



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Ref No: CCFSN BILT3, IGM-2 and LACT2 SBN-CPS-2018-017
Date: 03/12/2018
Type of Action: Field Safety Corrective Action (FSCA)

Product Affected: BILT3
LACT2
Lactate
IGM-2

System Affected: MODULAR ANALYTICS P
cobas c 311
cobas c 501
cobas c 502
cobas c 701
cobas c 702

Software Version: N/A

| Product No | Material No | Lot No |
|------------------------|-------------|--------|
| Bilirubin Total Gen. 3 | 05795320190 | N/A |
| Bilirubin Total Gen. 3 | 05795338190 | N/A |
| Bilirubin Total Gen. 3 | 05795346190 | N/A |
| Bilirubin Total Gen. 3 | 05795397190 | N/A |
| Bilirubin Total Gen. 3 | 05795419190 | N/A |
| Lactate | 11822837190 | N/A |
| Lactate Gen. 2 | 03183700190 | N/A |
| Lactate Gen. 2 | 05171881190 | N/A |
| Tina-quant IgM Gen. 2 | 03507041190 | N/A |
| Tina-quant IgM Gen. 2 | 03507149190 | N/A |
| Tina-quant IgM Gen. 2 | 03507190190 | N/A |
| Tina-quant IgM Gen. 2 | 05220726190 | N/A |

Summary of Issue

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

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

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Reason for Notice

Dear Valued Customer,

Description of Situation

In readiness for the introduction of a new analyser, 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.

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.

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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 μ mol/L) (simulated by human immunoglobulin G).

IGMP2 (Sensitive application):

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

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

LACT2 (CSF):

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

The updated e-packages will be available in cobas link at the end of the year 2018 the latest.

Due to the phase out of the Roche/Hitachi MODULAR ANALYTICS P analysers 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.

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Action Required

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) please be aware of the updated interference claims.

Please complete and return the **Acknowledgement Form** which accompanies this **Field Safety Notice** by 17th December 2018.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments

CCFSN BILT3, IGM-2 and LACT2 SBN-CPS-2018-017 Acknowledgement Form.

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Acknowledgement Form

Date: 03.12.2018

Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before 17th December 2018.

| | |
|----------------------------------|--|
| Product Catalogue No: | Bilirubin Total Gen. 3 Lactate Lactate Gen. 2 Tina-quant IgM Gen. 2 |
| System: | MODULAR ANALYTICS P cobas c 311/501/502/701/702 |
| Customer Name & Dept: | |
| Address: | |

Are the above contact details correct? (Please circle) Yes No (If no please insert correct details below)

Contact Name:

Department:

Telephone:

If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying **Field Safety Notice**.

Please bring this notice to the attention of all personnel in your hospital or healthcare facility who need to be aware of this safety issue.

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Roche Diagnostics
Charles Avenue
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West Sussex
RH15 9RY

Registered No 571546

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Acknowledgement Form

Date: 03.12.2018

Type of Action: Field Safety Corrective Action (FSCA)

I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

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