December 2019

ALLINA HEALTH LABORATORY

LabConnect

In This Issue

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Allina Health LABORATORY

UPDATED FDA warning about Biotin interference with lab tests

On November 5, 2019 the FDA issued an updated biotin warning to remind physicians and patients about potential interference with laboratory tests:

UPDATE: The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication | FDA

This FDA update, coming 2 years after the initial alert, notes that while manufacturers have taken some steps to mitigate biotin interference, this is still an issue. The FDA alert will likely generate fresh media attention and questions about testing performed at Allina Health Laboratory. Please read the following information and distribute this information widely to clinical staff for awareness.

Summary of Updated FDA Biotin Alert recommendations for clinicians with *Allina-specific information*:

- Talk to your patients about any biotin supplements they may be taking, including supplements marketed 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.***
  - ◊ ***Troponin tests at Alina are NOT affected by biotin.***
  - ◊ ***The only in-house test affected is: Thyroglobulin Tumor Marker (Tg).***
- Communicate to the lab conducting the testing if your patient is taking biotin.
  - ◊ ***Biotin may interfere with tests performed at facilities outside of Allina.***
  - ◊ ***In the case of Tg or certain sendout tests (see list next page), the patient should discontinue 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 (such as send outs to reference lab).***
  - ◊ ***See attached FAQ for tests and illustrations to identify the performing lab for results in Excellian.***
  - ◊ ***Contact the laboratory for clarity as needed.***
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin, and nail growth in levels that may interfere lab tests ***performed outside of Allina.***
- 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

The major test systems used at Allina Health Laboratory do NOT use biotin technology and test results are NOT affected. Biotin does NOT interfere with troponin tests used at Allina Health.

The only test affected by biotin in our laboratory is Thyroglobulin (Tg) Tumor Marker. Biotin interference will cause falsely low results.

Biotin may interfere with tests performed at outside facilities. Typically, patients must avoid biotin-containing supplements for at least 12 hours before a blood draw.

If you need clarity about a specific test or result, contact Client Services:
(612) 863-4678

Allina Health Laboratory list of tests that are affected by Biotin:

In-house	**Test Code**	
Thyroglobulin Tumor Marker	429	This is the only in-house test affected.
Sendout	**Test Code**	All are sendout tests
Adrenocorticotropic hormone (ACTH)	13326	
Calcitonin, Fine-Needle Aspiration biopsy (FNAB)-needle wash, lymph node	994	
C-telopeptide	994	
GAD-65 autoantibody	13403	
Gastrin, blood	13324	
Growth hormone, serum	13321	
Hepatitis Be antigen	13338	
Human epididymis protein 4	994	
Inhibin A, ultrasensitive	13405	
Insulin-Like Growth Factor-1 (IGF-1) with Z-Score	13348	
Insulin-like growth factor-binding protein 3 (IGFBP-3)	13396	
NT-proBNP	7095	
Ovarian malignancy risk	994	
Prostate health index (PHI), serum	994	
Prostatic specific antigen, ultrasensitive	994	
Sex hormone-binding globulin	13363	
T3 Uptake	994	
Thyrotropin receptor antibody, serum	13346	
Troponin T (sendout for special reasons)	13395	

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 for basic biochemical tests including all tests in common metabolic panels (BMP, CMP, lipids, renal, LFTs, lytes). These tests are not affected by biotin.

Does this mean that I don't have to worry about biotin interference for tests that are not on the above list of affected tests?
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, temporary sendouts due to test problems, rarely ordered tests, and the diversity of outside labs, test methods, and test orders.

