Effective March 1, 2014

Specimen Collection and Handling Update for Complement Component 4A (Test Order Code COMP4A)

Effective immediately, updated specimen collection and handling guidelines have been added for Complement Component 4A (Test Order Code COMP4A).

Specimen Requirements
Collect: One lavender (EDTA) 3.0 mL blood

Special Handling Requirements:
Specimen collection **MUST** be scheduled. Please call Client Services at 1.800.877.7016 extension #4 to schedule collection at a designated ACL hospital based laboratory. Designated ACL hospital collection locations are listed below:

Illinois-Hospital Sites: Advocate Christ Medical Center, Advocate Condell Hospital, Advocate Good Samaritan Hospital, Advocate Good Shepherd Hospital, Advocate Illinois Masonic Medical Center, Advocate Lutheran General Hospital, Advocate South Suburban Hospital, and Advocate Trinity Hospital

Wisconsin-Hospital Sites: Aurora Bay Area Medical Center, Aurora Baycare Medical Center, Aurora Lakeland Medical Center, Aurora Medical Center Grafton, Aurora Medical Center Hartford, Aurora Medical Center Kenosha, Aurora Medical Center of Manitowoc County, Aurora Medical Center of Sheboygan County, Aurora Medical Center Oshkosh, Aurora Medical Center Summit, Aurora Memorial Hospital of Burlington, Aurora St. Lukes Medical Center, Aurora St. Lukes South Shore, Aurora Sinai Medical Center, and the Aurora West Allis Medical Center Patient Service Center (PSC)

Dry ice requirement – If dry ice is not readily available, contact ACL Logistics at 1.800.877.7016 extension #3 to have dry ice delivered to the site **prior** to collection.

SAFETY PRECAUTIONS when handling dry ice:

- **Never** allow any unprotected part of your skin to touch solid carbon dioxide (CO2). Dry ice will cause severe frostbite or injury.
- When handling dry ice, personal protective equipment **MUST** be used at all times. This includes loose fitting insulated gloves, metal scoop and safety glasses.
- Store dry ice in a Styrofoam container or special cooler designed for the storage of dry ice.
  - **Caution:** Placing dry ice into a tightly sealed container can permit sufficient gas build up to cause an explosion.
- Do **not** store dry ice in confined areas such as refrigerators or freezers.

Separate plasma from cells:
4° C centrifuge – separate cells within 1 hour and place plasma on dry ice or in a -70° C freezer.
Room Temperature centrifuge – separate cells within 30 minutes and place plasma on dry ice or in -70°C freezer.

Transport: 1.0 mL (min: 1.0 mL) plasma frozen on dry ice.

CRITICAL: Specimen must be frozen. Specimen **MUST** be maintained at -70°C or on dry ice throughout the entire process. Package specimen alone in a Styrofoam container containing dry ice. Do **not** place with or include other specimens. Specimen container and specimen bag **MUST** be labeled with a Special Handling sticker and a label stating “Specimen **MUST** be kept on dry ice at all times.” Logistics should **not** remove the specimen from the container. Logistics should deliver the specimen in the container to the Central Laboratory for specimen processing.

If you are calling for a special pickup, please inform ACL Logistics that specimen **needs to** be transported on dry ice. Call ACL Logistics at 1.800.877.7016 extension #3 for special pickups.
Specimen Identification and Labeling

All specimens submitted to ACL Laboratories for testing must be appropriately labeled. This requirement assures positive identifications and optimum integrity of patient specimens from time of collection until testing is completed and results reported. Clients will be notified of inappropriately labeled specimens. Unlabeled or incompletely labeled specimens will not be tested (see Specimen Rejection Criteria below).

Specimen Labels

Proper positioning of the patient label is important for automated analyzers. If not positioned properly, results could be delayed.

- Patient labels need to be positioned directly below the tube cap.
- For 13 x 75 tubes: Hold tube horizontally with the cap facing left. Align the patient label as close to the top of the cap as possible.

