## Potential for Biotin interference in 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 Clinical Chemistry. This arises because biotin is involved the assay design for many biomarker immunoassays.

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 mega doses (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 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.

- 1. <5 mg supplements are not thought to interfere
- 2. 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.

While <u>ALL</u> immunoassay tests may be affected some of the most significant effects are summarised below.

The extent of the interference is dose and time related.

Test	Effect of 5-10 mg supplement
Troponin T	Inappropriately LOW result
TSH	Inappropriately LOW result
LH	Inappropriately LOW result
PSA	Inappropriately LOW result
Testosterone	Inappropriately HIGH result
Free T4	Inappropriately HIGH result
Free T3	Inappropriately HIGH result
Anti-TPO	Inappropriately HIGH result

3. 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

Please contact the laboratory if you need further information on this.