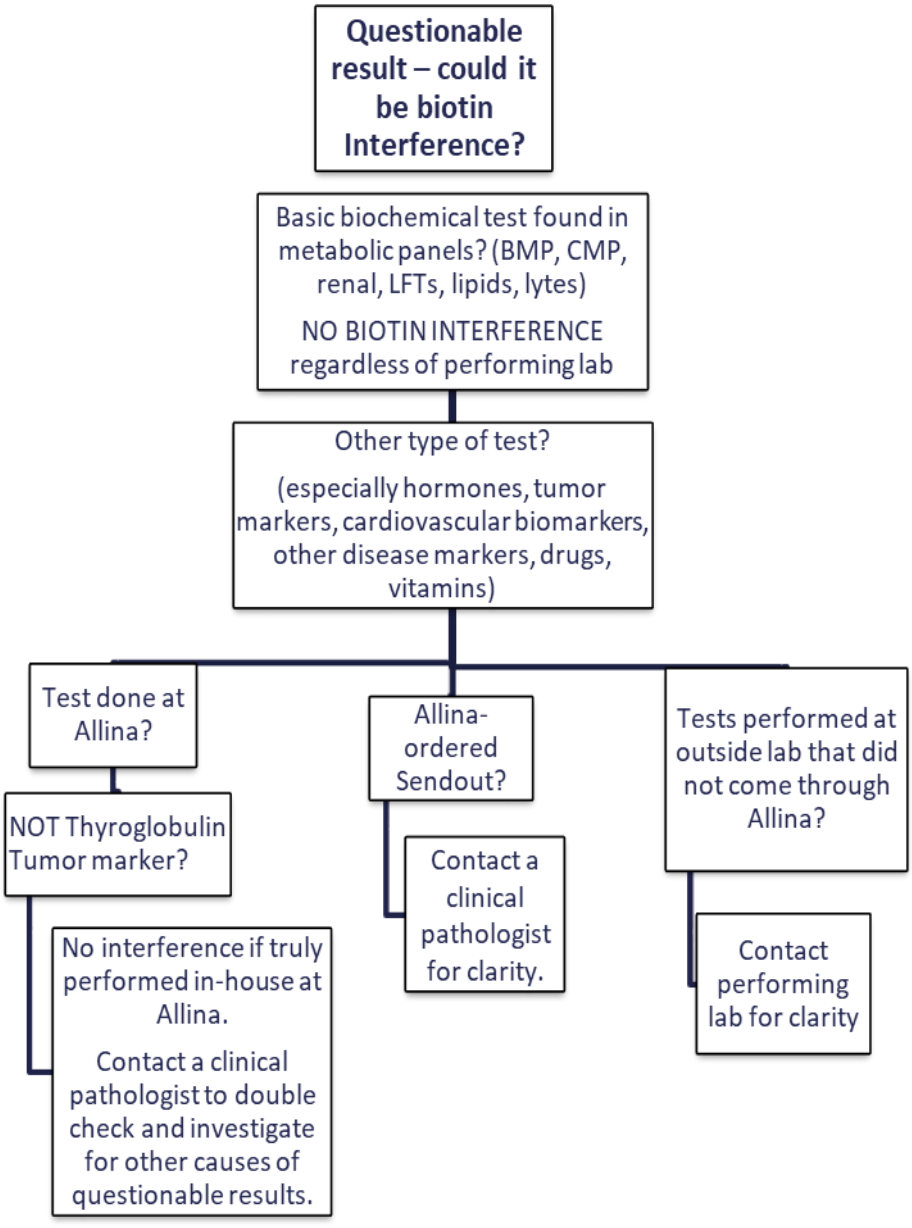
> **Example:** A physician orders a test that is sent out to our reference lab. Later a TSH is added on. Even though TSH is performed in our laboratory, the specimen is now at the reference lab. In these situations, we ask the reference lab to perform the TSH to expedite results while the original specimen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

What should I tell patients?

Tell them to not take any 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 testing by a biotin method for reasons explained above. The FDA alert states that "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 included on the following page 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.

