

Field Safety Notice

SBN-RMD-2017-009

RMD / **cobas**[®] Liat[®]
Version 1
03-Nov-2017

Decrease in the sensitivity of the **cobas**[®] MRSA/SA Nucleic acid test for use on the **cobas**[®] Liat[®] System

Product Name	cobas [®] MRSA/SA Nucleic acid test for use on the cobas [®] Liat [®] System
GMMI / Part No	GMMI: 07454988190
Device Identifier	Device Identifier: 00875197005691
Production Identifier (Lot No./Serial No.)	70712A, 70601W, 70713A, 70718A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche Diagnostics is advising that you discontinue the use of and discard any remaining inventory of the **cobas**[®] MRSA/SA Nucleic acid test for use on the **cobas**[®] Liat[®] System (GMMI: 07454988190), lots: 70712A, 70601W, 70713A, and 70718A, immediately. During an internal investigation it was identified that there is a decrease in the performance of the aforementioned lots compared to the claimed analytical sensitivity for MRSA detection at 1x Limit of Detection (LOD).

The **cobas**[®] MRSA/SA test is intended for screening and not for diagnosis of active infection. A screening failure can lead to infection in the colonized patient being tested as well as the spread of MRSA to others. In the worst case scenario for a false negative MRSA result, unrecognized colonization may lead to infection of the patient or other patients following colonization with potentially severe outcomes including sepsis and death. There is a “remote” probability that use of the test will cause adverse health consequences.

Actions taken by Roche Diagnostics

Corrective and Preventive Actions (CAPA) has been initiated and the root cause investigation is on-going

Actions to be taken by the customer/user

This situation represents a safety concern, and as such, we are advising you to discontinue use of and discard any remaining inventory of the affected kit lots, immediately.

Patient samples that generated negative results with the use of the affected kits lots (70712A, 70601W, 70713A, 70718A) must be repeat tested with an alternative method.

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.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com