Urgent Field Safety Notice

SBN-RDS-CoreLab-2021-016

RDS/ CoreLab / Core Reagents
Version 1

MYO2: Standardization Issue on cobas® c 503

Product Name	MYO2 (Tina-quant Myoglobin Gen.2)
Product Description	MYO2, 200T, cobas c pack green
GMMI / Part No **Device Identifier**	08252629190 **cobas c** 503
Production Identifier (Lot No./Serial No.)	all lots
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

Recently, one customer complaint was received alleging discrepant results in Myoglobin test during method comparison between **cobas c** 503 and **cobas c** 501. A low bias was observed with QC and patient samples on **cobas c** 503. No allegation of an adverse event was made.

Internal investigations confirmed the finding and an under recovery up to -59% at the lower end and -32% at the upper end of expected value range was shown on **cobas c** 503. Root cause is a standardization difference between the platforms.

Note that the issue is specific to the MYO2 application (MYO2 ACN 20920) on **cobas c** 503, other applications for other instrument platforms are not affected.

Due to the residual risk related to the issue, affected customers must be informed using the FSN-RDS-CoreLab-2021-016.

MYO2: Standardization Issue on cobas® c 503

Actions taken by Roche Diagnostics

Re-standardization of the MYO2 assay for **cobas c** 503 has been performed and updated e-Library packages for the application (updated instrument factor *from -12 to +8*), and all calibrator and control lots within shelf life (re-assigned values and ranges) will be released to e-Content Portal by end of November 2021. Updated e-Library packages are to be released by local Country e-Library Managers.

Myoglobin values for human serum obtained on **cobas c** 503 updated standardization (y) were compared with those on **cobas c** 503 current standardization (x). As a result from re-standardization, expected recoveries on patient samples will change according to the following equation $y = 0.9166x + 18.150$.

Consistently, the method comparison data for **cobas c** 503 vs. **cobas c** 501 in the Instructions for Use (IFU) for **cobas c** 503 will be updated in line with IVDR registration. Updated IFU is expected to be available by end of December 2021.
The Supplemental Value Sheet (SVS) and "Important Note" listing updated application settings, re-assigned calibrator set-points and control values for all lots currently within shelf life are attached to the FSN-RDS-CoreLab-2021-016.

Actions to be taken by the customer/user

Until the updated application settings are available, customers should stop using MYO2 application on **cobas c** 503, alternatively, the customers should switch to an alternative **cobas c** or **cobas e** system.

Customers are advised to download updated e-packages for application settings, re-assigned calibrator set-points and control values once available. Re-assigned values and ranges will be released to e-Content Portal by end of November 2021. Updated IFU is expected to be available by end of December 2021.

Note that for the MYO2 application on **cobas c** 503, the instrument factor is given in the application settings and does not have to be edited manually. Also, note that on **cobas c** 503 the Technical Limit is independent of the Instrument Factor and remains unchanged.

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:

MYO2: Standardization Issue on cobas® c 503

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

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.