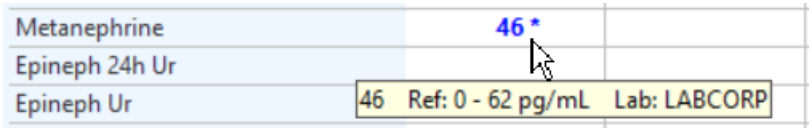

Questionable result – could it be biotin Interference?
Basic biochemical test found in metabolic panels? (BMP, CMP, renal, LFTs, lipids, lytes)
NO BIOTIN INTERFERENCE regardless of performing lab
Other type of test?
(especially hormones, tumor markers, cardiovascular biomarkers, other disease markers, drugs, vitamins)
Test done at Allina?
NOT Thyroglobulin Tumor marker?
No interference if truly performed in-house at Allina.
Contact a clinical pathologist to double check and investigate for other causes of questionable results.
Allina-ordered Sendout?
Contact a clinical pathologist for clarity.
Tests performed at outside lab that did not come through Allina?
Contact performing lab for clarity

How can I tell which laboratory performed a test?

See the following page for examples and screenshots.

How to determine where a laboratory test was performed when viewing results in Excellian.

Results Review: ***Hover over the result to see the performing lab.***



Test performed at Allina Health (United Hospital)

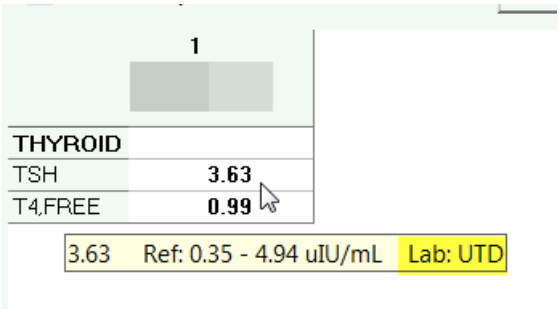
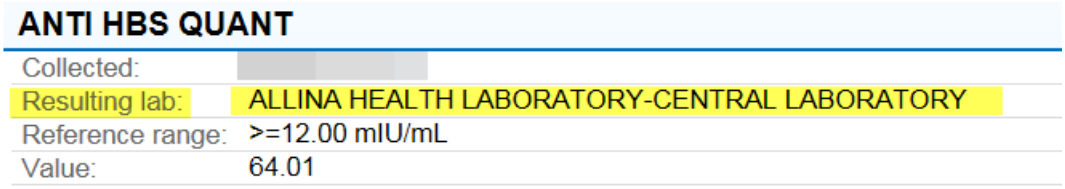
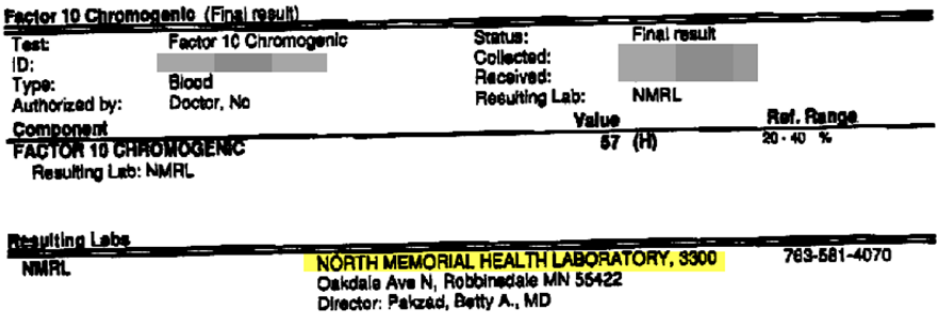


Chart review:



Printed and scanned lab reports always show the performing lab.



Billing and compliance

Changes to Medicare card formatting reminder

The Centers for Medicare and Medicaid Services (CMS), has issued new Medicare cards. The new cards, which were issued between April of 2018 and April of 2019, feature a new Medicare Beneficiary Identifier (MBI) unique to the patient in place of the patient's Social Security number.

After December 31, 2019, CMS will no longer accept the old card and/or subscriber ID.

