


URGENT FIELD SAFETY NOTICE – FSN 30836

Synchron Systems AQUA Cal 1

| REF | LOT |  |
|---------------|-----------------|---|
| 471288 | 72645074 | 2018-04-30 |

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

| | |
|--------------------|--|
| ISSUE: | <ul style="list-style-type: none"> Beckman Coulter has confirmed a negative shift of 5 mmol/L for sodium recovery in Synchron Control Level 3 when calibrated with AQUA Cal 1 lot 72645074. A linearity study using Maine Linearity standards also indicated a negative shift of up to 8 mmol/L at values between 150 and 180 mmol/L. |
| IMPACT: | <ul style="list-style-type: none"> Patient results may show a negative shift of 2 to 9 mmol/L for sodium values above 140 mmol/L. A negative shift in recovery may cause quality control results to fall below the lower limit of your laboratory's established QC range for sodium. There is no impact to K, CL, CO₂, CALC, BUNm/UREAm, CR-E, CR-S, CREm, GLUCm, GLUH and PHOSm when calibrated with AQUA Cal 1 lot 72645074. |
| ACTION: | <ul style="list-style-type: none"> Discontinue use and discard AQUA Cal 1 lot 72645074 according to your laboratory disposal protocol. A retrospective review of sodium results is at the discretion of the Laboratory Director. Sodium results are considered within the parameters of acceptable performance after successful calibration and when quality control recovery are within your laboratory's established QC range. Please contact your local Beckman Coulter Representative for replacement on 0870 243 60001 – Option 1 or bcieorders@beckman.com. |
| RESOLUTION: | Investigation into root cause of this issue is ongoing. |



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Website www.beckman.com

Directors: P Devereux, P Della Puca
Registered in Ireland no 485929 Registered Office: 70 Sir John Rogerson's Quay, Dublin 2, Ireland

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

You may request replacement product by contacting your local Beckman Coulter Representative on 0870 243 60001 – Option 1 or bcieorders@beckman.com.

We apologize for any inconvenience that this caused your laboratory.

Yours sincerely,



Fabien Chirouze
Quality / Regulatory Affairs Manager - Northern Region Europe
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Fax +44 (0) 1494 429182

Enclosed: Vigilance Response Form

| | | |
|---|--------------------------------|--------------------------|
|  | Document: | Document #: |
| | VIGILANCE RESPONSE FORM | UKIE-REG-FRM-0004 |

Please complete the appropriate sections below:


Site Name: _____

Instrument Type: _____

Instance/Serial Number(s): _____

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The Notification has been actioned – I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any recommended actions taken and records retained as part of our Laboratory Quality System documentation.

For Kit related Notifications only:

| | | | | | |
|-----------------------------|--|--------------------------|--|--|--|
| Number of Kits already used | | Number of Kits discarded | | Number of Kits returned to Beckman Coulter | |
|-----------------------------|--|--------------------------|--|--|--|

For product replacement please contact the Sales Office on 0870 243 60001 – Option 1 or bcieorders@beckman.com.

Or:

The Notification has not been actioned – We do not have this product.

Signed: _____ Date: _____

Name: _____ Tel: _____
(Please Print):

Email: _____

Please return this form by fax, post or email to:

Lynn Walker
Beckman Coulter UK Ltd
Oakley Court
Kingsmead Business Park
London Road, High Wycombe
BUCKS, HP11 1JU

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Tel no: 44+ (0) 1494 429184
Email: ukqualityadmin@beckman.com

FSN Number: 30836