

# Urgent Field Safety Notice

## SBN-RPD-2015-017

RPD / Laboratory Integration  
Version 1  
09-Sep-2015

### PVT Bulk Loader Module (BLM): Tube decapping during sample processing

<b>Product Name</b>	Bulk Loader Module for cobas p 512/612 Bulk Loader Module for cobas p 471
<b>GMMI / Part No</b>	GMMI 07135645001
<b>Device Identifier</b>	GMMI 07084285001
<b>Production Identifier (Lot No./Serial No.)</b>	All lot numbers
<b>SW Version</b>	All SW versions
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

#### Description of Situation

Roche received one complaint that one sample tube was opened inadvertently in a Bulk Loader Module (BLM) during the transport. The opened sample tube fell down into the funnel and the sample material was spilled contaminating the system and other samples on outer surface. Sample material could not be used to carry out the analysis.

Lab personal is required to wear adequate Personal Protective Equipment (PPE) since it acts as a barrier against exposure as assessed previously during "hazard assessment" for each lab/working environment. However, unanticipated splashes, sprays, splatters, or droplets of blood are likely to occur with de-capping since the issue represents an unexpected instrument behavior. In this case, PPE might not be sufficient and may lead to unnecessary exposure to blood borne pathogens, such as HBV, HCV, HIV and others. A subsequent infection of the operator cannot be excluded (worst case scenario).

The purpose of this Field Safety Notice (FSN) is to inform of this situation and clarify the extent of the recommend field safety corrective action.

#### Actions taken by Roche Diagnostics

Roche started an investigation and identified that the root cause is the design of the lead-in chamfer of the repel plate.

To prevent the malfunction described, a modification kit for the hardware was developed and determined to be effective through verification tests performed by the manufacturer. The modification kit will be released by the end of September 2015. Modifications will be carried out within three months, after the release, by a Roche Field

# Sample tube opened in a Bulk Loader Module

Service Representative.

## Actions to be taken by the customer/user

Until the fixing measure with the modification kit is implemented, if the issue occurs, the complete instrument has to be cleaned according to the actual Bulk Loader Module (BLM) operator manual.

## 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 maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

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.

Sincerely,

## Contact Details

*To be completed locally:*

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com