

## In This Issue

### Coagulation

- New aPTT reference ranges

### Help us help you

- Keeping your provider list current

### Immunology

- Cryoglobulin assay to be discontinued

### Molecular Diagnostics

- Cystic Fibrosis screen to transition to referral test

### Referral Testing

- Cryoglobulin, qualitative with quantitative reflex referred to LabCorp available
- New Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis to be offered

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## COAGULATION

### New aPTT reference ranges

#### Quick Reference

Changing to a new lot of aPTT reagent 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.

#### Details

As we prepare for changing to a new aPTT 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.

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.

This change will go into effect on Aug 16, 2022.

	Current (seconds)	New (seconds)
Normal Reference Range	25 - 36	24 - 33
Heparin Therapeutic Range	76 - 99	70 - 95

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## 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 billing page of our website, or contact your Account Representative for assistance.

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## IMMUNOLOGY

### Cryoglobulin assay to be discontinued

#### QUICK REFERENCE

Effective August 16, 2022, Allina Health Laboratory will no longer perform the Cryoglobulin assay in house. The test will be made obsolete and not orderable.

#### DETAILS

The suggested alternative test is the Cryoglobulin with Quantitative Reflex (14596/LAB14956) which will be referred to LabCorp.

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## MOLECULAR DIAGNOSTICS

### Cystic Fibrosis screen to transition to referral test

#### QUICK REFERENCE

In mid-August (*exact date to be determined*), the Cystic Fibrosis Screen (5520/LAB5520) will become obsolete and made not orderable.

#### DETAILS

The reagent used by Allina Health Laboratory to perform the Cystic Fibrosis Screen assay has been discontinued by the manufacturer. It is expected that our current supply will allow us to continue to perform the assay in-house until mid-August. Once the supply is exhausted, the test will become obsolete.

The suggested alternative test is the new Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis assay (14545/LAB14545), referred to LabCorp, which will become orderable at the same time that the in-house test is made obsolete. Complete test information for the referral test will be available in our Test Catalog at the time of go live.

#### Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis-14545

Test info	Specimen	Performance	Clinical and Interpretive info	Billing	Tracking
Test name:	Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis				
Test number:	14545				
Excellian order number:	LAB14545				
Abbreviation:	CFPLC				
Alternate names:	CF carrier				
Tests included:	Detection of 32 CF mutations: G85E; ΔI507; R553X; 711+1G>T; 3659delC; R117H; ΔF508; R560T; 1078delT; 3849+10kbC>T; V520F; R1162X; 1717-1G>A; 3876delA; R334W; G542X; W1282X; 1898+1G>A; 3905insT; R347P; S549N; N1303K; 2183AA>G; 2184delA; R347H; S549R; 394delTT; 2789+5G>A; A455E; G551D; 621+1G>T; 3120+1G>A				
Useful for:	Help determine affected or carrier status for the 32 most common CF mutations				
Limitations:	This assay detects as many as 90% of cystic fibrosis carriers in the Caucasian population. Within other ethnic groups, there may be higher or lower detection efficiency. Includes the mutation profile currently recommended by the ACMG and the ACOG.				

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## REFERRAL TESTING

### Cryoglobulin, qualitative with quantitative reflex referred to LabCorp available August 16th

#### QUICK REFERENCE

Effective August 16, 2022, Allina Health Laboratory will offer the Cryoglobulin with quantitative reflex assay (14596/LAB14596) assay referred to LabCorp.

#### DETAILS

### Cryoglobulin, qualitative with quantitative reflex-14596

Test info	Specimen	Performance	Clinical and Interpretive info	Billing	Tracking
Test name:	Cryoglobulin, qualitative with quantitative reflex				
Test number:	14596				
Excellian order number:	LAB14596				
Abbreviation:	CRYOGLOBULIN				
Tests included:	Qualitative test for cryoglobulin Reflex quantitation (as percentage) and immunofixation of cryoprecipitate if positive.				
Useful for:	Cryoglobulins may be present in macroglobulinemia of Waldenström, myeloma, chronic lymphocytic leukemia, lupus, chronic active hepatitis, and other viral infections.				

Complete test information will be available in the Test Catalog on the effective date; however, there will be no changes to the current specimen collection or processing information.

### New Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis to be offered

#### QUICK REFERENCE

In mid-August (*exact date to be determined*), the Cystic fibrosis (CF) profile, 32 mutations, DNA analysis assay (14545/LAB14545), referred to LabCorp, will become available to order.

## DETAILS

This test is the suggested alternative test for the Cystic fibrosis screen (5520/LAB5520) which will become obsolete upon exhaustion of current reagent supplies.

Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis-14545					
Test info	Specimen	Performance	Clinical and Interpretive info	Billing	Tracking
Test name:	Cystic Fibrosis (CF) profile, 32 mutations, DNA analysis				
Test number:	14545				
Excellian order number:	LAB14545				
Abbreviation:	CFPLC				
Alternate names:	CF carrier				
Tests included:	Detection of 32 CF mutations: G85E; ΔI507; R553X; 711+1G>T; 3659delC; R117H; ΔF508; R560T; 1078delT; 3849+10kbC>T; V520F; R1162X; 1717-1G>A; 3876delA; R334W; G542X; W1282X; 1898+1G>A; 3905insT; R347P; S549N; N1303K; 2183AA>G; 2184delA; R347H; S549R; 394delTT; 2789+5G>A; A455E; G551D; 621+1G>T; 3120+1G>A				
Useful for:	Help determine affected or carrier status for the 32 most common CF mutations				
Limitations:	This assay detects as many as 90% of cystic fibrosis carriers in the Caucasian population. Within other ethnic groups, there may be higher or lower detection efficiency. Includes the mutation profile currently recommended by the ACMG and the ACOG.				

Complete test information will be available in the Test catalog on the yet to be determined effective date.

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

***We value your business!***