Field Safety Notice

SBN-CPS-2019-017

CPS / Serum Work Area Systems
Version 1
08-Aug-2019

AssayTips with abnormal internal structure used on cobas e 801

Product Name	AssayTip/AssayCup tray
GMMI / Part No Device Identifier	05694302001
Instrument/System Affected	**cobas e** 801 module **cobas e** 801 analytical unit
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)
Lots	18656170 and 18661170 Note: There are other affected lots globally. Please contact the product owner if the device is obtained from an overseas dealer.

Dear Valued Customer,

Roche has identified AssayTips with abnormal internal structure in some lots. The AssayTips are part of the AssayTip/AssayCup tray (GMMI 05694302001), used on **cobas e** 801 analyzers in combination with **cobas®** 8000 modular analyzer series and/or **cobas pro** integrated solutions.

Description of Situation

Roche has received a small number of customer complaints regarding defective AssayTips (Figure 3) and after subsequent internal investigations, lots with abnormal internal structure were identified.

The affected AssayTip/AssayCup tray lots have been globally distributed from August 2018 to July 2019

The average amount of potentially affected AssayTips in these lots is ≈1.5%. The overall incidence rate represents 0.14% of the AssayTips production since the introduction of the **cobas e** 801.

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Internal investigations revealed that:

- Due to the abnormal internal structure, there might be a not optimal fit of the AssayTip with the sample probe. Thus, insufficient sample volume could be pipetted.
- Discrepant results without alarm message and/or flag cannot be excluded. Typically, low results of several consecutive measurements may occur.
- AssayTips with abnormal internal structure are likely to be found in groups in the tray (i.e. not a single isolated AssayTip with abnormal internal structure). Not all AssayTips from the affected lots are out of specification.

Due to the residual medical risk associated with this issue, customers using the affected product must be informed using this FSN.

The affected lot numbers can be visually identified on the tray (Figure 1) and on the tray box (Figure 2).

