# URGENT FIELD SAFETY NOTICE
## IMMEDIATE ACTION REQUIRED

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| Ref No: | EFSN ProCell II M SBN-CPS-2018-025 |
| Date: | 12/03/2019 |
| Type of Action: | Field Safety Corrective Action (FSCA) |

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| Product Affected: | ProCell II M |
| System Affected: | cobas e 801 |

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| Software Version: | N/A |

| Product Name | Material No | Lot No |
|---|---|---|
| ProCell II M | 06908799190 | N/A |
| cobas e 801 module | 07682913001 | N/A |
| cobas e 801 analytical unit | 08454345001 | N/A |

### Summary of Issue

cobas e 801 signal drop after ProCell II M bottle changeover.

### Reason for Notice

Dear Valued Customer,

## Description of Situation

We regret to inform you that we have received complaints describing signal drops on some cobas e 801 modules, due to degrading of ProCell II M in the flowpath caused by bacterial contamination. Investigations have shown that when this issue occurs, it may cause discrepant results approximately 15 determinations after the ProCell II M bottle changeover, for a period of up to 20 consecutive measurements.

ProCell II M is a system solution used on cobas e 801 for the transport of the assay reactant mixture to the measuring cell and for Electrochemiluminescence (ECL) signal generation. There are 2 bottles of ProCell II M present on cobas e 801: an active bottle that is used for measurements and a stand-by bottle that is automatically used right after the first bottle is empty

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(ProCell II M bottle changeover).

Roche has received 27 global complaints involving 21 out of 2000 active cobas e 801 module/analytical units.

The potentially affected cobas e 801 modules/analytical units are only those that show at least two of the following conditions:

- Bacterial contamination of the flowpath or other signs of contamination
- [Finalization] is not daily performed
- Occurrence of alarms for “ProCell On Board Stability Time (744-xxxxxx or 346-xxxxxx)”
- Reoccurrence of alarms for “Abnormal Signal Low (345-000001)”
- The system is operated in CLAS connection mode or rack reception mode > 8h

Please note that ProCell M (used on cobas e 601 module, cobas e 602 module and MODULAR ANALYTICS E-170) and ProCell (used on cobas e 411 analyzer) are not affected.

Please follow the recommendations given in the section “Actions to be taken by the customer/user” if at least two of the above described conditions apply.

## Important Information

On affected cobas e 801 modules/analytical units, the ProCell II M flowpath is covered by a biofilm with ProCell II M resistant bacteria. If ProCell II M inside the flowpath is not exchanged regularly, like for example in the stand-by ProCell II M bottle flowpath, bacteria can degrade the components of ProCell II M resulting in a reduced ECL signal generating capacity. The impact of this degradation is described for sandwich and competitive assays, as follows:

- Sandwich assays:

The issue might lead to incorrect low signals and data alarms “Abnormal Low Signal (345-000001)” and “Signal low (<SigL)" may be issued. These alarms indicate a technical issue with the measurement. Also incorrect results without flag and alarm might be generated. If no alarm and/or flag, which invalidates the result, occurs and if the incorrect result is believed to be correct with an unpredictable deviation, a medical risk cannot be excluded.

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|---|---|---|---|
| Elecsys ACTH | Elecsys Active B12 | Elecsys AFP | Elecsys AMH |
| Elecsys AMH Plus | Elecsys Anti-CCP | Elecsys Anti-HAV IgM | Elecsys Anti-HBc IgM |
| Elecsys Anti-HBs II | Elecsys Anti-HCV II | Elecsys BRAHMS PCT | Elecsys CA 125 II |

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| Elecsys CA 15-3 II | Elecsys CA 19-9 | Elecsys CA 72-4 | Elecsys Calcitonin |
| Elecsys CEA | Elecsys Chagas | Elecsys CK-MB | Elecsys CMV IgG |
| Elecsys CMV IgG Avidity | Elecsys CMV IgM | Elecsys C-Peptide | Elecsys CYFRA 21-1 |
| Elecsys Ferritin | Elecsys free PSA | Elecsys free βhCG | Elecsys FSH |
| Elecsys GDF-15 | Elecsys HBeAg | Elecsys HBsAg II | Elecsys HBsAg II quant II |
| Elecsys HCG STAT | Elecsys HCG+β | Elecsys HE4 | Elecsys hGH |
| Elecsys HIV Duo | Elecsys HSV-1 IgG | Elecsys HSV-2 IgG | Elecsys HTLV-I/II |
| Elecsys IgE II | Elecsys IGFBP-3 | Elecsys IL-6 | Elecsys Insulin |
| Elecsys LH | Elecsys Myoglobin | Elecsys N-MID Osteocalcin | Elecsys NSE |
| Elecsys PAPP-A | Elecsys PlGF | Elecsys proBNP II | Elecsys ProGRP |
| Elecsys Prolactin II | Elecsys PTH | Elecsys PTH (1-84) | Elecsys Rubella IgG |
| Elecsys Rubella IgM | Elecsys S100 | Elecsys SCC | Elecsys sFlt-1 |
| Elecsys SHBG | Elecsys Syphilis | Elecsys Tg II | Elecsys total P1NP |
| Elecsys total PSA | Elecsys Toxo IgG | Elecsys Toxo IgG Avidity | Elecsys Toxo IgM |
| Elecsys Troponin I | Elecsys Troponin T hs | Elecsys TSH | Elecsys β-CrossLaps/serum |

Table 1 - Sandwich assays that may present abnormal low results

- Competitive assays:

The flag ">Test" for competitive tests may be generated, however incorrect results without flag and alarm might be generated as well. If no alarm and/or flag, which invalidates the result, occurs and if the incorrect result is believed to be correct with an unpredictable deviation, a medical risk cannot be excluded.

