

Effects of Biotin Supplements on Laboratory Testing

The Issue:

The increased prevalence of hyper-supplementation of biotin, vitamin B7, in the general population has raised concern over its effect on the results of many routine laboratory medicine tests, as outlined in a recent FDA Safety Notification.¹ For over a decade manufacturers of many laboratory medicine tests have utilized biotin-streptavidin bonding in their immunoassays. Biotin-streptavidin is one of the strongest non-covalent bonds in nature that is resistant to extremes of pH and strong surfactants, as well as being relatively biologically/chemically inert. For these reasons, it is used in immunoassay platforms to isolate properly captured antigens to facilitate sensitive and specific measurements.

The recommended daily intake for biotin is just 0.03 mg, and at this level there is no risk of interference with biotin-streptavidin containing laboratory assays. However, it is not uncommon for many supplements, including multi-vitamins, to contain 1, 5, 10, or 20 mg of biotin in a daily dose. Some patients may even be taking up to 300 mg/day for conditions such as multiple sclerosis. At these quantities of ingestion, the serum biotin level can reach concentrations that directly interfere with biotin-streptavidin containing laboratory assays. Depending on the measuring principles of the assays, the results could be falsely raised or lowered.

What We are Doing:

We have identified all tests performed at UVMHN/Porter Medical Center that may be effected by biotin supplementation. Based on recent studies obtained from the lab test manufacturers, we have determined how increased biotin concentrations could affect each individual test. The list of all tests performed at UVMHN/Porter Medical Center that could be affected by biotin supplementation and how the presence of excess biotin would affect the result is given in the table at the end of this communication.

Moving forward, all tests performed at UVMHN/Porter Medical Center that may be affected by biotin supplementation will be resulted with an additional comment. This comment will identify the test as being susceptible to biotin interference and state whether the result could either be falsely raised or lowered by the presence of excess biotin. Below is an example of such a comment:

“The results of this assay can be falsely elevated due to the consumption of Biotin.”

In addition, we will be adding a note in the UVMHN/Porter Medical Center Test Catalog <https://porterlab.testcatalog.org/>

for all tests that could be affected by biotin supplementation and how the presence of excess biotin would affect the result. The note for each test will also include the following statement:

“Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw.”

What You Can Do:

1. Ask each of your patients about biotin supplementation, remember that it can be present in a general multi-vitamin or dietary supplement or be called a hair and nail supplement, and document their usage including daily dose in the EHR.
2. Instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw when ordering the tests affected by biotin supplementation listed in this communication.
3. For patients taking more than 20 mg/day, consult Dr. Maureen Harmon to discuss how long a patient would need to abstain from their supplement to ensure testing is not effected.

If your patient's test results do not fit with their clinical presentation or you have concern that biotin supplementation could be affecting the result, do not hesitate to consult Dr. Maureen Harmon for help.

Table of UVMHN/Porter Medical Center Laboratory Tests affected by Biotin Supplementation:

TEST NAME	TEST CODE	EFFECT ON TEST	COMMENT
Troponin I	TROP	FALSELY DECREASE	The results of this assay can be falsely decreased due to the consumption of Biotin. Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw.
Thyroid Stimulating Hormone (TSH)	TSH	FALSELY DECREASE	
Free T4	FT4	FALSELY ELEVATE	The results of this assay can be falsely elevated due to the consumption of Biotin. Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw.
Vitamin B12	VB12	FALSELY ELEVATE	
Folate	FOL	FALSELY ELEVATE	

References:

1. Biotin (Vitamin B7): Safety Communication - May Interfere with Lab Tests. FDA Safety Alerts for Human Medical Products. <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586641.htm>
2. Siemens Customer Bulletin December 2017: Biotin Interference in Certain Immunoassays