If an old card copy or old subscriber ID is submitted after December 31, 2019 Allina Health Laboratory billing will fax a letter to the ordering provider's office requesting the new MBI. This includes information supplied on face sheets.

Example of new card

IMMUNOLOGY

Discontinuation of Urea breath test for H pylori

Our laboratory has received several questions and concerns about no longer offering the Urea Breath Test (UBT) for Helicobacter pylori infection. Our laboratory has standardized to a new monoclonal H. pylori stool antigen test that provides equivalent diagnostic sensitivity and specificity with a lower cost to the healthcare system.

Per Up-To-Date (last updated Oct 29, 2019):

"Of the available tests, stool antigen testing is the most cost-effective in areas of low to intermediate prevalence of H. pylori. The sensitivity and specificity of the laboratory-based monoclonal enzyme immunoassay (94 and 97 percent, respectively) are comparable to the UBT."

There is a single vendor for the UBT and the test requires a drink containing a carbon isotope, breath collection devices, and a dedicated instrument for the analysis. The test is costly to provide and the extra costs are passed on to patients and payers.

Some physicians have expressed that the UBT is more acceptable to patients than the stool test, yet data show that in 9 months prior to Allina Health Laboratory UBT discontinuation*, 604 (75%) of all ordering clinicians (n=810) used only the stool test for their patients.

The laboratory stewardship team routinely evaluates the test formulary to ensure high quality, clinically relevant and cost effective methods. Allina Health is in transformation to value-based care and this decision reflects that commitment.

**December 2018 through August 2019*

Anti-native DNA assay name change

New regulatory requirements require that test names be more specific so that physicians are more aware of the methods used when they are ordering. In response to the the new requirements, effective January 14, 2020, the name of the Anti-native DNA assay (605/86225.0) will be changing.

Current name: Anti-native DNA
New name: DNA double-stranded (dsDNA) antibodies by Crithidia luciliae IFA

MICROBIOLOGY

New test order for Vaginal/rectal Group B Strep PCR (14203)

On November 19, 2019, Allina Health laboratory began using new technology to improve detection of Group B strep (GBS) colonization in pregnant patients. The change has elicited some great questions and the information below should provide some clarity.

The new test is not the same as the existing rapid GBS test performed for patients who present in labor with unknown GBS status. Both tests are available.

The new Vaginal/Rectal Group B PCR test [VRB/LAB14203] is performed on an actively growing culture. The specimen swab is inoculated into a selective enrichment broth and incubated overnight. The following day, the GBS PCR test is performed on the enriched broth culture with shorter turnaround time that culture alone. When needed, sensitivities can be performed from the broth culture.

The new method is more sensititive for true GBS colonization compared to the traditional pure culture method. Explanation: Using a pure culture method, GBS colonies are identified by beta-hemolysis on the culture plate. The problem is that 5-8% of GBS don't produce beta-hemolytic colonies and will be missed by culture. DNA detection by PCR (also called Nucleic Acid Amplification Test or NAAT) overcomes this limitation and detects colonization by non-hemolytic GBS that have the same risks for neonatal infection. In a published study of 500 vaginal/rectal specimens from pregnant patients, PCR detected 40 additional GBS positives compared to culture alone.*

In summary, the PCR test supplements culture to improve GBS detection and outcomes. The new test is FDA-approved for GBS detection in pregnant patients. Other than the test name we hope that the only change you notice is faster turnaround time.

*Shin, J; Pride, D; Comparison of Three Nucleic Acid Amplification Tests and Culture for Detection of Group B Streptococcus from Enrichment Broth; Journal of Clinical Microbiology; June 2019 Volume 57 Issue 6; 1-9.

REFERRAL TESTING

Myasthenia gravis evaluation changes

On December 17, 2019, the Myasthenia gravis evaluation assay (8072/LAB8072), referred to Mayo Clinic Laboratories (MCL), was made obsolete and not orderable.

