Northern Devon Healthcare
NHS Trust

Biochemistry Laboratory

Potential Assay Interference – Immunoassay Tests

The immunoassay methods used in the Biochemistry laboratory at NDDH use a streptavidin-biotin system in their design. If patients are taking large doses of Biotin (Vitamin B7), there is potential for interference in immunoassays analysed within Biochemistry.

Biotin is a water soluble B vitamin, with a recommended daily intake of 50 µg/day (UK guidance). This should be easily attainable, as it is widely available in food, and the vitamin may also be produced by bacteria in the intestine.

The use of large doses of Biotin as a health supplement for a variety of issues has recently been promoted in the popular press. It's use may therefore pass unnoticed or disregarded by patients when they are asked about over the counter medication/supplements which they may be taking. These supplements from health food shops, or obtained online, may contain Biotin concentrations of up to 10,000 µg per tablet. The tests highlighted below may be somewhat affected by these supplements.

Clinical trials of supraphysiological doses of Biotin (up to 300,000 µg/day) are currently underway in patients who have been diagnosed with multiple sclerosis and other neurodegenerative disorders. Patients with metabolic disturbances may also be prescribed with high dose Biotin. All immunoassays analysed at NDDH may be significantly affected at these concentrations.

Interference is not anticipated in patients not taking these high dose supplements.

If you have a test result which 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 supplements they may have taken or check for a prescription. No commercial assay is available to measure the concentration of Biotin in blood samples.

Particular care should be taken in interpreting Troponin levels, where Negative interference has been reported.

Biotin is renally excreted, with a half-life of approximately 2 hours in low doses. The manufacturers of the methods used in the Biochemistry laboratory advise that samples should not be taken from patients receiving therapy with high biotin doses (>5,000 µg/day) until at least after 8 hours since the last biotin administration.

Elimination of supraphysiological doses (>100,000 µg/day) is thought to take up to 7 days. However, this information relies on a number of factors, including the renal status of the patient. Levels in patients with CKD/AKI may be higher as a result.

Please contact the Biochemist [mary.stapleton@nhs.net] if you wish to discuss this issue further.

Reference:

Jenkins Colon, P, Greene, D.N. Biotin Interference in Clinical Immunoassays. J Appl Lab Med (2018) **DOI**: 10.1373/jalm.2017.024257

This table indicates the levels of Biotin above which the assay may be affected.
The concentration of Biotin in the blood of a person not taking supplements is <1nmol/L.

Assay name	Biotin (nmol/L)	Biotin Effect Positive/Negative
AFP	246	Negative
CA 125	143	Negative
CEA	491	Negative
Ferritin	205	Negative
FSH	246	Negative
hCG	327	Negative
LH	205	Negative
NT-pro BNP	123	Negative
Prolactin	164	Negative
PTH	205	Negative
SHBG	246	Negative
total PSA	246	Negative
Troponin T hs	82	Negative
TSH	102	Negative
Anti-TPO	40.9	Positive
Cortisol	123	Positive
Digoxin	409	Positive
Estradiol	147	Positive
Folate	86.1	Positive
FT3	286	Positive
FT4	81.8	Positive
Progesterone	123	Positive
Testosterone	123	Positive
Vitamin B12	246	Positive
Vitamin D	123	Positive