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Test Bulletin

November 2024

ACL Laboratories Respiratory Pathogen Panel Testing

Test Intended for Inpatient Testing Only

The Rapid Respiratory Pathogen Panel (Test Order Code LAB9039) offered by ACL Laboratories can detect 19 different respiratory viruses (including types and subtypes) and 4 different bacterial pathogens. In times of high influenza, respiratory syncytial virus (RSV), and/or SARS-CoV-2 (COVID) activity, it will be most effective to prioritize ordering the COVID/FLU/RSV Panel (Test Order Code LAB10789) rather than the Rapid Respiratory Pathogen Panel (Test Order Code LAB9039). It may be reasonable to consider increased use of the Rapid Respiratory Pathogen Panel in times of low influenza, RSV, and COVID activity.

It should be noted that outside of specific outbreaks, the prevalence of the bacterial targets on the panel is low and, at most times, less than 1% of tests performed at ACL are positive for bacterial pathogens. The vast majority of patients tested will receive either a negative result or a positive result for a viral target that is treated supportively and has no specific antiviral treatment regimen. For that reason, the test is often not covered by insurance companies (including Medicare), resulting in high costs to providers and patients. Due to the decreased coverage and the limited number of results that are directly actionable, it is recommended that this test is reserved for those situations in which the result will specifically direct the next step in the patient's treatment rather than as a means to simply "identify" which virus the patient is infected with. This includes utilizing the test in situations where the result may directly impact whether antibiotics are prescribed or whether the result may dictate whether a patient is admitted to the hospital for further care.

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/>.

In-House Allergy Testing

Effective **Monday, November 11, 2024**, ACL Laboratories will perform allergy testing in-house. Previously testing was sent to various reference laboratories. The technology or methodology used for testing will **not** change. Testing will continue to be performed using the Quantitative ImmunoCAP™ Fluorescent Enzyme Immunoassay on the Phadia™ 1000 system. The Phadia™ ImmunoCAP™ Specific IgE is an invitro quantitative assay which measures the concentration of circulating specific IgE in serum. Specific IgE values should be used in conjunction with other clinical findings for clinical diagnosis of IgE mediated allergic disorders.

Internalization of the testing will lead to an improved turnaround time of 72 hours and offer an expanded menu of orderable panels.

Collection Requirements:

For individual allergens or allergy panels with 6 or fewer allergens:

- **Tube Type:** One gold gel (SST) 5.0 mL OR One red (plain) 6.0 mL.
- **Specimen Preparation:** Centrifuge the tubes to separate the serum from the cells within 2 hours. If not using a gel separator tube, use a pipette to aliquot the serum from the cells within 2 hours.

For larger allergy panels (greater than 6 allergens):

- **Tube Type:** Two gold gel (SST) 5 mL OR Two red (plain) 6 mL.
- **Specimen Preparation:** Centrifuge the tubes to separate the serum from the cells within 2 hours. If not using a gel separator tube, use a pipette to aliquot the serum from the cells within 2 hours.

Important Note: Submitting the minimum volume will **not** allow for repeat testing or add-ons. Add 0.1 mL (minimum 0.05 mL) for each additional allergen ordered.

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/>.

The following reference ranges will append with all the quantitative results.

Reference Range	Units	Interpretation
<0.10	kU/L	None Detected
0.10 - 0.34	kU/L	Equivocal / Very Low
0.35 - 0.69	kU/L	Low
0.70 - 3.49	kU/L	Moderate
3.50 - 17.49	kU/L	High
>17.5	kU/L	Very High


ImmunoCAP™ Specific IgE (SIgE) results above 0.1 kU/L indicates sensitization to the allergen/component tested. Likelihood of allergy is directly related to concentration of SIgE. The absence of detectable SIgE does **not** rule out allergy to an allergen/component. Results must be interpreted with attention to the patient's complete medical history.

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ACL Testing Options for *Mycoplasma pneumoniae* by PCR

The Centers for Disease Control and Prevention (CDC) released an article on **October 18, 2024**, to alert health care providers of the increased prevalence of *Mycoplasma pneumoniae*. While infections have increased among all age groups, the greatest impact has been observed in children and young adults. Most cases of *M. pneumoniae* will result in mild respiratory illness and will resolve without treatment; however, infection can progress to more serious disease (most commonly pneumonia).

The most effective way to diagnose an *M. pneumoniae* infection is with a PCR test from a nasopharyngeal swab or lower respiratory specimen (e.g. sputum, bronchoalveolar lavage, etc.). While ACL does not have a specific orderable test code within EPIC for standalone *M. pneumoniae* PCR testing, testing may be sent to our primary reference laboratory partner, ARUP, through a Miscellaneous Test order as indicated below:

Test Information	
Test Order Code	Miscellaneous Test (LAB10119)
Test Name	<i>M. pneumoniae</i> PCR
Performing Laboratory	ARUP, Test 0060256
Specimen Type	Nasopharyngeal swab in viral transport medium, Sputum, tracheal aspirate, or bronchoalveolar lavage
Specimen Collection	Workday Catalog # 1056987 
Transport	Frozen
Stability	Ambient: 24 Hours Refrigerated: 5 Days Frozen: 1 Year
Methodology	Polymerase chain reaction (PCR)
TAT	6 days
Performing Laboratory	ARUP Laboratories

The CDC recommends that providers consider testing in children for whom *M. pneumoniae* infection is suspected, especially those who are hospitalized with community-acquired pneumonia (CAP) or that have CAP that is not responding to antibiotics known to be ineffective against *M. pneumoniae* (e.g. beta-lactams).

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

References:

<https://www.cdc.gov/ncird/whats-new/mycoplasma-pneumoniae-infections-have-been-increasing.html>

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.aclaboratories.com/providers/test-directory/>.

ACL Makes Methodology Changes in Special Coagulation

Effective **Tuesday, November 19, 2024**, ACL Laboratories will transition the following tests from the Siemens BCS platform to the Werfen ACL Top 750 platform:

- Antithrombin III Antigen (Test Order Code LAB8426)
- Fondaparinux Assay (Test Order Code LAB8408)
- Chromogenic Factor 10, Drug Monitoring (Test Order Code LAB8398)
- Thrombin Time (Test Order Code LAB8422)
- Lupus Anticoagulant (Test Order Code LAB8434)

The collection, shipping/handling instructions and turnaround times will remain same. There will be a modification to reference ranges as follow:

Test Name	Test Order Code	Reference Range Before 11/19/2024	Reference Range After 11/19/2024
Antithrombin III Antigen	LAB8426	78-131 %	>80 %
Chromogenic Factor 10, Drug Monitoring	LAB8398	50-150 % (> 17 yr.)	>70 % (> 17 yr.)
Thrombin Time	LAB8422	15.3 – 21.1 seconds	12.0 – 17.0 seconds

Key Updates to Lupus Anticoagulant test:

- Hexagonal Phospholipid Neutralization performed on Stago ST4-BIO will be discontinued and replaced with Silica Clotting Time (SCT).
- SCT Screen and SCT Confirm are reagents intended to simplify and standardize the detection of Lupus Anticoagulant (LA) in clinical evaluations.
- SCT Screen and SCT Confirm are unaffected by factor VII deficiencies or inhibitors.
- Using a ratio of screen and confirm allows the SCT to be insensitive to warfarin treated samples.
- SCT Screen and SCT Confirm are more specific tests for the evaluation of LA than APTT or dilute PT.

For additional information regarding this test, 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/>.