



**MEMORANDUM #142**

TO: UNCHCS Attending Physicians, Housestaff, Department Heads and Supervisors

FROM: *NKS* Nichole Korpi-Steiner, PhD, DABCC; Director, Special Chemistry Laboratory  
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SUBJECT: **Safety Communication on Biotin Interference with Select Laboratory Tests**

DATE: February 26, 2018

The US Food and Drug Administration recently released a Safety Communication warning to the public and healthcare professionals that “**Biotin May Interfere with Lab Tests.**”<sup>1</sup>

**About Biotin<sup>2</sup>:** Biotin (Vitamin B7) is a water-soluble vitamin that helps metabolize fats, carbohydrates, and proteins into energy. Biotin is an essential nutrient present in various foods, and is available in multivitamins, prenatal vitamins and other supplements. The recommended daily intake (RDI) varies by age (adults: 30 µg/day). However, select over-the-counter products marketed for hair, skin and nail growth, as well as supplements for the treatment of select conditions (e.g. biotinidase deficiency, multiple sclerosis) can contain biotin concentrations that exceed the RDI more than 600 fold.

**Potential Biotin Interference with Testing:** While standard intake levels ( $\leq$  RDI) of biotin do not typically cause interference with testing, higher levels of biotin in patient samples may cause significant interference and cause falsely high or falsely low results, potentially leading to misdiagnosis.<sup>1</sup> In February 2018, manufacturers of commonly-used immunoassay test systems communicated with labs about biotin interference with certain tests. The UNCH MCL Core Laboratory identified tests that use biotin methodology and the table below describes the directional effect of biotin interference on test results.

Biotin Interference May Cause:			
Falsely High Results		Falsely Low Results	
MCL Core Lab Tests	Cortisol	AFP	hCG
	Estradiol	CA 19-9	PTH
	Folate	CA 125	LH
	Progesterone	CEA	NT-pBNP
	Testosterone	CK-MB	Prolactin
	Vitamin B12	Ferritin	PSA
		FSH	Troponin I
			TSH

**Recommendations for Healthcare Providers:**

- Patients may be unaware that they are taking higher-than-recommended levels of biotin. Talk with your patients about any biotin supplements they may be taking, including beauty products marketed for hair, skin, and nail growth.
- Record any biotin supplements and dose (if known) in the patient’s electronic medical record medication list.

- When possible, instruct patients to discontinue vitamins or supplements containing biotin > RDI for a period of 2 weeks prior to blood collection, which may help minimize potential biotin interference with testing. Patients with renal insufficiency may potentially exhibit delayed clearance of biotin. Noteworthy, the exact length of time for biotin clearance from blood to support safe testing is unknown.<sup>1</sup>
- If a test result(s) is inconsistent with the clinical picture, consider biotin interference as a possible source of error.
- Consult with the laboratory if your patient is taking biotin supplements > RDI, and/or biotin interference with lab testing is suspected. Call the Core Laboratory at 984-974-2361 and ask for the Supervisor. Please communicate with the lab as soon as possible (within 3 days since time of sample collection).

If you have any questions related to this safety communication, please contact Dr. Korpi-Steiner at 984-974-1498 or the Core Laboratory at 984-974-2361.

### **References**

<sup>1</sup>U.S. Food and Drug Administration. Biotin (vitamin B7): safety communication—may interfere with lab tests. <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm586505.htm>

<sup>2</sup>National Institutes of Health Office of Dietary Supplements. Biotin Fact Sheet. <https://ods.od.nih.gov/factsheets/Biotin-HealthProfessional/>

### **Additional Resources**

AACC. Biotin and laboratory testing: Recognizing interferences and preventing misdiagnosis. <https://www.aacc.org/store/webinars/11200/biotin-and-laboratory-testing-recognizing-interferences-and-preventing-misdiagnosis>