



To: CAHAN San Diego Participants
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From: Public Health Services, Epidemiology and Immunizations Services Branch

Biotin Supplements Can Cause False Laboratory Results

This health advisory informs local healthcare providers and laboratory personnel that the Food and Drug Administration (FDA) issued a [safety alert](#) on November 28, 2017 that biotin, a nutritional supplement (also known as vitamin B7, vitamin H, and coenzyme R) can significantly interfere with certain lab tests and cause incorrect results. Recommendations and resources are provided.

Key messages:

- Biotin is a water-soluble vitamin often found in multi-vitamins, prenatal vitamins, and dietary supplements marketed for hair, skin, and nail growth.
- Some enzyme-linked immunosorbent assay (ELISA) laboratory tests use biotin technology, and blood or other samples taken from patients who are ingesting high amounts of biotin can cause clinically significant incorrect test results.
- Lab tests that can have falsely high or falsely low results include, but are not limited to, cardiovascular diagnostic tests, antibody tests, and hormone tests.
- Patients may not be aware of the amounts of biotin in the supplements they take.
- Providers should ask patients about all dietary supplement use, and inquire about biotin use when ordering diagnostic tests that may be affected by biotin.
- Lab personnel should educate providers about which lab tests use biotin technology and may be affected by biotin use.

Situation

FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests. Many dietary supplements promoted for hair, skin, and nail benefits contain biotin levels up to 650 times the recommended daily intake of biotin. Physicians may also be recommending high levels of biotin for patients with certain conditions such as multiple sclerosis. Biotin in blood or other samples taken from patients who are ingesting high levels of biotin in dietary supplements can cause clinically significant incorrect lab test results.

Biotin in patient samples can cause **falsely low** results in [enzyme-linked immunosorbent assay](#) (ELISA) tests that utilize biotin technology in a “sandwich” assay technique, and can cause **falsely high** results in ELISA tests that utilize a biotin-based “competitive” assay. Incorrect test results may lead to inappropriate patient management or misdiagnosis. For example, a falsely low result for troponin, a clinically important cardiac biomarker, may lead to a missed diagnosis and potentially serious clinical implications. FDA has received a [report](#) that one patient taking high levels of biotin died following falsely low troponin test results when a troponin test known to have biotin interference was used. The potential inappropriate diagnosis of Grave’s disease has been [reported](#) after the combination of falsely high results for anti-thyroid antibodies and falsely low results for thyroid hormone in several patients taking biotin. Commonly used [viral hepatitis panels](#) are among the other tests that may also be affected by high biotin intake.

Patients and physicians may be unaware of biotin interference in laboratory assays. Even physicians who are aware of this interference are likely unaware as to whether, and how much biotin, patients are taking. Since patients are unaware of biotin interference, patients may not report taking biotin supplements to their physicians, and may even be unaware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails).

Currently available data are insufficient to support recommendations for safe testing using affected tests in patients taking high levels of biotin, including about the length of time for biotin clearance from the blood. FDA is working to better understand biotin interference with lab tests, and to develop additional future recommendations for safe testing in patients who have taken high levels of biotin when using lab tests that use biotin technology. Package inserts for specific laboratory tests may provide guidance on how long persons should refrain from taking high dose biotin supplements before a specimen is drawn for testing.

Recommendations

For Healthcare Providers:

- Talk to patients about **any** supplements they may be taking, especially those that are labeled as containing biotin or those marketed for hair, skin, and nail growth.
- Be aware that many lab tests, including but not limited to cardiovascular diagnostic tests, antibody 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 patient's clinical presentation, consider biotin interference as a possible source of error.
- 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.
- [Report](#) to FDA any patient experiencing an adverse event following potentially incorrect lab test results due to biotin interference, and [sign up](#) for FDA MedWatch alerts for updates on this and other safety issues related to medical products.

For Laboratory Personnel:

- Educate and communicate with healthcare providers and patients to prevent incorrect test results on assays that utilize biotin technology. Clear indications on laboratory order and results forms highlighting which tests utilize biotin technology may assist in preventing inappropriate interpretation.
- When collecting samples in the lab, ask whether the patient is taking biotin, or consider signage that prompts patients to discuss any supplements that they are taking.
- Communicate with the lab test manufacturer with any questions about biotin interference.

A fact sheet for healthcare professionals on biotin may be found at the National Institutes of Health Office of Dietary Supplements website [here](#).

Thank you for your participation.

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