

Clinical Pathology Laboratories

Biotin Interference in Laboratory Testing: Patient and Provider Notice

Laboratory tests such as immunoassays use antibodies to detect and quantitate analytical compounds and often use a biotin linker to enhance sensitivity and accuracy. High dose biotin taken within 1 or 2 days or lower dose biotin taken within a few hours prior to sampling may affect the accuracy of laboratory testing for those assays that include a biotin component.

As a consequence, the US Food and Drug Administration (FDA) has issued a **Safety Communication: The FDA Warns that Biotin May Interfere with Lab Tests**

(<https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm>).

What does this mean for patients and providers?

- Patients on high dose supplements of biotin, such as hair/nail/skin supplements, should refrain from taking them in the 24 hours prior to laboratory testing.
- These supplements may or may not indicate they contain biotin prominently.
- Patients taking prescribed megadose regimens (>150 mg biotin) should refrain from taking the supplement for 24-48 hours prior to laboratory testing, upon the advice of their physician.
- Patients and physicians should review any lab test result that does not match the clinical presentation and consider if biotin interference is present.

Background information:

- Biotin, or vitamin B7, is often found in multi-vitamins, prenatal vitamins, and dietary supplements, which may not be clear from the name of the supplement.
- Patients and clinicians should be aware that a number of immunoassay lab tests, including but not limited to cardiovascular diagnostic tests, thyroid tests, and certain other hormone tests, may be affected by biotin interference.
- The US recommended daily allowance (US RDA) for biotin is 0.03 mg.
 - The amount of biotin often found in multivitamins does not typically cause significant interference.
 - Supplements containing high biotin levels including those marketed for hair, skin, and nail benefits may contain 5-20 mg of biotin (200-600 times US RDA).
 - Biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests.

References:

1. The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication. Date Issued: 11/28/2017
<https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm>
2. Kummer, S et al. Biotin Treatment Mimicking Graves' Disease. NEJM 2016; 375:704-706.
3. Paxton, Anne. Beauty fad's ugly downside: test interference. CAP Today. September 2016.

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