT3, LACT2 [CSF]) and existing claims reduced (IGMP2).

BILT3:

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

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.

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LACT2 (CSF):
Ditaurobilirubin: No significant interference from ditaurobilirubin up to an approximate concentration of 102 µmol/L (6 mg/dL).

Updated e-Library packages for **cobas c** 311/501/502/701/702 were provided electronically to the cobas e-Content Portal by the end of November 2018. However, the serum index values encoded in the updated e-barcode (=e-bc) version for IGMP2 ACN 8274 on **cobas c** 502/701/702 published in Q4/2018 remained **unchanged**.
In consequence, there will be another updated e-library package published for these 3 modules by the end of April 2019.

Due to the phase out of the Roche/Hitachi MODULAR *ANALYTICS* <P> and <D> analyzers by the end of Q1/2019, the instructions for use will not be updated with the newly measured endogenous interferences. The new claims on the **cobas c** systems will also apply to the MODULAR *ANALYTICS* platform.

With relation to COBAS INTEGRA® 400 plus and cobas c 111, the interference assessment for BILT3, IGMP2 and LACT2 will be completed by the end of January 2019. Depending on the outcome of the assessment, the subsequent update of the corresponding Limitations – interference section for COBAS INTEGRA® 400 plus and cobas c 111 platforms will be completed by Q2/2019. Roche will inform you accordingly.

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)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

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.

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We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:
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Company Name
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