On November 28, the FDA issued the following alert [weblink]:

Biotin (Vitamin B7): Safety Communication - May Interfere with Lab Tests

This alert will likely generate media attention and concerns from your clinicians and patients about lab test results at Allina Health Laboratory.

FDA recommendations for clinicians with Allina Health-specific information:

Talk to your patients about any biotin supplements they may be taking. Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements and dietary supplements for hair, skin and nail growth.

Be aware that many lab tests, including, but not limited to cardiovascular diagnostic tests and hormone tests that use biotin technology are potentially affected, and incorrect test results may be generated if there is biotin in the patient’s specimen.

- The major test systems in Allina Health Laboratory (central lab, Allina-owned hospitals & clinics) do NOT use biotin technology and are NOT affected.
- The only in-house test affected is: Thyroglobulin (Tg) Tumor Marker (429). Biotin in a patient’s specimen may cause falsely low results for this test.

Communicate to the lab conducting the testing if your patient is taking biotin.

- Biotin may interfere with tests performed at facilities outside of Allina Health. Depending on the test, biotin in a specimen can cause either falsely high or falsely low results.
- In the case of Tg or certain sendout tests, the patient must not take supplements containing biotin for at least 12 hours prior to sample collection.
If a lab test result doesn't match the clinical presentation of your patient, consider biotin interference as a possible source of error **IF the test was performed at a facility outside of Allina Health (such as referrals to an outside performing lab).**

- **See the FAQ on the following pages for tests and illustrations to identify the performing lab for results.**
- **Contact the laboratory for clarity as needed.**

If you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference **consult with a pathologist by calling (612) 863-4678. The laboratory will investigate and assist in reporting the case to the FDA.**
Biotin Interference – FAQ

In general, what types of laboratory tests might use biotin technology?

Biotin technology is used by some manufacturers for trace immunoassays – i.e. tests for substances that circulate in miniscule amounts, such as: hormones, tumor markers, cardiovascular biomarkers, other disease markers, certain drugs and vitamins.

Biotin technology is not used in any test system for basic biochemical tests including all tests in common metabolic panels (BMP, CMP, lipids, renal, LFTs, lytes). These tests are not affected by biotin, regardless of where the test was performed.

Is there a list of the Allina Health Laboratory sendout tests known to be affected by biotin?

Below are tests actually ordered through Allina Health Laboratory within the last 12 months that are known to be susceptible to biotin interference in patients taking supplements (not a complete list of all possible rarely ordered miscellaneous sendout tests or future sendout tests that could be affected by biotin).

<table>
<thead>
<tr>
<th>Test name</th>
<th>Test #</th>
</tr>
</thead>
<tbody>
<tr>
<td>THYROGLOBULIN TUMOR MARKER</td>
<td>429</td>
</tr>
<tr>
<td>NT-PRO BNP</td>
<td>7095</td>
</tr>
<tr>
<td>HEPATITIS BE ANTIGEN</td>
<td>687</td>
</tr>
<tr>
<td>THYROTROPIN RECEPTOR ABY</td>
<td>988A</td>
</tr>
<tr>
<td>N-TELOPEPTIDE (NTX), urine</td>
<td>2920</td>
</tr>
<tr>
<td>CALCITONIN</td>
<td>55</td>
</tr>
<tr>
<td>OSTEOCALCIN</td>
<td>7877</td>
</tr>
<tr>
<td>Prostate Health Index (phi)</td>
<td>994</td>
</tr>
</tbody>
</table>

This is the only in-house test affected.

All are sendout tests

Does this mean that I don’t have to worry about biotin interference for tests that are not on this list?

No, because exceptions are fairly common. It is not possible to determine in advance whether an individual specimen will be tested using a biotin method because of add-ons, reflex tests, temporarysendouts due to test problems, rarely ordered tests, and the diversity of outside labs, test methods, and test orders.

Example: A physician orders a test that is sent out to one of our reference labs. Later a TSH is added on. Even though TSH is performed in our laboratory, the specimen is now at the reference lab. In these situations, we ask the reference lab to perform the TSH to expedite results while the original specimen is still fresh enough for testing. If the patient is taking biotin and the outside lab uses a biotin method for TSH, the result could be affected.

What should I tell patients?

Tell them to not take vitamin supplements for at least 12 hours before any blood draw. This is because (1) patients do not always know if a supplement contains biotin and, (2) their specimen could end up getting tested by a biotin method for reasons explained above. The FDA alert states that the “safe period” after taking biotin is not known, so stay aware that interference cannot be totally excluded even after 12 hours in the case of questionable results for specimens tested with a biotin method.
My patient has a questionable result and I want to exclude biotin interference. What are the next steps?

The diagram below is provided as a reference. As mentioned above, there are sporadic occasions where an outside lab may perform a test normally performed at Allina Health Laboratory. Please consult with a clinical pathologist to investigate questionable results.

How can I tell which laboratory performed a test?
The performing laboratory for each test is identified on the patient report.