




December 09, 2016

IMPORTANT PRODUCT NOTICE
UniCel DxC Synchron Wash Concentrate II

REF	LOT	
445865	Z505212	04/30/2017
	Z507201	06/30/2017
	Z511202	10/31/2017

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding UniCel DxC Synchron Wash Concentrate II. Test results are not affected.

ISSUE:	Beckman Coulter has determined that DxC Wash Concentrate II, REF 445865 lot Z505212, Z507201, and Z511202, can cause a failure in calibration of Thermo-Fisher Lithium reagent (REF A19611).
IMPACT:	<ul style="list-style-type: none">• Lithium calibration failure can potentially lead to a delay of reporting Lithium results.• Reassessment of past results is not required. The consequence of calibration failure does not allow for patient results to be generated. Patient results reported under acceptable calibration and quality control evaluation are not affected by this issue.
ACTION:	If you are a Thermo-Fisher Lithium assay user, discontinue use of DxC Wash Concentrate II lot Z505212, Z507201, and Z511202 and discard any unused reagent bottles.
RESOLUTION:	Beckman Coulter is continuing to investigate the root cause of 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 product(s) listed above to another laboratory, please provide them a copy of this letter.

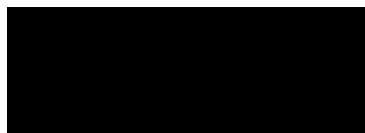
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via 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 any inconvenience that this caused your laboratory.

Sincerely,



David Davis
Director, Regulatory Affairs

Enclosure:
Response Form
Replacement Form

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