DIAGNOSTICS

Biotin Interference: Scientific Updates, Assessment of On-Market Assays, FDA Recommendations and FAQ

*Abbott Diagnostics, Abbott Park, Illinois 60064. Authors contributed equally to this document.

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BACKGROUND

Recent changes in clinical practice and consumer use of biotin-based supplements have contributed to an increased prevalence of biotin use and have shifted the risk profile of lab test results produced by streptavidin-based immunoassays. As a result, biotin interference in immunoassays from several manufacturers has been described in the literature, with examples of clinically misleading test results, including one associated death.[1-2]

MEDICAL AND SUPPLEMENTATION USE

Biotin (vitamin B_7) is a hydrophilic compound that acts as a coenzyme in carboxylase reactions, and therefore, it is an essential nutrient for supporting normal biochemical functions. Although biotin is readily available in a balanced diet with a recommended daily intake (~30 µg per day), higher doses of biotin (5 mg–20 mg) have been used for the purported health benefits they may provide for hair, skin and nails while prescription doses (50 mg–300 mg) have been used to treat inherited enzyme deficiencies and basal ganglia disease and, more recently, has been included in a clinical trial for secondary progressive multiple sclerosis.[3-5]

ASSAY INTERFERENCE

The mechanisms of biotin interference will differ, depending on the immunoassay format used, but they have been associated specifically with free-capture methodologies.[6-8] When biotin-streptavidin binding is used as part of a sandwich method, excess biotin in the sample can displace biotinylated antibodies, resulting in falsely **low** results. In contrast, for competitive immunoassays, excess biotin in the specimen can compete with the biotinylated analog for the binding sites on streptavidin, resulting in falsely **high** results.

Immunoassays using free-capture streptavidin-biotin mechanisms are used by many reagent manufacturers and have the potential to show interference from biotin through one of the mechanisms described above. Therefore, they should be assessed and risk-profiled to understand the clinical impact to patients. Susceptible on-market assays have been summarized by the AACC Academy (Figure 1).[9]

Figure 1

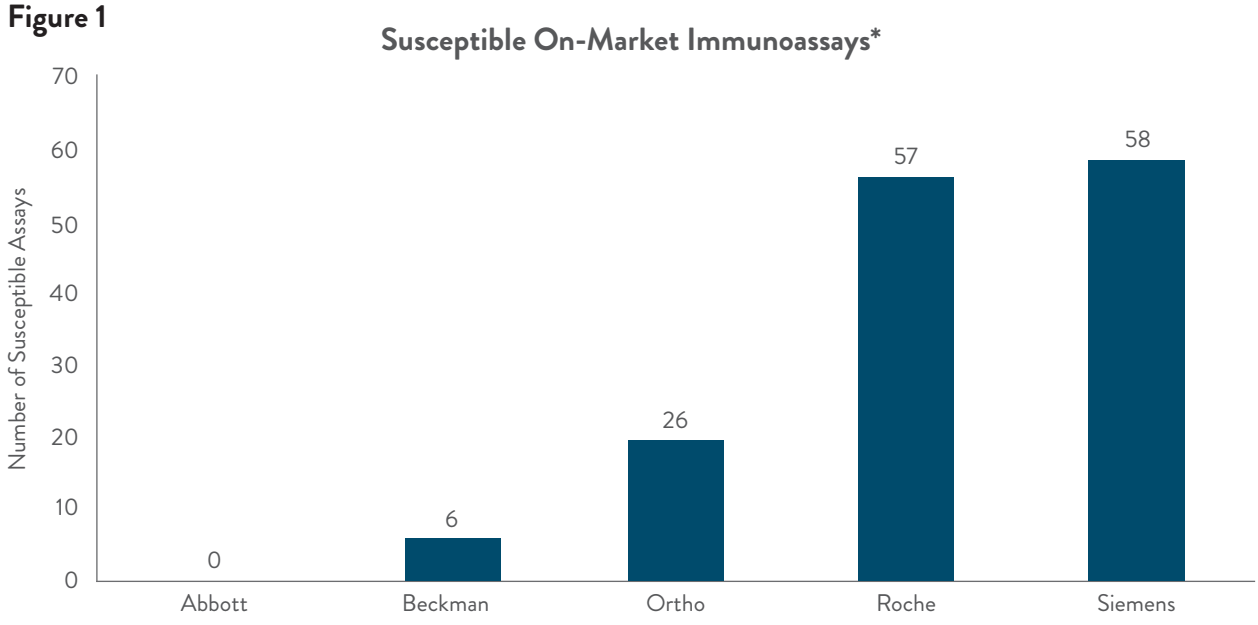


Table adapted from AACC Guidance Document on Biotin Interference in Laboratory Tests. *J Appl Lab Med. 2020*
*Data on file at Abbott

