Urgent Field Safety Notice

SBN-SIS-2018-001

SIS / Laboratory Integration
Version 1
25-Jun-2018

Foreign Material on the cobas p 612 ADP Nozzle

Product Name	cobas p 612 pre-analytical system (LCP1)
GMMI / Part No Device Identifier	07563116001
Production Identifier (Lot No./Serial No.)	N/A
SW Version	All versions from 2.0 and higher
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche has confirmed that sample material may potentially come in contact with the pipetting nozzle during operation. The possible presence of biological material on the nozzle has the potential to cause contamination resulting in potential false positive results, depending on the sensitivity of the analytical technology. However, no complaints of false positives have been received from customers. cobas p 612 (63x) (LCP1) systems that use disposable filter tips are not affected by a potential contamination as the filter tips create a physical barrier preventing liquid exposure to the nozzle.

The current issue deals with the occasional deposition of sample material at the bottom of the sample nozzle and its possible carry over to other specimens. In the case of molecular tests, even trace amount of nucleic acids may be amplified to detectable concentration and cause false positive results (e.g. HIV RNA, HCV RNA, HBV DNA). This may lead to an incorrect diagnosis and inappropriate clinical management of the patient under examination.

Actions taken by Roche Diagnostics

The root cause investigation is still ongoing. Roche Diagnostics will send out an update as soon the root cause is identified and corrective measures are available.

Actions to be taken by the customer/user

If you are using cobas p 612 pre-analytical systems (63x) for aliquoting in combination with non-filter tips, you must use filter tips until the root cause is identified and appropriate Corrective Actions have been implemented.

Foreign Material on the cobas p 612 ADP Nozzle

You will be informed when an update of the situation is available. Costs incurred with this measure will be taken by Roche Diagnostics.

Please be reminded to perform the daily preparation and weekly device care procedures described in the Operator's Manual.

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.

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

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:

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