Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Ammonia II (300 tests)
Device Model	08058024190
Manufacturer	Roche Diagnostics
Country of Origin	Germany
Reference	Attached
Reason of Alert	NHRA initiates this FSN due to incorrect application settings in the Ammonia II (NH3L2) assay on the cobas® c 503 analyzer, which caused unnecessary >Abs flags in highly lipemic samples, despite test results being analytically correct.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative General Medical W.L.L at registration.medics@intercol.com & meher.medics@intercol.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Quality Notification

QN-RDS-CoreLab-2025-048

RDS/ClinChem fully automated
Post-Market Quality
Version 1
03-Jun-2025

Ammonia II (NH3L2): Application Setting Update to reduce unnecessary >Abs flags for samples with L-Index >250 for cobas c 503

Ammonia II (300 tests)	08058024190
Ammonia II (300 tests)	08058024214

Instrument / System	**cobas**® c 503 analytical unit
Components	Reagent e-library
Target Group	Application

Ammonia II (NH3L2): Application Setting Update to reduce unnecessary >Abs flags for samples with L-Index >250 for cobas c 503

Executive Summary

For the Ammonia II (NH3L2) assay on **cobas**® c 503, the application settings for ACN 20940 contain an incorrect sample blank measuring point. Due to this error, highly lipemic samples (with high absorption, lipemia L-index >250) are incorrectly and unnecessarily flagged >Abs.

The sample blank measuring point is used by the reaction limit check to compensate for the absorbance/color of the sample at the main wavelength.

With communication of this *Quality Notification*, the application settings are corrected, implementing the correct sample blank measuring point. This will lead to a reduction of unnecessary >Abs flagging.
The numerical value of the NH3L2 analytical test results displayed on the analyzer are correct.

By implementing the correct sample blank measuring point, only the >Abs flagging is affected, in the way of an improvement by less unnecessary >Abs flagging of highly lipemic samples (L- index >250 and <700).
No other assay performance parameters are affected.
No other application setting parameters for the NH3L2 ACN 20940 are affected.
The Method Sheet is not affected by this setting update.

Subject

For the Ammonia II (NH3L2) assay on **cobas**® c 503, the application settings for ACN 20940 contain an incorrect sample blank measuring point. Due to this error, highly lipemic samples (with high absorption, lipemia L-index >250) are incorrectly and unnecessarily flagged >Abs.

The sample blank measuring point is used by the reaction limit check to compensate for the absorbance/color of the sample at the main wavelength.

With communication of this *Quality Notification*, the application settings are corrected, implementing the correct sample blank measuring point. This will lead to a reduction of unnecessary >Abs flagging.

The numerical value of the NH3L2 analytical test results displayed on the analyzer are correct.

By implementing the correct sample blank measuring point, only the >Abs flagging is affected, in the way of an improvement by less unnecessary >Abs flagging of highly lipemic samples (L- index >250 and <700).
No other assay performance parameters are affected.
No other application setting parameters for the NH3L2 ACN 20940 are affected.
The Method Sheet is not affected by this setting update.

Internal measurements with the corrected application settings confirmed no >Abs flagging of samples with L-index >250 and <700.

Ammonia II (NH3L2): Application Setting Update to reduce unnecessary >Abs flags for samples with L-Index >250 for cobas c 503

Situation before and after change of application settings for **cobas**® c 503

- Situation before correction: The application settings are set to measure the sample blank for the reaction limit check at the **first** measuring point, MP**1**.
- Situation after correction: The application settings are set to measure the sample blank for the reaction limit check at the **last** measuring point, MP **34**.

Root Cause

Human error during application work.

Risk Assessment

Severity

No medical risk for patients exists. The reported values are correct, but invalid due to the >Abs flag.

A diluted re-run will generate an unflagged, correct result.

No patient or diagnostic test results are affected and a medical risk to patients and users can be excluded. Therefore, a Health Hazard Evaluation is not required.

Important Information

Not affected:

- **cobas**® c 311, **cobas**® c 501/502, **cobas**® c 701/702: The sample blank measuring point for 2-point assays is not used on these systems.
- **cobas**® c 303 and **cobas**® c 703: These systems have correct application settings and show no unnecessary flagging.
- **cobas**® c 111, COBAS INTEGRA® 400 plus: The NH3L2 assay is not marketed on these instruments.

All updated e-library packages will be published to e-Content Portal with reference to this *Quality Notification*.

Ammonia II (NH3L2): Application Setting Update to reduce unnecessary >Abs flags for samples with L-Index >250 for cobas c 503

Customer Details:

Notification Reference: QN-RDS-CoreLab-2025-048 Facility Name: Contact Name: Position: Phone: Date: Signature and Stamp:

If you have any questions, please do not hesitate to contact our Application Support Team or your local Account Manager.

Yours sincerely,

For on behalf of
Roche Diagnostics Middle East FZCO



Subchapter Lead Quality



Regional Quality & Product Safety Lead, Middle East

NH3L2

Ammonia II

REF 08058024190, 08058024214

cobas c 503



Reason for change

ACN20940 / NH3L2		
Version	0203	0204
Ranges / Reaction Limit / Sample Blank Point	1	34

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NH3L2

cobas®

Ammonia II

REF 08058024190

cobas c 503



Reason for change

ACN20940 / NH3L2		
Version	0203	0204
Ranges / Reaction Limit / Sample Blank Point	1	34

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