SCIENTIFIC AND REGULATORY AWARENESS

While an increase in case reports linking biotin use and laboratory test interferences has been observed in recent years,[7,10] review articles and mechanistic studies have helped further educate and describe the risk to patients.[6-8,10-11] In 2017, the FDA issued a safety communication to alert the public, healthcare providers, lab personnel and lab-test developers that biotin

can significantly interfere with certain assays and cause incorrect test results. These results, if undetected, could lead to diagnostic errors or misdiagnoses.[1,2]

The FDA recommendations, **summarized in Supplement section**, provide guidance to help raise awareness, reduce risk and prompt action by manufacturers to assess and communicate to their customers the potential risk of biotin interference in the assays they develop and market. Additional scientific and medical professional organizations have created and disseminated similar position statements globally to raise awareness (Table 1).

More recently, on November 5, 2019, the FDA updated the original safety warning to include currently impacted on-market assays (**table 4 in supplement section**). The new communication was prompted by continued reports of adverse events, indicating that biotin interference was causing falsely low troponin results. In an effort to increase the transparency of this clinically important interference, the FDA has decided to notify the public about troponin assays that have not addressed the risk of biotin interference[1,2] and has included a link for future reporting.*

Table 1[§]

Title	Date	Source	Region/Country
Testing for Biotin Interference in *In Vitro* Diagnostic Devices	November 2017	Food and Drug Administration	USA
Biotin Safety Communications – May Interfere With Lab Tests	November 2017	Department of Health Drug Office	Hong Kong
Biotin and Vitamin B_7 Containing Products May End Up With Misleading Lab Results	January 2018	Saudi Food and Drug Authority	Saudi Arabia
EP37: Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition	April 2018	Clinical & Laboratory Standards Institute	International
A Statement From ACB Scientific Committee Regarding Biotin	July 2018	Association for Clinical Biochemistry and Laboratory Medicine	U.K.
Lab Test Interference From Biotin	October 2018	Health Product Vigilance Center	Thailand
PRAC Recommendations on Signals	January 2019	Pharmacovigilance Risk Assessment Committee	Europe
Warning of Biotin Interference in Laboratory Tests	April 2019	Health Products Regulatory Authority	Ireland
Cardiac Troponin Interference Designated by Manufacturer: Hemolysis and Biotin	June 2019	International Federation of Clinical Chemistry	International
Biotin Beware	September 2019	New Zealand Medicines and Medical Devices Safety Authority	New Zealand
Biotin Interference With Clinical Laboratory Tests	September 2019	Health Sciences Authority	Singapore
Administrative Announcement About Voluntary Review of IVD Products' IFUs That Use Biotin	September 2019	Ministry of Health, Labor and Welfare	Japan
UPDATE: The FDA Warns That Biotin May Interfere With Lab Tests: FDA Safety Communication	November 2019	Food and Drug Administration	USA
Biotin Interference With Troponin Lab Tests – Assays Subject to Biotin Interference	November 2019	Food and Drug Administration	USA
AACC Guidance Document on Biotin Interference in Laboratory Tests	January 2020	American Association of Clinical Chemistry	USA

[§]Data on file at Abbott

*If you suspect or experience a problem with a laboratory test while taking biotin, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form. https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

