ACL Laboratories
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Test Bulletin

August 2024

Alpha Defensin, Lateral (Test Order Code LAB11582) No Longer Orderable – Other Testing Options Available

Effective immediately, due to a reagent shipping issue, Mayo Laboratory has made this test non-orderable. A referral test option is not available. Alternative test options that ACL performs inhouse is Synovial Fluid Analysis (includes count and differential) (Test Order Code LAB8388) or Prosthetic Joint (14-day hold) Anaerobe, Aerobe, Bacterial Culture with Gram Stain (Test Order Code LAB8989).

Specimen Transport Change for Suspect Measles Panel - WSLH (Test Order Code LAB12290)

Effective Tuesday, August 20, 2024, Suspect Measles Panel - WSLH (Test Order Code LAB12290), transport temperature has been updated from refrigerated to frozen.

New Orderable Code for Procollagen Type I Intact N-Terminal Propeptide

Effective Tuesday, August 20, 2024, Procollagen Type I Intact N-Terminal Propeptide (Test Order Code LAB12424) is available as an orderable test code with testing being performed at ARUP Laboratories. Providers no longer have to utilize a Miscellaneous test order code for ordering. Test information is below.

Test Information	Procollagen Type I Intact N-Terminal Propeptide (Test Order Code LAB12424)
Specimen Requirements	0.5 mL (min 0.2 mL) serum
Collection Tube	Gold Gel
Temperature	Refrigerated
Stability	5 days
Methodology	Quantitative Radioimmunoassay
Turnaround Time	10 days
Performing Lab	ARUP

New Orderable Code for POLE Mutation Analysis, Next-Generation Sequencing

Effective Tuesday, August 20, 2024, POLE Mutation Analysis, Next-Generation Sequencing (Test Order Code LAB12324) is available as an orderable test code with testing being performed at Mayo Laboratories. Providers no longer have to utilize a Miscellaneous test order code for ordering. Test information is below.

Test Information	POLE Mutation Analysis, Next-Generation Sequencing (Test Order Code LAB12324)
Specimen Requirements	Tissue block (preferred) or Tissue Slides
Collection Tube	Tissue Block: Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue. Slides: 1 Stained and 10 unstained
Temperature	Ambient
Stability	Varies
Methodology	Sequence Capture Next-Generation Sequencing (NGS)
Turnaround Time	20 days
Performing Lab	Mayo

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Updated Referral Testing Orderable Codes

Effective Tuesday, August 20, 2024, the following send out assays were updated:

Allergic Bronchopulmonary Aspergillosis (ABPA) Panel		
	Former (Deactivated) Effective Tuesday, August 20, 2024	**Current (Activated) Effective Tuesday, August 20, 2024**
Test Name	Allergic Bronchopulmonary Aspergillosis Panel	Allergic Bronchopulmonary Aspergillosis (ABPA) Panel
Test Order Code	LAB9329	LAB12449
Performing Lab	CCL	ARUP
Specimen Type	Serum	2.3 mL (min 1.0 mL) serum
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	4 weeks	2 weeks
Methodology	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay/Qualitative Immunodiffusion	Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay/Qualitative Immunodiffusion
TAT	9 days	9 days

Neisseria meningitidis Tetravalent Antibodies (Serogroups A, C, W-135 and Y), IgG		
	Former (Deactivated) Effective Tuesday, August 20, 2024	**Current (Activated) Effective Tuesday, August 20, 2024**
Test Name	Neisseria Meningitidis, IgG Vaccine Response	Neisseria meningitidis Tetravalent Antibodies (Serogroups A, C, W-135 and Y), IgG
Test Order Code	LAB9705	LAB12450
Performing Lab	CCL	ARUP
Specimen Type	Serum	1.5 mL (min 0.25 mL) serum
Collection Tube	Gold Gel	Gold Gel
Temperature	Refrigerated	Refrigerated
Stability	2 weeks	2 weeks
Methodology	Quantitative Multiplex Bead Assay	Quantitative Multiplex Bead Assay
TAT	10 days	10 days

