

Urgent Field Safety Notice



SBN-CPS-2019-011

CPS / ClinChem fully automated

Version 3

Sep-2019

Tina-quant Myoglobin Gen.2 imprecision and calibration issues on cobas c 311/501/502

Product Name	MYO2 (Tina-quant Myoglobin Gen.2)
System	cobas c 311/501/502
GMMI / Part No	04580010190
Device Identifier	
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

In the version 2 of this document we reported that recent reagent lots of the Myoglobin test show susceptibility to neighbor cell mixing which causes inaccuracy issues on QCs and patient samples. In order to prevent false results, customers were recommended to manually implement extra wash cycles (EWC) for **cobas c** 311/501/502 and customers using **cobas c** 501/502 additionally had to run the Myoglobin test in batch mode.

For **cobas c** 501/502, updated application setting for MYO2 will be available in September 2019. Therefore, as soon as the updated application has been installed on customers' systems the manual implementation of EWC and working in batch mode is not needed anymore for those systems.

For **cobas c** 311, the EWC solved the issue and updating the application settings is not needed.

Actions taken by Roche Diagnostics

For **cobas c** 311, Roche will implement updated Special Wash Requirements Method Sheet and publish in GRIPS and e-Content Portal in October 2019. For **cobas c** 501/502, updated application setting for MYO2 will be available in September 2019.

Actions to be taken by the customer/user

For **cobas c** 501/502, customers must update the MYO2 application as soon as it becomes available via **cobas** link.

Tina-quant Myoglobin Gen.2 imprecision and calibration issues on cobas c 311/501/502



Until the new application has been installed on customers' systems, customers are advised to use the assay in batch mode as described in the V2 of this FSN.

For **cobas c 311**, the EWC solves the issue, therefore no application update is needed.

Until the EWC have been installed (October 2019), customers are advised to manually program the EWC as described in the V1 and V2 of this FSN.

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.

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