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| Elecsys Anti-HAV | Elecsys Anti-HBc II | Elecsys Anti-HBe | Elecsys Anti-Tg |
| Elecsys Anti-TPO | Elecsys Anti-TSHR | Elecsys Cortisol II | Elecsys Cyclosporine |
| Elecsys DHEA-S | Elecsys Digitoxin | Elecsys Digoxin | Elecsys Estradiol III |
| Elecsys Everolimus | Elecsys Folate | Elecsys FT3 III | Elecsys FT4 II |
| Elecsys Progesterone III | Elecsys Sirolimus | Elecsys T3 | Elecsys T4 |
| Elecsys Tacrolimus | Elecsys Testosterone II | Elecsys T-Uptake | Elecsys Vitamin B12 II |
| Elecsys Vitamin D total II | | | |

Table 2 – Competitive assays that may present incorrect high results

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## Actions taken by Roche Diagnostics

1. ProCell II M improvement:
    a. An updated ProCell II M with improved preservation will be available at Roche global warehouse from calendar week 12/2019 (March 18th to 22nd) onwards. Tests revealed that this updated ProCell II M remains stable even after contamination with the same kind of bacteria as described under "Important Information".
    b. All customers will be contacted by Roche representatives to proactively schedule a visit to switch cobas e 801 modules/analytical units to the updated ProCell II M.

2. ProCell II M flowpath decontamination:
    a. Until the updated ProCell II M is available at customer sites, a decontamination of the ProCell II M flowpath every 4 weeks should be performed by a Roche representative, for cobas e 801 modules/analytical units that show at least two of the following conditions:
        - Bacterial contamination of the flowpath or other signs of contamination
        - [Finalization] is not daily performed
        - Occurrence of alarms for "ProCell On Board Stability Time (744-xxxxxx or 346-xxxxxx)"
        - Reoccurrence of alarms for "Abnormal Signal Low (345-000001)"
        - The system is operated in CLAS connection mode or rack reception mode > 8h
    b. In order to improve the efficiency of the ProCell II M flowpath decontamination procedure, the related service procedure has been revised and proven to mitigate the risk of contamination.

Action Required

## Actions to be taken by the customer/user

The actions described below under "Short-term workaround" are only limited to the potentially affected cobas e 801 modules/analytical units that show at least two of the following conditions:

- Bacterial contamination of the flowpath or other signs of contamination
- [Finalization] is not daily performed
- Occurrence of alarms for "ProCell On Board Stability Time (744-xxxxxx or 346-xxxxxx)"
- Reoccurrence of alarms for "Abnormal Signal Low (345-000001)"
- The system is operated in CLAS connection mode or rack reception mode > 8h

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## Short-term workaround

If you have a potentially affected cobas e 801 module/analytical unit (based on the above described criteria), then please perform the below instructions only until the decontamination is performed by a Roche FSR or the updated ProCell II M is available for routine operation:

- During operation:
  - Every 4 hours, mask and unmask the affected cobas e 801 module/analytical unit.
  - This procedure exchanges the ProCell II M inside the flowpath of both bottles and avoids the issue to occur.
- After idle periods exceeding 4 hours without performing measurements in rack reception mode / CLAS connection mode, before restarting measurements:
  - Mask and unmask the affected cobas e 801 module/analytical unit.
  - This procedure exchanges the ProCell II M inside the flowpath of both bottles and avoids the issue to occur after longer idle periods.

How to mask and unmask a cobas e 801 module/analytical unit:

- Choose the [Start] global button, then press [Masking], then press [Module Masking], press repeatedly the cobas e 801 [AU] button until Module Mask is displayed and press [Execute].
- Wait until the masking process is complete, then repeat the procedure to unmask the same module/ analytical unit and bring it back to Operation.

## Long-term solution

Contact Roche to change to the updated ProCell II M, available at Roche global warehouse from calendar week 12/2019 (March 18th to 22nd) onwards, with support from a Roche FSR.

## How to retrospectively identify and correct potentially affected patient sample results

Affected cobas e 801 modules/analytical units may generate discrepant results as follows:

- 15 to 35 measurements after generation of alarm 343-00009 or 343-00010 (ProCell II M bottle changeover)
- 15 to 35 measurements after restarting operation without any measurements for more than 4 hours in rack reception mode

If you have a potentially affected cobas e 801 module/analytical unit the following steps may be

used to retrospectively identify and correct potentially discrepant results:

1. Rerun the 15th to 35th consecutive measurements after the above mentioned conditions occurred to detect and correct affected results.

2. Follow the “Short-term workaround” or “Long-term solution” to avoid the reoccurrence of this issue.

If you have any questions, please contact Roche Technical Support.

Please complete and return the Acknowledgement Form which accompanies this Field Safety Notice by 26th March 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 ProCell II M SBN-CPS-2018-025 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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# ACKNOWLEDGEMENT

## URGENT FIELD SAFETY NOTICE

### IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: EFSN ProCell II M SBN-CPS-2018-025 Acknowledgement Form
Date: 12/03/2019
Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before 26th March 2019.

| | |
|---|---|
| Product Catalogue No: | ProCell II M 06908799190 |
| System: | cobas e 801 module<br>cobas e 801 analytical module |
| 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:

If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice.

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.

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

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email to burgesshill.techsupportdocs@roche.com

# ACKNOWLEDGEMENT

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Field Safety Notice Ref No: EFSN ProCell II M SBN-CPS-2018-025 Acknowledgement Form
Date: 12/03/2019
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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