PREVALENCE

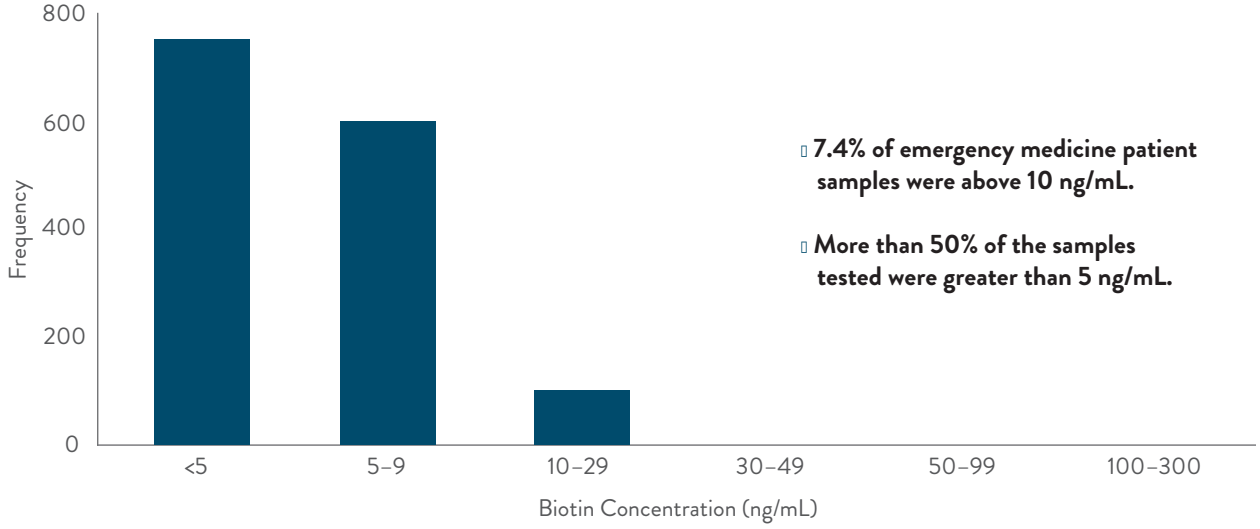
One of the questions that remains largely unanswered regards the prevalence of both biotin usage and, clinically, the concentration in blood at the time of lab testing or when presenting to acute care settings, such as the emergency department (ED), where treatment decisions frequently rely on laboratory tests for patients with critical conditions. In a recent publication, the Mayo Clinic reported[13] on its findings from both outpatient patient surveys (estimate of biotin usage) and biotin quantification in plasma samples collected from ED patients.

Results from completed surveys suggested that 7.7% of patients (n=1,944) use biotin while 7.4% of ED patient samples tested (n=1,442) had biotin concentrations at or above 10 ng/mL, the lowest known threshold for biotin interference reported by Roche Diagnostics. The authors of the paper also noted that nearly 50% of emergency department patients had measurable levels of biotin over 5 ng/mL (Figure 2).*

The authors concluded that reported use of biotin was common, with nearly 50% of patients in the study having detectable biotin concentrations, and that 7.4% of the ED population signified an alarmingly high percentage. The range of biotin concentrations in ED patients highlights the magnitude of the biotin interference and identifies a population at risk for potential harm.

Furthermore, the authors highlighted the serious threat to patient safety, considering key biomarkers could be impacted, such as cTn, hCG and natriuretic peptides. Finally, extrapolating these findings to a subset of the U.S. population presenting with chest pain (6–8 million people annually) underscores the substantial impact and should guide laboratorians and clinicians in developing effective strategies to mitigate safety risks and in assessing biotin usage trends within their own patient populations.

Figure 2



*Adapted from publication.

RISK-MITIGATION STRATEGIES

Lab-test interferences are a known limitation to antibody-mediated immunoassays and have been previously described in the literature.[14,15] Similarly, laboratory professionals are trained to interpret, troubleshoot, assess risk and educate medical professionals on test results impacted by interferences.

Once an interference has been identified, there are a number of strategies a laboratory can make to help reduce the risk of diagnostic errors. Education and awareness initiatives will continue to be a front-line response for quickly alerting medical professionals, so accurate diagnoses of their patients can be maintained. Additional mid- and long-term strategies can

be implemented but may be limited based on availability of resources and time to implement, for example replacement of existing assays that are not susceptible to biotin interference (Table 2). As manufacturers improve assays to remove interferences, laboratorians will have options for selecting the platforms and assays that best meet the quality needs of their institutions.

