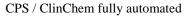
Field Safety Notice





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	20763454122 (Tina-quant Soluble Transferrin
Device Identifier	Receptor, cobas c 311, cobas c 501/502, COBAS
	INTEGRA 400 plus)
	05950821190 (Tina-quant Soluble Transferrin
	Receptor, cobas c 701/702)
Production Identifier	n/a
(Product name/Product code)	
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.

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

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

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

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.

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

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

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com