المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Biotin Interference with Specific Lab Tests

Device/ Product Name:	biotin technology
Lot numbers/Serials:	Not specific
Manufacturer:	Various manufacturers
Problem:	SFDA would like to bring to your attention the potential risk of incorrect laboratory test results for individuals taking biotin-containing drugs or supplements. Many laboratory tests use biotin because of their ability to bind to specific proteins that can be useful in detecting certain health conditions. However, **some high levels of biotin in patient samples may interfere with the performance of some laboratory tests using biotin technology.** Individuals who take biotin or ingest high levels of biotin in dietary supplements may have clinically incorrect laboratory results that may result inappropriate patient management or misdiagnosis.
Recommendation/Actions:	**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 SFDA. **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. 5- Forward a copy of this Safety Notice to all those that need to be aware within your organization or to any organization/person to which/whom these tests have been transferred. You can read the complete Safety Alert that includes recommendations from (HERE).

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2479
Fax: +966 (11) 2757245

Or

Saudi Vigilance

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Sincerely,
NCMDR Team