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## Memorandum

To: Physicians and Health Care Providers  
From: Orin Buetens , MD  
Date: December 19, 2017  
Subject: Biotin Interference in Immunoassay

**ALI Clients:**

The Food and Drug Administration (FDA) has recently issued a warning regarding potential lab test interference in people taking biotin supplements. See the attached FDA advisory notice dated 11/28/17 and/or the below link.

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

In summary, biotin in blood from patients who are ingesting large doses of biotin in dietary supplements can cause clinically significant incorrect lab test results (falsely high and falsely low). Numerous immunoassay tests use biotin technology due to its ability to bind with proteins.

A recent small study demonstrated that biotin in routine multivitamins is not sufficient to cause spurious results; however, large doses of biotin (typically > 1mg) including those in many dietary supplements promoted for hair, skin and nails, and those used for treatment of multiple sclerosis and other rheumatologic diseases may cause interference in these immunoassays, depending upon the time of ingestion, the dose and the interference level for each assay. If possible, the best practice is for patients to refrain from taking biotin supplements prior to having their blood drawn (possibly at least 24 hours depending upon the dose).

Affiliated Laboratory performs the following biotin based immunoassays that may be affected by high dose biotin ingestion:

CK-MB	Anti-thyroglobulin antibody	Anti-thyroid peroxidase
CA-125	CEA	Cortisol
DHEA sulfate	Estradiol	Ferritin
Folate	Follicle stimulating hormone	HAV antibody, IgM
HAV antibody, total	HBc antibody, IgM	HBc antibody, total
HBs antibody	HBsAG	hCG, quantitative
HCV antibody	Insulin	NT – proBNP
PTH, intact	Progesterone	Prolactin
PSA	PSA , free	T3, uptake

T3, free	T3, total	T4, free
T4, total	Testosterone, total	TSH
Vitamin B12	Vitamin D, 25-hydroxy	

Keep in mind that reference laboratory immunoassays may also utilize a biotin/streptavidin complex and could be affected as well.

If you have any additional questions or concerns, please contact Dr. Orin Buetens , laboratory medical director at 941-8200 or Kristan Rancourt, Department Supervisor at 973-6963. Roche, the main supplier of our immunoassay equipment, also has helpful information regarding biotin interference on its website: <http://biotinfacts.roche.com/>

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1. Grimsey, Paul et. al. Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. International Journal of Pharmacokinetics; Volume 2, No. 4, pp. 247-256.

References:

[http://biotinfacts.roche.com/wp-content/uploads/Physician\\_FactSheet.pdf](http://biotinfacts.roche.com/wp-content/uploads/Physician_FactSheet.pdf)

<http://www.captodayonline.com/beauty-fads-ugly-downsidetest-interference/>

<http://www.clinlabnavigator.com/biotin-interference-with-immunoassays.html>