Urgent Field Safety Notice

SBN-CPS-2018-026

CPS / ClinChem fully automated
Version 1
August-2019

Tina-quant Soluble Transferrin Receptor (sTFR) assay: Updated claim for Rheumatoid Factors interference

Product Name	**STFR (Tina-quant Soluble Transferrin Receptor)**
System	**cobas c** 311 **cobas c** 501 **cobas c** 502 **cobas c** 701 **cobas c** 702 COBAS INTEGRA 400 plus analyzer
GMMI / Part No **Device Identifier**	20763454122 (Tina-quant Soluble Transferrin Receptor, **cobas c** 311, **cobas c** 501/502, COBAS INTEGRA 400 plus) 05950821190 (Tina-quant Soluble Transferrin Receptor, **cobas c** 701/702)
Production Identifier (Product name/Product code)	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

During the feasibility study for the new **Tina-quant Soluble Transferrin Receptor** assay generation, it was observed that the current claim for rheumatoid factors (RF) interference cannot be confirmed for the current STFR assay. Currently, the claim for this assay is that there is no significant interference of RF up to a concentration of 750 IU/mL for **cobas c** systems and 500 IU/mL for COBAS INTEGRA 400 plus analyzer. The most recent internal investigations have confirmed that there is no significant interference of rheumatoid factors up to a concentration of 150 IU/mL for **cobas c** systems and 120 IU/mL for COBAS INTEGRA 400 plus analyzer.

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Due to the fact that the RF value is not known by the customer in most cases, the detectability of the interference is difficult. However, implausible results should be noted, since STFR should never be used alone for diagnosis, but always interpreted in combination with other parameters (e.g. Ferritin, Transferrin, Iron).

Due to the residual medical risk associated with this issue, customers using the affected product must follow the actions as described below

Actions taken by Roche Diagnostics

Roche will update the claims in the respective method sheets as described below:

For cobas c 311/501/502/701/702
"Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 150 IU/mL."

For COBAS INTEGRA 400 plus
"Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 120 IU/mL."

The updated method sheets will be available in 11/2019.

Actions to be taken by the customer/user

Take into consideration the new RF interference limits.

For **cobas c** 311/501/502/701/702

*"Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of **150** IU/mL."*

For COBAS INTEGRA 400 plus

*"Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of **120** IU/mL."*

Communication of this Field Safety Notice (if appropriate)

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

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

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

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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