June 2022

ALLINA HEALTH LABORATORY

LabConnect

In This Issue

Billing and compliance

- New payor coverage policies announced

Chemistry

- Lyme confirmatory testing methodology change
- Lyme Western blot assay discontinued

Coagulation

- Fibrinogen and Thrombin time reference range changes
- Protime/INR reference range change

Help us help you

- Keeping your provider list current

Microbiology

- Meningitis/Encephalitis (ME) pathogen multiplex PCR, CSF available
- Wet prep, genital assay discontinued

Referral Testing

- Lyme disease, line blot assay available July 19th

Supplies

- Navy blue tube shortage for metal testing

Phone
612-863-4678
800-281-4379

Fax
612-863-4067

BILLING AND COMPLIANCE

New payor coverage policies announced

Allina Health Laboratory has been notified of three new payor coverage policies. If coverage guidelines are not met and the payor does not deem the testing to be medically necessary, testing will not be reimbursable. If a non-covered diagnosis code is submitted with the order, Allina Health Laboratory billing will contact your office with an attempt to obtain a covered diagnosis code(s). If a coverable code is not available, your facility will be subject to a bill back for charges incurred. This change will be effective on anything processed on or after July 1, 2022. The affected polices are listed below.

Aetna

Colorectal Cancer Screening - Coverage Policy 0516

Homocysteine - Coverage Policy 0763

This includes the following Aetna payors:

Payer Name	Address	City	State	Zip
AETNA	PO BOX 14079	LEXINGTON	KY	40512-4079
AETNA AFFORDABLE HLTH CHOICES	PO BOX 14079	Lexington	KY	40512-4079
AETNA POS	PO BOX 981106	El Paso	TX	79998-1106

United Healthcare (UHC)

Vitamin D - Coverage Policy 2022T0631A

This includes the following United Healthcare payors:

Payer Name	Address	City	State	Zip
MEDICA - (UHC)	PO BOX 30990	SALT LAKE CITY	UT	84130
MEDICA UNITED HEALTHCARE	PO BOX 30555	SALT LAKE CITY	UT	84130
UNITED HEALTHCARE	PO BOX 30555	SALT LAKE CITY	UT	84130
UNITED HEALTHCARE CHOICE PLUS	PO BOX 740800	ATLANTA	GA	30374-0800
UNITED HEALTHCARE EMPIRE PLAN	PO BOX 1600	KINGSTON	NY	12402

CHEMISTRY

Lyme confirmatory testing methodology change

QUICK REFERENCE

Effective July 19, 2022, the Lyme Disease serology, polyvalent with reflex assay (659/86612.2) will undergo a change to the methodology used to confirm positive screening results.

DETAILS

On July 19, 2022, Allina Health Laboratory will begin using the modified two-tier testing (MTTT) algorithm for Lyme screening and confirmation. The assay will continue to be the first line of testing used to screen for Lyme disease, however, with the MTTT, positive screening test will reflex to a Lyme Confirmatory Panel which consists of Lyme IgG and Lyme IgM by chemiluminescent immunoassay for confirmation rather than the Lyme Western Blot (LWB) currently used.

Traditionally the CDC recommended a standard two-tier testing (STTT) algorithm for Lyme's disease, consisting of a first-tier chemiluminescent assay screen which, if positive or equivocal, was followed by a second-tier Western Blot confirmatory assay that tested for the presence of IgM and IgG antibodies associated with Lyme disease. Recently, a modified two-tier testing (MTTT) recommendation was introduced that replaces the second-tier western blot with distinct chemiluminescent assays for IgG and IgM antibodies. The MTTT assay screen and confirmation has specificity that is equivalent to STTT and most importantly has been shown to have increased sensitivity in early infection. Note that if a patient has a negative result on the Lyme disease screen there is NO indication to perform further testing and confirmatory testing will not be performed.

The results of Modified Two Tier Testing for Lyme Disease will be released with interpretative comments according to American Public Health Laboratories (APHL) guidelines which will give clinicians information regarding the results and any further recommended actions.

The new Lyme Confirmation panel which is part of MTTT will not be orderable as an independent test as it can only be used to confirm positive screening test performed using our current chemiluminescent assay.

Lyme Western Blot testing will no longer be performed within Allina Health Laboratories. Request for LWB will be referred to LabCorp for testing and will be available only to reference lab clients who perform their own version of a Lyme screen in their laboratory.

