Urgent Field Safety Notice

SBN-RDS-CoreLab-2026-007

RDS / CoreLab
Version 1

cobas® c 303 Potential Rupture of Vacuum Rinse Tubing

Product Name	cobas c 303 Analytical Unit cobas c 303 Analytical Unit-EMC
BASIC UDI-DI/GMMI / Part No Device Identifier (UDI)	cobas c 303 analytical unit: 09031529001 UDI: 07613336226971 cobas c 303 analytical unit-EMC (U.S. only): 09793194001 UDI: 07613336220153
Production Identifier (Lot No./Serial No.)	cobas c 303 analytical unit: all S/N until and including 2628-10 and U6V1-10 cobas c 303 analytical unit-EMC (U.S. only): all S/N until and including 7696-10
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We have received complaints where vacuum tubing of the cell rinse unit of the **cobas® c** 303 analytical unit prematurely deteriorated. Investigations confirmed the issue. In the event of small pinholes or cracks, no clear impact on analytical performance was identified. However, in case of tubing rupture, the following can occur as a result of the issue:

- Undetected leakage: Fluid may drip into random reaction cells.
- Result impact: Increased risk of erroneous patient and QC results.

The medical risk of inaccurate results depends on clinical context, test variation, and overall patient presentation. Together, in specific clinical scenarios, it is possible that clinical care could be influenced by incorrect test results, potentially causing adverse health consequences for patients, and therefore a medical risk cannot be excluded.

No harm to patients or adverse events have been reported regarding this issue.

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Actions taken by Roche Diagnostics

A Corrective and Preventive Action (CAPA) investigation was done, and appropriate corrective and preventive measures were defined. As a long-term solution, the length of the tubing was updated. To prevent occurrences of premature rupture, Roche Diagnostics Service team will replace the tubing on all affected instruments within the next 12 months (with the next service visit or upon customer request / complaint).

Actions to be taken by the Customer/User:

Customers can continue to use the system. Until the affected tubing has been replaced they must perform the following actions:

- Daily QC measurement with QC panel of available tests on the analyzer before releasing patient results. In case you identify a systematic deviation of multiple results of the QC, immediately stop usage of the **cobas c** 303 because a tubing rupture cannot be excluded. Please contact a Roche Service Representative for troubleshooting and potential tubing replacement.
- No general recommendations with respect to the review of previous results can be given by using the **cobas c** 303 analytical unit. 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.

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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)