UPDATE: The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication

This updated safety communication provides new information on biotin interference with certain troponin lab tests. For more information, refer to Biotin Interference with Certain Troponin Lab Tests (/medical-devices/vitro-diagnostics/biotin-interference-troponin-lab-tests-assays-subject-biotin-interference) for details on specific tests.

Date Issued: November 5, 2019

The U.S. Food and Drug Administration (FDA) is updating our 2017 safety communication to remind the public, health care providers, lab personnel, and lab test developers that biotin, often found in dietary supplements, can significantly interfere with certain lab tests and cause incorrect results that may go undetected. The FDA wants to make the public and health care providers aware about biotin interference with lab tests so that patients, physicians, and laboratories can work together to help prevent adverse events.

As noted in the original safety communication, while biotin in patient samples can cause falsely high or falsely low results, depending on the type of test, the FDA is particularly concerned about biotin interference causing a falsely low result for troponin, a clinically important biomarker to aid in the diagnosis of heart attacks, which may lead to a missed diagnosis and potentially serious clinical implications. The FDA continues to receive adverse events reports indicating biotin interference caused falsely low troponin results.

Since the FDA's safety communication on this topic in 2017, some lab test developers have been successful at mitigating the biotin interference of their assays, but others have not yet addressed it. The FDA remains concerned about troponin laboratory tests that have not addressed the risk of biotin interference. The FDA has posted a webpage on Biotin Interference with Troponin Lab Tests - Assays Subject to Biotin Interference (/medical-devices/vitro-diagnostics/biotin-interference-troponin-lab-tests-assays-subject-biotin-interference) to notify the public about troponin assays where the risk of biotin interference has not yet been addressed.

Recommendations for Consumers

- Talk to your doctor if you are currently taking biotin (also called vitamin B7) or are considering adding biotin, or a supplement containing biotin, to your diet.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and supplements for hair, skin, and nail growth in levels that may interfere with laboratory tests. However, the amount of biotin can vary significantly among different products. Consider that the daily recommended allowance for biotin is 0.03 mg and that amount does not typically cause interference in lab tests
- Be aware that some supplements, particularly those labeled to benefit hair, skin, and nails, may have high levels of biotin, which may not always be clear from the name of the supplement. FDA is aware of many supplements containing 20mg of biotin, and some containing up to 100mg per pill, with recommendations to take multiple pills per day. Supplements containing high biotin levels may interfere with affected lab tests.
- Sufficient information is not available to know if stopping biotin consumption for any number of hours prior to testing will prevent incorrect test results.
- If you had a lab test done and are concerned about the results, talk to your health care provider about the possibility of biotin interference.
- For more information, see NIH Biotin Fact Sheet for Consumers (https://ods.od.nih.gov/factsheets/Biotin-Consumer/)

Recommendations for Health Care Providers

- 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.

Recommendations for Lab Personnel

- If you use assays with biotin technology, be aware that it is difficult to identify samples that contain biotin; therefore, it is important to communicate with health care providers and patients to prevent incorrect test results.
- If you are collecting samples in the lab, ask whether the patient is taking biotin or a biotin containing supplement.
- Educate health care providers about biotin interference with certain lab tests used in your lab.
- Consider that the daily recommended allowance for biotin is 0.03 mg for adults and these biotin levels do not typically cause significant interference. However, supplements containing high biotin levels including those marketed for hair, skin, and nail benefits, may contain up to 20 mg of biotin, and physicians may recommend up to 300 mg per day for conditions such as multiple sclerosis. Biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests.
- Be aware that specimens collected from patients taking high levels of biotin may contain more than 100 ng/mL biotin. Concentrations of biotin up to 1200 ng/mL may be present in specimens collected from patients taking up to 300 mg per day.
- Currently available data is 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.
- Communicate with the lab test manufacturer if you have questions about biotin interference.
- Be aware of certain troponin assays where the risk of biotin interference has not yet been addressed. See Biotin Interference with Troponin Lab Tests - Assays Subject to Biotin Interference.

Recommendations for Lab Test Manufacturers and Developers

- If your assay uses biotin technology, contact the FDA to discuss biotin interference.
- Investigate interference from biotin (up to at least 1200 ng/mL biotin) in your assays that use biotin technology. Determine the lowest concentration of biotin that may cause clinically significant interference with your test(s).
- Communicate with your customers if they may be unaware that your test uses biotin technology and how it may be affected.
- Contact the FDA if you have any questions about biotin technology and interference.

Biotin Interference with Certain Lab Tests May Lead to Incorrect Test Results

Many lab tests use biotin technology due to its ability to bond with specific proteins which can be measured to detect certain health conditions. For example, biotin is used in hormone tests and tests for markers of cardiac health like troponin. Biotin, also known as vitamin B7, is a water-soluble vitamin often found in multi-vitamins, prenatal vitamins, and dietary supplements marketed for hair, skin, and nail growth.

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 continues to see reports of adverse events, in addition to the one death reported prior to the 2017 safety communication, related to biotin interference with lab tests.

Incorrect test results may lead to inappropriate patient management or misdiagnosis. 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. Prior to the 2017 safety communication, the FDA had received a report that one patient taking high levels of biotin died following low troponin test results when a troponin test subject to biotin interference was used.

The FDA is aware of people taking high levels of biotin that would interfere 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 (MS). Biotin levels higher than the recommended daily allowance may cause interference with lab tests.

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 (for example, when taking products generally labeled for their benefits to hair and nails).

FDA Actions

On November 28, 2017, the FDA issued a Safety Communication, The FDA Warns that Biotin May Interfere with Lab Tests (/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication), that discussed concerns with biotin interference in certain laboratory tests.

On November 5, 2019, the FDA published this updated Safety Communication because the FDA remains concerned about certain laboratory tests that have not addressed the risk of biotin interference.

In addition, the FDA also published a webpage Biotin Interference with Troponin Lab Tests - Assays Subject to Biotin Interference (/medical-devices/vitro-diagnostics/biotin-interference-troponin-lab-tests-assays-subject-biotin-interference) to notify the public about troponin assays where the risk of biotin interference has not yet been addressed.

The FDA continues to monitor reports of adverse events associated with biotin interference with laboratory tests and will update the public if significant new information becomes available.

Reporting Problems to the FDA

If you suspect or experience a problem with a laboratory test while taking biotin, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.