• If your patient label is >2 inches long, you will need to trim the label to fit properly on the 13x75 tube. DO NOT wrap label to bottom of the tube.

The College of American Pathologists (CAP) requires that primary specimen containers are labeled with at least 2 identifiers (CAP GEN.40491).

1. The patient’s name (full last name, then full first name or initial) is always required.

2. The second patient identifier may be one of the following:
   - Date of birth (month/date/year)
   - Other unique patient identifier that is also on the test requisition, e.g. hospital or patient ID code or file number
   - ACL requisition number or specimen barcode label
   - Other barcode labels can be used if barcode matches the unique identifiers on the printed requisition (the barcode does not need to be human readable)
Each specimen must have a securely affixed label with the following information:

- The patient’s full name written exactly as it appears on the test requisition (e.g., Doe, Jane)
- A second patient identifier as noted above
- Date and time of collection

If the label is hand-written, use a ballpoint pen—do not use a felt tip pen. If glass slides are submitted, use a pencil for labeling the frosted end—two identifiers on the slide are preferred although the patient’s name alone is acceptable.

*When using an electronically generated ACL Laboratories test requisition, place the label lengthwise on the tube.*

**Transfer Tubes:** When submitting a specimen in a container other than the tube used to draw the sample (e.g., transfer vials), also indicate specimen type on the label (e.g., serum, plasma, urine, etc.).

**Cultures:** When submitting specimens for microbiological testing (e.g., cultures, bacterial antigen, microscopic examination) for non-blood specimens, the anatomic source of the sample and the specific organism(s) to be detected, if any, should be specified.

**Surgical Specimens:** Include patient name, date of birth, age, sex, physician name and location, specimen type or source.

**Specimen Rejection Criteria**
Specimens will be rejected and the tests and charges canceled under the following conditions:

- Unlabeled or incompletely labeled specimens
- Name on specimen does not match name on requisition or electronic order
- Leaking specimen
- Broken container
- Incorrect specimen submitted for test requested
- Insufficient volume (QNS)
- Improper specimen transport temperature
- Age of the specimen (test dependent)
- Hemolysis (test dependent)
- Specimens received with no written or electronic order

**ACL Laboratories Implements New Gastrointestinal Pathogen Panel (Test Order Code GPPNL)**

**Effective Wednesday, March 16, 2016,** ACL Laboratories will implement a new multiplex assay. This new assay Gastrointestinal Pathogen Panel (Test Order Code GPPNL) is based on FDA approved reagents from Luminex.

Diarrheal illnesses are caused by a wide range of bacterial, viral and parasitic organisms. Because symptoms are often virtually identical, clinical distinction and selection of appropriate antibiotics is problematic, often leading to inappropriate antibiotic usage. Benefits of the new test offering are:

- Fast, comprehensive results detect and identify > 90% of the causative bacterial, viral, and parasitic causes of gastroenteritis\(^1\)\(^2\)
- One test providing results for 13 pathogens
- Accurate data to aid in better patient management
- 99% Negative Predictive Value (NPV) provides confidence in a negative results
### Bacteria and Bacterial Toxins

<table>
<thead>
<tr>
<th>Bacteria and Bacterial Toxins</th>
<th>Viruses</th>
<th>Parasites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>Adenovirus 40/41</td>
<td>Cryptosporidium</td>
</tr>
<tr>
<td>(C. jejuni, C. coli, lari only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Escherichia coli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(E. coli) 0157</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterotoxigenic E. coli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ETEC) LT/ST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shiga-like Toxin producing E. coli</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(STEC) stx1/stx2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shigella</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(S. boydii, S. sonnei, S. flexneri, and S. dysenteriae)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibrio cholerae</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cholera toxin gene (ctx)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Specimen Requirements:

**Collect:** Stool sample in sterile container or in C&S (Cary-Blair) media

**Transport:** Stool – 5.0 mL (min: 1.0 mL) – refrigerated

For additional information regarding specimen collection requirements, visit ACL Laboratories Directory of Services at http://www.acllaboratories.com/test-catalog/.