Table 2. Biotin Interference Risk-Mitigation Strategies*

Mitigation Strategy	Available	Time to Implement	Capital Investment	Cost to Implement	Effectiveness	Considerations
Healthcare Provider Education	Yes	Variable	No	Minimal	Variable	Available Resources
Consumer Education	Yes	Variable	No	Minimal	Variable	Effectiveness
Patient Guidance	Yes	Minimal	No	Minimal	Variable	Compliance
Health IT Solutions	Yes	Moderate	Maybe	Variable	Moderate to Maximum	Availability
Lab-Developed Pre-Analytical Step	Yes	Moderate	Maybe	Moderate	TBD	May Require Extensive Validation
Migration of At-Risk Assays to Alternative Platforms	Dependent on Available Equipment in Lab	Minimal	Dependent on Existing Infrastructure	Dependent on Existing Infrastructure	Maximum	Existing Contractual Agreements
Change Equipment	Yes	Moderate	Moderate	Variable	Maximum	Existing Contractual Agreements/ Resources
Assay Redesign	Opportunity	Maximum	Maximum	Maximum	Maximum	Time, Resources, Regulatory Approval

*Data on file at Abbott

*Summary table is based on Abbott scientific review of the literature.

Comprehensive Assessment of Abbott ARCHITECT Assays

153 ABBOTT ASSAYS* (Clinical Chemistry and Immunoassay)	
CLINICAL CHEMISTRY (n = 90)	Clinical chemistry assays do not use streptavidin surfaces in product design.
IMMUNOASSAY (n = 63)	None of Abbott's current on-market assays use a biotin-streptavidin free-capture methodology. Three assays use precomplexed biotin in assay design. Internal studies between 0 ng/mL and 4,250 ng/mL showed no interference.
n = 0	None of Abbott's on-market assays (n = 153) are impacted by biotin (confirmed by assay design and after explicit interference testing, per CLSI EP37).

*Approximate number; number may vary by country. Alinity assay menu available upon request.

Table 3. Biotin Interference Testing — U.S. Document

			BIOTIN TEST LEVELS (ng/mL)				
SYSTEM	**ASSAY**	**ANALYTE CONCENTRATION**	**1,500**	**2,000**	**2,500**	**3,550**	**4,250**
ARCHITECT	**Active-B_{12}**	51.3 pmol/L	2.29%	0.42%	1.35%	1.65%	1.49%
	(3P24)	87.3 pmol/L	2.27%	0.82%	2.36%	0.53%	1.05%
	Anti-CCP	4.3 U/mL	2.17%	1.19%	-0.23%	1.47%	1.20%
	(1P65)	14.2 U/mL	0.64%	0.75%	-0.81%	2.34%	1.64%
	Second-Generation Testosterone	244.5 ng/dL	-5.13%	-5.59%	-6.35%	-6.62%	-5.20%
	(2P13)	933.5 ng/dL	-4.98%	-5.85%	-4.74%	-5.21%	-4.24%

Acceptability criteria: +/-10% (95% confidence) from target concentration.

Assessment of each assay design and format was performed through a comprehensive review of all ARCHITECT assay formats. Results confirmed that no on-market ARCHITECT assay formulations use a free capture streptavidin/biotin assay format referenced in recent articles and associated with interference from biotin. Although not in the free capture streptavidin/biotin format, 3 on market assays utilize preformed biotin in the assay design. To confirm these assays are not impacted, samples spiked with biotin at concentrations up to 4,250ng/mL were evaluated. The highest level of biotin tested (4,250 ng/mL) was selected to exceed the Clinical and Laboratory Standards Institute (CLSI) guidelines (EP-37) of 3,510 ng/mL13. Results show the concentration and % difference with 95% confidence (Table 3).

Table 4. The following table lists the FDA listed troponin In Vitro Diagnostic Devices that are subject to biotin interference but have not addressed this risk.

