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Test Bulletin

September 2023

Activated Partial Thromboplastin Time (Test Order Code APTT) Reference Range Changes

Effective Monday, September 18, 2023, ACL Laboratories standardized a new lot of coagulation reagents and began using a new adult and pediatric reference range for Activated Partial Thromboplastin Time (Test Order Code APTT). ACL has provided Advocate Health Care pharmacies with the new data needed to update the weight-based heparin dosing nomograms.

Prior Reference Range					Reference Range Effective Monday, September 18, 2023		
Test Name	ACL Test Order Code	Age	Reference Range (seconds)	Critical Value	Age	Reference Range (seconds)	Critical Value
Activated Partial Thromboplastin Time	PTT	1 Year and up	22-30	>85	>6months to Adult	22-32	>85
		4 Months up to 1 Year	23-32	>85	<=6months*	Not Established	>85
		28 Days up to 4 Months	20-37	>85			
		6 Days up to 28 Days	21-41	>85			
		2 Days up to 6 Days	21-45	>85			
		0 up to 2 Days	26-41	>85			

*The following comment will be appended to patient result that are <=6 months: "Pediatric reference intervals and Pediatric Therapeutic Range have not been established. Based on published literature, the adult reference interval (22 – 32 seconds) and adult therapeutic range (45 – 65 seconds) is generally applicable down to approximately 6 months of age with younger patients having a slightly higher upper limit by several seconds."

ACL Implements two New In-House Tests for MPN (myeloproliferative neoplasms)

Effective Tuesday, September 19, 2023, ACL Laboratories will implement new tests for MPN (myeloproliferative neoplasms). EPIC Test Order Codes are: LAB11791 and LAB11792.

Clinical indication:

ACL tests offers a comprehensive testing to identify mutations associated with the myeloproliferative neoplasms; polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF). Mutation analysis helps differentiate reactive conditions from MPNs, may provide prognostic diagnostic and therapeutic information related to ET, PMF and PV.

ACL new in-house tests include following test order codes:

JAK2_ET_PMF - JAK2 (V617F) Mutation, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutations with Reflex to MPL Exon 10 Mutations Detection [LAB11791]

JAK2_PV - JAK2 (V617F) Mutation, Qualitative with Reflex to JAK2 Exons; 12,13,14,15 Mutations Detection [LAB11792]

JAK2 QUANTITATIVE [LAB9941]

The following send out and in-house tests will be discontinued effective **Wednesday, September 19, 2023**.

1. ARUP Send out:

- JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to JAK2 Exon 12 Mutation Analysis by PCR [LAB10892]
- JAK2 (V617F) Mutation by ddPCR, Qualitative with Reflex to CALR (Calreticulin) Exon 9 Mutation Analysis by PCR with Reflex to MPL Mutation Detection [LAB10894]
- JAK2 Exon 12 Mutation A [LAB10815]
- Calreticulin Exon 9 Mutation Analysis [LAB9419]
- MPL Mutation Detection by Capillary Electrophoresis [LAB10308]

2. In-house:

- JAK2 QUALITATIVE [LAB8847]

Test Method: This test is performed by Next Generation Sequencing.

Preferred Specimen:

- **Blood:** One lavender (K2EDTA) 3 mL **OR** One pink (K2EDTA) 6 mL
(Also acceptable: One green (sodium heparin, no gel) 3 mL **OR** One green (lithium heparin, no gel))
- **Bone marrow:** One lavender (K2EDTA) 3 mL
(Also acceptable: One green (sodium heparin, no gel) 3 mL **OR** One green (lithium heparin, no gel) 3 mL)

Transport: Refrigerated

Performed: Weekdays

Performing Sites: Illinois Central Laboratory – Molecular Pathology

Reporting Time: Final within 14 days

These new ACL assays have the performance characteristics comparable to the current reference laboratory assays ARUP and Neogenomics and will detect the same relevant DNA mutation variants.

If you have any questions, please contact:

ACL Molecular Pathology Laboratory at Rosemont (ph. 847-349-7182), or
Michael Mihalov, MD – Medical Director (ph. 847-349-7401), or
Lech Mazur, MS – Technical Director (ph. 847-349-7182)

ACL Laboratories Updates Respiratory Pathogen Panel Testing

Test intended for Inpatient Testing Only

Effective, Tuesday, October 17, 2023, ACL Laboratories will change the testing platforms for the Respiratory Pathogen Panel (Test Order Code LAB9955). The current Respiratory Pathogen Panel detects 19 different respiratory viruses (including subtypes) and three different bacterial pathogens. The new panel utilizes similar technology, detects similar pathogens, and has similar sensitivity and specificity as the current panel. As a result updating this panel, testing is simpler to perform enabling a quicker turn-around on test results.

As with the previous version of the respiratory pathogen panel assay, the new version of the panel is **only** intended for use in the inpatient setting on patients who are negative for the presence of influenza, respiratory syncytial virus, and SARS-CoV-2.

For ambulatory and emergency room patients who have signs and symptoms of upper respiratory infection, ACL recommends testing only for the presence of influenza, respiratory syncytial virus, and SARS-CoV-2. Larger respiratory panels have limited clinical utility in the outpatient setting and are often not covered by insurance companies, leading to significant patient out of pocket expenses.

The changes between the current Respiratory Pathogen Panel and the new Panel are outlined below:

- 1) Test name and test order code change.
 - a. **Current and will be discontinued effective Tuesday, October 17, 2023:** — Respiratory Pathogen Panel (Test Order Code LAB9955)
 - b. **Effective Tuesday, October 17, 2023:** Rapid Respiratory Pathogen by PCR (Test Order Code LAB9039)
- 2) The test will no longer be performed by the Illinois Central Molecular Pathology Laboratory.
 - a. **Effective Tuesday, October 17, 2023:** Testing will take place within all Advocate Health Midwest Region Hospitals and within the Illinois and Wisconsin Central Microbiology Departments.
 - b. The turnaround time of the test should decrease significantly with efforts being made to complete testing within 8 hours of receipt within the laboratory.
- 3) The composition of the panel will have the following changes:

Effective Tuesday, October 17, 2023: The following results will be eliminated from the panel	Effective Tuesday, October 17, 2023: The following results will be included in the panel
Human Bocavirus	SARS-CoV-2
<i>Legionella pneumophila</i>	<i>Bordetella pertussis</i>
Respiratory Syncytial Virus A and B will no longer be differentiated (both will still be detected)	<i>Bordetella parapertussis</i>

- 4) **Effective Tuesday, October 17, 2023:** Testing for *Legionella pneumophila* will be referred to ACL’s primary reference laboratory, ARUP Laboratories, using orderable test, “Legionella species by Qualitative PCR.”

The Respiratory Pathogen Panel (Test Order Code LAB9955) will be discontinued **effective Tuesday, October 17, 2023**, and all orders for this test should be placed using Rapid Respiratory Pathogen by PCR (Test Order Code LAB9039).

Outpatient Providers should test for influenza, respiratory syncytial virus, and SARS-CoV-2 as appropriate based on clinical needs.

Please contact ACL Client Services at 1.800.877.7016 with any questions regarding this updated testing approach.