Urgent Field Safety Notice

SBN-RDS-CoreLab-2026-007

RDS / CoreLab
Version 1 - HHT

cobas® c 303 Potential Rupture of Vacuum Rinse Tubing

Product Name	cobas c 303 Analytical Unit
BASIC UDI-DI/GMMI / Part No Device Identifier (UDI)	cobas c 303 analytical unit: 09031529001 UDI: UDI: 07613336172483 (Legal Manufacturer: Hitachi High-Tech Corporation)
Production Identifier (Lot No./Serial No.)	GMMI : 09031529001 GTIN : 07613336172483 S/N : until and including 22S0-10 GMMI : 09031529001 GTIN : 07613336172483 S/N : until and including U347-10
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Note: *In the past there was a change of legal manufacturer for the affected product. Affected cobas c 303 analytical units could belong to either Roche Diagnostics GmbH or to Hitachi High-Tech Corporation (HHT). This FSN is formally needed to cover the instruments that fall under the responsibility of HHT as legal manufacturer.*

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 pin holes 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.

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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.

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.

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

Hitachi High-Tech Corporation (HHT) - SRN: JP-MF-000016991 (legal manufacturer)