The following page includes examples of reports for both negative and positive results for the new Modified Two-Tier Testing for Lyme Disease.

EXAMPLE REPORTS:

Negative

Lyme Screen w/Reflex (Final result)

ID:	22CL-172L0003	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1244
Resulting Lab:	ANWLCR	Received:	6/21/2022 1242

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Positive (A)	Negative

Reflexed to Lyme Serology Confirmatory Panel. See Lyme Serology Confirmatory Panel results.

Lyme Screen w/Reflex (Final result)

ID:	22CL-172L0004	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1249
Resulting Lab:	ANWLCR	Received:	6/21/2022 1249

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Negative	Negative

No laboratory evidence of infection with B. burgdorferi (Lyme disease).

Negative results may occur in patients recently infected (less than or equal to 14 days) with B. burgdorferi. If recent infection is suspected, repeat testing on a new sample collected in 7-14 days is recommended.

Lyme Serology Confirmatory Panel (Final result)

ID:	22CL-172L0003	Collected:	6/21/2022 1238
Source:	Blood	Verified On:	6/21/2022 1244
Resulting Lab:	ANWLCR	Received:	6/21/2022 1242

Component	Value	Ref. Interval
Lyme IgG Confirmation Interpretation	Negative	Negative
Lyme IgM Confirmation Interpretation	Negative	Negative

Comments:
No laboratory evidence of infection with B. burgdorferi (Lyme disease).

Negative results may occur in patients recently infected (less than or equal to 14 days) with B. burgdorferi. If recent infection is suspected, repeat testing on a new sample collected in 7-14 days is recommended.

Legend

Positive

Lyme Screen w/Reflex (Final result)

ID:	22CL-178L0001	Collected:	6/27/2022 0948
Source:	Blood	Verified On:	6/27/2022 0949
Resulting Lab:	ANWLCR	Received:	6/27/2022 0949

Component	Value	Ref. Interval
LYME SCREEN W/REFLEX	Positive (A)	Negative

Reflexed to Lyme Serology Confirmatory Panel. See Lyme Serology Confirmatory Panel results.

Lyme Serology Confirmatory Panel (Final result)

ID:	22CL-178L0001	Collected:	6/27/2022 0948
Source:	Blood	Verified On:	6/27/2022 0949
Resulting Lab:	ANWLCR	Received:	6/27/2022 0949

Component	Value	Ref. Interval
Lyme IgG Confirmation Interpretation	Positive (A)	Negative
Lyme IgM Confirmation Interpretation	Positive (A)	Negative

Comments:
Results are consistent with B. burgdorferi infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection.

Results should not be used to monitor or establish adequate response to therapy. Response to therapy is confirmed through resolution of clinical symptoms; additional laboratory testing should not be performed. If both tests are equivocal consider repeat testing in 7-14 days if clinically warranted.

