# Letters, 11/17

## Biotin pharmacokinetic study results

In Anne Paxton's September 2016 article, "Beauty fad's ugly downside: test interference," I stated a commitment from Roche to reduce possible interferences, including biotin, and provide clear test labeling to ensure that physicians and laboratories can mitigate risk. Since that time, we have published a study of biotin pharmacokinetics that provides clarity and context on the topic of biotin (doi.org/10.4155/ipk-2017-0013).

Our pharmacokinetic study (n=54) confirmed how biotin is metabolized, which provides useful guidance to laboratories regarding biotin doses and washout periods. Topline findings are:

- Biotin as one ingredient within a daily multivitamin (30–40 mcg) has no effect on our assays.
- 100 percent of subjects in the study taking 5 mg of biotin per day were below a tolerance threshold of 30 ng/mL within 3.5 hours.
- 100 percent of subjects in the study taking 10 mg of biotin per day are below a tolerance threshold of 30 ng/mL within eight hours.

Subjects taking 20 mg of biotin per day may need to discontinue biotin intake for longer than eight hours prior to testing.

In a separate internal study, we re-measured the thresholds of our Elecsys assays and confirmed the stated thresholds in our package inserts. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. >5 mg/day) until at least eight hours following the last biotin administration.

Nielsen data about biotin sales may also be reassuring to laboratorians and clinicians. Over a three-year period (July 2014–June 2017), biotin sales in the U.S. have been trending slightly upward with the steadiest sales growth in doses 2.5 mg and under, levels that pose a very low risk to lead to interference. Sales of 5 mg doses have declined (Nielsen FDM Data ending June 2017).

In a free American Association for Clinical Chemistry webinar, "Biotin and Laboratory Testing: Recognizing Interferences and Preventing Misdiagnosis," cosponsored by Roche and Abbott, speakers Nikola Baumann, PhD, director of the central clinical laboratory and central processing laboratory, and Brooke Katzman, PhD, co-director of the hospital clinical laboratory and point of care, both at Mayo Clinic, offered comprehensive recommendations for how laboratorians can educate physicians and patients about reporting biotin use and mitigating interference in general. A recording of this Sept. 28 webinar is available on-demand from AACC.

Finally, we offer more detailed information within our new online resource for laboratorians, at http://biotinfacts.roche.com.

In this era of outcome-based health care, diagnostics remain foundational to medical decision-making, helping to inform the full clinical picture. That's why ongoing study, education, and scientific partnership are critical to driving the best practices that enhance patient safety.

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