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# COAGULATION

## aPTT reference range change

On July 20, 2021, Allina Health Laboratory will be transitioning to a new lot of aPTT reagent, which requires thorough validation testing to establish new “Normal Reference” and “Therapeutic Heparin Response” ranges. This process occurs approximately every 12 months when a new lot of reagent is made available by the instrumentation reagent vendor.

As we prepare for changing to a new aPTT 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. Heparin responsiveness of the new lot of aPTT reagent is also assessed in more than 100 patients currently on heparin therapy, which is correlated with anti-Xa chromogenic heparin levels. This correlation study is the basis for the new heparin aPTT therapeutic range.

	Current	<i>NEW</i>
Normal reference range	24 – 34 seconds	25 – 36 seconds
Heparin therapeutic range	74 – 104 seconds	76 – 99 seconds

## Prottime/INR reference range change

On July 6, 2021, Allina Health Laboratory will be transitioning to a new lot of Prothrombin Time reagent, which requires thorough validation testing to establish a new mean normal reference time. The new normal Prottime is used to calculate the International Normalized Ratio (INR) for each new lot of thromboplastin. This process occurs approximately every 12 months when a new lot of reagent has been made available by the instrumentation reagent vendor.

As we prepare for changing to a new Prottime reagent lot, Allina Health Laboratories 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 Prottime 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 Prottime reference range	12.0 – 14.6 sec
<i>NEW</i> Prottime reference range	11.8 – 13.9 sec

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# MOLECULAR DIAGNOSTICS

## HPV high risk reporting changes

Effective June 1, 2021, a reporting change for the HPV high risk (6595/87621.0) assay went into effect.

With this change, for any orders for HPV high risk PCR received on or after June 1st, the results include discrete results for HPV type 16, HPV type 18 and HPV other high risk types. Prior to this, a single positive or negative result was reported for all high risk HPV types. There was no change to CPT code or pricing associated with this reporting change.

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## REFERRAL TESTING

### Immune cell function assay no longer available

The Immune cell function assay (8782/LAB8782), referred to Viracor-IBT, is no longer available.

The suggested replacement test is the ImmuKnow assay (994/LAB994) referred to LabCorp.

### ImmuKnow assay available

Effective immediately, the Immuknow assay (994/LAB994), referred to LabCorp, is available to order.

The Immuknow assay, a transplant physician's means of obtaining and monitoring information about immune status, is the suggested replacement assay for the Immune cell function assay, which is no longer available.

## ImmuKnow-994

Test Info	Specimen	Performance	Clinical and Interpretive info	Billing	Tracking
<b>Test name:</b>		ImmuKnow			
<b>Test number:</b>		994			
<b>Excellian order number:</b>		LAB994			
<b>Abbreviation:</b>		MSO			
<b>Alternate names:</b>		Cellular Function Assay (involving stimulation and detection of a biomarker) Cylex Immune Assay Immuno Test Immunosuppression Level Assay Immune cell function			
<b>Useful for:</b>		This test is a transplant physician's means of obtaining and monitoring information about immune status. ImmuKnow® measures the adenosine triphosphate (ATP) response of stimulated peripheral blood lymphocytes.			

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## RESULTS RELEASE

### 21<sup>st</sup> Century Cures Act and release of results to My Account

In December of 2016, the US congress developed federal regulations called the 21<sup>st</sup> Century Cures Act. A part of this act addresses giving patients and their health care providers secure access to health information and promotion of timely sharing of patient data.

Teams throughout Allina Health have worked for months to design and determine the display of patient health information via the Allina Health account (MyChart). The decisions around what clinical information and timing of display has been determined with input from clinical and operational stakeholders, Excellian application teams and others.

To accommodate the new 21st Century Cures Act, as a temporary measure to alleviate concerns and allow additional time to adjust, on April 12, 2021, Allina Health shifted identified lab results (STD's, pathology and genetic testing) to a seven day delay to allow the ordering provider time to review the results and communicate to the patient.

In response to recent additional clarifying information from the Office of the National Coordinator (ONC) indicating that delays are not in compliance with the intent of the Cures Act, and could be considered information blocking and result in fines, Allina Health will shift to an *immediate release of all lab results* including pathology. This transition will occur on Tuesday, July 13, 2021.

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## SUPPLIES

### Critical nation-wide Sodium citrate tube shortage

Becton Dickinson (BD) has discontinued production of the 4.5mL Light blue Sodium citrate (Na cit) tubes. We have exhausted our stock, and the item has been removed from our Supply Catalog.

At the same time, there is a rolling manufacturer backorder of the 2.7mL Light blue Sodium citrate (Na cit) tubes causing a critical nationwide shortage of these tubes.



In order for Allina Health Laboratory to best manage our limited supplies of these tubes we are asking the following of our clients:

- Review your inventory of the light blue sodium citrate tubes and return any unexpired excess
- Use your shortest outdate tubes first to ensure that we are using all available items prior to expiration
- If you are drawing a specimen using a butterfly or a central/PICC line and need to prime the tubing, do not use a sodium citrate tube for this purpose
  - \* 3mL No additive (Z) vial/tubes are available to order in our catalog to use for priming in these situations

If you have any questions regarding the contents of this message, contact your account

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***Thank you for choosing Allina Health Laboratory -  
we value your business!***