Registered Establishment Name	Assay Trade Name(s)/Listed Name(s)	510(k)-Cleared Device Name	510(k)
INTERNATIONAL POINT OF CARE INC.	Cardiac STATus	SPECTRAL'S TROPONIN I	K014105
INTERNATIONAL POINT OF CARE INC.	Cardiac STATus	SPECTRAL'S 2 IN 1 (TNI-MYO)	K020950
NANO-DITECH CORPORATION	Nano-Check AMI 3 IN 1 cTnI/CK-MB/ Myo Test	NANO-CHECK AMI 3 IN 1 CARDIAC DISEASE TEST FOR CARDIAC TROPONIN I, CREATINE KINASE MB AND MYOGLOBIN	K050975
NANO-DITECH CORPORATION	Nano-Check AMI cTnI Test	NANO-CHECK AMI CTNI CARDIAC MARKER TEST	K102131
NANO-DITECH CORPORATION	Nano-Check AMI 2 IN 1 cTnI/Myo Test	NANO-CHECK AMI 2 IN 1 CARDIAC MARKER TEST, CTNI AND MYOGLOBIN; NANO-CHECK AMI 2 IN 1 CARDIAC DISEASE TEST FOR CARDIAC TROPONIN I AND MYOGLOBIN	K102441
ORTHO CLINICAL DIAGNOSTICS	VITROS Immunodiagnostic Products Troponin I ES Reagent Pack; VITROS Immunodiagnostic Products Troponin I ES Calibrators; VITROS Immunodiagnostic Products Troponin I ES Range Verifiers	VITROS TROPONIN I ES ASSAY, INCLUDING REAGENT PACK, CALIBRATORS AND RANGE VERIFIERS, MODELS 680 2301, 2302 AND 2303	K062838
PRINCETON BIOMEDITECH CORP.	LifeSign MI Myoglobin/Troponin I	LIFESIGN MI MYOGLOBIN/TROPONIN I RAPID TEST	K022946
PRINCETON BIOMEDITECH CORP.	LifeSign MI Troponin I	CARDIAC STATUS TROPONIN I	K963513
PRINCETON BIOMEDITECH CORP.	LifeSign MI CK-MB/Myoglobin/Trop I	CARDIAC STATUS CK-MB/MYOGLOBIN/TROPONIN I RAPID TEST	K981882
ROCHE DIAGNOSTICS GMBH	CARDIAC Control Troponin-T; CARDIAC Reader IQC; CARDIAC Reader System; CARDIAC T Quantitative 10 Tests; ROCHE CARDIAC Test Strip Troponin-T; TROP T Sensitive 5 Tests	THE CARDIAC READER SYSTEM	K000784
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin T STAT	ROCHE ELECSYS TROPONIN T STAT (SHORT TURNAROUND TIME)	K051752
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin I; Elecsys Troponin I STAT	ELECSYS TROPONIN I AND TROPONIN I STAT TEST SYSTEMS	K082699
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin T Gen 5 STAT	ELECSYS TROPONIN T GEN 5 STAT ASSAY; ELECSYS TROPONIN T GEN 5 STAT CALSET, ELECSYS PRECICONTROL TROPONIN; ELECSYS TROPONIN T GEN 5 CALCHECK 5	K162895
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin T	ELECSYS TROPONIN T	K961500
SIEMENS HEALTHCARE DIAGNOSTICS INC.	ADVIA Centaur TnI-Ultra; Atellica IM TnI-Ultra	TNL-ULTRA ASSAY FOR THE ADVIA CENTAUR SYSTEM	K053020
SIEMENS HEALTHCARE DIAGNOSTICS INC.	Dimension Vista CTNI Flex Reagent Cartridge	DIMENSION VISTA CTNI FLEX REAGENT CARTRIDGE	K063756
SIEMENS HEALTHCARE DIAGNOSTICS INC.	Dimension EXL Module TNI Flex Reagent Cartridge	DIMENSION TNI FLEX REAGENT CARTRIDGE AND CTNI SAMPLE DILUENT WITH MODELS RF621, KD692	K081643

The data has been taken from the FDA website (Last accessed: Feb 20th 2020)
Abbott has not conducted any independent investigation to confirm either the accuracy or completeness of this information.

FDA RECOMMENDATIONS[1-2]

For Healthcare Providers:

- Talk to your patients about any biotin supplements they may be taking, including supplements marketed for hair, skin and nail growth.
- Be aware that many lab 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 there is biotin in the patient's specimen.
- Communicate to the lab conducting the testing if your patient is taking biotin.
- If a lab test result doesn't match the clinical presentation of your patient, consider biotin interference as a possible source of error.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin and nail growth, in levels that may interfere with lab tests.
- Report to the lab-test manufacturer and the FDA if you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

For Lab Personnel:

- If you use assays with biotin technology, be aware that it is difficult to identify samples that contain biotin; therefore, it is important to communicate with healthcare providers and patients to prevent incorrect test results.
- If you are collecting samples in the lab, ask whether the patient is taking biotin.
- Educate healthcare providers about biotin interference with certain lab tests used in your lab.
- Consider that the daily recommended allowance for biotin is 0.03 mg and these biotin levels do not typically cause significant interference. However, supplements containing high biotin levels, including those marketed for hair, skin and nail benefits, may contain up to 20 mg of biotin, and physicians may recommend up to 300 mg per day for conditions such as multiple sclerosis. Biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests.
- Be aware that specimens collected from patients taking high levels of biotin may contain more than 100 ng/mL biotin. Concentrations of biotin up to 1,200 ng/mL may be present in specimens collected from patients taking up to 300 mg per day.
- Currently available data is insufficient to support recommendations for safe testing using affected tests in patients taking high levels of biotin, including about the length of time for biotin clearance from the blood.
- Communicate with the lab-test manufacturer if you have questions about biotin interference.