The suggested alternative test is the Myasthenia gravis profile with reflex (14217/LAB14217) referred to LabCorp Burlington.

Test Name: Myasthenia gravis profile with reflex
Test Number: 14217

Myasthenia gravis profile with reflex now available

Effective Tuesday, December 17, the Myasthenia gravis panel with reflex (14217/LAB13217) referred to LabCorp, became available for order.

Test Name:	Myasthenia gravis profile with reflex
Test Number:	14217
Collect:	2 mL serum - SST
Container:	Gold SST or LabCorp 12 mL transport tube
Processing:	Spin within 45 minutes of collection
Transport/Stability:	Ambient (preferred) - 7 days; Refrigerated - 14 days; Frozen - 2 months
Alternate names:	MGE; LAB14271
Performing Lab:	LabCorp Burlington (086001): R-LC
Days Set Up:	AChR Ab: Mo - Fr; Reflex AChR-modulating Ab: Mo, We, Fr
Expected TAT:	5 - 12 days
Ref. Ranges:	An AChR-binding antibody result <0.25 will reflex to the AChR-modulating antibody (at an additional charge)
Collection/ Processing Details:	*Useful for: Diagnose myasthenia gravis (MG and Monitor response of treatment of myasthenia gravis* **Testing includes:** AChR-binding antibody and Striational antibody **Caution:** False positives can occur in patients with serum drawn within 48 hours of administration of general anesthesia and muscle relaxants. Antibodies to alpha-bunarotoxin may sometimes be found in patients treated with snake venom. Recently administered isotopes may interfere with the assay in unpredictable ways. Acetylcholine receptor autoantibodies are not typically found in congenital myasthenia gravis
Method:	AChR-binding assay: radioimmunoassay (RIA); Antimuscle (striational antibody): indirect fluorescent antibody (IFA); AChR-modulating antibody (reflex): cell culture based radioimmunoassay (RIA)
CPT Codes:	83519, 86255

Interfaced clients: If this is a test that may be utilized at your practice, contact your account representative to arrange for build and testing of this assay.

Myasthenia gravis (MG)/Lambert-Eaton syndrome (LES) evaluation changes

Effective December 17, 2019, the Myasthenia gravis (MG)/Lambert-Eaton syndrome (LES) evaluation assay (1085/LAB1085), referred to Mayo Clinic Laboratories (MCL), became obsolete and was made not orderable.

The suggested alternative test is the Myasthenia gravis profile with reflex (14217/LAB14217) referred to LabCorp Burlington.

Test Name: Myasthenia gravis profile with reflex
Test Number: 14217

Von Willebrand Factor multimers test code change

The Von Willebrand Factor multimer assay, referred to LabCorp Esoterix (500148), is being built with a unique test ordering code and will no longer require use of the Miscellaneous send out (MSO) test code.

The Von Willebrand Factor multimer assay is useful as an aid in the determination of Von Willebrand factor (VWF) deficiency subtype 6-9. This test is a reflex to Von Willebrand screen when there is a decrease in the VWF:RoC and/or the VWF:Agn results, and is also available as a standalone order.

Effective December 17, 2019, this assay will be orderable using the test number 14206.

	Current	New
Test number	994	14206
Abbreviation	MSO	VWF

Interfaced clients:
If this is a test that will be utilized by your site, contact your account representative for build information and to arrange testing.

