Field Safety Notice

SBN-CPS-2017-020

CPS / Urinalysis
Version 1
05-Sep-2017

Bacteria like artefacts in cuvettes of cobas u cuvette

Product Name	cobas u cuvette cobas u 701 microscopy analyzer
Production Identifier (Lot No./Serial No.)	06390552001 (cobas u cuvette) Lot: 16483701 06390501001 (cobas u 701 microscopy analyzer)
Type of Action	Field Safety Corrective Action (FSCA)

Affected lot is not available in Singapore

Dear Valued Customer,

Description of Situation

With this Notification we would like to inform you about the possible contamination of cuvettes of cobas u cuvette with small plastic particles. When used on cobas u 701 microscopy analyzer, these particles will be recognized as bacteria by the analyzer. Hence, a false positive result for the parameter bacteria (BAC) is the potential consequence. This can lead to wrong diagnosis of asymptomatic bacteriuria. In the worst case, a treatment decision can be made based on erroneous positive results for bacteria in urine.

Only lot 16483701 was reported as affected. Roche Diagnostics received one customer complaint regarding this issue.

Actions taken by Roche Diagnostics

Roche Diagnostics internal stocks have been checked for remaining products of the affected lot. Any remaining material was disposed. Investigation on manufacturer side revealed a production issue for lot 16483701. Corrective and preventive action has been initiated.

Actions to be taken by the customer/user

Please check inventory for remaining cobas u cuvette of lot 16483701, discard them locally and use any other lot instead.

Please cross-check results where BAC is positively reported. Comparison with test strip result, manual

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image validation on the analyzer, or even manual microscopy of the sample might be appropriate measures. Always assess the results in conjunction with the patient's medical history, clinical examination, and other findings.

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Respectfully yours,

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