Urgent Field Safety Notice
SBN-RDS-CoreLab-2024-004

RDS / CoreLab
Version 1
08-Oct-2024

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

Product Name	HCYS, 200 tests
BASIC UDI-DI/GMMI / Part No **Device Identifier (UDI)**	06542921190 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)>

Dear Valued Customer,

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.

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.

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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.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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. (If appropriate).

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate). >

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>,

Contact Details

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

Roche Diagnostics GmbH - SRN: DE-MF-000006260 (legal manufacturer)