



# URGENT FIELD SAFETY NOTICE

## IMMEDIATE ACTION REQUIRED

Ref No: EFSN cobas e 801 SBN-CPS-2019-017  
Date: 06/08/2019  
Type of Action: Field Safety Corrective Action (FSCA)

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Product Affected: AssayTip/AssayCup Tray

System Affected: cobas e 801

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Software Version: N/A

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Product Name	Material No	Lot No
AssayTip/AssayCup Tray	05694302001	Please see EFSN cobas e 801 SBN-CPS-2019-017 Attachment 1

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### Summary of Issue

AssayTips with abnormal internal structure used on cobas e 801.

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### Reason for Notice

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 analysers in combination with cobas® 8000 modular analyser 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 (EFSN cobas e 801 SBN-CPS-2019-017 Attachment 1)

✓	Immediate Action Required
	Action Required
	Information Only

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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:

- 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 (EFSN cobas e 801 SBN-CPS-2019-017 Attachment 1).

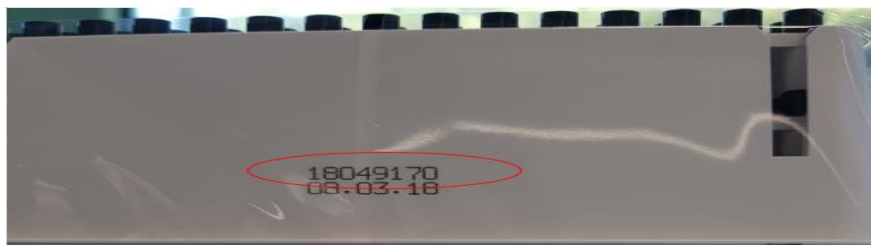


Figure 1: Example of a lot number printed on the AssayTip/AssayCup tray

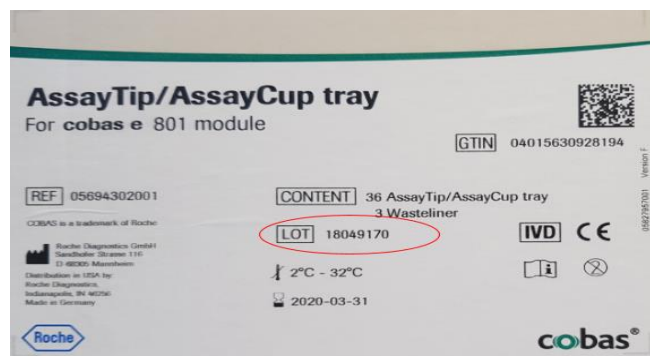


Figure 2: Example of a lot number printed on the AssayTip/AssayCup tray box

Roche Diagnostics  
Charles Avenue  
Burgess Hill  
West Sussex  
RH15 9RY

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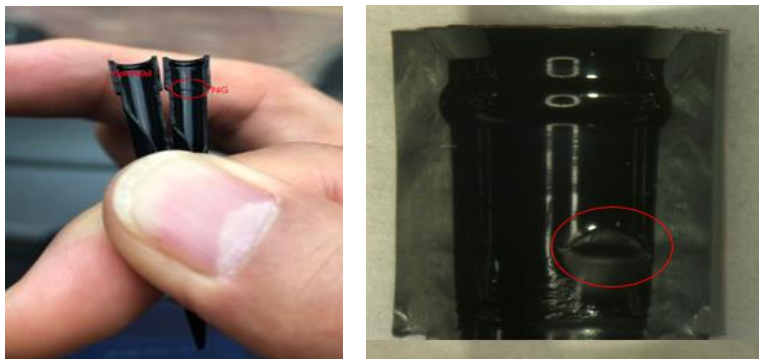


Figure 3: Examples of cut AssayTips with abnormal internal structure. The AssayTip includes a burr marked by a red circle.

### 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

### Action Required

### 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 (EFSN cobas e 801 SBN-CPS-2019-017 Attachment 1).
- Customer must stop using the affected AssayTip/AssayCup tray lots and must discard the affected products locally.

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- 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.

Please complete and return the **Acknowledgement Form** which accompanies this **Field Safety Notice** by 21<sup>st</sup> August 2019.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

### Attachments

EFSN cobas e 801 SBN-CPS-2019-017 Attachment 1  
EFSN cobas e 801 SBN-CPS-2019-017 Acknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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## List of affected lots

### GMMI 05694302001 AssayTip/AssayCup tray

18210274	18245274	18278274	18668170	19304274
18211274	18246274	18279274	18669170	19305274
18212274	18247274	18280274	18670170	19306274
18213274	18248274	18281274	18689170	19307274
18214274	18249274	18282274	18690170	19308274
18215274	18250274	18283274	18703170	19309274
18216274	18251274	18635170	19204274	19310274
18217274	18252274	18636170	19205274	19311274
18218274	18253274	18637170	19206274	19312274
18219274	18254274	18638170	19207274	19313274
18221274	18255274	18643170	19208274	19314274
18222274	18256274	18644170	19209274	19320274
18223274	18257274	18645170	19228274	19321274
18224274	18258274	18646170	19229274	19322274
18225274	18259274	18647170	19230274	19323274
18226274	18260274	18648170	19235274	19324274
18227274	18261274	18649170	19236274	19325274
18228274	18262274	18650170	19237274	19326274
18229274	18263274	18653170	19238274	19327274
18230274	18264274	18654170	19239274	19328274
18231274	18265274	18655170	19269274	19377274
18232274	18266274	18656170	19270274	19378274
18233274	18267274	18657170	19271274	19379274
18234274	18268274	18658170	19285274	19380274
18235274	18269274	18659170	19286274	19381274
18236274	18270274	18660170	19287274	19382274
18237274	18271274	18661170	19288274	19383274
18238274	18272274	18662170	19289274	18639170
18239274	18273274	18663170	19299274	18640170
18241274	18274274	18664170	19300274	18641170
18242274	18275274	18665170	19301274	18642170
18243274	18276274	18666170	19302274	18651170
18244274	18277274	18667170	19303274	18652170

Total 165 affected lots  
2.Aug.2019

Kindly note: Highlighted lot numbers are those that have been identified as having been sent to UK and IE customer accounts.



# ACKNOWLEDGEMENT

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Field Safety Notice Ref No: EFSN cobas e 801 SBN-CPS-2019-017 Acknowledgement Form  
Date: 06/08/2219  
Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before 21<sup>st</sup> August 2019.

Product Catalogue No:	AssayTip/AssayCup tray
System:	cobas e 801
Customer Name & Dept:	
Address:	

Are the above contact details correct? (Please circle)    Yes    No    (If no please insert correct details below)

Contact Name:
Department:
Telephone:
<p>If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:</p>
Email:
<p>Please acknowledge receipt of information and awareness of any required actions described within the accompanying <b>Field Safety Notice</b>.</p>
<p>Please bring this notice to the attention of all personnel in your hospital or healthcare facility who need to be aware of this safety issue.</p>
<p>If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.</p>



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Field Safety Notice Ref No: EFSN cobas e 801 SBN-CPS-2019-017 Acknowledgement Form  
Date: 06/08/2019  
Type of Action: Field Safety Corrective Action (FSCA)

I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

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