

Field Safety Notice

SBN-CPS-2016-019

CPS / ClinChem fully automated
Version 1
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Tina-quant HbA1c Gen.2: possible Over-Recovery

Product Name	A1C-2 A1CX2 (Not applicable in Singapore)	
Product Description	Tina-quant Hemoglobin A1c Gen.2	
GMMI / Part No	Product	GMMI
Device Identifier	Tina-quant HbA1c Gen.2	04528123-190
	Tina-quant HbA1c Gen.2	05401640-190
	Not applicable in Singapore :	
	Tina-quant HbA1cDx Gen.2	04528123-160
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 possible over-recovery of QC materials and patient samples on individual c packs across multiple lots of Tina-quant HbA1c Gen. 2 and Tina-quant HbA1c Dx Gen.2 (not applicable in Singapore) reagent 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 (not applicable in Singapore) 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

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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 bottle / c pack cassette in order to detect potentially affected products.

If QC cannot be kept within specified range, the bottle / c-pack cassette should not be used for further measurement. Repeat testing with a different bottle / c-pack cassette of reagent.

Suitable workarounds include usage of the cobas c 513 system and/or the Tina-quant HbA1c Gen.3 reagent on cobas c systems. They are not affected.

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Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

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

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com