May 17th, 2017

URGENT FIELD SAFETY NOTICE

Access Total T3, Access Thyroglobulin, Access Free T4, Access GI Monitor
For use with the Access Family of Immunoassay Systems*

REF	LOT	
33830 Total T3	All Lots	Multiple
33860 Thyroglobulin		
33880 Free T4		
387687 GI Monitor		

*The Access Family of Immunoassay Systems includes the Access 2, UniCel DxI 600 and UniCel DxI 800, UniCel DxC 600i and the 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 product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	• Beckman Coulter has determined through customer feedback and an internal investigation that the four Access immunoassays listed above are susceptible to biotin interference. During interference testing the interference occurred with samples that contained 100 ng/mL of biotin. • This level of biotin is greater than the maximum biotin concentration observed in the normal healthy population.

IMPACT:

- Specimens from patients who are undergoing biotin therapy and/or ingesting biotin supplements may contain high levels of biotin. The higher biotin concentration in these specimens interferes with the biotin-streptavidin assay design of the four Access assays listed previously.
  - Other Access assays with a biotin-streptavidin assay design were also tested. These assays are not affected by higher biotin concentrations.
- Specimens that contain high levels of biotin may cause:
  - **false low** results for the Access GI Monitor and Thyroglobulin assays.
  - **false high** results for the Access Free T4 and Total T3 assays.

		100 ng/mL Biotin		
Assay	**Analyte Level**	**Expected Concentration**	**Observed Concentration**	**% Interference**
Total T3 ng/mL	Low	1.1	3.4	203
	High	2.6	7.2	179
Thyroglobulin ng/mL	Low	15.3	9.6	-37
	High	90.7	61.6	-32
Free T4 ng/mL	Low	1.0	2.0	103
	High	2.8	4.6	64
GI Monitor U/mL	Low	19.3	16.3	-16
	High	946.0	960.3	2

ACTION:

- Review this letter with your Medical Director to determine if any future actions are warranted.
- A retrospective review of results is not recommended.
- Interpret results in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.

RESOLUTION:

Beckman Coulter will update the LIMITATIONS section of the Access Total T3, Thyroglobulin, Free T4, and GI Monitor Instructions for Use with this biotin interference information.

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 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,

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Enclosure: *Response Form*