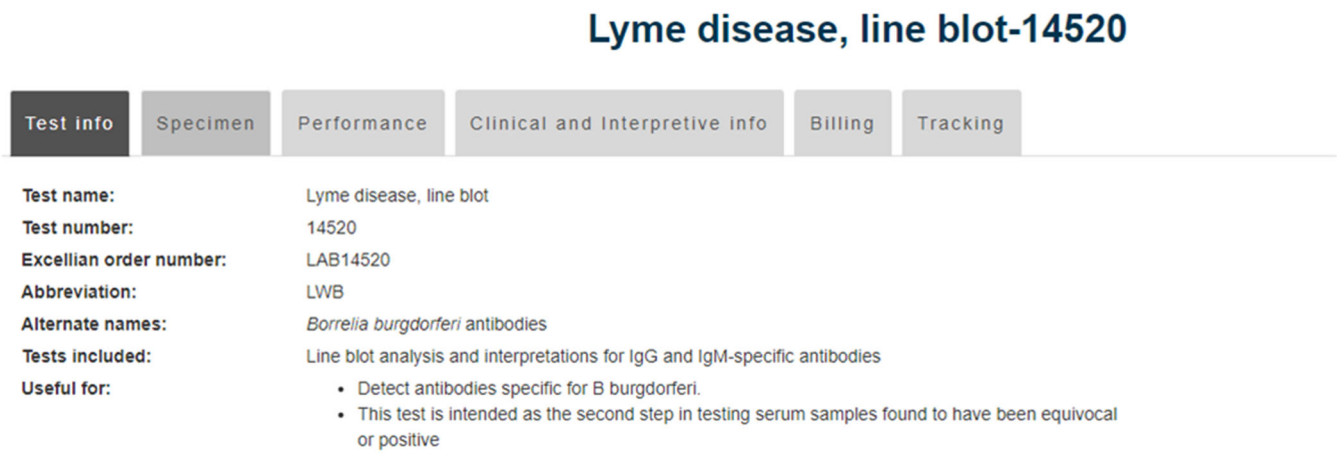
Legend

A - Abnormal

Lyme Western blot assay discontinued

Effective July 19, 2022, the Allina Health Laboratory will no longer perform the Lyme Western blot assay in house. The test will become obsolete and made not orderable.

The suggested alternate test for confirmation of Lyme screening assays is the Lyme disease, line blot assay (14520/LAB14520) referred to LabCorp.



Lyme disease, line blot-14520

Test info | Specimen | Performance | Clinical and Interpretive info | Billing | Tracking

Test name:	Lyme disease, line blot
Test number:	14520
Excellian order number:	LAB14520
Abbreviation:	LWB
Alternate names:	*Borrelia burgdorferi* antibodies
Tests included:	Line blot analysis and interpretations for IgG and IgM-specific antibodies
Useful for:	• Detect antibodies specific for B burgdorferi. • This test is intended as the second step in testing serum samples found to have been equivocal or positive

COAGULATION

Fibrinogen and Thrombin time reference range changes

Due to implementation of a new reagent lot number, effective June 21, 2022, the Fibrinogen, quantitative and Thrombin time reference ranges changed.

Changing to a new lot of coagulation assay reagent requires thorough validation testing to establish a new mean normal reference value. This process occurs approximately every 12 months when a new lot of reagent is made available by the instrumentation reagent vendor.

Fibrinogen, quantitative (101/85384.0)

Current (mg/dL)	NEW (mg/dL)
233 - 384	240 - 410

Thrombin time (510/85670.2)

Current (seconds)	NEW (seconds)
<17	<19

Protime/INR reference range change

Quick Reference

On July 19, 2022, Allina will be changing to a new lot of Prothrombin time reagent which requires thorough validation testing to establish a new mean normal reference time. The new normal Protime is used to calculate the International Normalized Ratio or INR for each new lot of thromboplastin. This process occurs approximately every 12 months when a new lot of reagents has been made available by the instrumentation reagent vendor.

As we prepare for changing to a new Protime reagent lot, the Allina Health Laboratory Coagulation Department undertakes a new normal range study using 25 specimens from persons known to be free of coagulation abnormalities and not on any current medications. These samples are run at every site, on each analyzer to give us a large volume dataset and a thorough representation of instrument comparability.

These normal Protime results are compiled to establish a reference time for the INR calculation. They also provide data that can be used for a new normal reference range.

	Current (seconds)	New (seconds)
Normal reference range	11.8 - 13.9	12.0 - 13.8

HELP US HELP YOU

Keeping your provider list current

To ensure accurate reports as well as accurate billing insurance claims, please review your Allina Health Laboratory request forms on a regular basis to make sure that we are maintaining a complete and accurate provider listing for your facility.

If any updates (removals or additions) are needed, please submit a completed Provider change request form, available on the Forms page of our website, or contact your Account Representative for assistance.

MICROBIOLOGY

Meningitis/Encephalitis (ME) pathogen multiplex PCR, CSF available

The Allina Health Central Microbiology Laboratory now offers an in-house Meningitis/ Encephalitis Pathogen Multiplex PCR Panel (ME Panel/14504) for rapid detection of pathogens from cerebrospinal fluid (CSF). Previously this panel was available only as a send out.

Historically, CSF evaluation for suspected meningitis/encephalitis required orders for multiple individual PCR tests. The new multiplex panel test includes 6 bacterial, 7 viral, and one fungal target, eliminating the need for individual orders. The new panel will allow initial diagnosis of Central nervous system (CNS) infections with a turnaround time of less than 24 hours, depending on location and transport time.

