

# What you should know about BIOTIN INTERFERENCE

## HIGH DOSE BIOTIN SUPPLEMENTATION IS A GROWING TREND

Biotin or Vit B7 mainstream use, particularly in the 5,000 to 10,000 mcg dosages<sup>1</sup>, is growing rapidly due to increased awareness of its benefits to hair, skin and nails. Surveys have shown that the magnitude of biotin use in the patient population extends to outpatients as well as patients presenting themselves to the emergency department.<sup>2</sup>

## INTERFERENCE IMPACTS PATIENT SAFETY & COSTS

Biotin interference in lab tests of patients taking biotin supplementation can lead to falsely high or falsely low results.<sup>2-3</sup> Physicians are misguided with erroneous results leading to misdiagnoses, inappropriate or delayed treatment and continued health concern.<sup>4</sup> The interference is widespread among the different applications and extends into acute and chronic testing needs, such as cardiac, thyroid, fertility, and oncology.<sup>4,5</sup>

**THE AMERICAN THYROID ASSOCIATION GUIDELINES RECOMMEND CESSATION OF HIGH-DOSE BIOTIN THERAPY FOR AT LEAST TWO DAYS PRIOR TO BLOOD TESTS**

## BIOTIN-RELATED TESTING INTERFERENCE IS ON THE RISE

There is an increasing trend of malfunction reports<sup>6</sup> and misdiagnosis<sup>2-3</sup> due to biotin interference in immunoassays reported to the FDA.

**COMPARED TO THE PREVIOUS YEAR, 2018 SHOWED A 20% INCREASE IN ADVERSE (MAUDE) EVENTS RELATED TO BIOTIN INTERFERENCE<sup>6</sup>**

**40%**

**OF 23 LAB TEST METHODS ARE AFFECTED BY BIOTIN INTERFERENCE.<sup>5</sup> TOSOH LAB TESTS HAVE ZERO RISK FROM BIOTIN INTERFERENCE.**

## FDA ISSUES RECOMMENDATIONS TO TEST FOR BIOTIN INTERFERENCE

Recently, the Food and Drug Administration (FDA) issued a draft guidance for industry to set recommendations on testing for biotin interference on the performance of in vitro diagnostic devices (IVDs).<sup>7</sup> The current guidance depends on awareness, communication, compliance and alternative testing methods when a specimen is deemed suspicious. Together, the

limitations of implementation can lead to missed cases, confusion and increased costs.

Despite the exposure on the impact of biotin interference, the problem has yet to be overcome. A simple solution is to use alternative methods that are not vulnerable to biotin interference such as Tosoh's AIA-PACK, a menu of assays that are 100% free from biotin interference.

## TOSOH IS FREE FROM BIOTIN INTERFERENCE

Tosoh Bioscience's proprietary dry-reagent, unit dose test cup technology is **free from biotin interference**, offers calibration stability of up to 90 days, and achieves consistency and accuracy with reduced waste. The test cup is interchangeable across Tosoh's portfolio of automated immunoassay analyzers. Tosoh analyzers are suited for a variety of different throughput requirements, from small physician office labs to large reference labs, and are easy to use, robust, and precise, and offer a simplified workflow with minimal downtime.

### References

1. Nielsen FDM Data on Biotin Monthly Volume (Ending 03/26/16) Abbott website
2. Katzman et al. Clin. Biochem. Vol. 60, September 2018, 11-16
3. Colon PJ et al. JALM Vol. 2, Issue 6 May 2018
4. Elston MS et al. J Clin Endocrinol Metab. 2016 Sep;101(9):3251-5
5. Piketty, M-L et al. Clin Chem Lab Med 2017; 55(6): 780-788
6. Data from US FDA MAUDE database
7. FDA Draft Guidance Document FDA-2019-D-1876



## Biotin-Free Tests

Zero Biotin Interference Risk

The increase in biotin supplementation use combined with the limitations in many immunoassays has led to false lab results, misdiagnosis and mismanagement of patients, triggering the FDA to issue a warning against biotin interfering with some lab tests<sup>1-3</sup>.

Tosoh's ST AIA-PACK<sup>®</sup> Test Menu of immunoassays utilizes our proprietary method that is **free from biotin interference**.

Not all immunoassays are the same. Using the right immunoassay gives you confidence in the results you deliver. **Choose wisely. Choose Tosoh.**



### References

1. FDA Safety Communication, November 28, 2017.
2. Elston et al. J Clin Endocrinol Metab, September 2016, 101(9):3251-3255.
3. Nielsen FDM Data on Biotin Monthly Volume (Ending 03/26/16) Abbott website

## TOSOH BIOSCIENCE

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