Urgent Field Safety Notice

SBN-RDS-Corelab-2025-008

RDS/ Corelab
Version 1

cobas pro/pure Non-monotonous Spline calibration

Product Name	cobas pro Sample supply unit cobas pro SSU cobas pure sample supply unit
BASIC UDI-DI/GMMI / Part No Device Identifier (UDI)	08464502001 UDI- 07613336158784 09324437001 UDI- 07613336158784 09031537001 UDI- 07613336220153 09793178001 UDI- 07613336220146
Production Identifier (Lot No./Serial No.)	cobas pro Sample supply unit all serial numbers cobas pro SSU <4401-01 cobas pure sample supply unit <25V2-01 and <7574-01
SW Version	cobas pro- SW <03-01 cobas pure-SW <01-04
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

A software malfunction has been identified on the cobas pro (c503) and cobas pure (c303) platforms affecting the Calibration Library. This defect allows the system to accept erroneous, non-monotonous calibrations for Spline-type assays. When an erroneous calibration is active, the instrument fails to calculate new values and instead repeats the last successfully calculated result from any Spline-type

assay for all subsequent measurements, leading to identical and erroneous patient and QC results. Please refer to attachment 1 of the FSN for additional background information and affected assays.

The medical risk attributable to incorrect test results depends significantly on the constellation of diagnostic and
clinical parameters such as the degree of analytical variation of affected results, detectability by technical indices, detectability due to clinical implausibility, additional diagnostic testing results and congruence of the overall clinical picture. 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 relevant medical risk cannot be excluded.

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

Actions taken by Roche Diagnostics

A Corrective and Preventive Action (CAPA) investigation has been initiated, and the root cause investigation continues. Once the root cause analysis is complete, appropriate corrective and preventive measures will be defined and communicated, as needed.

Actions to be taken by the customer/user

- Only use one reagent pack for the affected Spline-type assays per analytical unit; do not load standby reagent packs for the affected Spline assays.
- The issue can be detected by running at least two different levels of QC at the same time, although the User guide does not explicitly define the number of QC levels to be run.
- No general recommendations with respect to the review of previous results can be given by using the cobas c503/303 analytical units. Customers should follow their standard laboratory operating procedures. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

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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

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Hitachi High Technologies Corporation (HHT) - SRN: JP-MF-000016991 (legal manufacturer)
Roche Diagnostics GmbH- SRN: DE-AR-000006262 (EU authorized representative)