# Urgent Field Safety Notice

*SBN-CPS-2019-017*

CPS / Serum Work Area Systems
Version 1
Aug-2019

# AssayTips with abnormal internal structure used on cobas e 801

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|---|---|
| **Product Name** | **AssayTip/AssayCup tray** |
| **GMMI / Part No** | 05694302001 |
| **Instrument/System Affected** | **cobas e** 801 module<br>**cobas e** 801 analytical unit |
| **SW Version** | Not applicable |
| **Type of Action** | Field Safety Corrective Action (FSCA) |

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). AssayTip/AssayCup tray are used on **cobas e** 801 analyzers in combination with **cobas**® 8000 modular analyzer series and/or **cobas pro** integrated solutions.

**Description of Situation**
We want to advise you that we have identified AssayTips with abnormal internal structure in some lots. The AssayTips are part of the AssayTip/AssayCup tray (GMMI 05694302001).

Recently, Roche has received a small number of customer complaints regarding defective AssayTips.
The affected AssayTip/AssayCup tray lots have been distributed from August 2018 until July 2019 (list of affected lots attached).

In total there are **165** lots affected. Internal investigation shows that the average amount of potentially affected AssayTips in those lots is approximately 1.5%.
The overall incidence rate represents 0.14% of the AssayTips production since the introduction of the **cobas e** 801.

Internal investigations revealed that:

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- 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. typically 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 visually be identified as seen in the examples below. Please compare your lots to the list of lot numbers provided (attached to this FSN).


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

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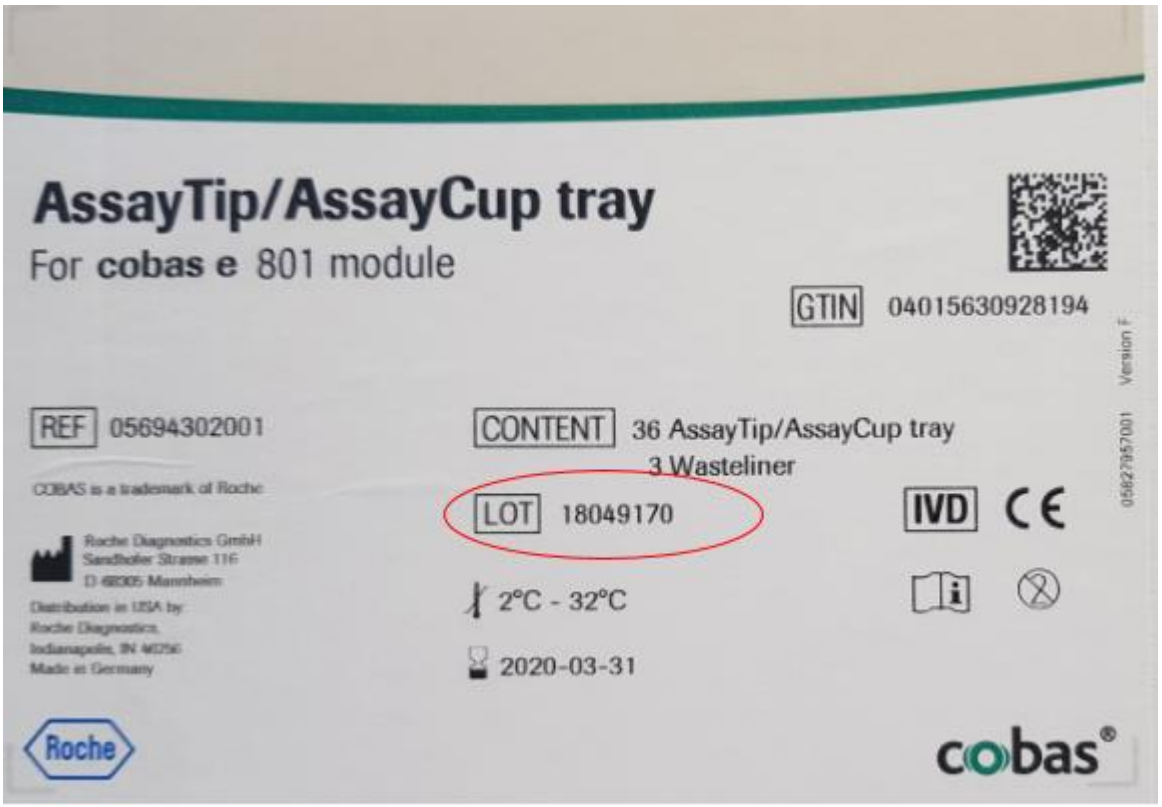


**Figure 2:** Example of a lot number printed on the AssayTip/AssayCup tray box

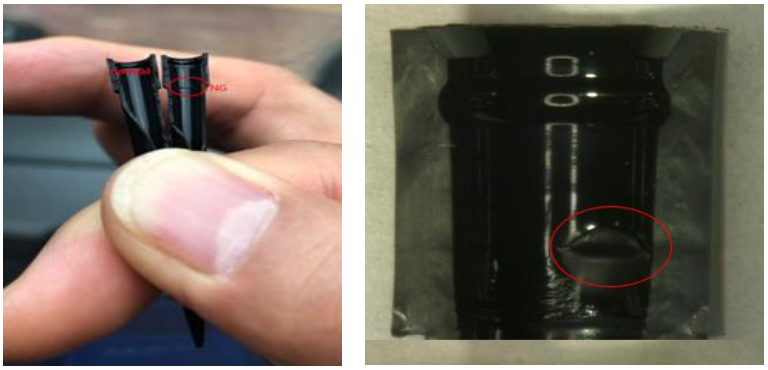

**Figure 3:** Examples of cut AssayTips with abnormal internal structure. The AssayTip includes a burr marked by a red circle.

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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 to be 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

- Customers must check if they received affected AssayTips/AssayCup tray lots. Please compare your lots to the list of lot numbers provided (attached to this FSN).
- Customer must stop using the affected AssayTip/AssayCup tray lots and must discard the affected products locally.
- Customers are advised to also check the lot numbers of the trays placed on the instruments.
- 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.

## 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.

**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.

# AssayTips with abnormal internal structure used on cobas e 801

Best regards,

**Contact Details**

*To be completed locally:*
Name
Title
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