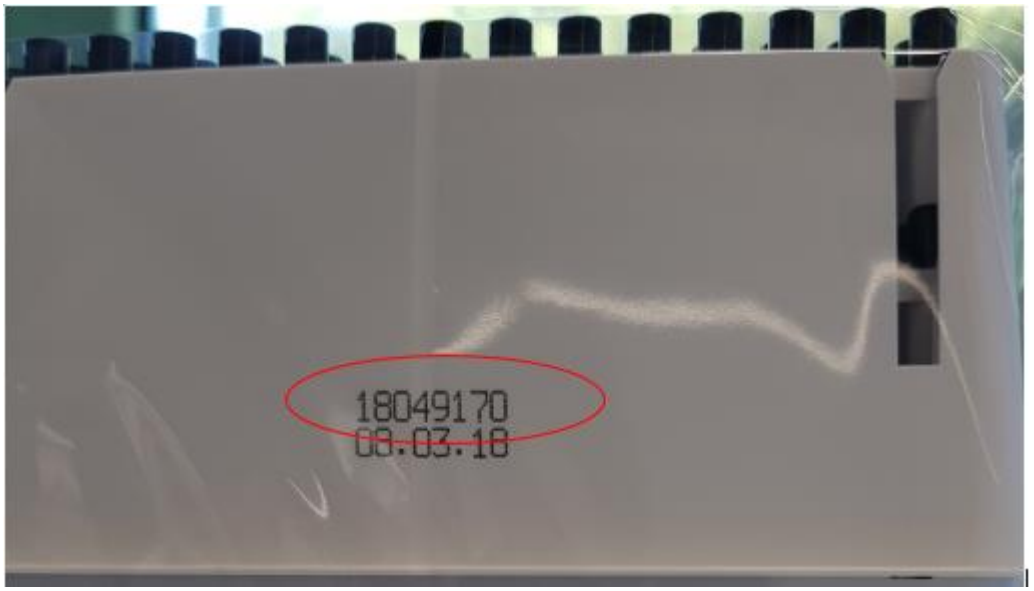

Figure 1: Example of a lot number printed on the AssayTip/AssayCup tray

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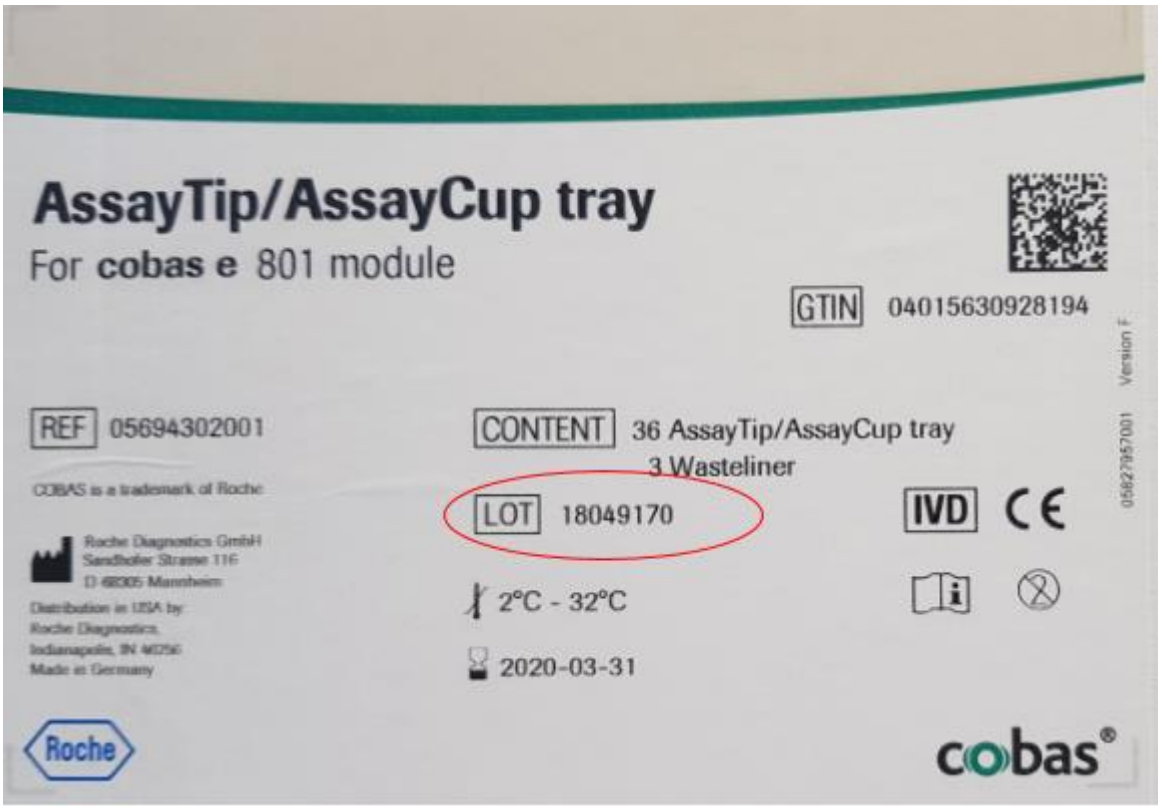

Figure 2: Example of a lot number printed on the AssayTip/AssayCup tray box

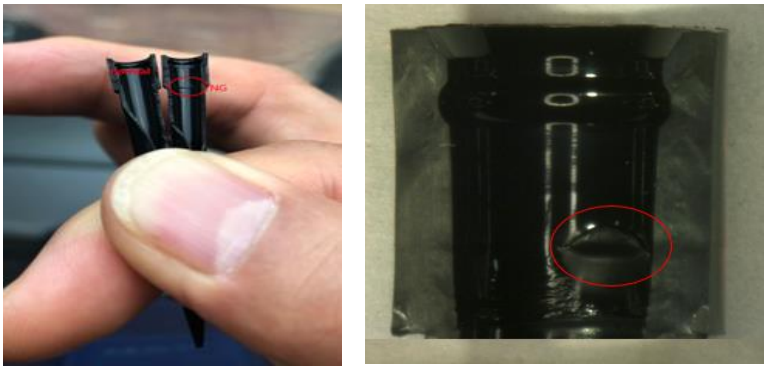

Figure 3: Examples of cut AssayTips with abnormal internal structure. The AssayTip includes a burr marked by a red circle.

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Root Cause
An error affecting certain cavities of the production molds occurred in part of the production lines at our external supplier. This error led to the production of AssayTips with abnormal internal structure. The supplier has taken immediate corrective action in order to avoid re-occurrence of this issue. Current production is not affected by this error.

Actions taken by Roche Diagnostics

- The external supplier has identified the root cause and has immediately taken corrective action to avoid re-occurrence of this issue.
- Roche Diagnostics have stopped distribution of the affected AssayTip/AssayCup tray lots.

Actions to be taken by the customer/user

- We have identified 2 affected lots, 18656170 and 18661170, that were delivered to your laboratory from Nov 2018 to Jan 2019. Subsequent deliveries to the laboratory are checked to be of unaffected lots.
- The remaining (if any) affected AssayTip/AssayCup tray lots (in storage as well as in instrument) cannot be used and must be discarded immediately.
- In case that discrepant results are suspected during use of the affected lots, appropriate patient re-testing may be advisable, taking into account the patients' medical history and clinical examinations.

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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 you and thank you for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
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