HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Biotin Interference

Priority 2 – Warning

HPRA Safety Notice: SN2019(09) **Issue Date: 9th April 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	SD36260

ISSUE
The HPRA is raising awareness of the risk of generating incorrect results with some laboratory tests for individuals taking medications or supplements containing biotin. Many lab tests use biotin technology due to its ability to bond with specific proteins which can be useful in detecting certain health conditions. However, high levels of biotin in patient samples may interfere with the performance of certain laboratory tests that use biotin technology. As a consequence, individuals who are taking medications containing biotin or ingesting high levels of biotin in dietary supplements may have clinically significant incorrect laboratory test results.

ACTION OR RECOMMENDATIONS
The HPRA advises that Health Care Providers: 1. Be aware that many laboratory tests, including but not limited to cardiovascular diagnostic tests and hormone tests that use biotin technology, are potentially affected, and incorrect test results may be generated if biotin is present in the patient's specimen. 2. Talk to your patients to identify any biotin use before ordering laboratory tests. If a patient is taking biotin, including medications containing biotin or supplements marketed for hair, skin and nail growth, consult the laboratory personnel before ordering the tests.

3. Be aware that manufacturers apply different test methods and, therefore, alternative tests might be available or a period of biotin withdrawal may be required to ensure accurate results. Discuss the available options with the laboratory personnel.
4. If results of laboratory tests do not match the clinical presentation and/or other investigations, the possibility of error or interference, including biotin interference, should be considered. In clinical circumstances in which a result is unexpected, it is reasonable to further observe the patient and repeat the test.
5. Report any adverse events/incidents associated with these tests to the relevant manufacturer and the HPRA.

The HPRA advises that consumers:

1. Talk to your doctor if you are currently taking biotin or are considering adding biotin, or a supplement containing biotin, to your diet.
2. Be aware that biotin may be found in multivitamins, including prenatal multivitamins, biotin supplements and supplements for hair, skin and nail growth in levels that may interfere with laboratory tests.
3. Be aware that biotin is also present in certain medications. It may not be clear from the name of the supplement or the medication that it contains biotin.
4. Before undergoing any laboratory tests, you should tell your doctor or the laboratory personnel if you are taking or have recently taken biotin. If you are taking biotin for therapeutic purposes, do not stop taking biotin without consulting your health care provider.
5. Discuss any concerns you may have with your health care provider.

The HPRA advises that Laboratory Personnel:

1. Maintain awareness of this notice if any of your tests are based on biotin technology.
2. Read and follow the instructions for use provided by the manufacturer. Contact the manufacturer of the test if you have questions regarding biotin interference.
3. Maintain awareness that specimens collected from patients taking biotin may yield incorrect test results.
4. Consider implementing quality assurance practices in order to prevent and detect biotin interference, including but not limited to: education and feedback on the risk of biotin interference when delivering test results obtained with susceptible tests to medical personnel; information on tests susceptible to interference and the impact of the interference on the test result (is the result falsely increased or falsely decreased) and whether alternative assays are available.
5. Forward a copy of this Safety Notice to all those that need to be aware within your organisation or to any organisation/person to which/whom these tests have been transferred.
6. Report any adverse events/incidents associated with these products to the relevant manufacturer and the HPRA.

TARGET GROUPS	
A&E Departments	Nursing Managers
Carers	Nursing Staff
General Practitioners	Pharmacists
Hospital Laboratories	Phlebotomy Clinics
Hospital Managers / CEOs	Purchasing Managers
Members of the Public	Risk Managers

BACKGROUND

Biotin, also known as vitamin B_7, vitamin H and co-enzyme R, is an important vitamin that can be found in medications and a wide range of multivitamins and supplements.

Test methods that utilise the streptavidin-biotin interaction are commonly used in clinical practice for a variety of measurements including hormones, cardiac markers, tumour markers and infection markers. These tests are also commonly used in therapeutic drug monitoring.

Biotin which may be present in specimens from patients who are taking products containing biotin, can interfere in such assays and cause clinically significant incorrect results. Depending on the test design, results may be falsely increased or falsely decreased and may lead to inappropriate patient management or misdiagnosis. Cases of laboratory test interference have been reported at various biotin dosages, including dosages as low as 300 µg daily.

For example, a falsely low result for troponin may lead to a missed diagnosis of heart attack and potentially serious clinical implications. Biotin may also lead to a pattern of thyroid test results that mimic primary hyperthyroidism and cause unnecessary treatment with anti-thyroid agents. As with all laboratory tests, if the result obtained does not match the clinical presentation and/or other investigations, the possibility of error or interference including biotin interference should be considered. Similar to other clinical circumstances in which a result is not expected, it is reasonable to further observe the patient and repeat the test.

The risk of obtaining false results from laboratory tests due to biotin is higher in the following patient groups:

- Patients with renal impairment, as they are likely to have higher biotin concentrations in the blood and longer elimination times
- Patients suffering from multiple sclerosis that are exposed to high doses of biotin (300 mg per day) in clinical trials
- Children with rare metabolic diseases (biotindase deficiency, holocarboxylase synthetase deficiency, biotin-thiamine-responsive basal ganglia disease), as they are dependent on high doses of biotin

A number of Field Safety Corrective Actions have been undertaken by different manufacturers highlighting the risk of inaccurate test results as a result of biotin interference. The topic of biotin interference has also recently been discussed at the Pharmacovigilance risk assessment committee (PRAC) in the European Medicines Agency. The FDA has also communicated on this topic.

The HPRA is issuing this safety notice to raise awareness of the risk of biotin interference with some laboratory tests.

The focus of this safety notice is on laboratory tests, however there is evidence in the literature of biotin interference in some Point of Care (near-patient tests). The HPRA advises users of Point of Care tests to be vigilant. If the result obtained does not match the clinical presentation and/or other investigations, the possibility of error or interference, including biotin interference should be considered.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to the contact details found on the device labelling / instructions for use.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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