ST. JAMES'S HOSPITAL
DUBLIN . IRELAND

From: Biochemistry Department,
Centre for Laboratory Medicine
and Molecular Pathology

To: Biochemistry Clinical Diagnostic Service users

Subject: Potential Biotin Interference in Immunoassays

It is increasingly recognised that the use of high dose biotin can cause significant interference in certain immunoassays used for analysis of commonly requested endocrine tests, proteins, tumour and cardiac markers, amongst other tests.

More specifically Biotin interference affects those immunoassays which use streptavidin-biotin interaction as a component in the assay design. **This may result in falsely elevated or low results depending upon**:

1. The analyte measured.
2. The type of assay.
3. The biotin dose.
4. The time between the dose and the blood specimen collection.

Therefore, it is important that physicians should be aware of this issue and should consider this, particularly when test results do not correlate with clinical scenario and show an obvious discordance.

Biotin (vitamin B7) is ubiquitous in dietary products and daily intake is estimated to be 35-70 mcg/day. Historically, most multivitamins available over the counter contain low dose of biotin i.e. 30mcg. While normal dietary intake or low dose biotin supplements do not seems to affect the biotin based immunoassays, it is the use of new high dose Biotin formulations for hair, nails and skin growth (doses of 5-10 mg) and prescription doses for certain clinical conditions such as multiple sclerosis (doses of up to 300 mg) and metabolic disorders e.g. biotinidase deficiency, propionic aciduria, mitochondrial diseases etc. which can result in potential analytical interference.

Action Required:

In St. James's Hospital Biochemistry Laboratory we use Roche Cobas platforms for analysis of most analytes. The manufacturer is aware of the potential impact of biotin on assay interference **and recommends 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.** However, literature suggests that **if a patient is on very high dose of biotin supplement then this should be discontinued for a period of 48 hours prior to specimen collection.**

In cases of clinically discordant results you may wish to exclude possible biotin interference as a cause by enquiring about the use of supplements. It is also important to record biotin use on the laboratory request form in such circumstances.

Particular care should be taken in interpreting Troponin T results, where high concentrations of biotin may cause negative interference and give falsely low results. Therefore, while assessing patients with suspected AMI/ACS clinicians should ask about biotin supplementation before requesting and interpreting Troponin test.

If you suspect biotin interference, please notify the laboratory and we will have the specimen analysed on an instrument/platform that does not use biotin-based technology where possible.

While ALL immunoassays tests using Streptavidin-Biotin technology may be affected some of the most significant effects are summarised below in Table 1.

Table 1

Immunoassay	Effect
Negative Interference	
Troponin T	Inappropriately LOW result
TSH	Inappropriately LOW result
βHCG	Inappropriately LOW result
FSH	Inappropriately LOW result
LH	Inappropriately LOW result
PSA	Inappropriately LOW result
CA 125	Inappropriately LOW result
NT-proBNP	Inappropriately LOW result
PTH	Inappropriately LOW result
Aldosterone	Inappropriately LOW result
Renin	Inappropriately LOW result
IGF-1	Inappropriately LOW result
Positive Interference	
Free T4	Inappropriately HIGH result
TT4	Inappropriately HIGH result
T3	Inappropriately HIGH result
Cortisol	Inappropriately HIGH result
Estradiol	Inappropriately HIGH result

Summary details

- **Test results affected:** see Table 1
- **Issue:** The potential for high dose Biotin to interfere in laboratory assays
- **Suggested action:** Be aware of the issue. Enquire if patients are taking Biotin supplements, particularly if aberrant results are reported where the biochemical and clinical picture is discordant. Contact the Biochemistry Department to discuss further.

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