




August 4th 2015

FOLLOW-UP URGENT FIELD SAFETY NOTICE – FSN 25775

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

REF	LOT	
33860	430969	31-AUG-16
	431990	31-OCT-16
	434727	31-DEC-16
	522896	30-APR-17
	523251	31-MAY-17

*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.

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that the Access Thyroglobulin reagent pack lots listed above may exhibit greater than 10% imprecision at concentrations <10 ng/mL.
IMPACT:	<ul style="list-style-type: none"> The Access Thyroglobulin reagent pack lots listed above may generate falsely elevated results at concentrations <10 ng/mL. The estimated maximum magnitude of the potential error in the affected range is a shift of up to 0.36 ng/mL high at concentrations <10 ng/mL. Acceptable total imprecision was observed at values of 10 ng/mL and higher.
ACTION:	<ul style="list-style-type: none"> Discard all Access Thyroglobulin reagent pack lots listed above. Evaluate Access Thyroglobulin results <10 ng/mL when using the reagent pack lot numbers listed above to determine if controls and/or patients were higher than expected or did not match the clinical status of the patient. At the discretion of your Laboratory Director, notify clinicians that it is possible the Access Thyroglobulin sample results reported by your laboratory are affected by this issue.
RESOLUTION:	<ul style="list-style-type: none"> The affected Access Thyroglobulin reagent pack lots are no longer being distributed. Your laboratory will be contacted separately regarding an updated Access Thyroglobulin Assay Protocol File (APF) which is compatible with all future lots.

The national competent authority has been informed of this follow-up 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 any of the affected instrument systems have been moved 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 +353 1407 3082 or techsupportie@beckman.com.

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,



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

Enclosed: Fax Response Form

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