Targets included:

BACTERIA:	**VIRUSES:**
Escherichia coli K1 *Haemophilus influenzae* *Listeria monocytogenes* *Neisseria meningitidis* *Streptococcus agalactiae (Group B strep)* *Streptococcus pneumonia*	Cytomegalovirus (CMV) Enterovirus Herpes simplex virus 1 (HSV1) Herpes simplex virus 2 (HSV2) Human herpesvirus 6 (HHV-6) Human parechovirus Varicella zoster virus (VZV)
YEAST: *Cryptococcus neoformans/gattii*	

- Physicians can order a new ME multiplex panel when central nervous infection is suspected.
- For initial diagnoses of central nervous infections, *avoid* ordering multiple single tests (HSV1/2, VZV, Enterovirus, CMV, etc.) as the turnaround time for these tests is longer. Order the ME panel instead.
- Do *not* order duplicate ME panel within 7 days of initial testing (in a single admission) unless approved by Infectious disease clinicians.
- Spinal Fluid from lumbar puncture is the only acceptable sample type; shunt fluid is not acceptable as pathogens caused by shunt infections are not included in the panel.
- The panel ***does not replace*** the Spinal fluid culture, stain (6557/LAB6557). A culture and stain should be ordered *in conjunction with* the ME Panel.

Wet prep, genital assay discontinued

Effective June 21, 2022, the Wet prep, genital assay (6619/87210.2) became obsolete and was made not orderable.

The suggested alternative test is the Trichomonas, Candida and Bacterial vaginosis by NAA assay (14413/LAB14413) which has a much better sensitivity than the wet prep along with an increased sample stability time.

Trichomonas, Candida and Bacterial vaginosis by NAA-14413

Test info | Specimen | Performance | Clinical and Interpretive info | Billing | Tracking

Test name:	Trichomonas, Candida and Bacterial vaginosis by NAA
Test number:	14413
Excellian order number:	LAB14413
Abbreviation:	VVA
Alternate names:	BV Clue cells STI Trich Trichomonas wet prep Vaginal wet prep Vaginitis probe Vaginosis Wet mount Wet prep Yeast wet prep
Useful for:	Candidiasis and Bacterial Vaginosis (BV) involve overgrowth of organisms normally present in flora. Trichomonas, Candida, and BV by nucleic acid amplification (NAA) is the preferred diagnostic test for the common causes of vaginal symptoms, including bacterial vaginosis, Candida, and Trichomonas.

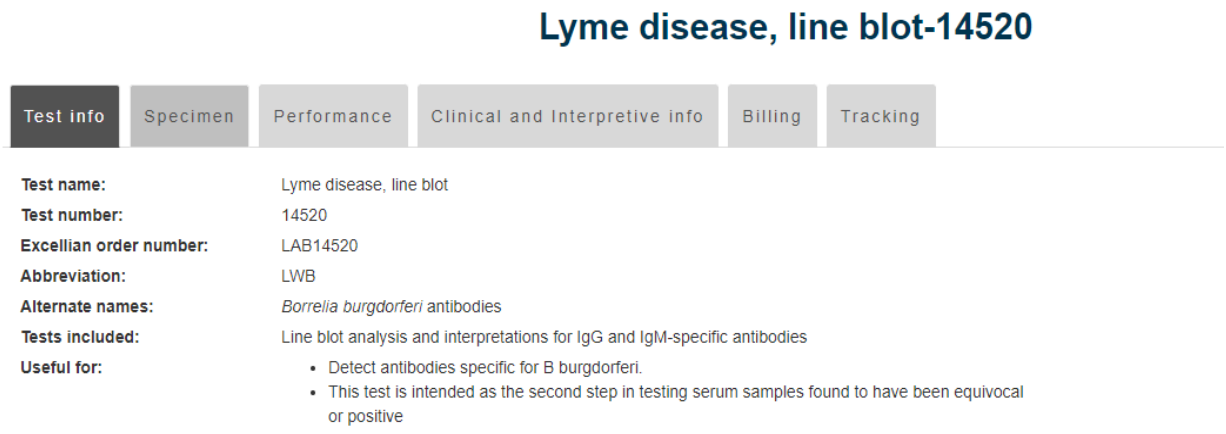
Limitations:	• Reliable results are dependent on adequate specimen collection, transport, storage, and processing. Because the transport system used for this assay does not permit microscopic assessment of specimen adequacy, proper specimen collection techniques are necessary.
	• Performance of the assay has not been evaluated in women less than 14 years of age
	• Collection and testing of patient-collected vaginal swab specimens with the assay is not intended to replace clinical examination. Vaginal infections may result from other causes or concurrent infections may occur
	• Interference with the assay was observed in the presence of the following substances:
	  ◦ Tioconazole 6.5% Ointment (3% W/V, all analytes)
	  ◦ Vaginal Moisturizing Gel (1% W/V, C spp; 5% W/V, C. glabrata 3% W/V, TV)
	  ◦ Glacial Acetic Acid (5% V/V, C spp only)
	• Low levels of *C. glabrata* may be masked by high level of Trichomonas
	• Not all organisms detected are viable; positive results can be caused by trace organisma RNA
	• Assay results cannot be used to indicate successful antimicrobial therapy
	• The organisms tested may be present in a healthy microbiome; results should not be used by themselves and should correlate to the other clinical data
	• Negative results should not be considered as definitively negative as pre-analytical errors may influence results
	• Other organisms associated with bacterial vaginosis and similar conditions such as *Prevotella, Mobilunus, Mycoplasma* and *Ureaplasma* are not examined by these assays.

