



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 151 dated 23/10/2024 Regarding SFDA Field Safety Notice of HCYS, 200 tests from (mfr: Roche Diagnostics GmbH).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



Circular No. 151 / 2024

بتقدم بثقة
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19 -04-1446 H
23 -10-2024

Field Safety Notice of HCYS, 200 tests from Roche Diagnostics GmbH.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/139
Product	HCYS, 200 tests.
Manufacturer	Roche Diagnostics GmbH.
Local agent	National Pharmacy.
The affected products	BASIC UDI-DI/GMMI / Part No: 06542921190 Device Identifier (UDI): UDI 04015630929979 Production Identifier (Lot No./Serial No.): 747029 (expired 30-Sep-2024) that used on Cobas® c701/702.
Reason	The potential of the calibration absorbance values were lower than expected.
Action	1. Customers should follow their standard laboratory operating procedures to the review of previous results, refer to the attachment for more information. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





Urgent Field Safety Notice

SBN-RDS-CoreLab-2024-004

RDS / CoreLab
Version 1
10-10-2024

Dear Valued Customer,

Please find here attached a Field Safety Notice (FSN) related to version 1 of SBN-RDS-CoreLab-2024-004 Related to "HCYS lot 747029 abnormal absorbance values on cobas® c701/702"

We kindly ask you to acknowledge receipt of the attached FSN by completing the relevant details and signing where indicated.

Finally, please forward the attached FSN to your customers having purchased and utilizing the related products and collect their required information and signature.

We thank you for your understanding and collaboration and apologize for any inconvenience.

Yours sincerely,

On behalf of
Roche Diagnostics Saudi Arabia Limited

Sultan Albalawi
Senior Quality Specialist

Ali Alhabib
Regulatory Affairs Manager

Roche Diagnostics Saudi Arabia Limited
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سجل تجاري: ١٠١٠٤٧٩٣٣٦
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هاتف: +966 114 149 400



HCYS lot 747029 abnormal absorbance values on cobas® c701/702

Product Name	HCYS, 200 tests
BASIC UDI-DI/GMMI / Part No	06542921190
Device Identifier (UDI)	UDI 04015630929979
Production Identifier (Lot No./Serial No.)	747029 (expired 30-Sep-2024)
SW Version	n/a
Type of Action	<e.g., Field Safety Corrective Action (FSCA)>

Description of Situation

Roche has received several customer complaints for HCYS lot 747029 (exp. date Sep-2024) on **cobas c 701/702** alleging abnormal calibration signals and control recovery issues. The calibration absorbance values were lower than expected.

No allegation of an adverse event has been made.

Internal investigations confirmed these complaints and showed that only reagent lot 747029 was affected. In addition, **cobas c 111**, **cobas c pack (c 311/501/502)** and **cobas c pack green (c 303, c 503 and c 703)** are not affected.

The issue only affected a limited number of cassettes from the above-mentioned lot; the majority of cassettes continued to perform within specification. More specifically, around 800 cassettes (~12% of the lot size) with a sequence number > 6,000 were affected by the issue.

The issue is detectable in case of control recovery beyond the 2s range or by calibration or quality control errors for affected cassettes. Nevertheless, the issue is not fully detectable, because in general, for the HCYS assay, a lot calibration is recommended and thus not every cassette is calibrated. Affected cassettes might show abnormal calibration signals but no flag.

The generation of inaccurate patient results cannot be excluded completely.



HCYS lot 747029 abnormal absorbance values on cobas® c701/702

Actions taken by Roche Diagnostics

The root cause is still under investigation by Roche, and after its completion, appropriate corrective/preventive actions will be defined and implemented.

Actions to be taken by the customer/user

No customer-specific action is required because the issue can be limited to lot 747029, which expired 30-Sept-2024.

So far, no adverse medical events have been alleged by customers. In this case, no general recommendations with respect to the review of previous results can be given, taking into account that the issue may have occurred only under certain, rare circumstances, using one of the affected cassettes. Customers should follow their standard laboratory operating procedures. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

I have received the FSN and read/understand its content.

Customer Details:

Facility Name:
Contact Name:
Position:
Phone:
Date:
Signature and Stamp: