CONE HEALTH

STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

Beckman Coulter Update: Biotin Interference with FT4 Testing

Description:	Beckman Coulter has released a product recall entitled *Access Free T4, GI Monitor, Thyroglobulin, and Total T3 Test Kits: May Be Susceptible to Biotin Interference* (FA-30796 May 9, 2017).
Implementation Date:	06/08/2017
Performing Locations:	**Click on the boxes that apply:** ☒Alamance Regional ☐Annie Penn Hospital ☒Moses Cone Hospital ☐Med Center at High Point ☐Wesley Long Hospital ☐Women's Hospital
Affected Locations:	**Click on the boxes that apply:** ☒Alamance Regional ☒Annie Penn Hospital ☒Moses Cone Hospital ☒Med Center at High Point ☒Wesley Long Hospital ☒Women's Hospital
Affected Departments:	**Click on the boxes that apply:** ☐Blood Bank ☐Cytology ☐Flow Cytometry ☐Histology ☐Microbiology ☐Phlebotomy ☐Point of Care ☒Rapid Response Lab ☐Respiratory Therapy ☐Specimen Processing
Specimen Type:	Serum Only (Moses Cone), Serum/Li Heparin Plasma (Alamance)
Updated Clinical Lab Procedures:	N/A

Retired Clinical Lab Procedures:	N/A
Notification to Client:	**Click on the boxes that apply:** ☐Section Not Applicable ☒Memo Needed Provider memo needed **Distribution of Memo:** ☒Medical Staff ☒ Allied Health Professionals (PA, Nurse Practioners) ☒ Anesthesia ☒ Annie Penn (Primary Source Physicians) ☒ Dentist ☒ Emergency Department/Urgent Care Centers ☒ Family Practice ☒ Infectious Docs #ID Docs (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam) ☒ OB/GYN ☒ Pathology ☒ Pediatricians ☒ Psych ☒ Radiology ☒ Surgery ☐ #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager) ☐ Pharmacy - Send to DeAnne Brooks & Jim Hasspacher ☐ #IM Residents ☐ Kim Helsabeck ☐ Phlebotomy Managers and Supervisors ☐ Point of Care: Sheila, Kim & Marty
Accreditation Section:	**Click on the boxes that apply:** ☒Section Not Applicable ☐CAP Test menu change needed ☐CMS Analyte form change needed ☐Proficiency Testing surveys changes needed or ordered
Laboratory IT section:	**Click box and type needed changes/additions:** ☐Section Not Applicable ☐LIS changes ☐Reference range change/addition ☐Technical Failure change/addition

	☐Critical Value change/add ☒Text comments needed Add the following comment to FT4: *Biotin ingestion may interfere with free T4 tests. If the results are inconsistent with the TSH level, previous test results, or the clinical presentation, then consider biotin interference. If needed, order repeat testing after stopping biotin.* ☐Specimen collection instructions ☐Need to monitor TAT ☐CPT code for tests(s)
Technical Staff Update:	In response to Beckman Coulter's Urgent Medical Device Recall (FA-30796 05/09/2017), the Cone Health laboratories will add the following statement to FT4 results: *Biotin ingestion may interfere with free T4 tests. If the results are inconsistent with the TSH level, previous test results, or the clinical presentation, then consider biotin interference. If needed, order repeat testing after stopping biotin.* Please read the attached physician memo and Beckman Coulter FA-30796 for more information.
STOP Initiator:	Jackie Hobbins
Alamance Medical Director Signature:	Quality Department will obtain signature: Sara C. Rubanos M.D. 6/7/17
Greensboro/Reidsville Medical Director Signature:	Quality Department will obtain signature: [illegible] MD 6/8/17

CONE HEALTH
The Network for Exceptional Care

TO: Cone Health Hospital Providers

FROM: Joshua B. Kish, MD, FCAP, FASCP
Chief of Pathology, Cone Health

John Patrick, MD, FCAP
Medical Director, Clinical Pathology, Cone Health

Tara C. Rubinas, MD, FCAP, FASCP, Medical Director, Anatomic and Clinical Pathology Laboratories, Alamance Regional – Cone Health
Tara C. Rubinas M.D.

DATE: June 8, 2017

SUBJECT: **Biotin Interference with Free T4 Testing**

The Cone Health hospital laboratories recently received notification from the test manufacturer that ingestion of biotin supplements or therapeutic biotin can interfere with thyroid test results. False elevation of free T4 can occur, which may cause a patient with euthyroid levels to appear to have abnormal high results, or cause a patient with hypothyroidism to seem to have normal results. There is no interference with the in-house TSH.

Consider biotin interference in the following circumstances:

- If there is a discrepancy between free T4 result and the TSH
- If there is an unexplained change from previous test results
- If the results do not make sense clinically

If you are aware that the patient is taking a biotin supplement, have them stop supplement for at least a day before having blood drawn for thyroid testing.

For further information, please contact the following:
Dr. Tara Rubinas: tara.rubinas@conehealth.com or 336-538-7832
Dr. John Patrick: jdpatrick@auroradx.com or 336-832-7531

Joshua B. Kish MD
6/8/17

May 09, 2017

URGENT MEDICAL DEVICE RECALL

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 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.

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.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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,

David G. Davis
Director, Regulatory Affairs

Enclosure: Response Form

BECKMAN COULTER

CUSTOMER RESPONSE FORM

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

*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.

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

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 these products.

Signed:_____ Date:_____

Name:_____ Title:_____

Tel: _____ Email: _____

Please return to: Beckman Coulter, Inc.
250 S. Kraemer Blvd
Mail Stop E1.SE.01
Brea, California 92822-8000
Attn: Regulatory Affairs
Fax number: (714) 961-4234
Email: regaffairsfax@beckman.com

Beckman Coulter is updating the customer address list for product notifications. If the contact information on your notification is inaccurate, please update:

Name:_____ Title:_____

Tel: _____ Email: _____