

Field Safety Notice

SBN-CPS-2016-022

CPS / SWA High/Mid Volume Solutions
Version 1
19-Oct-2016

Damaged assay cups in certain lots of AssayTip/AssayCup

Product Name	AssayTip/AssayCup
GMMI / Part No	12102137001
Device Identifier	
Production Identifier (Lot No./Serial No.)	Lot numbers: 16417713 and 16418713 <div style="border: 1px solid red; padding: 2px; display: inline-block; color: red;">Affected lots are not available in Singapore</div>
Instrument/System Affected	cobas e 601 module cobas e 602 module MODULAR ANALYTICS E combinations MODULAR ANALYTICS EVO E combinations
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We regret to inform you that we have identified two defective AssayTip/AssayCup lots that have been delivered with damaged assay cups.

The affected AssayTip/AssayCup are exclusively used on **MODULAR ANALYTICS** E combinations, **MODULAR ANALYTICS EVO** E combinations, **cobas e** 601 module and **cobas e** 602 module.

Description of Situation

According to internal investigations a maximum of 1.8% of the total amount of assay cups produced within the lot numbers 16417713 and 16418713 have a hole close to the assay cup bottom or plastic concentrated on the bottom.

Internal investigations revealed that damaged assay cups are assembled in sequences together on a tray and not found isolated. That means it is likely that certain alarms may appear, but it is not guaranteed that alarms will be associated with each and every damaged assay cup. Therefore discrepant results without alarm message and/or flag cannot be excluded.

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Using the assay cups with holes can lead to false patient results for all parameters in the worst case. All Elecsys parameters running on the affected system(s) can be affected.

The affected lot numbers (16417713 and 16418713) and the damaged assay cups can be visually identified, as seen in the below **examples**:



Figure 1: Example of a lot number printed in the AssayTip/AssayCup tray

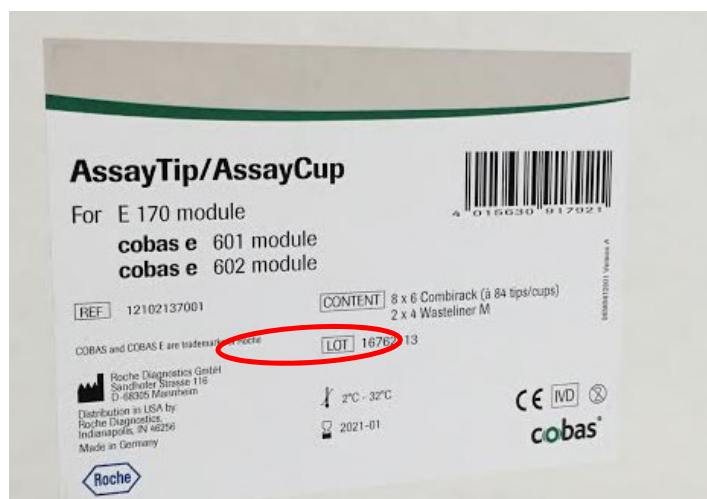


Figure 2: Example of a lot number printed in the AssayTip/AssayCup box

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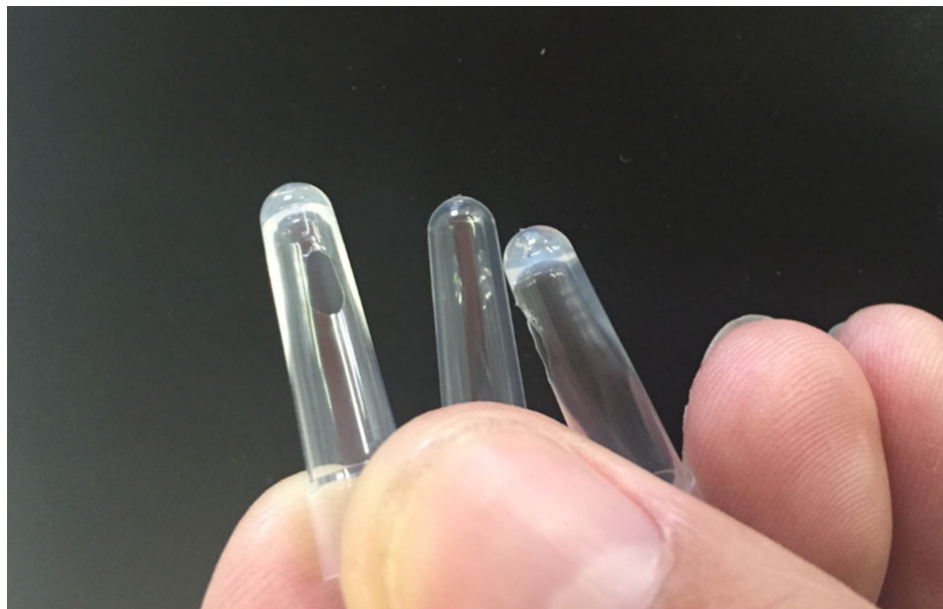


Figure 3: Example of damaged assay cups with holes close to the bottom

Actions taken by Roche Diagnostics

Recently we were informed by one of our external manufacturer partners that some damaged assay cups have been found during the manufacturing process of two lots of AssayTip/AssayCup.

The following actions were taken:

- Confirmation from the manufacturer that the root cause was detected and corrective actions were immediately taken to avoid re-occurrence of this issue.
- The affected lots – 16417713 and 16418713 - have been blocked.

Roche Diagnostics will replace the AssayTip/AssayCup from the affected lot numbers.

Actions to be taken by the customer/user

The following actions have to be taken:

- Identify if the lot numbers 16417713 and/or 16418713 of the AssayTip/AssayCup are available and/or installed in the mentioned instruments.
- AssayTip/AssayCup from the affected lot numbers must be discarded locally and replaced by different lot numbers.
- Appropriate patient re-testing may be advisable, taking into account patient's medical history, clinical examination, available diagnostic parameters, and other findings.



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Communication of this Field Safety Notice

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

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com