Urgent Field Safety Notice

SBN-RMD-2017-009

RMD / **cobas**® Liat®
Version 1
27-Oct-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
Product Description	Not Applicable
GMMI / Part No **Device Identifier**	GMMI: 07454988190 Device Identifier: 00875197005691
Production Identifier (Lot No./Serial No.)	70712A, 70601W, 70713A, 70718A
SW Version	Not Applicable
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.

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

Actions taken by Roche Diagnostics (if applicable)

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 (if appropriate)

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.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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