Urgent Field Safety Notice

SBN-RMD-2017-002

RMD / cobas® 6800/8800
Version 1
10-May-2017

cobas® MPX and DPX Test, CE-IVD – Potential for Discordant Results on User Interface and Laboratory Information System (LIS)

Product Name	**cobas®** MPX Test, CE-IVD **cobas®** DPX Test, CE-IVD
Product Description	**cobas®** MPX, for use on the **cobas®** 6800/8800 Systems, CE-IVD **cobas®** DPX, for use on the **cobas®** 6800/8800 Systems, CE-IVD
GMMI / Part No **Device Identifier**	**cobas®** MPX, for use on the **cobas®** 6800/8800 Systems, CE-IVD 96 Tests: 06997708190 (Device Identifier: 00875197004618) 480 Tests: 06997716190 (Device Identifier: 00875197004625) **cobas®** DPX, for use on the **cobas®** 6800/8800 system, CE-IVD 96 Tests: 07001088190 (Device Identifier: 00875197004984)
Production Identifier (Lot No./Serial No.)	Not Applicable
SW Version	SW 01.00.12 SW 01.01.09 SW 01.01.10 SW 01.02.12
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Under specific conditions, there is a possibility that Target specific results sent to a customer's LIS may not match those results displayed on the **cobas®** 6800/8800 Systems User Interface (UI). This applies to the **cobas®** 6800/8800 Systems Software versions 01.01.09, 01.01.10, and 01.02.12. Please read the information below to understand the issue and any actions that may be needed. Roche is working to resolve this issue with the highest priority and an updated software version will be available July 2017 to correct it.

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If the LIS is configured to utilize the Overall result for final result interpretation, the user may detect the discrepancy and no further action is required.

This issue applies to individual test results only, including pool resolution of individual donors on the **cobas p** 680 instrument. This does not apply to **cobas® Synergy** Solutions.

The situation occurs when a sample is Reactive for one target and Invalid for another. Samples with Invalid results should be re-tested. If during that repeat run the previously Reactive result for a target is now Non-Reactive (i.e., a sample with a low concentration of virus at or near the Limit of Detection [LoD] of the test), the individual target result transferred to the LIS would be the last test result obtained for the target. The Overall result for the donor sample, however, would be correct in the LIS, taking into account the initial Reactive test result and the repeat test result. Please see the examples below:

cobas® MPX test, using HIV-1 as the affected viral target; all viral targets detected with the **cobas®** MPX test (HIV-1, HCV, and HBV) could be affected in a similar manner.

Run ID	HIV-1 Target Result	HBV Target Result	HCV Target Result	Overall Result
1	Reactive	Invalid	Non-Reactive	Invalid
2	Non-Reactive	Non-Reactive	Non-Reactive	Non-Reactive
User Interface	**Reactive**	Non-Reactive	Non-Reactive	Reactive
LIS	**Non-Reactive**	Non-Reactive	Non-Reactive	Reactive

Below is an example of the impact to the **cobas®** DPX test, using B19 as the affected viral target; both B19 and HAV could be affected in a similar manner.

Run ID	HAV Target Result	B19 Target Result	Overall Result
1	Invalid	B19 >= cut off value	Invalid
2	Non-Reactive	Target not detected	Non-Reactive
User Interface	Non-Reactive	**Reactive**	Reactive
LIS	Non-Reactive	**Target Not Detected**	Reactive

If the LIS is configured to only utilize the individual target results, and not the Overall result, the discrepancy will likely not be detected. We recommend the following:

For results not released to the LIS:

1. For samples with an Overall Reactive result in the User Interface and Result Report, verify the individual target results.
2. If all of the individual results are Non-Reactive, do not release the sample result to the LIS and follow the appropriate guidelines as defined by your QA department.

For results released to the LIS:

1. Review samples with Reactive results only, on the User Interface, or on the Archive Viewer if results are already archived.
2. Filter samples on the User Interface or Archive Viewer with Status “Repeated”
3. Review remaining samples for discrepant individual channel results transmitted to the LIS by comparing the UI result, or Archive result, and the LIS transmitted result.

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Risk Assessment

The most significant risk associated with the wrong result transmitted to the LIS is the risk of a false Non-Reactive result. The risk of a false Non-Reactive result being transmitted was calculated for each virus, taking into account the risk of an invalid result and the impacted tests having a 95% confidence interval at the respective Limits of Detection (LoD).

HIV	~1 in 178,600,000 donations	(<5.6 x 10-9)
HCV	~1 in 178,600,000 donations	(<5.6 x 10-9)
HBV	~1 in 1,053,000 donations	(≤9.5 x 10-7)
HAV	~1 in 3,330,000,000 donations	(≤3 x10-10)
Parvovirus B19	~1 in 20,000,000 donations)	(≤5 x 10-8)

The risk for the recipient is likely lower than what is shown above because (1) the only samples impacted are those with viral loads near or below the tests' LoD; and (2) the risk of transmission at low viral concentrations is low.

Actions taken by Roche Diagnostics

This represents a *theoretical* safety concern. An updated software fix addressing this situation will be available 3Q2017.

The root cause is related to the **cobas®** 6800/8800 System Software, specifically the object fields used for the target result are different for UI and LIS sending.

Actions to be taken by the customer/user

If the LIS cannot be configured to include the Overall result, the following work scenarios must be implemented at the customer sites until the software fix is available.

1. **Customers are advised to change their current workflow as follows:**

   - Review all results with Reactive targets and an Overall result of Invalid
   - Perform a repeat test for those samples
   - If the repeat target results are all Non-Reactive and the Overall result is Reactive do not release the results to LIS. The transmitted result to the LIS will show a correct Overall Result but potentially incorrect individual target results. Follow the appropriate guidelines as defined by your QA department

2. **Customers are advised to perform the following steps to review already released results:**

- Review on the User Interface the samples with Reactive results only
- Filter samples on the User Interface with Status "Repeated"
- Review remaining samples for discrepant individual channel results transmitted to the LIS by comparing the UI result and the LIS transmitted result.

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3. **Customers are advised to perform the following step to review already released and archived results:**

- Review on the Archive Viewer the samples with Reactive results only
- Filter samples on the Archive Viewer with Status “Repeated”
- Review remaining samples for discrepant individual channel results transmitted to the LIS by comparing the archived result and the LIS transmitted result.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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. (If appropriate).>

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

Include if applicable: 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