

Urgent Field Safety Notice



SBN-CPS-2019-011

CPS / ClinChem fully automated

Version 2

Jul-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 1 of this document, we informed about the occurrence of signal drops with Tina-quant Myoglobin Gen.2 (MYO2) caused by neighbor cell mixing. As a workaround we described the introduction of an Extra Wash Cycle (EWC) on **cobas c** 311/501/502. Recently, we have received several customer complaints related to the described workaround and subsequent internal investigations confirmed that for **cobas c** 501/502 further actions (run samples in batch mode) need to be implemented for these systems.

As communicated in the version 1 of this FSN Roche has received a small number of customer complaints about sporadic quality controls (QCs) imprecision and calibration failures with the Tina-quant Myoglobin Gen.2 (MYO2) assay on **cobas c** 311/501/502 with reagent lot #34986001.

Internal investigations confirmed the QC imprecision and the calibration failures due to Dup.E.

It was shown that in the affected measurements a drop in the signal in the reaction kinetics occurred. This drop is caused by a break-up of a precipitate triggered by mixing in a neighboring cell.

Investigations showed that COBAS INTEGRA 400 plus and **cobas c** 701/702 systems are **not** affected.

Current findings suggest that upcoming lots will also be affected in the same manner.

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Due to incorrect low myoglobin levels affecting also patient results, a medical risk cannot be excluded. 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 implement required extra wash cycles (EWCs) into the respective EWC lists and files (available Q4/2019) for **cobas c 311/501/502**. These additional EWCs prevent effects from neighboring cell mixing.

Based on the results of the most recent investigations, additionally Roche will implement a change in the application settings of Tina-quant Myoglobin Gen.2 assay on **cobas c 501/502** in such a way that neighbor cuvettes are not used anymore in order to prevent cell neighbor mixing effects.

Actions to be taken by the customer/user

In addition to programming of extra wash cycles on **cobas c** instruments and in order to prevent the neighbor cell mixing effects

- customers using **cobas c 501/502** should implement the following advice:

As an additional action to the implementation of the EWC, customers now need to run the Tina-quant Myoglobin Gen. 2 assay in batch mode. The total amount of samples measured in each batch must not exceed 39 samples (n <39) and has to be measured independently from other tests/samples in a separate run for Myoglobin only. The instrument has to be in standby mode before and after the measurement of the Myoglobin batch. Additionally, the calibration for Myoglobin has to be requested separately and independently from other test calibrations. With this approach the neighbor cell mixing effect is avoided.

Note: Please be aware that STAT samples will interrupt the batch mode and the Myoglobin run will have to be repeated.

- customers using **cobas c 311** should implement the following advice:
No further actions for **cobas c 311** customers.

Customers are still advised to manually program the following EWCs:

on **cobas c 311**: go to: "Utility -> Special Wash -> "Reagent Probe" -> Edit"

From Test Reagent [Application]	From	To Test Reagent [Application]	To	Wash Type	Wash Vol [µL]
ALL	R1	MYO2 [620]	R1	Water	180

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on **cobas c 501**: go to "Utility -> Special Wash -> "Reagent Probe" -> Edit"

From Test Reagent [Application]	From	To Test Reagent [Application]	To	Wash Type	Wash Vol [µL]
ALL	R1	MYO2 [620]	R1	Water	180

on **cobas c 502**: go to "Utility -> Special Wash -> Reagent Probe -> User Rule -> Edit"

From Test Reagent [Application]	From	To Test Reagent [Application]	To	Wash Type	Wash Vol [µL]
ALL	R1	MYO2 [8620]	R1	Water	NA

As an alternative, customers can use the Tina-quant Myoglobin Gen.2 on COBAS INTEGRA® 400 plus or **cobas c** 701/702 instruments, or Elecsys Myoglobin on **cobas e** 411/601/602/801 instruments.

Important note: These workarounds are valid for all upcoming lots until the additional EWC and the updated application settings for Tina-quant Myoglobin Gen. 2 assay are available and have been installed. Customers will be informed accordingly.

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>,

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Contact Details

To be completed locally:

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