

# VeraTest Biotin™

## Biotin Interference in Lab Tests. Myth or Truth?

Truth. Many patients take biotin supplements or multivitamins containing biotin. Studies have shown that intake of high doses of biotin in patient samples can interfere with the accuracy of laboratory tests that use the biotin/streptavidin capture method.<sup>1</sup> This may lead to misdiagnosis, inappropriate patient management,<sup>2</sup> or adverse events.<sup>3</sup>

Fact is, the number of people who are taking over-the-counter, high-dose biotin supplements for health and cosmetic reasons is growing exponentially worldwide — increasing at a rate of nearly 20% annually.<sup>4</sup> Unfortunately, biotin-related analytical interference is also on the rise and is not always detectable by healthcare providers or the lab conducting the tests. The FDA has issued draft guidance advising diagnostics developers to test for biotin interference in their *in vitro* diagnostic devices (IVDs) that use biotin/streptavidin technology.

To mitigate this growing problem, Veravas is launching a portfolio of innovative products that address biotin interference and quality of care in patient testing.

## VeraTest Biotin: A Breakthrough Solution for Interference Detection

VeraTest Biotin is an easy-to-use digital qualitative test. It rapidly screens samples using a 5-minute protocol to identify biotin at levels greater than 15 ng/mL.

Because VeraTest Biotin is qualitative, no detailed interpretation is required, which is critical in a setting of uncertainty where accurate results are needed quickly to ensure proper diagnosis and treatment.



## Simple, 5-Minute Protocol

Implementing VeraTest Biotin couldn't be easier — all it takes is 4 simple steps.

1. Insert test strip into digital qualitative reader, timer will indicate
2. Pipette 20  $\mu$ L of plasma or serum directly onto the test strip
3. Follow with 200  $\mu$ L of assay buffer which activates the 5-minute timer
4. Read results
  - If result is Yes  $\geq$ 15 ng/mL, the concentration of biotin may interfere with tests based on biotin systems
  - If result is No  $<$ 15 ng/mL, the concentration of biotin is in acceptable range

## VeraPrep Biotin™: Removing the Risk

If biotin is detected, you can use VeraPrep Biotin to determine if it's clinically significant, and then rapidly remove free biotin from your sample, ensuring accurate and reliable reporting of patient lab results.

## When to Use VeraTest Biotin

- Settings of uncertainty
- When displayed testing isn't an option
- Patients with renal disease where biotin clearance may be impaired
- Patients on  $\geq$ 100 mg/day biotin therapy
- Patients taking  $\geq$ 10 mg/day OTC biotin

**Improve your lab tests' reliability.** Learn more at [veravas.com](https://veravas.com) or contact your Veravas representative at 1.888.466.4166.

## Method Comparison Summary: LC-MS/MS vs. VeraTest Biotin<sup>5</sup>

		LCMS CONCENTRATION		
		≥15 ng/mL	<15 ng/mL	
Biotin Test Outcome	Test Outcome Positive	True Positive (TP)=23	False Positive (FP)=0	Positive Predictive Value =TP/(TP+FP) =23/(23+0) =100%
	Test Outcome Negative	False Negative (FN)=0	True Negative (TN)=31	Negative Predictive Value =TN/(TN+FN) =31/(31+0) =100%
		sensitivity =TP/(TP+FN) =23/(23+0) =100%	specificity =TN/(FP+TN) =31/(31+0) =100%	

### To Demonstrate its Ability to Detect Biotin ≥15 ng/mL

- 54 patient samples with endogenous biotin values assigned by mass spec were evaluated with VeraTest Biotin
- 23 samples with biotin ≥15 ng/mL by mass spec tested positive with VeraTest Biotin
- 31 samples with biotin <15 ng/mL by mass spec tested negative with VeraTest Biotin

### VeraTest Delivered

- No false positives or false negatives
- Positive and negative predictive value: 100%
- Sensitivity and specificity: 100%
- A larger study is underway with results coming soon

### VeraTest Biotin At-A-Glance

- Quick 5-minute protocol
- Can be used on serum or plasma
- 20 µL sample size
- Determines if significant biotin, ≥15 ng/mL is present
- Qualitative test: no detailed interpretation needed
- Portable digital reader for easy use

## Raising the Standard for Clarity in Diagnostics

At Veravas, we strive to continually advance the quality of testing for new and existing diagnostic methods. To reduce the effects of complex interferences in patient samples, we innovate breakthrough sample preparation and diagnostics technologies — so laboratory and research professionals can identify, remove and measure targeted substances with more simplicity and greater accuracy than ever before.

NOTE: This is a research use only (RUO) test.

#### REFERENCES:

1. Transparency Market Research, July 3, 2018
2. Shanika Samarasinghe, Farah Meah, Vinita Singh, Arshi Basit, Nicholas Emanuele, Mary Ann Emanuele, Alaleh Mazhari, and Earle W. Holmes (2017) BIOTIN INTERFERENCE WITH ROUTINE CLINICAL IMMUNOASSAYS: UNDERSTAND THE CAUSES AND MITIGATE THE RISKS. Endocrine Practice: August 2017, Vol. 23, No. 8, pp. 989-998
3. FDA Safety Communication, November 28, 2017. <https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication>
4. Paul Grimsey, Nicolas Frey, Garnet Bendig, Juergen Zitzler, Oliver Lorenz, Dusanka Kasapic and Christian E Zaugg. (2017) Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. International Journal of Pharmacokinetics 37. Online publication date: 14-Sep-2017
5. Veravas, Inc. Data on file

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