Thiocyanate		
	Former (Deactivated) Effective Tuesday, August 20, 2024	**Current (Activated) Effective Tuesday, August 20, 2024**
Test Name	Thiocyanate	Thiocyanate
Test Order Code	LAB9844	LAB12451
Performing Lab	CCL	Quest
Specimen Type	Plasma	3.0 mL (min 1.5 mL) serum
Collection Tube	Lavender	Royal Blue No Additive
Temperature	Refrigerated	Refrigerated
Stability	2 weeks	14 days
Methodology	Spectrophotometry (S)	Colorometric©
TAT	2 days	5 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 our website at https://www.acllaboratories.com/providers/test-directory/.

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Specimen Collection Device Update for SARS-CoV-2 Testing

On Monday, May 6, 2024, the United States Food and Drug Administration (FDA) published a final rule, giving the FDA additional oversight over laboratory developed tests (LDTs). This rule adds significant additional regulation and cost for each test performed using testing platforms, collection devices, or specimen types that have not been formally approved for use by the FDA; even if the laboratory has done an extensive internal validation to demonstrate the accuracy of these methods or specimen types. This increased regulation and cost will require labs to scale back the number of LDTs they are able to perform to ***only*** those tests that are critical for patient care or that are performed in such high volume that the time commitment and cost associated with getting them formally approved for use by the FDA can be justified.

During the SARS-CoV-2 pandemic, due to supply shortages, ACL Laboratories performed an independent validation demonstrating that specimens collected in ESwab™ specimen collection devices were acceptable for use in the detection of SARS-CoV-2. Since these devices are not approved by the FDA for detection of SARS-CoV-2, their continued use will now be subject to additional regulation and cost. Because there are FDA approved devices readily accessible for this testing, ACL Laboratories will not pursue approval from the FDA to continue using ESwab™ collection devices for detection of SARS-CoV-2.

This testing change pertains to the following tests performed at ACL Laboratories:

- **Rapid SARS-CoV-2 by PCR (Test Order Code LAB10644)**
- **COVID/Flu by PCR (Test Order Code LAB10889)**
- **COVID/FLU/RSV Panel (Test Order Code LAB10789)**
- **2019 Novel Coronavirus (SARS-CoV-2) by PCR (Test Order Code LAB10635)**

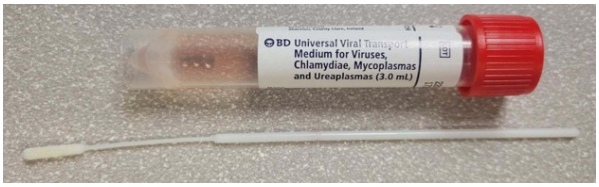
Beginning Monday, November 4, 2024, the following collection devices **will no longer be acceptable** for the tests listed above:

Workday # 1216307

Workday # 1216307

The following collection devices will continue to be acceptable for use with all four of the SARS-CoV-2 tests listed above.

Universal Viral Transport Medium w/ mini-tip nasopharyngeal swab (Workday# 1056987):



M4RT or Universal Viral Transport medium w/ standard tipped swab (Workday# 1215785):

Over the course of the next few months, ACL Laboratories will be updating ACL policies and procedures, ACL's Directory of Services, and the Advocate Health EPIC Procedure Catalog to reflect these changes. Please ensure that your units, hospitals, and clinics have the appropriate collection devices in stock as specimens collected in ESwab™ collection devices and submitted for SARS-CoV-2 detection **will no longer be accepted beginning Monday, November 4, 2024**.

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/.

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Specimen Collection Devices for Rapid Respiratory Pathogen Panel
(Test Order Code LAB9039)

On Monday, May 6, 2024, the United States Food and Drug Administration (FDA) published a final rule, giving the FDA additional oversight over laboratory developed tests (LDTs). This rule adds significant additional oversight and cost for each test performed using testing platforms, collection devices, or specimen types that have not been formally approved for use by the FDA; even if the laboratory has done an extensive internal validation to demonstrate the accuracy of these methods or specimen types. This increased regulation and cost will require labs to scale back the number of LDTs they are able to perform to ***only*** those tests that are critical for patient care or that are performed in such high volume that the time commitment and cost associated with getting them formally approved for use by the FDA can be justified.

