

Urgent Field Safety Notice

SBN-CPS-2019-009



CPS Serum Work Area Systems

Version 1

Mav-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	
Instrument/System Affected	cobas e 601 module cobas e 602 module MODULAR ANALYTICS E 170 MODULAR ANALYTICS EVO E combinations
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, **MODULAR ANALYTICS EVO 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:

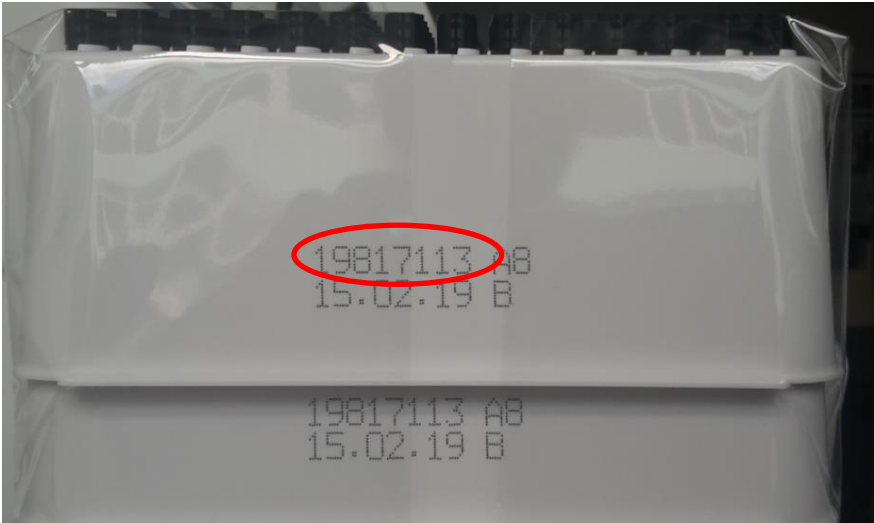


Figure 1: Example of a lot number printed in the AssayTip/AssayCup CombiRack tray

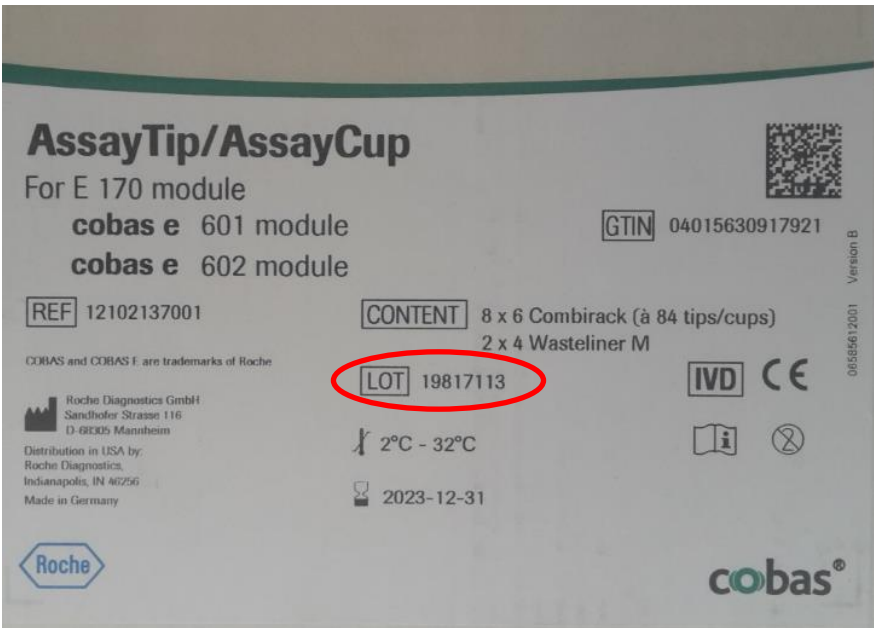


Figure 2: Example of a lot number printed in the AssayTip/AssayCup CombiRack box

The damaged AssayCups can be visually identified as below:

Damaged AssayCups in two lots of AssayTip/AssayCup



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.

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 lots 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.

Damaged AssayCups in two lots of AssayTip/AssayCup



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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com