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## **BILLING AND COMPLIANCE**

### **Newborn screening (PKU), Minnesota fee change**

Effective July 1, 2021, there was a fee increase for the Newborn screening (PKU), Minnesota assay.

#### **DETAILS**

The Minnesota legislature, with Governor Walz's approval, has increased the newborn screening fee outlined in Minnesota Statute 144.125. This legislation was passed on June 26th, signed by the governor on June 29th, and went into effect on July 1, 2021.

If your account is billed for testing that you submit to Allina Health Laboratory, and this is a test that is utilized at your facility, contact your account representative for pricing details.

### **2021 Fee schedule change**

Allina Health Laboratory reviews testing costs annually and adjusts rates for our reference lab work based on overall costs per test. Effective September 1, 2021, Allina Health Laboratory will be implementing new fee schedules based on our most recent cost analysis for our clinical, histology, molecular, flow, cytogenetics and cytology testing.

Fees for referral testing (testing not performed at Allina Health Laboratory) represent our costs with a small handling fee and are adjusted as we receive fee changes from our vendors.

The 2021 comprehensive Allina Health Laboratory fee schedule will be distributed to your facility as soon as it is available. Data to identify the specific impact to your facility is available upon request. Please contact your account representative to review this information.

As your local community laboratory, at Allina Health Laboratory we strive to provide quality laboratory service with a rapid turnaround time, at a competitive price.

Thank you for choosing Allina Health Laboratory. We look forward to meeting your reference laboratory needs throughout the coming year.

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## CHEMISTRY

### Lead, capillary blood assay obsolete

Effective Tuesday August 17, 2021, the Lead, capillary blood assay (147/83655.3) became obsolete and was made not orderable.

#### DETAILS

The suggested alternative test for capillary collections is the [Lead, capillary \(fingerstick\) blood, pediatric](#), 14467/LAB14467, referred to LabCorp. For venous specimens, order [Lead, venous blood](#), 13306/LAB13306

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## FLOW CYTOMETRY

### Hairy cell leukemia residual panel by flow cytometry panel changes

#### QUICK REFERENCE

Effective August 17, 2021, several changes were made to the Hairy Cell Leukemia Residual assay configuration, total markers billed, and report format.

#### DETAILS

The modified panel consists of two tubes with an antibody/fluorochrome configuration identical to the B1 and B3 tubes from the current Hairy Cell Diagnostic panel. The change includes removal of CD2 and addition of CD3, CD5, CD10, and CD123 to the HC residual assay for a net gain of three 88185 CPT charges per test. Standardized configuration between diagnostic and follow-up panels will allow direct comparison of a follow-up case with the diagnostic immunophenotype, improving the ability to detect low numbers of aberrant HCL cells at follow-up. The panel sensitivity is 0.02% (1 residual hairy cell out of 5,000 normal cells) if 100,000 total events is acquired.

The report summary will be enhanced by assay-specific quality metrics, including a calculated limit of detection (LOD) based on the total number of analyzed events for the specimen. Abnormal reports will include the relative frequency (percentage) and an immunophenotypic summary of the aberrant cells. Normal specimen reports will include percentages of B and T lymphocytes along with a calculated Kappa:Lambda ratio for B cells. Percent positivity for individual markers and peripheral blood reference ranges for CD11c/CD22, CD22/CD103, and CD25/CD103 will no longer be reported.

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# MICROBIOLOGY

## Group B Strep Rapid DNA PCR obsolete

### QUICK REFERENCE

On Tuesday, August 3, 2021, the “rapid” PCR test for Group B Strep (GBS) was discontinued at Allina Health.

### DETAILS

Due to changes in the ACOG guidelines for laboring patients with unknown GBS status, on August 3, 2021, the rapid PCR test for Group B Strep, Group B Strep Rapid DNA PCR (8127/LAB8127) was discontinued. Please note that the rapid GBS assay is not the same as the prenatal Group B Strep PCR screen. The rapid GBS test is performed directly from a vaginal/rectal swab but sensitivity as low as 62% has been reported whereas the Vaginal/rectal OB Strep PCR (14203/LAB14203) is performed on a culture broth after overnight incubation with high sensitivity (>92%).

Due to the poor sensitivity of the Group B Strep Rapid DNA PCR assay, the [2019 ACOG guidelines](#) no longer recommend rapid testing for laboring patients with unknown GBS status. Instead, the guidelines recommend intrapartum antibiotics based on risk-factors:

- Intrapartum fever  $\geq 100.4^{\circ}\text{F}$  ( $\geq 38^{\circ}\text{C}$ )
- Delivery before 37+0 weeks of gestation
- Rupture of membranes  $\geq 18$  hours
- Previous delivery of an infant affected by GBS disease
- GBS bacteriuria in the current pregnancy

## Cryptosporidium test obsolete

Due to nationwide manufacturing supply chain issues and for best practice in clinical diagnosis of infectious parasitic diarrhea, on August 17, 2021, the Cryptosporidium test, 6542/87328.0, became obsolete and was made not orderable.

### DETAILS

The suggested alternative test is the [Cryptosporidium/Giardia antigen combination assay](#) (14473/LAB14473).

## Giardia antigen assay obsolete

Due to nationwide manufacturing supply chain issues and for best practice in clinical diagnosis of infectious parasitic diarrhea, on August 17, 2021, the Giardia antigen assay, 6695/87329.0, became obsolete and was made not orderable.

### DETAILS

The suggested alternative test is the [Cryptosporidium/Giardia antigen combination assay](#) (14473/LAB14473).

## Cryptosporidium/Giardia antigen assay available

### QUICK REFERENCE

On Tuesday, August 17, 2021, a new test, [Cryptosporidium/Giardia antigen](#) (14473/LAB14473), was made available for order.

### DETAILS

The new Cryptosporidium/Giardia Antigen combination assay replaces the individual Cryptosporidium and Giardia tests. Both Cryptosporidium and Giardia antigens will be performed and results will be reported simultaneously. The new assay has higher sensitivities and specificities than the individual assays:

Giardia - 94% sensitivity and 100% specificity  
Cryptosporidium - 98% sensitivity and 100% specificity

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## REFERRAL TESTING

### ImmuKnow assay available with unique ordering code

Effective August 3, 2021, the ImmuKnow assay, referred to LabCorp, became orderable with a unique test code and no longer requires use of the Miscellaneous sendout test code (994/LAB994).

	Previous	NEW
<b>Test number</b>	994	14469
<b>Abbreviation</b>	MSO	ICF

*Interfaced clients: if this is a test utilized at your practice, contact your AHL account representative to obtain build information, and to arrange testing.*

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***Thank you for choosing Allina Health Laboratory ~***

***We appreciate your business!***