

ACL Implements New In-House Test Dihydropyrimidine Dehydrogenase (DPYD), 6 Variants

Effective Tuesday, September 17, 2024, ACL Laboratories implemented a new test Dihydropyrimidine Dehydrogenase (DPYD), 6 Variants. (Test Order Code LAB12430).

Clinical Indication: The DPYD gene encodes dihydropyrimidine dehydrogenase (DPD), the rate-limiting enzyme for fluoropyrimidine catabolism. Reduced activity of DPD results in reduced clearance and accumulation of 5-fluorouracil. The fluoropyrimidine drugs 5-fluorouracil and capecitabine are widely used in the treatment of solid tumors including colorectal and breast cancer, and cancers of the digestive tract. In individuals with reduced DPD activity, treatment with these drugs can lead to increased levels of 5-fluorouracil cause profound dose-related toxicities, such as severe digestive tract effects, neutropenia, and hand-foot syndrome. In some cases, these toxicities can lead to death.

Test Method: This test will be performed by ACL Laboratories using a laboratory developed test method based on PCR and Mass Spectrometry.

Specimen Requirements: One pink (K2EDTA) 6.0 mL OR Two lavender (K2EDTA) 3.0 mL OR One ORAc collect Dx Buccal Swab kit
Patient preparation for ORAc collect Dx Buccal Swab kit- Collect One buccal swab using the Oracollect collection kit ensuring the sponge tip does not come into contact with any surface prior to collection. Patient should not eat, drink, smoke, or chew gum for 30 minutes before collecting oral sample.

Buccal swab will be orderable for clients using Workday: item # 3029385 Container Collection Liquid Sample Painless Noninvasive Bacteriostatic ORAc collect.

Transport: 5.0 mL (minimum 1.0 mL) whole blood or buccal swab, Refrigerated

Stability: Ambient: 3 days whole blood, 1 week ORAc collect swab; Refrigerated: 2 weeks whole blood, 2 weeks ORAc collect swab; Frozen: Unacceptable

Performed: Weekdays

Performing Sites: Illinois Central Laboratory

Reporting Time: Final within 7 days

Effective Tuesday, September 17 2024, ARUP send out, Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants (Test Order Code LAB9065) has been discontinued.

This new ACL assay includes the three variants tested in the current reference laboratory DPYD assay, as well as three additional variants not in the reference laboratory assay.

| Allele | Clinical Functional Status |
|-----------------------------------|----------------------------|
| Reference (*1) | Normal function |
| c.1905+1G>A (*2A) | Nonfunctional |
| c.1679T>G (*13) | Nonfunctional |
| c.2846A>T | Decreased function |
| c.1129-5923C>G | Decreased function |
| c.1129-5923C>G, c.1236G>A (HapB3) | Decreased function |
| c.557A>G | Decreased function |

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL's website at <https://www.acllaboratories.com/providers/test-directory/>.

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Updated Reference Ranges for Varicella Zoster Virus Immunity IgG Testing

Effective Monday, September 23, 2024, the reference ranges and reporting units changed for Varicella Zoster Virus IgG (Test Order Code VARIC/LAB8230) testing. The manufacturer has reformulated the reagent. With the transition to the new reagent, units of the numerical results will change to “signal to the cut-off (S/CO)”. The reference range will also change from ≥ 165.0 index to ≥ 1.00 S/CO. Interpretative comments will be modified to reflect the changes to the reference range. There are no changes to specimen collection requirements or turnaround time. Summary of the changes are identified below:

| | Former Reagent | New Reagent Effective September 23, 2024 |
|-----------------|---|---|
| Units | Index | S/CO |
| Reference Range | ≥ 165.0 | ≥ 1.00 |
| Interpretation | <p>< 165.0 : Non Immune</p> <p>≥ 165.0 : Immune</p> | <p>< 1.00 : Non Immune</p> <p>≥ 1.00 : Immune</p> |

ACL Discontinues In-House Single Order JAK2 Quantitative (Test Order Code LAB9941)

Effective Tuesday, September 17, 2024, ACL Laboratories discontinued in-house single order JAK2 Quantitative (Test Order Code LAB9941).

This change is intended to eliminate ordering errors, improve turnaround time, and reduce patient cost.

An alternate laboratory test for JAK2 p.V617F Exon 14 analyte is Myeloproliferative Neoplasm Panel (MPN) (Test Order Code LAB12257). MPN panel includes the following genes: JAK2 p.V617F Exon 14, JAK2 Exon 12,13,14,15, CALR Exon 9, and MPL Exon 10. Limit of detection for p.V617F Exon 14 is $> 1\%$.

