

ST JAMES'S HOSPITAL HAEMATOLOGY LABORATORY, LABMED DIRECTORATE

Subject: Potential Biotin Interference in Immunoassays for serum Folate and for monitoring Cyclosporine drug levels

Date: 23rd September 2020

It is increasingly recognised that the use of high dose biotin can cause significant interference in certain immunoassays which use streptavidin-biotin interaction as a component in the assay design. The haematology laboratory uses Siemens assays for serum Folate and Cyclosporine that utilise this chemical interaction and thus the presence of high dose biotin may affect the accuracy of the test results. A serum biotin level of 50ng/mL can have an effect of 10% or greater on the test result for either analyte. **This may result in falsely elevated or low results depending upon:**

1. The biotin dose.
2. The time between the dose and blood specimen collection.

Therefore, it is important that physicians should be aware of this issue and should consider patient biotin intake, particularly when test results do not correlate with clinical scenario and show an obvious discordance. Biotin (vitamin B7) is ubiquitous in dietary products and typical daily intake is 35-70 µg/day. Most multivitamins available over the counter contain low dose of biotin i.e. 30µg. While normal dietary intake or low dose biotin supplements do not seem to affect the biotin based immunoassays, 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. can result in potential analytical interference.

Action Required:

The haematology laboratory uses Siemens assays for serum Folate and Cyclosporine that utilise streptavidin-biotin interaction. 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 (doses of up to 300 mg) then this should be discontinued for a period of 48 hours prior to specimen collection.**

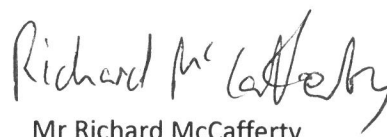
In cases of clinically discordant results you may wish to exclude possible biotin interference as a cause by enquiring about the use of supplements. It is also important to record biotin use on the laboratory request form in such circumstances.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Larry Bacon', written in a cursive style.

Dr Larry Bacon

Consultant Haematologist

A handwritten signature in black ink, appearing to be 'Richard McCafferty', written in a cursive style.

Mr Richard McCafferty

Chief Medical Scientist