

Field Safety Notice

SBN-CPS-2019-009

CPS Serum Work Area Systems

Version 1

28-May-2019



Damaged assay cups in two lots of AssayTip/AssayCup Combiracks

Product Name	AssayTip/AssayCup
GMMI / Part No	12102137001 / Lot #: 19817113 and 19818113
Device Identifier	Affected lots are not available in Singapore
Instrument/System Affected	cobas e 601 module cobas e 602 module MODULAR ANALYTICS E 170
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We wish to advise that we have identified defective assay cups from lots 19817113 and 19818113. The AssayTip/AssayCup (GMMI 12102137001) is used on the MODULAR ANALYTICS E combinations, cobas e 601 module and cobas e 602 module.

The defect consists of a small hole at the bottom of up to 3% of the total amount of Assay Cups produced in lots 19817113 and 19818113. The affected products represent 0,06 % of the yearly production of this product (GMMI 12102137001).

Description of Situation

Internal investigations revealed that:

- Damaged AssayCups are likely to be found in groups in the package (i.e. not a single isolated damaged AssayCup).
- The use of the defective AssayCups from the two affected lots may trigger alarms on the analyzers; however, it is not guaranteed that alarms will be associated with each and every damaged AssayCup.
- Discrepant results without an alarm message and/or flag cannot be excluded.
- Customer may also observe a leaking AssayCup, or AssayCups may fall near the incubator.

Damaged AssayCups in two lots of AssayTip/AssayCup



The lot numbers can be visually identified as below:

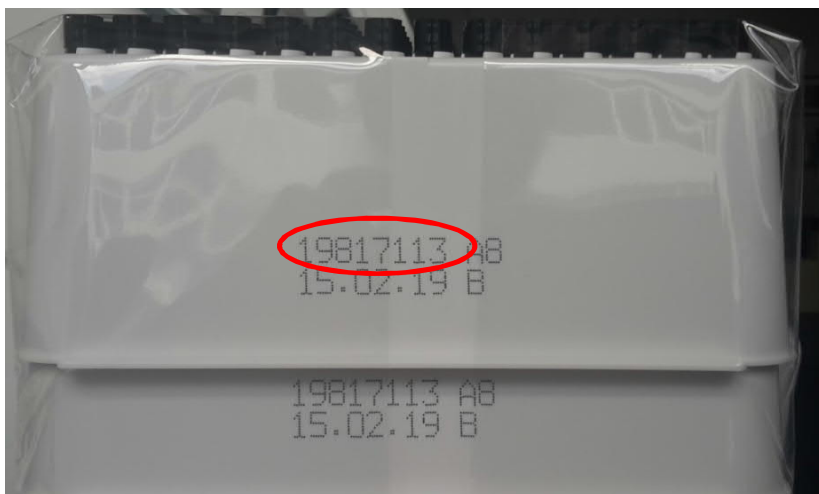


Figure 1: Example of a lot number printed in the AssayTip/AssayCup CombiRack tray

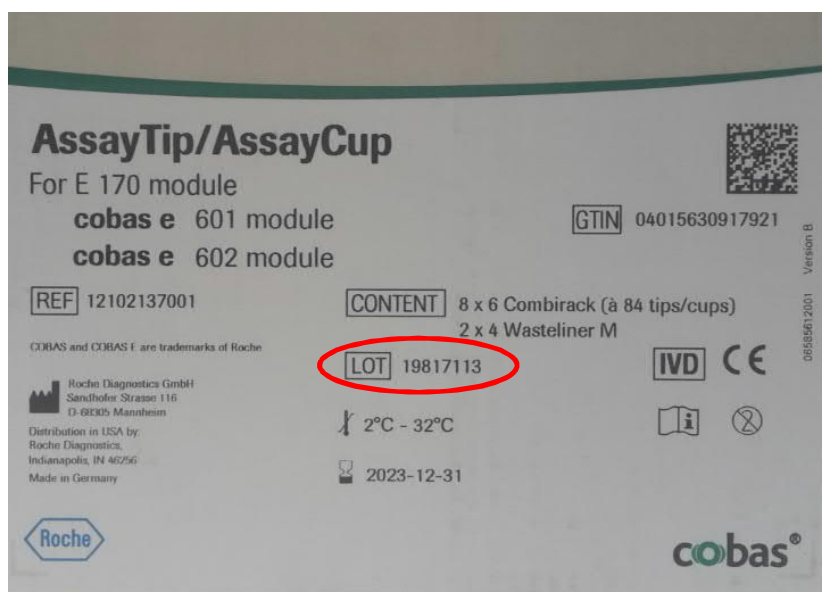


Figure 2: Example of a lot number printed in the AssayTip/AssayCup CombiRack box

Damaged AssayCups in two lots of AssayTip/AssayCup



The damaged AssayCups can be visually identified as below:



Figure 3: Example of a damaged AssayCup with the small hole at the bottom, which can only be seen with magnifying glasses. The small hole is marked by the red arrow. Blue colored water and the three water droplets next to the small hole are the result from previous investigations.

It cannot be excluded, that incorrect results may have occurred due to the damaged AssayCups.

Actions taken by Roche Diagnostics

This issue was caused by a partial blockage in two out of 32 cavities used in the production of the AssayCups for a short time. An immediate corrective action was taken in order to avoid recurrence of the issue. No other lots were affected.

Actions to be taken by the customer/user

- Customers must check if they received AssayTips/Assay cups from one of the lots: 19817113 and 19818113.
- Customers must stop using the affected AssayTip/AssayCup lots.
- AssayTips/AssayCups from the affected lot numbers must be discarded locally and replaced by different lot numbers. Customers are advised to also check the lot numbers of the trays placed in the instruments.
- In case patients' results were released using those two lots, appropriate patient re-testing may be advisable, taking into account patients' medical history and clinical examination.

Damaged AssayCups in two lots of AssayTip/AssayCup



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,

Roche Diagnostics Asia Pacific Pte Ltd
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