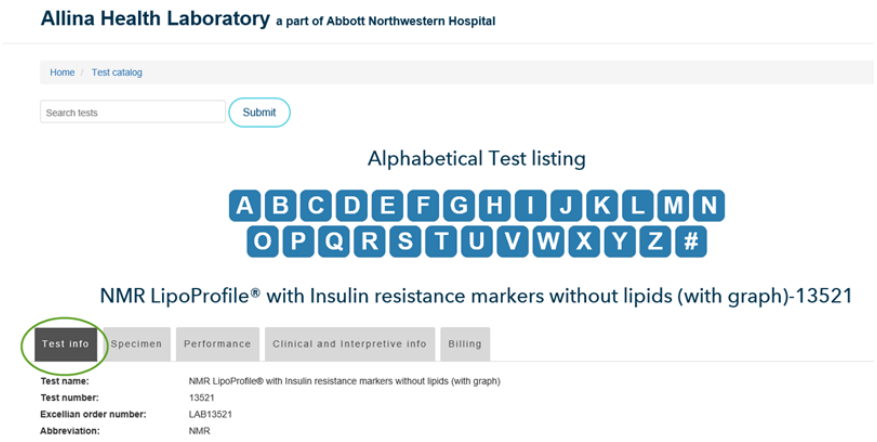
WEBSITE

Allina Health Laboratory website changes coming Friday Dec 20th

Effective Friday, December 20th, changes are going into place for the Allina Health Laboratory

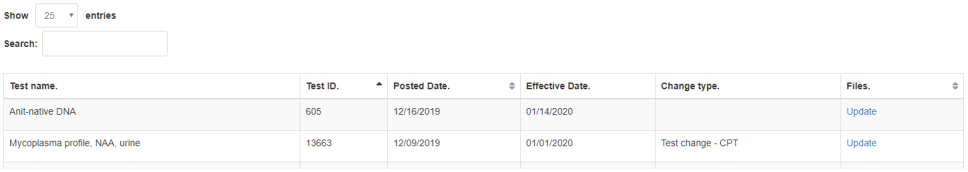
- New URL
  - The new URL is www.allinahealth.org/allinahealthlaboratory
  - Be sure to update any saved shortcuts that you might have created!

- Test catalog
  - Test catalog entries now appear in tabbed format



  - Over time, we will be adding picture of collection and transport containers

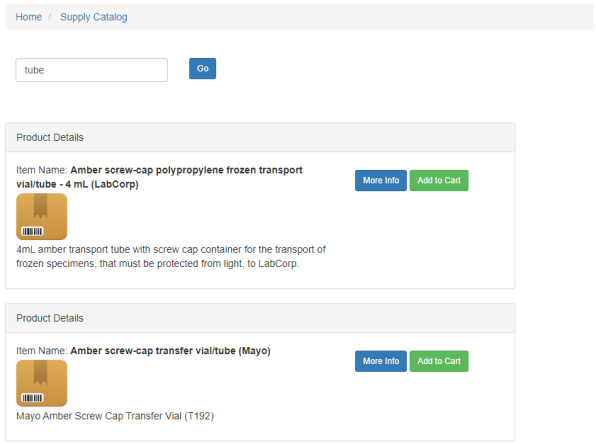
* Test updates, that are searchable, and will be sortable, have been added



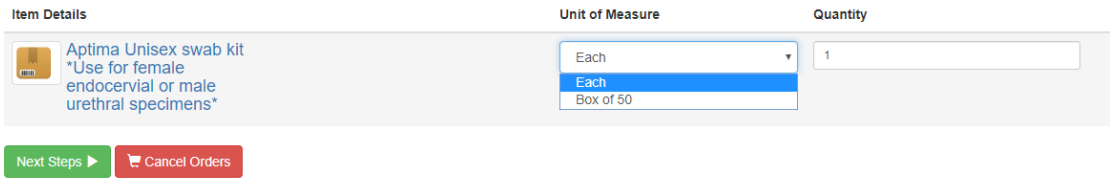
- Supply catalog
  * You can now check recent orders from your site by entering your customer code ***or*** order number and clicking *Check your order status*

  * Some supply categories also have subcategories

  * The supply catalog is searchable by item name



* Some supply items are now available with multiple quantity options



If you have questions about the new website, please contact your Account Representative.

During this joyous holiday season, all of us at Allina Health Laboratory would like to wish you health, happiness and good fortune.

We are grateful for your continued loyalty.

Best wishes for a wonderful new year!

Allina Health Laboratory