


## URGENT FIELD SAFETY NOTICE – FSN 28096

Access Free T3 Reagent Kit

For use with the Access Family of Immunoassay Systems\*


| REF    | LOT                       |  |
|--------|---------------------------|---|
| A13422 | 524087                    | 31-05-2016  |
|        | 526807                    | 30-06-2016  |
|        | 528874                    | 31-07-2016  |
|        | 529913                    | 31-08-2016  |
|        | 530102                    | 31-08-2016  |
|        | 531647                    | 30-09-2016  |
|        | 532473                    | 31-10-2016  |
|        | 534080                    | 30-11-2016  |
|        | 534081                    | 31-12-2016  |
|        | 534336                    | 31-12-2016  |
|        | 535481                    | 31-01-2017  |
|        | 570090                    | 31-05-2016  |
|        | 570116                    | 30-06-2016  |
|        | 570222                    | 31-07-2016  |
|        | 570236                    | 31-08-2016  |
|        | 570239                    | 31-08-2016  |
|        | 570245                    | 31-08-2016  |
|        | 570246                    | 31-08-2016  |
|        | 622173                    | 28-02-2017  |
|        | 622174                    | 31-03-2017  |
|        | 671016                    | 31-01-2017  |
|        | 671025                    | 31-01-2017  |
| 671033 | 28-02-2017                |   |
|        | Including all future lots | N/A   |

\* The Access Family of Immunoassay Systems includes the Access 2, UniCel DxI 800 and UniCel DxI 600, UniCel DxC 600i, and the UniCel DxC 880i, UniCel DxC 860i, UniCel DxC 680i, and UniCel DxC 660i systems.

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.

|               |   |
|---------------|---|
| <b>ISSUE:</b> | <ul style="list-style-type: none"> <li>Beckman Coulter has determined through customer feedback and internal testing that the Access Free T3 Reagent lots listed above demonstrate an upward shift in patient results. The preliminary results indicate this upward shift may be related to a June 2015 formulation design change that was introduced to improve the Access Free T3 open reagent pack stability. The</li> </ul> |
|---------------|---|

 **Move healthcare forward.**

Beckman Coulter Diagnostics Limited  
Lismeehan  
O'Callaghans Mills  
Co. Clare  
Ireland

Telephone +353 65 6831100  
Fax +353 65 6831122  
e-mail [infoie@beckman.com](mailto:infoie@beckman.com)  
Website [www.beckman.com](http://www.beckman.com)

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

|                |   |
|----------------|---|
|                | upward shift in patient test results, therefore, is expected to be maintained for all future lots.  |
| <b>IMPACT:</b> | <ul style="list-style-type: none"> <li>• Patient sample results will shift upward by approximately 10-14% across the reference interval when compared to the results generated with reagent lots manufactured prior to the June 2015 design change.</li> <li>• Additional assay performance characteristics are not affected.</li> <li>• Due to matrix differences, QC values may not demonstrate a shift.</li> </ul>   |
| <b>ACTION:</b> | <ul style="list-style-type: none"> <li>• Discontinue using the Access Free T3 lots listed within the above table until your laboratory either: <ul style="list-style-type: none"> <li>➢ Verifies that your current Access Free T3 reference interval(s) is appropriate; or</li> <li>➢ Adjusts or establishes new reference interval(s).</li> </ul> </li> <li>• To verify, adjust or establish new Access Free T3 reference interval(s), consider the following options: <ul style="list-style-type: none"> <li>➢ Use your current laboratory procedures to review and verify your reference intervals.</li> <li>➢ Refer to CLSI Approved Guideline EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory: Approved Guideline - Third Edition. The CLSI Guideline includes the following three methods: <ul style="list-style-type: none"> <li>▪ Verify the reference interval; this may be accomplished by testing as few as 20 samples from qualified reference individuals.</li> <li>▪ Adjust the reference interval by transference.</li> <li>▪ Establish a new reference interval by analyzing samples from a sufficient number of qualified reference individuals for analysis.</li> </ul> </li> </ul> </li> <li>• Resume using the Access Free T3 lots listed above and all future lots once your laboratory has completed the reference interval evaluation.</li> <li>• At the discretion of your Laboratory Director, notify clinicians that it is possible the Access Free T3 sample results previously reported by your laboratory were affected by this issue.</li> </ul> |

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 products 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 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](mailto:techsupportie@beckman.com).

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'John Winter', is centered on a light gray rectangular background.

John Winter  
Quality / Regulatory Affairs Manager - Northern Region Europe  
Tel +44 (0) 1494 429184/+44 (0)1494 429128  
Fax +44 (0) 1494 429182

Enclosed: Vigilance Response Form

|   |   |   |
|---|---|---|
|  | Document:<br><b>VIGILANCE RESPONSE FORM</b> | Document #:<br><b>UKIE-REG-FRM-0004</b> |
|---|---|---|

Please complete the appropriate sections below:

Site Name: \_\_\_\_\_

Instrument Type: \_\_\_\_\_

Instance/Serial Number(s): \_\_\_\_\_

**URGENT FIELD SAFETY NOTICE – FSN 28096**

Access Free T3 Reagent Kit  
For use with the Access Family of Immunoassay Systems\*

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.

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

Fax no: 44+ (0) 1494 429182  
Tel no: 44+ (0) 1494 429184  
Email: ukqualityadmin@beckman.com

FSN Number: 28096