REFERRAL TESTING

Lyme disease, line blot assay available July 19th

QUICK REFERENCE

Effective July 19, 2022, the Lyme disease, line blot assay (14520/LAB14520), referred to LabCorp, will be available to order. The Lyme disease, line blot assay is useful for confirmation of positive Lyme screening assays.



Complete test information will be available in the Allina Health Laboratory Test catalog on the effective date.

SUPPLIES

Navy blue tube shortage for metal testing

Trace concentrations of metals are ubiquitous in the environment and trace metal testing in blood requires certified metal-free collection tubes for accurate results. There is now a severe national shortage of metal-free blood collection tubes. As with other tube shortages, the vendors cite multiple contributing factors. We must take immediate steps to conserve the remaining supply of metal-free tubes for critical testing only.

FOR LAB STAFF:

All sites will need to limit the use of both the Navy EDTA and Navy No Additive collection tubes and begin to use alternate tube types. Refer to the table on the following page for acceptable alternate tubes for metals testing. Alternate tube type alerts will also be in the Allina Health Laboratory Test Catalog.

Exception: Zinc, Selenium, and Copper testing will be restricted and only orderable for specific conditions. These tests will continue to be collected in the Navy EDTA or Navy No additive.

- Copper serum/plasma 13302
- Selenium, serum/plasma 13666
- Zinc, red blood cell (RBC) 12520
- Zinc, serum/plasma 13305

Selenium, whole blood (994) will require pathologist approval.

Note that the blood collection tube supply continues to be an evolving situation, and sites may be asked to use different tubes again depending on available inventory.

To Do:

1. If you get a request for a heavy metal draw, collect the alternate tube type if indicated in the chart on the following page.
2. Continue to collect zinc, selenium and copper in navy tubes
3. If a provider receives an elevated result with the disclaimer to draw confirmatory testing in a navy metal free tube, they will order it with a comment of “need confirmatory testing for elevated results—must draw in navy blue tube
4. Tan K2EDTA tubes:
   a. Central lab supply will be sending out tubes to our affiliate sites monthly, based on test utilization. All other clients must order from the supply catalog only as needed
   b. Order of draw: Collect tan tubes after Lavender EDTA and before Grey sodium fluoride

Test name	**Test #**	**Alternative tube type**
Aluminum, serum or plasma	994	Lavender EDTA
Antimony, blood	994	Lavender EDTA
Arsenic, blood	2556	Lavender EDTA
Barium, blood	12519	Lavender EDTA
Bismuth, whole blood	994	Lavender EDTA
Cadmium	1636	Lavender EDTA
Chromium, plasma	994	Lavender EDTA
Chromium, serum/plasma	12463	Lavender EDTA
Chromium, whole blood	12464	Lavender EDTA
Cobalt, serum	2562	Lavender EDTA
Cobalt, whole blood	12518	Lavender EDTA
Fluoride serum/plasma	994	Lavender EDTA
Iodine serum/plasma	994	Lavender EDTA
Lead, venous	13306	Tan K2EDTA
Manganese plasma	13360	Lavender EDTA
Mercury, blood	13312	Lavender EDTA
Metal panel (As, Cd, Hg, Pb) blood	13309	Lavender EDTA
Methyl bromide as metabolite, blood	994	Lavender EDTA
Nickel, blood	2578	Lavender EDTA
Thallium, serum or plasma	994	Lavender EDTA
Titanium, serum or plasma	994	Lavender EDTA
Zinc protoporphyrin	13303	Lavender EDTA

