

VeraPrep Biotin™

Mitigate the Risk of Biotin Interference in Lab Tests

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.¹ Unfortunately, biotin-related analytical interference is also on the rise and is not always detectable to healthcare providers or the lab conducting the tests, which puts patients at risk of misdiagnosis, inappropriate patient management,² or adverse events.³ The FDA has issued draft guidance advising diagnostics developers to test for biotin interference in their *in vitro* diagnostic devices (IVDs) that use biotin/streptavidin technology.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.

VeraPrep Biotin: A Breakthrough Solution for Interference Removal

As many as 59% of immunoassay diagnostic tests on the market today use biotin in their assay design.⁴ Where VeraTest Biotin detects previously undetectable levels of free biotin in serum and plasma, VeraPrep Biotin is a sample pre-treatment reagent that enables you to determine if biotin levels are clinically significant, and then rapidly removes biotin from a patient sample.



VeraPrep Biotin At-A-Glance

- Simple, 15-minute protocol
- Uses serum or plasma
- Uses a strong VeraMag™ magnet to capture and remove free biotin
- No sample dilution
- Depletes biotin to <1.0 ng/mL⁵
- No centrifugation necessary
- May reduce number of send outs
- Shorter turnaround time than current methods
- Reagent designed so it doesn't alter the sample (No matrix affect)

When to Use VeraPrep Biotin

- As a reflex test, if VeraTest Biotin™ is positive, >15 ng/mL
- Settings of uncertainty
- When delayed testing isn't an option
- Patients with renal disease where biotin clearance may be impaired
- Patients on ≥100 mg/day biotin therapy
- Patients taking ≥10 mg/day OTC biotin

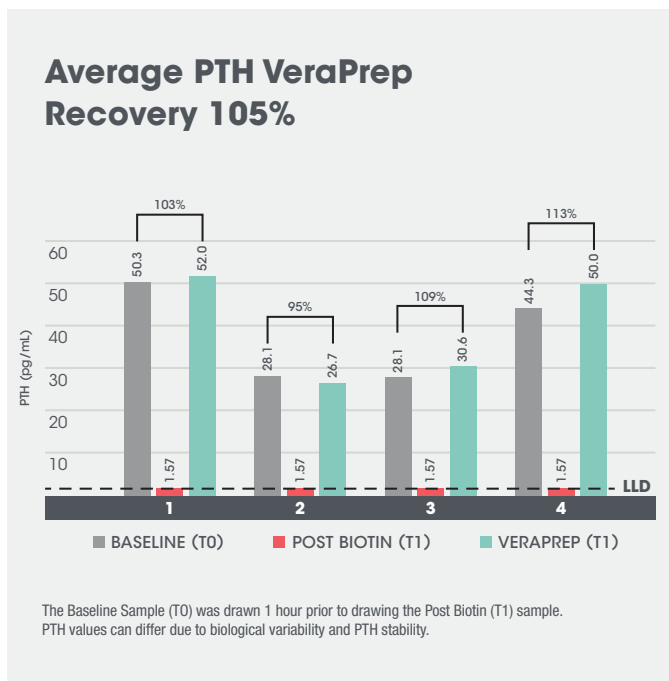
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Veravas representative at 1.888.466.4166.

Biotin Depletion Study⁴

A proof-of-concept study demonstrated how VeraPrep Biotin can deplete biotin and rule in biotin interference.

- Samples were drawn from 4 patients to establish baseline levels of free biotin
- The patients ingested high-dose biotin supplements and a second set of samples were drawn 1-hour post ingestion
- The PTH (parathyroid hormone) blood test, which is susceptible to free biotin interference, was run on:
 - The baseline samples (gray column)
 - The samples post biotin-ingestion (red column)
 - The biotin-ingestion samples after being cleared of free biotin by VeraPrep Biotin (green column)

VeraPrep Biotin depleted the free biotin to within physiological concentrations (200–1000 pg/mL). PTH results, previously undetectable (<1.57 pg/mL) due to biotin interference, were recovered to within 95–113% of baseline. In all four patients, biotin interference was correctly ruled in.



The VeraPrep Biotin Difference

	VeraPrep Biotin	Streptavidin Agarose
Deplete free biotin up to 500 ng/mL	Yes	Yes
Deplete free biotin >500 ng/mL	Yes, using advanced protocol	Yes
Sample volume (* use more or less as needed)	400 µL*	500 µL
Sample dilution	No dilution effect	10% dilution
Incubation time	10 minutes	60 minutes
Centrifugation required	No	Yes
100% sample aspiration	Yes	No
Can be automated (*requires a custom magnet)	Yes*	No
Total process time	15 minutes	>60 minutes

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:

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3. Shanika Samarasinghe, Farah Meah, Vinita Singh, Arshi Basit, Nicholas Emanuele, Mary Ann Emanuele, Alaleh Mazhari, and Earle

4. 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
5. <https://www.webmd.com/vitamins-and-supplements/news/20171129/fda-warns-biotin-can-distort-lab-tests>
5. Veravas, Inc. Data on file

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