Urgent Field Safety Notice

SBN-RDS-Corelab-2025-007

RDS CoreLab
Version 2

CleanCell M (04880293190) QC Shift for **cobas®** e 601, **cobas®** e 602, **cobas®** e 801 and **cobas®** e 402 analytical units

Product Name	CleanCell M
BASIC UDI-DI/GMMI / Part No **Device Identifier (UDI)**	GMMI: 04880293190 UDI: 04015630922697
Production Identifier **(Lot No./Serial No.)**	Lots 9168600**01**, 9168610**01** and 9168630**01** **Note:** The affected lots have not changed. Technically the full lot number has 8 digits, therefore the digits 01 were added for correctness.
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche Diagnostics has identified a performance issue linked to three specific lots 9168600**01**, 9168610**01** and 9168630**01** of the CleanCell M solution, which is used to clean the measuring cell and tubing system of **cobas®** e 601, **cobas®** e 602, **cobas®** e 801 and **cobas®** e 402 analytical units. Upon switching to one of the three affected CleanCell M lots, a significant decrease in signals of Quality Control (QC) results was observed. Based on our investigation, it was confirmed that a wrong detergent was used for the production of the three affected CleanCell M lots.

There are no reports of patient harm linked to this issue.

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 serious or chronic adverse health consequences for patients such as transfusions of an infected blood component to a recipient. Therefore, a relevant medical risk cannot be excluded.

Actions taken by Roche Diagnostics

Roche Diagnostics has on 21-Nov-2025 immediately implemented an additional performance test sensitive to the effect observed with the affected CleanCell M (CC) lots in release testing to ensure that all newly produced CleanCell M (CC) lots are only released when their performance on a **cobas®** e 801 analytical unit is verified.

Actions to be taken by the customer/user

Please **immediately discontinue the use of and discard** any inventory of affected lots

- 91686001
- 91686101
- 91686301

Please check your records, if these lots were used in the past. If so, please check your QC results in detail in case you can observe a synchronous up- and/or downshift over all parameters.
If you have used an affected lot and performed an assay calibration and now switch to a not affected lot, please perform again a calibration.

Informations about the use of CleanCell M on the analyzers:
There is no active tracking of CleanCell M lots on the analyzers via technical measures (e.g. RFID).
To trace a CleanCell M bottle changeover, the Alarm Log can be checked or an external inventory management, if one is in place.

In this case, no general recommendations with respect to the review of previous measurement results can be given using the affected CleanCell M lots. Please follow your standard laboratory operating procedures. Any specific questions raised 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).

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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)