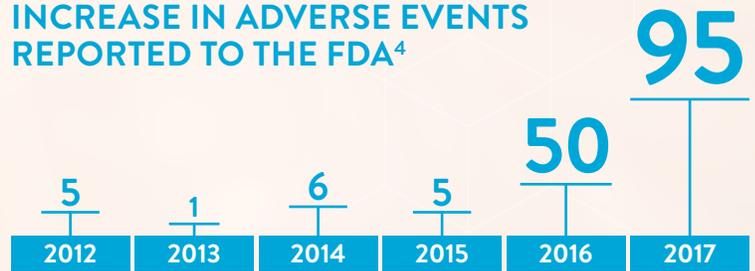


# FDA WARNS BIOTIN MAY INTERFERE WITH LAB TESTS

The FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests.<sup>1</sup> This follows numerous review articles including in CAP Today<sup>2</sup> and Endocrine News.<sup>3</sup>

## INCREASE IN ADVERSE EVENTS REPORTED TO THE FDA<sup>4</sup>



## WHY IS BIOTIN A CONCERN NOW?

Biotin is a water-soluble vitamin that is part of the vitamin B complex-group of key nutrients needed for healthy metabolic, nerve, digestives and cardiovascular functions. Biotin supplementation use continues to grow in popularity with dietary supplements for hair, skin, and nail benefits.

## BIOTIN USERS: BY THE NUMBERS\*

Of patients surveyed,

**17%** report taking biotin.\*\*

Biotin is more likely to be used by females in the US.



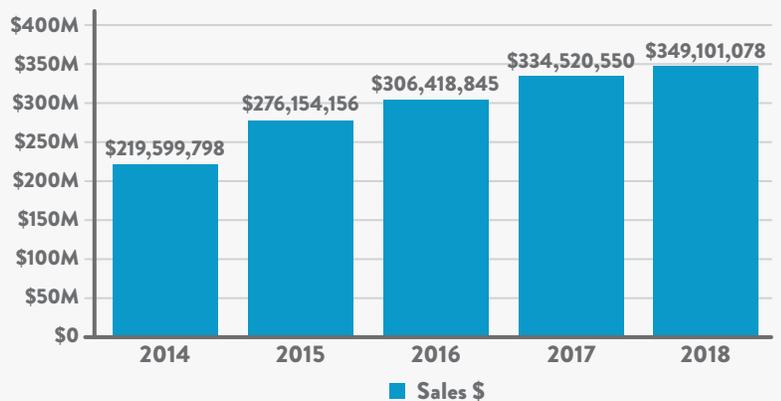
\*\*Biotin consumption taken from 2017 quantitative study among 400 US patients between the ages of 30-69 who have used either inpatient or outpatient hospital services and have had a blood test.

- Nielsen market data for in-store sales of biotin supplements has increased 58% from 2014 to 2018.<sup>5</sup>
- Not included in the Nielsen data are the sales through on-line retailers like Amazon, with the biotin dosage of 5,000 mcg as the number one selling biotin supplement.<sup>6</sup>

The Mayo Clinic conducted their own study on biotin usage and surveyed 1,944 of their outpatients and found that 7.7% of them take biotin. They also tested 1,442 of their ED patients and 7.4% of them had biotin concentrations at or above 10ng/ml which is the lowest threshold for biotin interference in the tests utilized at Mayo Clinic.<sup>7</sup>

\*Data on file at Abbott

## 58% INCREASE IN BIOTIN SALES OVER 5 YEARS



## BIOTIN AWARENESS: WHAT DO PATIENTS KNOW?\*

Although generally a health conscious group, only a small fraction of patients surveyed who take biotin know about the potential risks.



of patients are aware of issues with lab testing and biotin.

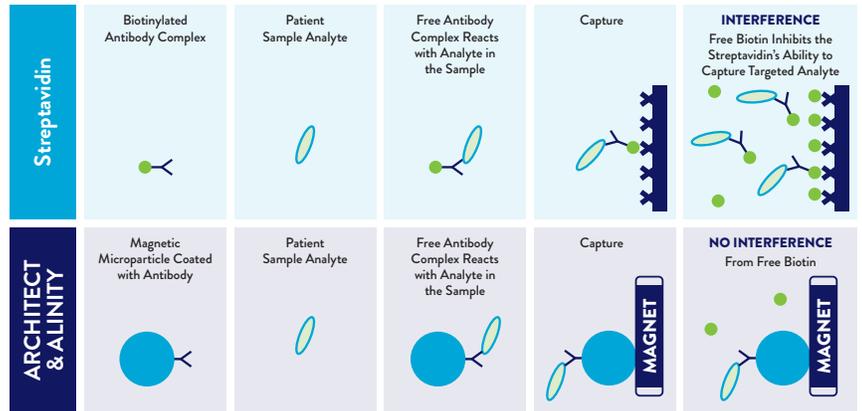


# HAVE CONFIDENCE WITH ABBOTT

Clinicians rely on accurate test results for patient diagnosis and treatment. Fortunately not all laboratory testing methods are impacted by biotin.

## TECHNOLOGY EXPLAINED

Lab tests that use the free biotin-streptavidin method can be impacted by biotin. Abbott Laboratory test technology coats microparticles with unique antibodies and antigens to capture the target. This ensures that test results are not impacted by biotin.



## MAKE LAB TESTING DECISIONS QUICKER AND EASIER

When using a testing methodology that can be impacted by biotin, the patient management and lab testing process can become complex.

- Identifying patients taking biotin supplements at the time of drawing the patient sample
  - Patients may not be aware
- Delaying the blood draw for a period of time
  - FDA states the current data is insufficient to support a recommendation
  - Studies demonstrated that biotin interference was still present at 25 hours after taking a single 30 mg dose,<sup>8</sup> and in some studies it lasted up to seven days<sup>9</sup>
  - In urgent care situations delaying draws may not be feasible

Abbott laboratory assay technology is not impacted by biotin so there is no need to identify patients taking biotin and no waiting to draw patient samples.



**PATIENT SAFETY DRIVES EVERYTHING WE DO. WE KNOW YOU FEEL THE SAME.**

With Abbott ARCHITECT and Alinity, inaccurate results due to biotin interference aren't our concern, your concern, or your patients' concern. Have confidence with Abbott.

1. Print reference accessed on 2.27.18 <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm586505.htm>. 2. Paxton A. Beauty fad's ugly downside: test interference. CAP Today, September 20, 2016. 3. Seaborg, E. January 2016: Thyroid Month: Beware of Biotin, Endocrine News, 2016. 4. Data from US FDA Manufacturer and User Facility Device Experience database. The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>. 5. Nielsen data on file at Abbott. 6. Amazon.com Top Selling Biotin: February 2019. 7. Katzman BM et al, Clinical BioChemistry, 2018; 60:11-16. 8. Wijeratne N, et al. Positive and negative interference in immunoassays following biotin ingestion: A pharmacokinetic study. Pathology. 2012 Dec;44(7):674-5. 9. Kummer S, et al. Biotin treatment mimicking graves' disease. NEJM. 2016 Aug 18;375(7):704-6.

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