Urgent Field Safety Notice

SBN-CPS-2018-007

CPS / ClinChem fully automated
Specific Proteins
Version 1
xx-May-2018

Tina-quant IgG Gen.2, Urine application: Changed signal levels cause calibration misfits

Product Name	IGG-2
Product Description	Tina-quant IgG Gen.2 on **cobas c** 311/501/502 analyzers
GMMI / Part No Device Identifier	03507432190
Production Identifier (Lot No./Serial No.)	24242601
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Using the urine application of the Tina-quant IgG Gen.2 assay (Application Short Name: IGGU2) on **cobas c** 311/501/502 analyzers with the reagent lot #24242601, shows higher signal levels which may cause a misfit of the calibration curve, resulting in over-recovery of a maximal bias of +37% at lower sample concentrations (e.g. 5 mg/L to 10 mg/L).

No complaints have been received by Roche.

In general, determination of IgG in urine is used to allow the differentiation between selective and unselective glomerular proteinuria, as well as for the monitoring and assessment of already established proteinuria. The issue may result in erroneous elevated IgG results in urine, which can further lead to unnecessary diagnostic measures and possibly wrong interpretation of the results.

Other applications (serum/plasma, CSF) and other reagent lots perform within specifications. Reagent lots for use on the **cobas c** 701/702, COBAS INTEGRA® 400 plus and **MODULAR** P analyzers are not affected.

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Actions taken by Roche Diagnostics (if applicable)

- Root cause has been identified and all necessary preventative actions have been implemented to avoid the recurrence of the issue in future lots.

Actions to be taken by the customer/user

- Please stop using the affected lot (#24242601) and discard any remaining kits
- Please change to a different available lot on market (#26358201, 28573901, 30922401, 33072401)

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.

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

<closing salutations>,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com