

Biotin Interference in Some Immunoassays



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

The FDA investigated the effects on common laboratory tests of high concentrations of biotin in human lab specimens. As a result of these investigations the FDA issued a warning on November 28, 2017 that states:

“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 has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests. Biotin in patient samples can cause falsely high or falsely low results, depending on the test. Incorrect test results may lead to inappropriate patient management or misdiagnosis... 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)...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).¹

Many modern immunoassays contain biotin along with streptavidin. Samples from patients taking mega doses of biotin can produce falsely high or falsely low results, depending on the assay mechanism. As such, it is important for physicians to remind patients to refrain from taking mega doses of biotin for at least 24 hours prior to immunoassay test collection.

References

1. <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm586505.htm>