

ALERT: THE FDA IS ALERTING THE PUBLIC, HEALTH CARE PROVIDERS, LAB PERSONNEL, AND LAB TEST DEVELOPERS THAT BIOTIN CAN SIGNIFICANTLY INTERFERE WITH CERTAIN LAB TESTS AND CAUSE INCORRECT TEST RESULTS WHICH MAY GO UNDETECTED. MANY LAB TESTS USE IMMUNOASSAY TESTS THAT INCORPORATE BIOTIN TECHNOLOGY DUE TO ITS ABILITY TO BOND WITH SPECIFIC PROTEINS WHICH CAN BE MEASURED TO DETECT CERTAIN HEALTH CONDITIONS.

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

Summary of Problem and Scope

Biotin, also known as vitamin B7, is a water-soluble vitamin often found in multi-vitamins, prenatal vitamins, and dietary supplements marketed for hair, skin, and nail growth.

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.

Supplements Containing Biotin

The FDA urges the general public to that know that biotin is found in many over-the-counter supplements in levels that may interfere with laboratory tests. Examples include:

- B-complex vitamins
- Coenzyme R
- Dietary supplements for hair, skin, or nail growth
- Multivitamins
- Prenatal vitamins
- Vitamin B7 supplements
- Vitamin H

Recommendations

For Consumers:

- Talk to your doctor if you are currently taking biotin or are considering adding biotin, or a supplement containing biotin, to your diet.
- Many dietary supplements promoted for hair, skin, and nail benefits contain biotin levels up to 650 times the recommended daily intake of biotin.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and supplements for hair, skin, and nail growth in levels that may interfere with laboratory tests.
- Be aware that some supplements, particularly those labeled for hair, skin, and nail benefits, may have high levels of biotin, which may not be clear from the name of the supplement.
- If you have had a lab test done and are concerned about the results, talk to your health care provider about the possibility of biotin interference.

For Health Care Providers:

- Be aware of the impact on laboratory results when recommending high levels of biotin for patients with certain conditions such as multiple sclerosis (MS).
- Talk to your patients about any biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth.
- Be aware that many lab tests, including but not limited to cardiovascular diagnostic tests and hormone tests, that use biotin technology are potentially affected, and incorrect test results may be generated if there is biotin in the patient's specimen.
- Communicate to the lab conducting the testing if your patient is taking biotin.
- If a lab test result doesn't match the clinical presentation of your patient, consider biotin interference as a possible source of error.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin, and nail growth in levels that may interfere with lab tests.
- Report to the lab test manufacturer and the FDA if you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

LIST OF TESTS AFFECTED BY FDA ANNOUNCEMENT

- Hepatitis A Virus Antibodies (Total)
- Hepatitis A Virus Antibody, IgM
- Hepatitis A Virus Panel
- Hepatitis B Virus (HBV) Perinatal Exposure Follow-up by CIA, Panel
- Hepatitis B Virus Core Antibodies (Total)
- Hepatitis B Virus Core Antibody, IgM
- Hepatitis B Virus Panel, Chronic with Reflex to HBsAg Confirmation
- Hepatitis B Virus Surface Antibody
- Hepatitis B Virus Surface Antibody, Clinical Trials (Only Orderable by Client 133989)
- Hepatitis B Virus Surface Antigen Confirmation, Prenatal
- Hepatitis B Virus Surface Antigen with Reflex to Confirmation
- Hepatitis B Virus Surface Antigen with Reflex to Confirmation, Prenatal
- Hepatitis B Virus Surface Antigen, Confirmation
- Hepatitis C Virus Antibody by CIA
- Hepatitis C Virus Antibody by CIA with Reflex to HCV by Quantitative PCR
- Hepatitis Panel, Acute with Reflex to HBsAg Confirmation
- Human Chorionic Gonadotropin (Beta-hCG) by Immunohistochemistry
- Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA with Reflex to HIV-1/HIV-2 Antibody Differentiation, Supplemental
- Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA, Reflexive Panel
- Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA, with Reflex to HIV-1 Antibody Confirmation by Western Blot
- Human Immunodeficiency Virus Type 1 (HIV-1) Antibody by CIA with Reflex to HIV-1 Antibody Confirmation by Western Blot
- Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) Antibodies by CIA with Reflex to HIV-1 Antibody Confirmation by Western Blot
- Prolactin by Immunohistochemistry
- Prostate Specific Antigen
- T3 Uptake
- Testosterone, Bioavailable and Sex Hormone Binding Globulin (Includes Total Testosterone), Females or Children
- Testosterone, Free and Total (Includes Sex Hormone Binding Globulin), Females or Children
- Thyroid Peroxidase (TPO) Antibody
- Triiodothyronine, Free (Free T3)
- Triiodothyronine, Total (Total T3)
- Thyroxine, Free (Free T4)
- Thyroxine, Total (Total T4)

Disclaimer: The tests listed are current tests within the InSource Diagnostics menu that can be affected by Biotin interference. This list is subject to change. Biotin may affect other tests not on the InSource Diagnostics menu. The risk of interference depends on the concentration of Biotin and the manufacturer of the assay.