Field Safety Notice
SBN-CPS-2017-010

CPS / Laboratory Integration
Version 1
17-May-2017

cobas p 512 pre-analytical system (64x) and cobas p 612 pre-analytical system (63x): Spin Status Detection improvements and re-labeling

Product Name	COBAS P 512 PRE-ANALYTICAL SYSTEM COBAS P 612 PRE-ANALYTICAL SYSTEM
Product Description	System Software cobas p 512 System Software cobas p 612
GMMI / Part No **Device Identifier**	cobas p 512 07563124001 cobas p 612 07563116001
Production Identifier (Lot No./Serial No.)	All cobas p 512 (64x) pre-analytical system All cobas p 612 (63x) pre-analytical system Affected instruments are not available in Singapore
SW Version	All software versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche Diagnostics received complaints from two customers that un-spun samples were incorrectly identified as “spun” by the spin status detection on cobas p 512 (64x) pre-analytical system. When non-centrifuged samples incorrectly identified as “spun” are further analyzed, erroneous results may occur and relevant medical risk cannot be entirely excluded. This case made us aware that we need to provide a better specification on the intended use of the spin status detection.

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The cobas p 512 (64x) and the cobas p 612 (63x) systems are not designed to make a sorting decision based on the spin status detection functionality. While investigating these complaints, we identified that all documentation related to the spin status detection needs to be updated to better reflect the correct intended use. Furthermore, the algorithm of the spin status detection will be improved in a future version of software.

Actions taken by Roche Diagnostics

Roche Diagnostics will update the Operator's Manuals in the chapter "System description", sub-chapter “Spin status detection”, with the following wording:

Spin status detection

The spin status functionality performs a cross-check on the centrifugation status of the samples. It cross-checks:

- Category of tubes that should have been centrifuged
- Category of tubes that should not have been centrifuged

The cross-check removes identified erroneous samples from the automated workflow into an error tray, in order to bring them back to the operator's attention.
The spin status detection can only be used on systems with Dynamic Interface.

The spin status detection uses the LASER-LLD system to locate the different media contained in the tubes to be processed.
The detection of the spin status is performed by analyzing the determined media, their position and their proportion within the tube and the following indicators which are retrieved from the LASER-LLD measurement:

- the tube height
- the filling level of the tube (total material height compared to the tube height)
- the presence of a cap: is the tube open or closed?
- the percentage of the serum or plasma region within the tube with respect to the filling level
- the presence of a separating gel and its position within the tube: at the tube bottom or at a higher position in the tube.

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There are some restrictions. The LASER-LLD is not able to make the distinction:

- between not centrifuged whole blood and a blood clot resulting from centrifugation.
- between a centrifuged sample and a not centrifuged sample after standing (with settled blood cells) in the absence of gel.

The spin status detection uses the Laser-LLD module. Conditions of use described for the Laser-LLD must be also ensured for the spin status detection.

NOTICE **Risk of system failure!**

Only vacuum system sample tubes using exclusively gel as a separation media are allowed when using the spin status function.

Spin status detection is not meant to sort samples based on the centrifugation status, rather perform a cross-check of whether tubes have or have not been centrifuged. In certain conditions the laser signal can be affected and lead to an invalid spin status determination (e.g. samples handled in a non-vertical position, sample labels are outside the specifications for Laser-LLD, diagonal (not horizontal) separation gel or sedimentation took place).

Tube requirements

The spin status detection has some restrictions on the tube type:

1. Only vacuum system sample tubes using exclusively gel as a separation media are allowed.
2. Tubes that use any other non-gel separation media, as for example granulates, are not allowed.

In addition, Roche Diagnostics is currently developing new software to improve the spin status detection algorithm. It is expected that the new software will be available by the end of August 2017.

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Actions to be taken by the customer/user

Please verify that the spin status detection functionality is used according to the updated Operator's Manuals.

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,

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