FDA Warns Biotin May Interfere With Lab Tests, Including Troponin

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SILVER SPRING, MD — The US Food and Drug Administration (FDA) warns that biotin, or vitamin B_7 , can interfere with the results of laboratory testing, including troponin testing for diagnosis of $MI^{[1]}$.

"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," the FDA says in a statement. "The FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests."

The supplement may cause falsely high or falsely low results depending on the test, leading to inappropriate patient management or misdiagnosis, the agency notes.

"For example, a falsely low result for troponin, a clinically important biomarker to aid in the diagnosis of heart attacks, may lead to a missed diagnosis and potentially serious clinical implications," the statement notes. "The 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."

Many lab tests use biotin technology for its ability to bond with specific protein biomarkers, the agency notes.

"The FDA is aware of people taking high levels of biotin that would interfere with lab tests," the statement says. Many dietary supplements promoted for hair, skin, and nail benefits contain levels up to 650 times the recommended daily intake of biotin, they note. "Physicians may also be recommending high levels of biotin for patients with certain conditions such as multiple sclerosis (MS)."

Physicians may not be aware of biotin interference with lab assays, and even when they are, they may not be aware of whether or not their patients are taking biotin supplements—patients themselves may be unaware they are taking biotin when taking products that are labeled for their benefits to hair and nails, the agency notes.

For physicians, the FDA recommends the following:

- Talk to patients about any biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth.
- Be aware that many laboratory tests, "including but not limited to cardiovascular diagnostic tests and hormone tests," that use biotin technology are potentially affected and may provide incorrect results if there is biotin in the patient's specimen.
- Communicate to the lab conducting the testing if the patient is taking biotin.
- If a lab result doesn't match the clinical presentation of the patient, physicians should 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 the lab test manufacturer and the FDA if physicians become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

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References

1. Food and Drug Administration. The FDA warns that biotin may interfere with lab tests: FDA safety

communication. November 28, 2017. Available here.

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