

Potential for Biotin interference in Immunoassays

The Biotin – Streptavidin couple is part of the assay design for many biomarker immunoassays. If patients are taking large doses of this Biotin / Vitamin B7, there is known potential for significant interference in immunoassays for a number of commonly requested tests in Biochemistry.

Although normal diets, and low dose multivitamin preparations are thought not to interfere, in recent times, health food enthusiasts have been recommending people take large doses of Biotin for healthy hair, skin and nails, and supplements up to 10mg per tablet are available over the counter in many health food stores and online. There are also a couple of ongoing clinical trials of megadoses (up to 300mg/d) of Biotin in Multiple Sclerosis.

If you have a test result that does not fit the clinical picture, you may wish to exclude possible biotin interference as a cause, by asking the patient / parent / carer about any over the counter supplements or checking for a biotin prescription.

Particular care should be taken in interpreting Troponin T or I levels, where appreciable concentrations of biotin may cause a negative interference and is therefore potentially falsely reassuring. Clinicians caring for patients being investigated for chest pain / ?AMI / ?ACS should ask about biotin supplements for all patients when a Troponin level is requested.

5-10 mg supplements are typical concentrations sold over the counter. Pharmacokinetic data extrapolation shows that these concentrations correspond to plasma concentrations of between 15.6-31.3 ng/ml.

High-dose biotin (100 mg) is sometimes used to treat metabolic diseases (isolated carboxylase defects and defects of biotin metabolism). A 100 mg biotin dose equates to 500 ng/mL plasma concentration. This concentration leads to gross analyte disturbance across all Roche assays

Yellow highlighting in the table below indicates the assays that may suffer from interference due to a 5-10 mg dose of biotin.

Analyte	Max plasma/serum biotin concentration cut-off concn nmol/L	Max plasma/serum biotin concentration cut-off concn ng/ml	Analyser	Type of assay	Will the interference increase or decrease the analyte level?
AFP	<246 nmol/L	<60.024	Cobas-Roche	sandwich	↓
AMH	≤143	≤34.892	Cobas-Roche	sandwich	↓
CA125	<143 nmol/L	<34.892	Cobas-Roche	sandwich	↓
CEA	<491	<119.804	Cobas-Roche	sandwich	↓
cortisol II	≤123	≤30.012	Cobas-Roche	competitive	↑
digoxin	<409 nmol/L	<99.796	Cobas-Roche	competitive	↑
Analyte	Max plasma/serum biotin concentration	Max plasma/serum biotin concentration	Analyser	Type of assay	Will the interference increase or decrease

	cut-off concn nmol/L	cut-off concn ng/ml			the analyte level?
Estradiol III	≤147	≤35.868	Cobas-Roche	competitive	↑
ferritin	<205 nmol/L	<50.02	Cobas-Roche	sandwich	↓
folate III	≤86.1 nmol/L	≤20.984	Cobas-Roche	competitive	↑
FSH	<246	<60.024	Cobas-Roche	sandwich	↓
FT3 III	<286 nmol/L	<69.784	Cobas-Roche	competitive	↑
FT4 II	< 81.8 nmol/L	<19.9592	Cobas-Roche	competitive	↑
HCG stat	<164 nmol/L	<40.016	Cobas-Roche	sandwich	↓
Calcitonin	<163	<39.772	Cobas-Roche	sandwich	↓
LH	<205	<50.02	Cobas-Roche	sandwich	↓
NT-proBNP	<123	<30.012	Cobas-Roche	sandwich	↓
PLGF	<123	<30.012	Cobas-Roche	sandwich	↓
progesterone II	<82 nmol/L	<20.008	Cobas-Roche	competitive	↑
prolactin II	<164	<40.016	Cobas-Roche	sandwich	↓
PTH	<205 nmol/L	<50.02	Cobas-Roche	sandwich	↓
SFLT	<123	<30.012	Cobas-Roche	sandwich	↓
SHBG	<246	<60.024	Cobas-Roche	sandwich	↓
Testosterone	<123	<30.012	Cobas-Roche	competitive	↑
total PSA	<246 nmol/L	<60.024	Cobas-Roche	sandwich	↓
trop t HS	<82 nmol/L	<20.008	Cobas-Roche	sandwich	↓
TSH	<102 nmol/L	<24.888	Cobas-Roche	sandwich	↓
Vit B12 II	≤205 nmol/L	≤50.02	Cobas-Roche	competitive	↑
direct renin	<25 nmol/L	<6.1	IDS-iSYS	sandwich	↓
PINP	<300 nmol/L	<73.2	IDS-iSYS	sandwich	↓
hGH	<300 nmol/L	<73.2	IDS-iSYS	sandwich	↓
IGF-1	<300 nmol/L	<73.2	IDS-iSYS	sandwich	↓
IGF BP-3	<300 nmol/L	<73.2	IDS-iSYS	sandwich	↓

- Biotin is renally excreted – it is therefore likely that in CKD/AKI plasma/serum concentrations of biotin can be higher than expected.
- For microgram doses of biotin the drug half-life is 1.8 hr.
- For 100-300 mg dose biotin the drug half-life is 7.8-18.8 hr.
- Cobas-Roche state that samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.