

Biotin Interference in Some Immunoassays



The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication



On 28 November 2017, the U.S. Food and Drug Administration (FDA) issued a warning that, “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...Patients and physicians may be unaware of biotin interference in laboratory assays. Even physicians who are aware of this interference are likely unaware as to whether, and how much biotin, patients are taking. Since patients are unaware of biotin interference, patients may not report taking biotin supplements to their physicians, and may even be unaware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails).”

It is recommended that for patients receiving therapy with high biotin doses (> 5 mg/day), no laboratory test specimen should be taken until at least 8 hours after the last biotin administration.

Biotin

Biotin, also known as vitamin B₇, is utilized in many tests in the clinical laboratory. Due to its small size and strong binding capacity to other molecules, such as streptavidin, biotin has been incorporated in many biochemical and immunologic assays. As a vitamin, biotin is an important component of many human enzymes involved in metabolizing fats and carbohydrates and synthesizing proteins. Though the amount of biotin needed by the human body is small, and a wide variety of food contain this vitamin, biotin is included in high amounts in products marketed for prenatal care and improved health of adult hair, skin and nails.

FDA Warning

The FDA has investigated the effects on common laboratory tests of high concentrations of biotin in human lab specimens. As a result of these investigations, they have issued a warning that, "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...Many dietary supplements promoted for hair, skin, and nail benefits contain biotin levels up to 650 times the recommended daily intake of biotin. Physicians may also be recommending high levels of biotin for patients with certain conditions such as multiple sclerosis (MS)...Patients and physicians may be unaware of biotin interference in laboratory assays. Even physicians who are aware of this interference are likely unaware as to whether, and how much biotin, patients are taking. Since patients are unaware of biotin interference, patients may not report taking biotin supplements to their physicians, and may even be unaware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails).¹

Possible Biotin Interference

Below is a list of laboratory tests performed at Interpath Laboratory where the presence of high concentrations of biotin could possibly interfere with accurate test results:

Test Name	Order #	Test Name	Order #
ACTH	5016	FREE T3	2296
AFP-TM	2631	FREE T4	2146
ANTI-HAV, IgM [FIRST CHOICE]	2201	FSH	2166
ANTI-HAV, TOTAL	2501	HBsAg	2103
ANTI-HBc, IgM	2225	HCG, QUANT	2135
ANTI-HBc, TOTAL	2203	IMMUNOGLOBULIN E	2274
ANTI-HBs	2104	INSULIN, FASTING	2227
ANTI-HBs QUANT [SECOND CHOICE]	1495	LH	2167
ANTI-HCV	2304	MYOGLOBIN	2272
ANTI-HCV w/REFLEX	2698	PROGESTERONE	2300
BETA HCG, TUMOR	2651	PROLACTIN	2131
CA 125	2278	PSA, TOTAL	2147
CA 15-3	2629	PTH	5028
CA 19-9	5019	RUBELLA	2340
CEA	2085	RUBELLA Ab, IgG	2643
CORTISOL (AM)	2073	SEX HB GLOBULIN	5024
CKMB	1244	T3 TOTAL	2187
C-PEPTIDE	2064	T3 UPTAKE	2001
DHEA-SULFATE	2214	T4 TOTAL	2003
ESTRADIOL	2231	TESTOSTERONE	2179
FERRITIN	2074	TROPONIN T	2688
FOLATE	2127	TSH, 3rd GEN.	2090
FREE PSA	2247	VITAMIN B12	2126

References

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