

ASK A SPECIALIST

Ask a Pathologist: Biotin Interference. A Cause for Concern?

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QUESTION

I've been hearing about biotin and biotin interference. What is it and do I need to be concerned about it?

ANSWER

Biotin is a water-soluble B-vitamin complex that is naturally found in food, with an average daily intake of 30-70 mcg per day. Physiologically, biotin has numerous functions including a role as an enzyme co-factor in carbohydrate and fat metabolism, and a role in histone modification, transcription factor activity, and gene regulation.¹ Biotin deficiency is exceptionally rare in western patients with a regular diet, but is associated with seborrheic dermatitis, alopecia, myalgia, hyperesthesia, and conjunctivitis.²

Biotin is commonly used as a dietary supplement. Multi-vitamin doses often contain between 30 and 60 mcg of biotin. Biotin marketed as a hair, skin, and nail supplement may have much higher doses, typically ranging from 5 to 10 mg per day (125 times the adequate daily intake). High-dose biotin (as much as 300 mg per day) is also used in some therapeutic regimens under physician's supervision for specific patients, such as those with multiple sclerosis.³

Biotin has been used extensively in laboratory testing for decades. It has a very

strong and essentially irreversible bond with avidin and streptavidin. This natural biologic interaction is exploited by immunoassays, western blots, and flow cytometry assays, where biotin serves as the link between the test antibody and a marker molecule. In a 2016 review of the 8 most popular immunoassay analyzers used in the United States, 221 of 374 test methods (59%) used biotin-based assays.⁴

High levels of serum biotin may interfere with testing resulting in delayed, incorrect, or missed diagnoses. Physiologic doses, such as those found in multi-vitamins and normal dietary intake, are not thought to demonstrate interference. Only biotin-based assays are affected, which often includes hormone testing (e.g., TSH), cardiac testing (e.g., troponin), and infectious disease serology (e.g., hepatitis B surface antigen), among many others. In one study, a single 10 mg dose of biotin interfered with thyroid function tests 24 hours after supplement administration.⁵ Biotin interference may cause results to be falsely increased (competitive assays) or falsely decreased (sandwich assays) depending on the specific method of the test. The FDA has reported biotin interference in a patient death where a

troponin assay returned as a falsely low result.⁶

Unfortunately, there are no specific recommendations from the FDA for testing patients taking high doses of biotin. Unlike other interferences, such as hemolysis, lipemia, or icterus, there is no easy way for the laboratory to detect biotin interference in a test run. Ask patients about dietary supplements, with specific emphasis on biotin, during admission histories. If the dose is between 5 mg and 10 mg, one instrument manufacturer recommends waiting at least 8 hours before drawing for labs that have potential interference; although the FDA reports that there is simply insufficient data to make a generic claim regarding the length of time for biotin clearance from the blood.^{6,7}

Dietary biotin supplementation does not guarantee interference with laboratory results, but the risk of interference is increased. Talk with your laboratory to find out if your instrumentation is susceptible to biotin interference, as not all are. If a lab test result does not match the clinical presentation of your patient, or if the result is discordant with other testing, consider biotin interference as a possible source of error.⁶ Consultation with the laboratory in these cases may be helpful as alternative tests or testing by non-biotin-based methods may be available.

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References

1. Zempleni J, et al, eds. Present Knowledge in Nutrition. 10th ed. Washington, DC: Wiley-Blackwell; 2012:359-74.
2. Combs GF, Jr. Biotin. In: Combs GF, Jr., ed. The vitamins: fundamental aspects in nutrition and health. Third ed. Burlington, MA: Elsevier Academic Press; 2008:331-44
3. Peyro Saint Paul L, et al. Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis Expert Opin. Drug Metab-Txicol. 2016; 12(3): 327-344.
4. Holmes E, et al. Biotin Interference in Clinical Immunoassays: A Cause for Concern. Arch Pathol Lab Med. 2017; 141:1459-1460.
5. Biscolla RPM, et al. A single 10 mg oral dose of biotin interferes with thyroid function tests. Thyroid. 2017; 27:1099-1100.
6. The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication. <https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm>. Nov 28, 2017. Accessed Sept 18, 2018.
7. Biotin Interference Facts. Roche Diagnostics. <https://biotinfacts.roche.com/toolkit/>. Accessed Sept 18, 2018.