Collection Requirements:

- Whole Blood: 3.0 mL (Min: 1.5 mL) whole blood refrigerated
- Bone Marrow: 3.0 mL (Min: 1.0 mL) bone marrow refrigerated

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL’s website at <https://www.acllaboratories.com/providers/test-directory/>.

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ACL Announces Methodology Changes in Special Coagulation

Effective Tuesday, September 17, 2024, ACL Laboratories transitioned the following tests from the Siemens BCS and ST4-BIO platform to the Werfen ACL Top 750 platform.

| Allele | Clinical Functional Status |
|---|--|
| Protein C Activity | Protein C Activity, Reflex |
| Protein S Activity | Protein S Activity, Reflex |
| Activated Protein C Resistance | Activated Protein C Resistance, with Reflex |
| Platelet Factor 4, Heparin Associated Antibody* | Platelet Factor 4, Heparin Associated Antibody with Reflex** |
| Inhibitor Screen | Decreased function |

* Replacing – Platelet Factor 4, Heparin Associated Antibody IgG

**Replacing - Platelet Factor 4, Heparin Associated Antibody IgG with Reflex

On ACL Top 750, Platelet Factor 4, Heparin (PF4) Associated Antibody assay will be fully automated latex enhanced immunoassay with ability to detect IgG, IgA and IgM antibody using PF4 polystyrene latex nanoparticle complexes. The PF4 test will report a numeric result and a qualitative result interpretation using ranges below:

| | |
|-------------------|-----------------|
| Negative | 0.0 - 0.9 U/mL |
| Weak Positive | 1.0 - 4.9 U/mL |
| Moderate Positive | 5.0 - 15.9 U/mL |
| Strong Positive | >= 16.0 U/mL |

Modifications to reference ranges and reflex testing are summarized below.

| Test | Before September 17, 2024 | Effective September 17, 2024 |
|--|---------------------------------|--|
| Protein C Activity | 74-116% (Female >16 yrs.) | >70% (Female >16 yrs.) |
| Protein C Activity | 65-121% (Male >16 yrs.) | >70% (Male >16 yrs.) |
| Protein S Activity | 60-110% (Female >16 yrs.) | >60% (Female >16 yrs.) |
| Protein S Activity | 65-125% (Male >16 yrs.) | >60% (Male >16 yrs.) |
| Reflex Changes: Test | Before September 17, 2024 | Effective September 17, 2024 |
| Protein C Activity, Reflex | <74% (Female) | <=70% (Female) |
| Protein C Activity, Reflex | <65% (Male) | <=70% (Male) |
| Protein S Activity, Reflex | <60% or >110% (Female >16 yrs.) | <=60% (Female >16 yrs.) |
| Protein S Activity, Reflex | <65% or >125% (Male >16 yrs.) | <=60% (Male >16 yrs.) |
| Platelet Factor 4, Heparin Associated Antibody IgG with Reflex | Positive or Equivocal | Weak Positive, Moderate Positive, or Strong Positive |

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL's website at <https://www.acllaboratories.com/providers/test-directory/>.

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ACL Laboratories Updates Test Order Codes

ACL is currently updating test order codes that have alpha codes, i.e., current Test Order Code BPNL will change to Test Order Code LAB8235.

August 2024 test order code updates were previously included in ACL’s monthly Outreach Bundle communication. We are including August, September, and October changes in this bulletin as another reminder. Changes are being made in batches and will continue to be provided in ACL’s Outreach Bundle communication as well as included in monthly Test Bulletins.

Below is a list of changes that will be happening in October, as well as the changes that occurred in August and September. Due to the holidays, we will not be making any changes in November, December, and January. We will begin updating test order codes in February 2025.

Please ensure your EMR test compendium is updated with ACL’s new test order codes.

Changes Effective August 2024

| Test Name | Prior Test Order Code | Current Test Order Code |
|---|-----------------------|-------------------------|
| Thyroid Stimulating Hormone Reflex | TSHR | LAB8168 |
| C Reactive Protein | CRP | LAB8181 |
| Vitamin D -25 Hydroxy | 25VDR | LAB8229 |
| Ferritin | FERR | LAB8259 |
| GGT | GGTP | LAB8263 |
| Glycohemoglobin | GLYH | LAB8266 |
| Magnesium | MG | LAB8274 |
| Sedimentation Rate | RESR | LAB8381 |
| HIV 1/HIV 2 Antigen/Antibody Screen | HIVSCR | LAB8483 |
| SYPT T. pallidum Total IgG/IgM Ab Reverse Syphilis Screen Algorithm | SYPT | LAB8563 |
| Urine, Bacterial Culture | URC | LAB9005 |
| QuantiFERON TB Plus | QUANTP | LAB9049 |

