The Association for Clinical Biochemistry & Laboratory Medicine

Better Science, Better Testing, Better Care

A statement from the ACB Scientific Committee regarding biotin / vitamin B7 interference in immunoassays issued July 2018

The use of over-the-counter (OTC) high dose biotin supplements has gained popularity in recent times. Biotin is also known as Vitamin B7. Many patients take biotin supplements (generally 5-10 mg tablets) marketed as beauty products to improve the health of hair, skin and nails. High-dose biotin (100 mg) is sometimes prescribed to treat metabolic diseases and there are also ongoing trials of mega-dose (up to 300mg/d) Biotin in Multiple Sclerosis.

There is now an increasing awareness among laboratory professionals that taking large doses of biotin can interfere with some laboratory immunoassay test results. Interference may be positive or negative depending on assay design: sandwich-type immunoassays are generally negatively affected, and competitive designs are usually positively affected. Appropriate steps must be taken to reduce the potential for clinically misleading test results in order to avoid patient harm.

This statement from the ACB Scientific Committee is primarily to raise awareness among clinical laboratory professionals and the following recommendations are set out to mitigate biotin interference:

1. Review your laboratory immunoassay repertoire to identify any assays using biotin technology. Communicate with the manufacturer to provide supplemental data on interference from biotin (up to at least 1200 ng/mL biotin) in their assays that use biotin technology, including the interference threshold for each assay (the lowest concentration of biotin in the sample that may cause clinically significant interference in the test result).

2. Perform a Risk Assessment for those tests identified as potentially susceptible to biotin interference. Many laboratory tests, including but not limited to cardiovascular diagnostic tests and endocrine tests, may potentially be affected. The Risk Assessment will help inform corrective/preventive action, including review of any alternative testing options / contingency plan.

3. In performing a risk assessment and designing a contingency plan, it may be useful to consider assays in three main categories:
    - High-volume endocrine / “screening” assays, often from GPs:
        - TSH, fT4, fT3, vit D etc
    - Urgent specialist assays, usually in hospital
        - e.g. hs-Troponin, NT-pro-BNP, PTH
    - Assays not identified as clinically significantly affected by any method

4. Some immunoassay designs are independent of the biotin/streptavidin couple, and could be considered as candidate assays for contingency testing. Laboratories are encouraged to incorporate a contingency pathway possibly involving a partnership with a nearby laboratory

5. Networks of laboratories may present an opportunity to moderate the risks. Harmonisation to a single manufacturer or platform renders laboratory networks susceptible to known and unknown risks related to interferences, supply problems or poor analytical performance. Networks of laboratories may wish to consider how to ensure a mixture of test platforms, manufacturers and techniques can be made available to help mitigate risk from biotin, as well as other as yet unknown issues

6. Educate laboratory staff and clinical users of the laboratory services about biotin interference for those tests in the laboratory identified as potentially susceptible.

7. Encourage clinicians to talk to their patients about any biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth. Clinicians must recognise that product labelling is sometimes obscure and patients may not even know they are on biotin.

8. If the laboratory/clinician have a test result that does not fit with the clinical picture, biotin ingestion as a potential cause of test interference will need to be excluded. Close communication between the laboratory, clinician and patient is vital in this context as it is difficult to positively identify samples that contain biotin.

9. Though manufacturer's have not given any official guidance regarding the minimum intervals for blood sampling following last biotin dose, we suggest that assays with an interference threshold <30 ng/mL could be classified as more susceptible as this corresponds to the expected peak serum biotin concentration from OTC supplements of 5-10mg. Pharmacokinetic data in the literature does provide some useful guidance on washout periods required for assays with biotin interference.

10. Report to the manufacturer and the MHRA if you encounter an adverse event following potentially incorrect laboratory test results where biotin interference is suspected.

11. The ACB Scientific Committee suggests that laboratories should implement these recommendations to mitigate biotin interference by no later than February 2019.