When an elevated result for a test that is originally expected to be collected in a navy blue metal free tube is collected in a Lavender EDTA tube, a disclaimer will be added to the results. "*The specimen submitted for Trace Metal testing was collected in a container that was not certified as 'metal free', which may produce a falsely elevated result. Repeat testing, utilizing a collection tube certified as metal free (royal-blue top), prior to initiating therapy or conducting environmental investigations is recommended.*"

FOR PROVIDERS:

Trace concentrations of metals are ubiquitous in the environment and trace metal testing in blood requires certified metal-free collection tubes for accurate results. There is now a severe national shortage of metal-free blood collection tubes. As with other tube shortages, the vendors cite multiple contributing factors.

We must take immediate steps to conserve the remaining supply of metal-free tubes for critical testing only. ***Please defer non-critical trace metal testing for three months.*** The conservation strategy for critical testing depends on the clinical indication.

Testing for <u>deficiency</u> of essential trace metals (Zinc, Copper, Selenium):

1. Over 90% of all trace metal testing at Allina Health is ordered to evaluate for deficiency of Zn, Cup or Se. A metal-free tube is essential for deficiency testing.
2. To conserve scarce metal-free tubes, all future orders for these tests with an expected collection date prior to October 2022 should be cancelled
3. New orders for these tests should be deferred for three months unless the patient has specific indications

Lead (Pb) testing:

Not affected at this time. We were able to source an alternate collection tube that is certified for Pb testing only.

Testing for <u>toxic</u> trace metals other than Pb: (As, Hg, Cd, Co, Cr, Al, etc.)

1. Blood will be collected in non-metal-free tubes
2. If the test result is *above* the reference range, you will see a disclaimer with the result stating *"The specimen submitted for Trace metal testing was collected in a container that was not certified as metal free which may produce a falsely elevated result. Repeat testing, utilizing a collection tube certified as metal-free (navy blue top), prior to initiating therapy or conducting environmental investigation is recommended"*
3. If you get an elevated result with the disclaimer:
   a. Place an order for a confirmatory test with the comment "need confirmatory testing for elevated result—must draw in a navy metal free tube"
   b. Contact your laboratory to ensure that they have the appropriate Navy EDTA or Navy no additive tube available.

TO DO:

1. Copper, zinc, selenium deficiency testing:
   a. Defer new orders for three months when possible
   b. Urgent testing is restricted to patients with specific indications

      ◊ **Copper, serum/plasma (13302/LAB13302) indications:**
      - Wilson's disease evaluation
      - Established diagnosis of malabsorption syndrome (Roux-en-Y, celiac disease)
      - Total parenteral nutrition (TPN)
      - Penicillamine therapy
      - Menkes disease evaluation
      - Malignancy with question of malnutrition
      - Toxic ingestion of zinc or iron supplements

◊ **Selenium, serum/plasma (13666/LAB13666) indications**
- Established diagnosis of malabsorption syndrome (Roux-en-Y, celiac disease)
- Known inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- Total parenteral nutrition (TPN)
- Malignancy with question of malnutrition

◊ **Zinc, red blood cell (RBC) 12520/LAB12520 indications**
- Total parenteral nutrition (TPN)
- Open wounds or burns
- Cirrhosis
- Malignancy with question of malnutrition

◊ **Zinc, serum/plasma 13305/LAB13305 indications**
- Established diagnosis of malabsorption syndrome (Roux-en-Y, celiac disease)
- Known inflammatory bowel disease (Crohn's disease, ulcerative colitis)

2. Lead (Pb) testing is not affected at this time

3. Toxic metals *other than lead*:
   a. Blood will be collected in a non-metal-free tube
   b. If you see a disclaimer for an elevated result, enter a new order with the comment noted previously
   c. Contact your site laboratory to ensure a metal-free tube is available.

Thank you for choosing Allina Health Laboratory -

We value your business!