During the SARS-CoV-2 pandemic, due to supply shortages, ACL Laboratories performed an independent validation demonstrating that specimens collected in ESwab™ specimen collection devices were acceptable for use with the Rapid Respiratory Pathogen Panel. However, since these devices are not approved by the FDA for this test, their continued use will now be subject to additional regulation and cost. Because there are FDA approved devices readily accessible for this testing, ACL Laboratories will not pursue approval from the FDA to continue using ESwab™ collection devices with the Rapid Respiratory Pathogen Panel.

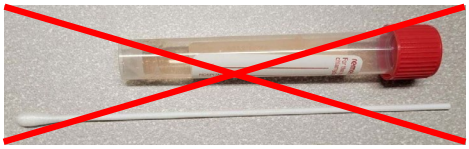
In addition, ACL Laboratories is seeing a significant number of swab specimens submitted with the standard sized tip, which cannot be used to appropriately collect a nasopharyngeal swab. The only swab specimens approved for use with this test by the FDA are mini-tipped (nasopharyngeal) swabs submitted in viral transport medium.

Beginning Monday, November 4, 2024, the following collection devices **will no longer be acceptable** for the Rapid Respiratory Pathogen Panel (Test Order Code LAB9039):

Workday # 1216307

Workday # 1216307

Workday # 1215785



The Universal Viral Transport Medium w/ mini-tip nasopharyngeal swab device (Workday # 1056987) **will be acceptable** for use with the Rapid Respiratory Pathogen Panel (Test Order Code LAB9039):

Over the course of the next few months, ACL Laboratories will be updating ACL policies and procedures, ACL's Directory of Services, and the Advocate Health EPIC Procedure Catalog to reflect these changes. Please ensure that your units, hospitals, and clinics have the appropriate collection devices in stock as swab specimens collected in ESwab™ collection devices and specimens submitted in viral transport medium with standard tipped swabs for the Rapid Respiratory Pathogen Panel **will no longer be accepted beginning Monday, November 4, 2024.**

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/**.**

2019 Novel Coronavirus (SARS-CoV-2) PCR (Test Order Code LAB10635) Testing Transitions from ACL's Illinois Central Laboratory to ACL's Wisconsin Central Laboratory

Effective Tuesday, August 20, 2024, ACL Laboratories transitioned testing of SARS-CoV2 by PCR (Test Order Code LAB10635) from ACL's Illinois Central Laboratory to ACL's Wisconsin Central Laboratory.

Specimen collection requirements will remain the same. Laboratory testing for both Wisconsin and Illinois will be routed to and performed at ACL's Wisconsin Central Laboratory's Cytology/Cyto-Molecular Department.

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 Implements New Methodology in Special Coagulation

Effective Tuesday, August 20, 2024, ACL Laboratories transitioned from the Siemens BCS platform to the Werfen ACL Top 750 platform for the following test order codes.

FACTOR II ASSAY	PLASMINOGEN ACTIVITY
FACTOR V ACTIVITY	FACTOR VIII INHIBITOR
FACTOR VII ASSAY	FACTOR IX INHIBITOR
FACTOR VIII ASSAY	COAGULATION INHIBITOR ASSAY
FACTOR IX ASSAY	VON WILLEBRAND ACTIVITY, REFLEX
FACTOR X ASSAY	VON WILLEBRAND ACTIVITY
FACTOR XI ASSAY	VON WILLEBRAND ANTIGEN
FACTOR XII ASSAY	FACTOR XIII ANTIGEN (Replacing Factor XIII Activity)

Additionally, the Factor XIII Activity test has been discontinued and replaced by the Factor XIII Antigen test. Both tests measure Factor XIII levels in vitro using different methods. The Factor XIII Activity test is a chromogenic assay that involves an enzymatic reaction measured at a specific absorbance.

