

Urgent Field Safety Notice

SBN-RMD-2015-008

RMD / cobas[®] 6800 / 8800 systems

Version 1

23-JUL-2015

Potential for Sample Under-aspiration with Low Sample Input Volume Assays - cobas[®] 6800 / 8800 systems

Product Name / GMMI / cobas[®] 6800 system GMMI 05524245001 UDI 04015630935406

Part No

Device Identifier cobas[®] 8800 system GMMI 05412722001 UDI 04015630935390

Production Identifier (Lot No./Serial No.) All

SW Version N/A

Type of Action Field Safety Corrective Action (FSCA)

Potential for Sample Under-aspiration with Low Sample Input Volume Assays - cobas[®] 6800 / 8800 systems

Dear Valued Customer,

Description of Situation

In extremely rare cases, sample under-aspiration may occur with sample volume input assays that are less than 450 µL. The affected assays and sample input workflows are:

- **cobas[®]** CMV GMMI 07001029190 UDI 20875197004926 (input volume 350 µL)
- **cobas[®]** HBV GMMI 07000979190 UDI 20875197004889 (with the 200 µL sample workflow only)
- **cobas[®]** HCV GMMI 06997732190 UDI 00875197004649 (with the 200 µL sample workflow only)
- **cobas[®]** HIV-1 GMMI 07000995190 UDI 00875197004908 (with the 200 µL sample workflow only)
- **cobas[®]** MPX-96 GMMI 06997708190 UDI 00875197004618 (with cadaveric use only - 150 µL)
- **cobas[®]** MPX-480 GMMI 06997716190 UDI 00875197004625 (with cadaveric use only - 150 µL)
- **cobas[®]** WNV-96 GMMI 07001061190 UDI 00875197004960 (with cadaveric use only - 150 µL)
- **cobas[®]** WNV-480 GMMI 07001070190 UDI 20875197004971 (with cadaveric use only -150 µL)

Bubbles / foam in the sample tube can lead to false sample liquid level detection and under-aspiration of sample. This can cause false negative / under-quantitated results that are not flagged. As stated in the **cobas[®]** 6800 / 8800 systems Safety Manual, users are instructed to ensure that no foam or bubbles are present in the tubes:

“Incorrect results may occur due to foam, fibrin clots, films or bubbles in reagents or samples. Ensure good sample preparation and reagent handling techniques to avoid the formation of foam, clots and bubbles in all reagents, samples and controls.”

Actions to taken by Roche Diagnostics

- Will develop a system and/or software update to detect under-aspiration on the **cobas[®]** 6800 / 8800 systems.

Actions to be taken by the customer/user

- Ensure good sample preparation techniques to avoid the formation of foam, clots and bubbles in all samples, as described within the safety manual and instructions for use.

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 organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

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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