8 June 2016

URGENT MEDICAL DEVICE RECALL

Access Free T3 Reagent Kit

For use with the Access Family of Immunoassay Systems*

REF	LOT	⌛
A13422	524087	5/31/2016
	526807	6/30/2016
	528874	7/31/2016
	529913	8/31/2016
	530102	8/31/2016
	531647	9/30/2016
	532473	10/31/2016
	534080	11/30/2016
	534081	12/31/2016
	534336	12/31/2016
	535481	1/31/2017
	570090	5/31/2016
	570116	6/30/2016
	570222	7/31/2016
	570236	8/31/2016
	570239	8/31/2016
	570245	8/31/2016
	570246	8/31/2016
	622173	2/28/2017
	622174	3/31/2017
	671016	1/31/2017
	671025	1/31/2017
	671033	2/28/2017
	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 an urgent medical device recall (field action) for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	• 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 upward shift in patient test results, therefore, is expected to be maintained for all future lots.

IMPACT:	• 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. • Additional assay performance characteristics are not affected. • Due to matrix differences, QC values may not demonstrate a shift.
ACTION:	• Discontinue using the Access Free T3 lots listed within the above table until your laboratory either: ➢ Verifies that your current Access Free T3 reference interval(s) is appropriate; or ➢ Adjusts or establishes new reference interval(s). • To verify, adjust or establish new Access Free T3 reference interval(s), consider the following options: ➢ Use your current laboratory procedures to review and verify your reference intervals. ➢ 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: ▪ Verify the reference interval; this may be accomplished by testing as few as 20 samples from qualified reference individuals. ▪ Adjust the reference interval by transference. ▪ Establish a new reference interval by analyzing samples from a sufficient number of qualified reference individuals for analysis. • Resume using the Access Free T3 lots listed above and all future lots once your laboratory has completed the reference interval evaluation. • 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.

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 our Customer Technical Support Center:

- From our website: http://www.beckmancoulter.com
- By phone: call 1-800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]egulatory Affairs

Enclosure: *Response Form*