The new Factor XIII Antigen test uses a photometric assay with latex particles coated with antibodies directed against the A-subunit of FXIII. The degree of agglutination is directly proportional to the concentration of FXIII antigen in the sample and is determined by measuring the decrease in transmitted light caused by the aggregates.

Apart from changes to the reference ranges, there will be no other modifications to ACL's Directory of Services. The new reference ranges are as follows:

Test Name	Test Order Code	New Reference Ranges Effective Tuesday, August 20, 2024	Reference Ranges Prior to Tuesday, August 20, 2024
FACTOR II ASSAY	LAB8404	**> 79%**	50-150%
FACTOR V ACTIVITY	LAB8430	**> 74%**	50-150%
FACTOR VII ASSAY	LAB8405	**> 64%**	50-150%
FACTOR VIII ASSAY	LAB8428	**> 50%**	50-150%
FACTOR IX ASSAY	LAB8429	**> 75%**	50-150%
FACTOR X ASSAY	LAB8400	**> 70%**	50-150%
FACTOR XI ASSAY	LAB8401	**> 75%**	50-150%
FACTOR XII ASSAY	LAB8402	**> 50%**	50-150%
FACTOR XIII ANTIGEN (Replaces FACTOR XIII Activity)	LAB12388	**> 50%**	60-146%
PLASMINOGEN ACTIVITY	LAB8435	**> 80%**	72-139%
VON WILLEBRAND ACTIVITY	LAB8441	**> 45%**	53-176% Male / 53-172% Female
VON WILLEBRAND ANTIGEN	LAB8442	**> 60%**	51-156% Male / 49-151% Female

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 Resumes Testing – Myeloid Malignancies Mutation Panel by Next Generation Sequencing

Effective Monday, August 19, 2024, ACL Laboratories Molecular Pathology Department resumed Myeloid Malignancies Mutation Panel by Next Generation Sequencing (Test Order Code LAB11222).

ARUP Test Order Code LAB10597 / NGAML has been deactivated.

Test is orderable in EPIC BKR LIS system.

If you have any questions, please contact: ACL Molecular Pathology Department at Rosemont (ph. 847.349.7182), Michael Mihalov, MD - Medical Director (ph. 847.349.7401), or Lech Mazur, MS - Technical Director (ph. 847.349.7185)

Prenatal Testing Guide

Test Order Code	Test Name(s)	When to Order
ABRHSN	Type (ABO.Rh) and antibody screen	When you need to know both the patient's blood type and if they have clinically significant antibodies that need to be monitored during pregnancy. This order includes the codes ABRH (ABO/ Rh) and AS (red cell antibody screen). This test should also be used for patients who are going to receive Rh Immune Globulin in a physician's office. Positive antibody screens with clinically significant antibodies will automatically reflex to an antibody titer.
ABRH	Type (ABO/Rh)	When you only need to know the patient's blood type (ABO and/ or Rh.)
AS	Antibody screen	When you only need to know if the patient has clinically significant antibodies that need to be monitored during pregnancy. Positive antibody screens with clinically significant antibodies will automatically reflex to an antibody titer.
TTR	Antibody titer	When you need to monitor the relative level of a clinically significant antibody throughout pregnancy. This test will be canceled if the antibody screen is negative, even if the patient has a history of a clinically significant antibody. Positive antibody screens with clinically significant antibodies will automatically have a titer performed.
PRENF	Prenatal Father (red cell antigen typing)	When you need to know if the presumed father possesses the antigen that the mother has formed an antibody against, to determine the likelihood that the fetus (or future fetuses) will have the antigen. You must provide the mother's information (name and DOB), as well as the antigen that the father's sample should be typed for.

Notes:

1. It is not possible to order only Rh typing on a patient. If you are only interested in Rh status, order ABRH.
    a. RHPT is a commonly misused test order code. This is to be used for sickle cell patients only and not prenatal patients or presumed fathers.
2. Do not order ABRH and AS separately if you need both tests. Use the code ABRHSN.
3. RHW or RHWED are not the correct tests for prenatal outpatients. Use ABRHSN.

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