Urgent Field Safety Notice
SBN-CPS-2016-019

CPS / ClinChem fully automated
Version 2
22-Sept-2016

Tina-quant HbA1c Gen.2: possible Over-Recovery

Product Name	A1C-2 A1CX2	
Product Description	Tina-quant Hemoglobin A1c Gen.2	
GMMI / Part No **Device Identifier**	**Product** Tina-quant HbA1c Gen.2 Tina-quant HbA1cDx Gen.2 Tina-quant HbA1c Gen. 2	**GMMI** 04528123-190 04528123-160 05401640-190
Production Identifier (Lot No./Serial No.)	All lot numbers	
Instruments/systems	COBAS INTEGRA® 400 plus analyzer / system COBAS INTEGRA® 800 analyzer / instrument **cobas c** 111 analyzer **cobas c** 311 analyzer **cobas c** 501 module **cobas c** 502 module	
SW Version	n.a.	
Type of Action	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

We regret to inform you about the over-recovery of QC materials and patient samples on individual c packs across multiple Tina-quant HbA1c Gen. 2 and Tina-quant HbA1c Dx Gen.2 reagent lots upon freezing.

Tina-quant HbA1c Gen.2: possible Over-Recovery

Description of Situation

Customers complained that individual c packs of Tina-quant HbA1c Gen. 2 and Tina-quant HbA1c Dx Gen. 2 reagent across multiple lots yielded elevated recoveries on QC materials and patient samples.

Tina-quant HbA1c Gen. 3 is not affected as the reagent is less sensitive to low temperature in comparison to the Tina-quant HbA1c Gen. 2 reagent.

Root cause analysis

The definite root cause is unknown. Investigations assumed that unintentional storage at low temperatures even below 0°C at the customer site or during transportation may cause the formation of precipitates in the antibody reagent, thus leading to falsely elevated results.

When calibration takes place with the affected cassette, the drift in most cases can be calibrated out on COBAS INTEGRA® and cobas c 311/501/502 analyzers.

On the cobas c 111 analyzer calibration might not solve the issue; if calibration does not bring the QC to normal range it is recommended to discard the affected bottles immediately.

Risk Assessment

The issue can lead to erroneous high HbA1c results. In case that a patient with known diabetes is affected, an erroneous high HbA1c result might lead to therapeutic consequences, such as therapy escalation (introduction of another oral antidiabetic medication or insulin) or increase of the dosage. This can further lead to an increased risk of hypoglycemia. Considering the unreliable detectability of the issue, relevant medical risk for the patient cannot entirely be excluded.

Actions taken by Roche Diagnostics

The **Control interval** in the Quality control section of the method sheets will be updated as follows:

COBAS INTEGRA®

Current: Control interval: 24 hours recommended
New: Control interval: 24 hours and with each cassette recommended

cobas c 111/311/501/502 analyzers

Current:

Quality control for Whole Blood and Hemolysate Application
For quality control, use control materials as listed in the "Order information" section.
In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective

measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

New:

Quality control for Whole Blood and Hemolysate Application
For quality control, use control materials as listed in the "Order information" section.
In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements (control measurement with each cassette/bottle recommended).
Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Usage of the cobas c 513 system and/or the Tina-quant HbA1c Gen. 3 reagent on cobas c systems are suitable workarounds, as they are not affected.

Updated method sheets will be available by end of 2016.

Actions to be taken by the customer/user

Ensure proper storage conditions are maintained as per the method sheet: 2-8 °C.

Based on the obviously ongoing but sporadically occurring issue customers using the Tina-quant HbA1c Gen.2 reagents are now recommended to perform QC measurements on every reagent c pack respectively bottle in order to detect potentially affected products.

If QC cannot be kept within specified range, the cassette respectively bottle should not be used for further measurement.

To follow these instructions is very inconvenient. Usage of the cobas c 513 system and/or the Tina-quant HbA1c Gen.3 reagent on cobas c systems are suitable workarounds, as they are not affected.

Tina-quant HbA1c Gen.2: possible Over-Recovery

Communication of this Field Safety Notice

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.

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.

Sincerely,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com