For Consumers:

- Talk to your doctor if you are currently taking biotin or are considering adding biotin or a supplement containing biotin to your diet.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and supplements for hair, skin and nail growth, in levels that may interfere with laboratory tests.
- Be aware that some supplements, particularly those labeled for hair, skin and nail benefits, may have high levels of biotin, which may not be clear from the name of the supplement.
- If you have had a lab test done and are concerned about the results, talk to your healthcare provider about the possibility of biotin interference.

For Lab-Test Manufacturers and Developers:

- If your assay uses biotin technology, contact the FDA to discuss biotin interference.
- Investigate interference from biotin (up to at least 1,200 ng/mL biotin) in your assays that use biotin technology. Determine the lowest concentration of biotin that may cause clinically significant interference with your test(s).
- Communicate with your customers if they may be unaware that your test uses biotin technology and how it may be affected.
- Contact the FDA if you have any questions about biotin technology and interference.

FREQUENTLY ASKED QUESTIONS REGARDING BIOTIN

1. **Why is biotin used in immunoassays?**
   Biotin is a small molecule that can be attached covalently to a variety of targets, from large proteins, such as antibodies, to tiny steroid hormones. Once attached to the analyte of interest, biotinylated complexes can form strong, stable and specific noncovalent bonds with streptavidin proteins, allowing the capture and quantification of analytes of interest in blood.

2. **What effect does biotin interference have?**
   The type of interference (bias) depends on the design of the assay. Interference can result in falsely increased or decreased results. Two of the most common immunoassay designs are the sandwich assay and the competitive assay formats.

   Sandwich Assay
   Direction of interference: Falsely decreased

   How biotin interferes: Free biotin binds to the streptavidin-coated capture surfaces, leaving fewer binding sites for the antibody complexes to bind. Subsequent washes falsely remove the analyte intended for measurement. The resulting signal produced is lower than it would be in the reaction without biotin interference. Sandwich assay results are proportional to the signal generated and, in the presence of excess free biotin, can cause falsely decreased results.

   Competitive Assay
   Direction of interference: Falsely increased

   How biotin interferes: Free biotin binds to the streptavidin-coated capture surfaces, leaving fewer binding sites for the antibody complex to bind. Subsequent washes falsely remove the analyte intended for measurement. The resulting signal produced is lower than it would be in the reaction without biotin present. Competitive assay results are inversely proportional to the signal generated and, in the presence of excess free biotin, can cause falsely elevated results.

3. **Are all immunoassays susceptible?**
   No. Some immunoassay platforms and assays are not susceptible because they do not use the biotin-streptavidin free-capture methodology.

4. **How long does it take for biotin to clear the body?**
   More research is needed to better understand the impact chronic use and different doses may have on clearance to provide accurate recommendations regarding timing. Higher doses have been shown to take longer to clear, and patients with poor renal function could take even longer. Because interference thresholds differ widely among assays and vendors, the timing of safe blood collection may vary, as well.

5. **Abbott has three immunoassays that use precomplexed biotin in the assay design. Why are they not affected by biotin interference?**
   Precomplexing biotin during the assay design eliminates binding sites for free (exogenous) biotin that may be in a patient's specimen following supplementation. To confirm these assays are not impacted by free biotin, internal studies were conducted according the FDA and CLSI recommendations. Interference testing up to 4,250ng/mL did not show any interference when compared to controls. Testing up to 4,250ng/mL exceeds the recommended threshold of 3,510ng/mL by CLSI.

6. **To my knowledge, I am not aware of any lab results impacted by biotin interference in my lab. Should I be concerned?**
   Unless your hospital and lab have a comprehensive risk-mitigation plan in place for educating and detecting biotin interference, it could go unnoticed and the impact could go unrealized. Recommendations from the FDA[1,2] describe what key stakeholders can do to help prevent diagnostic errors associated with biotin interference. If your assays are impacted by biotin, there will always be some level of risk to your patient population.

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