



To: Members of the Medical Staff

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Subject: Biotin interference in chemistry tests

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**Key Message:**

Biotin, when taken in high doses (greater than 5 mg per day), may positively or negatively interfere with several laboratory tests including cardiac markers (Troponin, CK-MB, NT-proBNP) and endocrine tests (TSH, free T4, free T3, estrogen, progesterone).

**FDA Health Alert:**

The Food and Drug Administration recently issued a health alert stating that Biotin interference led to one patient death due to a falsely low troponin result and that several cases of hyperthyroidism were wrongly diagnosed in patients taking high levels of Biotin.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586641.htm>

**Action Required:**

- Question all patients about Biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth (which may contain up to 20 mg of Biotin). Patients with some medical conditions including multiple sclerosis and some inborn errors of metabolism may be taking mega doses of Biotin (up to 300 mg per day).
- Normal dietary levels of Biotin and small doses present in multivitamins have NOT been associated with laboratory test interference.
- Request that all patients discontinue Biotin supplementation for 48 hours prior to specimen collection for laboratory tests.
- **If Biotin interference is suspected based on clinical history and testing cannot be delayed, please contact the laboratory.**

The lab has added a comment to the tests affected that states – *“High doses of Biotin may interfere with this test result. Correlation to clinical history and presentation recommended.”*

For further details on biotin, see page 2.

Please feel free to contact the lab if you have any questions.

**Background:**

Biotin (Vitamin H, Vitamin B7, coenzyme R) is a vitamin needed in only small quantities with recommended daily intake for adults being a low 30-100 mcg per day. However, new formulations of high dose Biotin (greater than 1 mg = 1,000 mcg) are now available over-the-counter at pharmacies and marketed for improvement of hair, skin, and nail quality. Mega dose formulations of 100 – 300 mg/day are currently in clinical trials for Multiple Sclerosis patients and are also prescribed for some inherited metabolic disorders.

**Keep in mind Three Patient Populations:**

1. **Daily multivitamin use:** Many consumers take Biotin within a standard daily multivitamin. This dose is typically 30–100 mcg. This will not interfere with lab testing.
2. **Medical high-dose Biotin therapy:** High-dose Biotin is used as a therapy for some inherited conditions and as a potential treatment for patients with multiple sclerosis.
3. **OTC lifestyle high-dose Biotin supplementation:** Some consumers take high-dose Biotin supplements (5,000–10,000 mcg) currently packaged to promote hair, skin, and nail beauty.

**What dosage levels might cause interference?**

Very high doses (more than 5 mg per day) have the potential to lead to test interference.

**Biotin interference on certain lab tests**

Troponin I	- Biotin interference causes results <b>lower</b> than actual levels
NT-proBNP	- Biotin interference causes results <b>lower</b> than actual levels
CK-MB	- Biotin interference causes results <b>lower</b> than actual levels
TSH	- Biotin interference causes results <b>lower</b> than actual levels
Free T4	- Biotin interference causes results <b>higher</b> than actual levels
Free T3	- Biotin interference causes results <b>higher</b> than actual levels
Progesterone	- Biotin interference causes results <b>higher</b> than actual levels
Estrogen	- Biotin interference causes results <b>higher</b> than actual levels