

Field Safety Notice

SBN-CPS-2016-007

CPS / Immunology
Version 1
27-Apr-2016

Partly Damaged AssayTips in Certain Lots of AssayTip/AssayCup

Product Name	AssayTip/AssayCup
GMMI / Part No	12102137001
Device Identifier	
Production Identifier (Lot No./Serial No.)	15908113 15909113 15910113 16751113 16752113 16753113 16754113 16755113 16756113 16761113 16779113 16791113
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Affected lots are not available in Singapore

Dear Valued Customer,

Description of Situation

We regret to inform you that we have identified 12 defective lots (lot numbers as listed above) from the “AssayTip/AssayCup” (material number as listed above). The “AssayTip/AssayCup” is used on the MODULAR ANALYTICS E 170 module, MODULAR ANALYTICS EVO E 170 module, **cobas e** 601 module, **cobas e** 602 module.

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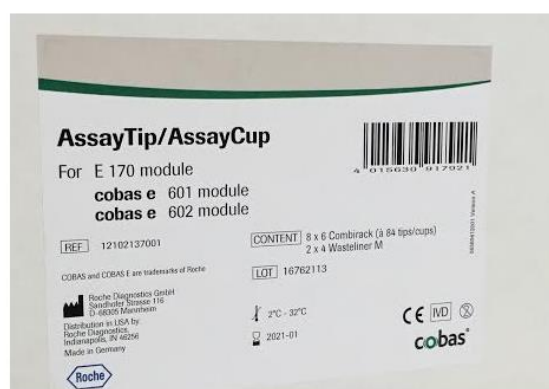
During the manufacturing process in one production line for one of our supplier's for the "AssayTip/AssayCup", a misaligned gripper tool for inserting the AssayTips into the AssayTip/AssayCup tray caused damage of some AssayTips. After molding each AssayTip is placed in an AssayTip rack and controlled by a camera (100% check). After this control step the AssayTips are transferred by a gripper unit to the AssayTip/AssayCup tray. While inserting the AssayTips into the AssayTip/AssayCup tray the gripper unit of the concerned production line damaged the AssayTips. The issue started after a maintenance action at one of our supplier's manufacturing line end of December 2015. The first affected AssayTip/AssayCup lot was distributed from 18. February 2016 onwards. The damage level varies from partly closed to fully closed AssayTips.

Within an affected lot 0.5 – 1% of AssayTips may have damages. Internal investigations revealed that for approximately 75% of the affected AssayTips an alarm message 531 to 555 "Abnormal Sample Aspiration" appears and no sample result is reported. The sample results without any alarms, measured with the approximately 25% affected AssayTips, showed a comparable precision and acceptable deviation in comparison to the results produced with non-affected AssayTips. According to the internal investigations the probability of incorrect results without any flag is low. This is in accordance that no complaints have been received up to now.

The affected lots can easily identified, see pictures below of the AssayTip/AssayCup tray and package:



AssayTip/AssayCup tray



Label of AssayTip/AssayCup package

Partly Damaged AssayTips in Certain Lots of AssayTip/AssayCup

Actions taken by Roche Diagnostics

- All the affected lots have been blocked
- The affected manufacturing line for the concerned supplier has been stopped until the full corrective / preventive actions will be implemented.

Actions to be taken by the customer/user

- In case if you have any of the affected lots please discard them immediately locally.

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.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com