April 24, 2019

URGENT FIELD SAFETY NOTICE

Access Free T3, Access Total T3, Access Free T4, Access GI Monitor (GI Mon), Access Thyroglobulin (Tg), Access Thyroglobulin Antibody II (TgAbII)

REF	LOT	
A13422 (Free T3)	All Lots	Multiple
33830 (Total T3)		
33880 (Free T4)		
387687 (GI Mon)		
33860 (Tg)		
A32898 (TgAbII)		

For use with the Access Family of Immunoassay Systems including: Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	• Beckman Coulter has further characterized the potential interference effects of biotin (up to 1,200 ng/mL) on all biotin-mediated Access assays following a field action in 2017 (FSN-30796), which tested biotin levels up to 100 ng/mL. • Only the six assays listed above displayed significant interference (defined as a result bias greater than ±10%) at 1,200 ng/mL of biotin. Additional testing of these six assays was then performed with decreasing biotin concentrations, to identify the actual concentration above which interference could be significant.
IMPACT:	• Significant interference from biotin can potentially be observed with the six affected assays if samples contain the following concentrations of biotin: ○ Access Free T3: potential of **falsely elevated** results when biotin concentrations are >10 ng/mL. ○ Access Total T3: potential of **falsely elevated** results when biotin concentrations are >1 ng/mL. ○ Access Free T4: potential of **falsely elevated** results when biotin concentrations are >10 ng/mL. ○ Access GI Monitor: potential of **falsely decreased** results when biotin concentrations are >25 ng/mL. ○ Access Thyroglobulin: potential of **falsely decreased** results when biotin concentrations are >10 ng/mL. ○ Access Thyroglobulin Antibody II: potential of **falsely decreased** results when biotin concentrations are >100 ng/mL.

ACTION:	• Interpret results in light of the total clinical presentation of the patient. • For each of the affected assays listed above that are used in your laboratory, obtain the most recent version of the Instructions for Use (IFU) document from the Beckman Coulter website and review for additional details. The updated IFU's contain the interference results observed at all of the biotin concentrations tested, as well as information on the clinical levels of biotin that are expected in patient samples, and possible approaches to reducing the risk of biotin interference. • Review this letter with your Medical Director to determine if any future actions are necessary. A retrospective review of patient results is not recommended.
RESOLUTION:	• Beckman Coulter has updated the IFU Limitations and Interferences sections for the six affected Access immunoassays listed above. Please refer to the Beckman Coulter website for the most recent version of the product IFU's.

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 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:

- From our website: http://www.beckmancoulter.com
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

David G. Davis
Director, Regulatory Affairs

Enclosure: Response Form

CUSTOMER RESPONSE FORM

Access Free T3, Access Total T3, Access Free T4, Access GI Monitor (GI Mon), Access Thyroglobulin (Tg), Access Thyroglobulin Antibody II (TgAbII)

REF	LOT	
A13422 (Free T3)	All Lots	Multiple
33830 (Total T3)		
33880 (Free T4)		
387687 (GI Mon)		
33860 (Tg)		
A32898 (TgAbII)		

Check the appropriate box below:

☐ I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken and records retained as part of our Laboratory Quality System documentation.

or:

☐ We do not have this product.

Signed:_____ Date:_____

Site Name: _____

Site Address: _____

Name:_____ Title:_____

Tel: _____ Email: _____

Please return to:

0848 850 810
Beckman Coulter Int. S.A.
Ms. Stella Eklou
Regulatory Affairs
22, Rue Juste-Olivier
1260 – Nyon

Beckman Coulter International S.A.
22, rue Juste-Olivier, Case Postale 1059
1260 Nyon 1, Switzerland

Tel. +41 (0)22 365 37 07

Bank: Bank of America, Geneva – VAT No. 204 228
For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact