PRODUCT ALERT NOTICE
ACTION REQUIRED

Alert Ref No:	**CA cobas u 701: Enhanced handling of very high-mucus crowded samples QN-RDS-CoreLab-2025-099**
Date:	**05/08/25**
System Affected:	**cobas u** 701

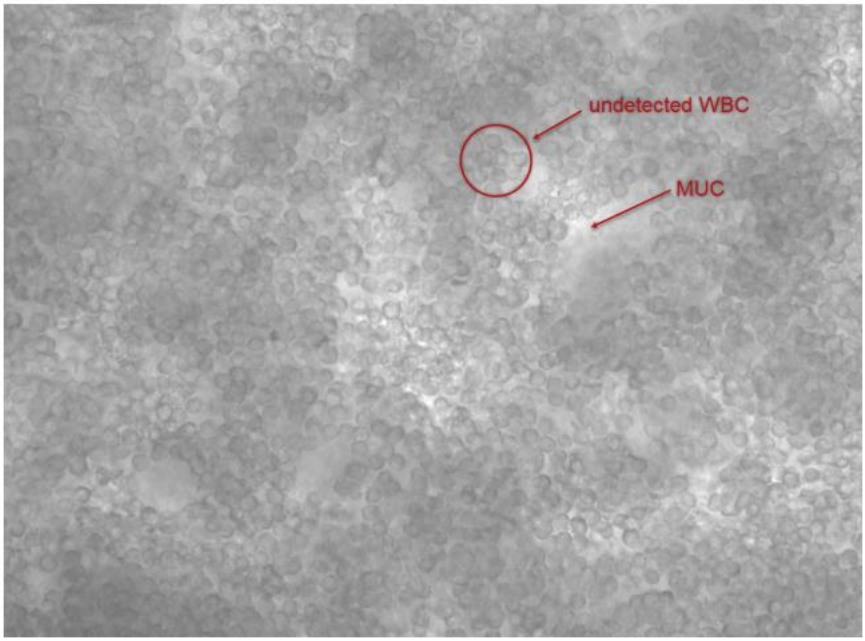
Summary of Issue:

cobas u 701: Enhanced handling of very high-mucus crowded samples

Reason for Notice

Roche would like to inform customers that false negative results may occur in rare pathological urine samples with extremely high MUC content when using the **cobas u** 701 analyser.

In such cases, crowding and blurring can prevent proper cell detection, and the system may not flag the sample for review, resulting in unintended autovalidation (no Uc flag triggered).



Typically, when the sample is too crowded, results are compromised. Nevertheless, the “crowded” flag (Uc) should have been triggered. In such cases, it is recommended to dilute the sample and re-run it, or alternatively, carry out a manual microscopic examination. Regardless of the course of

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action, such samples should be flagged to ensure the operator is alerted. In this case, the Uc flag was not triggered because the background cells were not detected due to the high MUC concentration.

Currently, the only way to screen and prevent this issue is to create a cross-check rule on the **cobas u** 701 for MUC, so that the samples are held for review. Results are marked with the data alarm "X" if a cross-check rule was triggered. Results with cross-check data alarms can be excluded from automatic validation. Those results have to be validated manually. Only validated results are sent to the host.

For customers using the **cobas** 6500 urine analyser system, discrepant results between the test strip (**u** 601) and microscopy (**u** 701) may help detect the issue in rare cases of very high-mucus crowded samples, and the Uc flag is not triggered. Specifically, while the test strip may detect leukocytes (LEU) and/or erythrocytes (ERY), **cobas u** 701 may not report corresponding WBC or RBC counts. The discrepancy is caused by excessive mucus interfering with cell detection.

A short-term workaround is now highly recommended (see Actions Required), using a cross-check rule between parameters to identify affected samples. In parallel, a software improvement is under development to introduce an additional review flag, which would help detect image crowding conditions caused by high mucus or similar obstructions. This change does not require modification of the evaluation module or retraining of its neural networks. This improvement will be included in a future software release.

Action Required

Customers are advised to follow the workaround (short-term solution) instructions provided below:

Set up a 3-condition cross-check rule on the **cobas u** 701 to flag samples for review when the following conditions are met:
MUC ≥ 1000 particles/µL AND WBC ≤ 0 AND RBC ≤ 0

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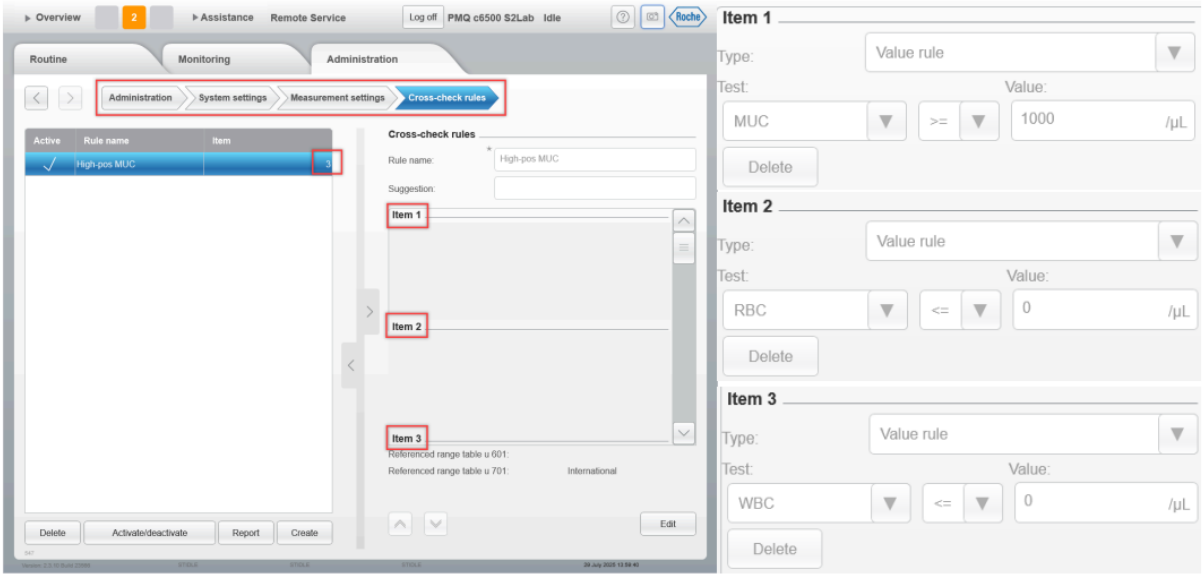
Create the cross-check rule under Administration > System settings > Measurement settings > Cross-check rule:



MUC in Conventional Units:

In conventional units, MUC is set to 1000 particles/µL.

MUC in Field of View Units:

For field of view units, the equivalent measurement is 227.27 particles/HPF, where the conversion factor from particles/µL to particles/HPF is 0.227.

This rule was validated on a large dataset and is designed to minimise unnecessary sample holds while preventing false negatives in affected cases.

Customers are advised to implement this rule immediately to prevent autovalidation of comparable samples.

Attachments

None

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