

Biotin Interference

Test Update

Immunoassay-based laboratory tests often utilize biotin-streptavidin chemistry to generate accurate quantification of small molecules. Although biotin has well established medical benefits for nutritional deficiency, biotin (also known as vitamin B7, vitamin H, coenzyme R, and others) use as a supplement has recently increased due to its purported effects on hair, nails, and skin. An unintended consequence is that biotin administration (especially in high doses) may impact common, immunoassay-based, laboratory tests.

Specifically, biotin interference may cause a falsely low result for troponin (biomarker to aid in the diagnosis of heart attacks), which may lead to a missed diagnosis and/or serious clinical implications.

Other immunoassays which may be affected by biotin inference include:

ACTH	Calcitonin	Ferritin	HE4	Progesterone	T3, Free	Testosterone, Free/Total	Troponin T Gen5
AFP	CEA	Folate	Inhibin B	Prolactin	T3, Total		TSH
Anti-Mullerian Hormone	CK-MB	FSH	Insulin	PSA	T4, Total	Testosterone, Total	TSH Receptor Antibody
C1 Esterase	Cortisol	Gastrin	LH	PSA, Free	T4, Free	Thyroglobulin Antibody	Vitamin B12
CA 125	C-Peptide	Glutamic Acid Decarboxylase	Myoglobin	PTH	Tacrolimus		
CA 15-3	C-Telopeptide	Growth Hormone	NT-proBNP	Renin Activity	Testosterone, Bioavailable	Toxoplasma IgG	
CA 19-9	Estradiol	HCG	Osteocalcin	SHBG		Toxoplasma IgM	
			Procalcitonin	T Uptake			

High levels of biotin can produce falsely high or falsely low results, depending on the assay mechanism.

Per guidance from the FDA, all healthcare providers should:

- Talk to your patients about any biotin supplements or multivitamin supplements they are taking that may contain biotin, including supplements marketed for hair, skin, and nail growth.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin, and nail growth in levels that may interfere with lab tests.
- Be aware that many lab tests, including but not limited to cardiovascular diagnostic tests and hormone tests, that use biotin technology are potentially affected, and incorrect test results may be generated if there is biotin in the patient's specimen.
- Communicate to the lab conducting the testing if your patient is taking biotin.
- If a lab test result does not match the clinical presentation of your patient, consider biotin interference as a possible source of error.
- Report to the lab test manufacturer and the FDA if you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

References:

- Update: The FDA warns that Biotin may interfere with lab tests: FDA Safety Communication. FDA.gov. 5 Nov. 2019. 5 Dec. 2019. <<https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication>>.
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- Paxton, Anne. Beauty fad's ugly downside: test interference. CAP Today. September 2016.
- Seaborg, Eric. Thyroid Month: Beware of Biotin. Endocrine News. January 2016.