

## Biotin Interference with Immunoassays

Biotin-streptavidin technology is widely utilized by manufacturers of immunoassays such as those used for routine clinical measurement of thyroid stimulating hormone and prolactin. Extremely high concentrations of circulating biotin can significantly interfere with immunoassays, leading to either falsely decreased or falsely increased results depending on the assay. In the general population, such elevated concentrations of biotin are unusual, but can be achieved following recent use of dietary/therapeutic supplements with biotin content greatly exceeding (i.e., >5 mg/day) nutritional requirements. Many of these supplements are over-the-counter products promoted for hair, skin, and nail benefits.

It is difficult for the laboratory to identify biotin-containing specimens. Therefore, whenever possible, patients should be asked if they have consumed biotin-containing supplements prior to having samples drawn for laboratory tests. The time required for patients to stop taking biotin supplements to avoid assay interference is variable, as discussed in a recent JAMA article (1). We recommend that patients do not take biotin-containing multivitamins or dietary supplements for at least 12 hours prior to specimen collection.

The following tables summarize the potential effect of biotin on immunoassays used by the University of Iowa Hospitals and Clinics core clinical laboratory and the Iowa River Landing laboratory.

### *Thyroid Markers*

Test	Potential impact of high-dose biotin on results
Thyroid Stimulating Hormone, Reflexive (LAB840)	Falsely decreases
Thyroid Stimulating Hormone (LAB129)	
Free T4 (LAB127)	Falsely increases
Free T3 (LAB137)	
Total T4 (LAB126)	
Total T3 (LAB136)	
Thyroid Peroxidase Antibody (LAB957)	
Thyroglobulin Antibodies (LAB956)	

### *Hormones*

Test	Potential impact of high-dose biotin on results
Parathyroid Hormone (LAB108)	Falsely decreases
Follicle Stimulating Hormone (LAB86)	
Luteinizing Hormone (LAB88)	
Adrenocorticotrophic Hormone (LAB511)	
Prolactin (LAB531)	
Growth Hormone (LAB525)	
Insulin (LAB7389)	
C-Peptide (LAB521)	
Cortisol (LAB61)	Falsely increases
Estradiol (LAB523)	
Testosterone (LAB124)	
Progesterone (LAB59)	
Dehydroepiandrosterone Sulfate (LAB524)	

### *Tumor Markers*

Test	Potential impact of high-dose biotin on results
Alpha Fetoprotein (LAB554)	Falsely decreases
Cancer Antigen 125 (LAB155)	
Carcinoembryonic Antigen (LAB57)	
Carbohydrate Antigen 19-9 (LAB2792)	
Prostate Specific Antigen, Total (LAB116)	
Prostate Specific Antigen, Screening (LAB670)	
Prostate Specific Antigen, Free (LAB117)	
HCG – Tumor Marker or Pregnancy (LAB142)	

*Cardiac Markers*

Test	Potential impact of high-dose biotin on results
Troponin T (LAB139)	Falsely decreases
NT-proBNP (LAB649)	

*Nutritional Markers*

Test	Potential impact of high-dose biotin on results
Ferritin (LAB68)	Falsely decreases
Vitamin D, 25-Hydroxy (LAB535)	Falsely increases
Vitamin B12 (LAB67)	
Vitamin B12, Reflexive (LAB882)	
Folate (LAB69)	

*Infectious Disease Serologies*

Test	Potential impact of high-dose biotin on results
HIV Antigen/Antibody Combo (LAB7444)	Falsely decreases
Hepatitis C Virus Antibody (LAB627)	
Hepatitis A Antibody, Total (LAB620)	
Hepatitis A Antibody, IgM (LAB621)	
Hepatitis B Surface Antigen (LAB625)	
Hepatitis B Surface Antibody (LAB619)	
Hepatitis Be Antigen (LAB3297)	
Hepatitis B Core Antibody, IgM (LAB624)	
Hepatitis B Core Antibody, Total (LAB622)	Falsely increases

*Pregnancy-Related Markers*

Test	Potential impact of high-dose biotin on results
Pregnancy Screen, Qualitative (LAB1166)	Falsely decreases
HCG – Pregnancy (LAB1148)	
HCG – Tumor Marker or Pregnancy (LAB142)	

*Therapeutic Drugs*

Test	Potential impact of high-dose biotin on results
Digoxin (LAB23)	Falsely increases

*Other Proteins*

Test	Potential impact of high-dose biotin on results
Immunoglobulin E (LAB74)	Falsely decreases
Myoglobin (LAB105)	
Sex Hormone Binding Globulin (LAB4945)	

Additional information:

(1) Li D, Radulescu A, Shrestha RT, et al. Association of Biotin Ingestion with Performance of Hormone and Nonhormone Assays in Health Adults. JAMA. 2017;318(12):1150-1160.

(2) FDA Safety Communication issued on 11/28/2017:

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