Changes Effective September 2024

| Test Name | Current Test Order Code | New Test Order Code Effective Tuesday, September 17, 2024 |
|--|-------------------------|---|
| Urinalysis & Reflex Microscopy with Culture if Indicated | UACS | LAB10221 |
| Pap Order | PAPTEST | LAB10332 |
| Lipid Panel with Reflex | LIPPNL | LAB8135 |
| Vitamin B12 and Folate | B12FOL | LAB8171 |
| Iron and Total Iron Binding Capacity | IRONP | LAB8203 |
| Basic Metabolic Panel | BPNL | LAB8235 |
| Comprehensive Metabolic Panel | CPNL | LAB8250 |
| Creatinine | CREATG | LAB8253 |
| Hepatic Function Panel | LIVPNL | LAB8267 |
| Lipid Panel Without Reflex | LIPDPL | LAB8270 |
| Phosphorus | PHOS | LAB8279 |
| Free T4 | Ft4 | LAB8262 |

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Changes Effective September 2024 (continued)

| Result Component | Current Test Order Code | New Test Order Code Effective Tuesday, September 17, 2024 |
|------------------|-------------------------|---|
| T4, Free | FT4 | 12300330 |

Changes Effective Tuesday, October 15, 2024

| Test Name | Current Test Order Code | New Test Order Code Effective Tuesday, October 15, 2024 |
|---|-------------------------|---|
| Potassium | K | LAB8282 |
| Sodium | NA | LAB8294 |
| Uric Acid | URIC | LAB8303 |
| Vitamin B12 | VB12 | LAB8306 |
| Prothrombin Time (INR/PT) | PTINR | LAB8443 |
| Urinalysis with Microscopy without Culture | UCOM | LAB8452 |
| Microalbumin Urine Random | MAR | LAB8567 |
| PSA | PSA | LAB9050 |
| Surgical Pathology | BIOPSY | LAB9054 |
| Chlamydia/Gonorrhea by Nucleic Acid Amplification | CGRNA | LAB9939 |

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL’s website at <https://www.acllaboratories.com/providers/test-directory/>.

Alpha Defensin, Lateral

Effective Wednesday, September 4, 2024, Alpha Defensin, Lateral (Test Order Code LAB11582) has been reactivated.

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL’s website at <https://www.acllaboratories.com/providers/test-directory/>.

New Orderable Code for IGF Binding Protein-3, Pediatric

Effective Tuesday, September 17, 2024, IGF Binding Protein-3, Pediatric (Test Order Code LAB12455) is now available as an orderable test code with testing performed at ARUP Laboratories. Providers will no longer have to utilize a Miscellaneous test order code for ordering. Test information is below.

| Test Information | IGF Binding Protein-3, Pediatric (Test Order Code LAB12455) |
|----------------------|---|
| Specimen Requirement | 0.5 mL (min 0.3 mL) serum |
| Collection Tube | Gold Gel |
| Temperature | Frozen |
| Stability | 5 days |
| Methodology | Quantitative Chemiluminescent Immunoassay |
| TAT | 4 days |
| Performing Lab | ARUP |

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL’s website at <https://www.acllaboratories.com/providers/test-directory/>.

Updated Referral Testing Orderable Codes

Effective Tuesday, September 17, 2024, the following send out assays have been updated.

| | Current (Deactivated 9.17.2024) | Replacement (Activated 9.17.2024) | Replacement (Activated 9.17.2024) |
|-----------------|------------------------------------|--|---|
| Test Name | Histoplasma Capsulatum Antigen | Histoplasma Antigen Quantitative by EIA, Serum | Histoplasma Galactomannan Antigen by EIA, Quantitative, Other Body Fluids |
| Test Order Code | LAB9593 | LAB12456 | LAB12457 |
| Performing Lab | CCL | ARUP | ARUP |
| Specimen Type | Serum, CSF, Body Fluid | 2.0mL (min 1.2mL) serum | 2.0mL (min 1.2mL) plasma 1.0mL (min 0.8mL) CSF 1.0mL (min 0.5mL) Bronchoalveolar Lavage |
| Collection Tube | Gold Gel or Sterile Container | Gold Gel | Lavender EDTA Sterile Container for CSF or Bronchoalveolar Lavage |
| Temperature | Refrigerated | Refrigerated | Refrigerated |
| Stability | 2 weeks | 2 weeks | 2 weeks |
| Methodology | Enzyme Immunoassay (EIA) | Enzyme Immunoassay (EIA) | Quantitative Enzyme-Linked Immunosorbent Assay (ELISA) |
| TAT | 6 days | 6 days | 6 days |

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL’s website at <https://www.acllaboratories.com/providers/test-directory/>.