




31 August 2015

URGENT MEDICAL DEVICE RECALL

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

REF	LOT	
A13422	431433	30-SEPT-15

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

Attention Beckman Coulter Customer:

Beckman Coulter is initiating a field 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 determined that some Access Free T3 reagent packs (P/N A13422) of lot 431433 were filled incorrectly. These packs contained insufficient quantity of reagents in one or more of the pack wells.
IMPACT:	<ul style="list-style-type: none">The impact is dependent upon the instrument and software version installed at the time the reagent lot was in use:<ul style="list-style-type: none">Access 2 systems running software version 3.3.1 or lower, and Access 2i systems running software version 6.1 or lower with this reagent lot:<ul style="list-style-type: none">All results from an affected pack would have been reported as > 30 pg/mL (the highest calibrator value) accompanied with a result flag OVR regardless of the true value of the sample.Access 2 systems running software version 3.4.2 and Access 2i systems running software version 6.2.2 or higher with this reagent lot:<ul style="list-style-type: none">The affected packs would have been detected by process monitoring with a result flag QSD and the pack would have been disabled by the instrument. No patient result would have been generated.UniCel DxI systems running any software version:<ul style="list-style-type: none">All results from a partially filled pack would have been reported as > 30 pg/mL (the highest calibrator value) accompanied with a result flag OVR regardless of the true value of the sample.The completely empty packs would have been detected by reagent pack monitoring with a result flag QSD and the pack would have been disabled by the instrument. No patient result would have been generated.



ACTION:	<ul style="list-style-type: none">• Discard the Access Free T3 reagent pack lot listed above.• Review your patient results that were reported out > 30 pg/mL and did not match the clinical status of the patients.• At the discretion of your Laboratory Director, notify clinicians that it is possible the Access Free T3 sample results reported by your laboratory were affected by this issue.
RESOLUTION:	<ul style="list-style-type: none">• The affected Access Free T3 reagent pack lot is no longer being distributed.• Beckman Coulter is implementing changes to the filling processes to mitigate a recurrence.

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.

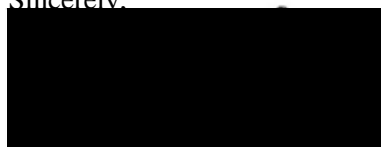
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

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



Vice President Quality & Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, the stylized logo, Access, UniCel, and DxI are trademarks of Beckman Coulter, Inc., and are registered with the USPTO.

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