### ACL Laboratories Discontinues Test Order Code HBVGEN for HBV genotype and Drug Resistance

Recently, ACL Laboratories implemented a new HBV genotyping test (Test Order Code HBVGT). **Effective Wednesday, March 16, 2016,** the current send out test HBVGEN will be de-activated. The new HBV genotyping test (Test Order Code HBVGT) is based on Laboratory Developed Test (LDT) reagents capable to detect HBV genomic mutations that confer resistance to specific types of antiretroviral drugs in RT polymerase and HBsAg region. This assay was validated on plasma samples, with minimum viral load of 1000 cp/mL. This test provides Drug Resistance status for the following drugs: lamivudine, adefovir, entecavir, telbivudine, tenofovi.

For additional information regarding this test as well as specimen collection requirements, visit ACL Laboratories Directory of Services at http://www.acllaboratories.com/test-catalog/.
### New Test Order Codes

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Current Test Order Code</th>
<th>New Test Order Code</th>
<th>Specimen Type</th>
<th>Preferred Volume</th>
<th>Tube Type</th>
<th>Temperature to Transport</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergen, Latex Specific IgE Panel by RIA</td>
<td>LTXRIA</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>This test had been discontinued. Latex IgE Allergen testing by ImmunoCAP is available. ACL Test Order Code LATEXA.</td>
</tr>
<tr>
<td>Allergen, Latex IgE ImmunoCAP – performed by Fluorescent Enzyme Immunoassay (FEIA) ImmunoCAP.</td>
<td>N/A</td>
<td>LATEXA</td>
<td>Serum</td>
<td>1.0 mL</td>
<td>Gold Gel</td>
<td>Refrigerated</td>
<td>Reported in 3 days. Refer to the ACL Directory of Services for stability and alternate specimen requirements.</td>
</tr>
</tbody>
</table>

### BRCA Test Update

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Current Test Order Code</th>
<th>New Test Order Code</th>
<th>Specimen Type</th>
<th>Preferred Volume</th>
<th>Tube Type</th>
<th>Temperature to Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRCA 1/2 Ashkenazi Founder Panel</td>
<td>BRCAA</td>
<td>BRCAPN</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>BRCA 1/2 Sequencing and Del/Dup Analysis</td>
<td>BRCAA</td>
<td>BRCAAN</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Breast/Ovarian Cancer Panel</td>
<td>NA</td>
<td>BOCP</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>High/Moderate Risk Panel</td>
<td>NA</td>
<td>HMRP</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Comprehensive Cancer Panel</td>
<td>NA</td>
<td>COMCAP</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Colorectal Cancer Panel</td>
<td>NA</td>
<td>COCAPN</td>
<td>Whole Blood</td>
<td>6 mL</td>
<td>Lavender</td>
<td>Refrigerated</td>
</tr>
</tbody>
</table>

For further discussion, please reach out to one of our genetic counselors at 847.349.7440 (ACL Laboratories) or 414.649.5639 (Aurora Health Care).

### CPT Code Update – Correction

#### Correct CPT Code

<table>
<thead>
<tr>
<th>CELPLS</th>
<th>CELIAC PLUS</th>
<th>83520 x3</th>
<th>88347</th>
<th>82784</th>
<th>83182 x2</th>
<th>83520x3</th>
<th>88346</th>
<th>82784</th>
<th>81382 x2</th>
</tr>
</thead>
</table>

#### Incorrect CPT Code from January 2016 Test Bulletin

<table>
<thead>
<tr>
<th>CELPLS</th>
<th>CELIAC PLUS</th>
<th>83520 x3</th>
<th>88347</th>
<th>82784</th>
<th>83182 x2</th>
<th>83520x3</th>
<th>88346</th>
<th>82784</th>
<th>83182 x2</th>
</tr>
</thead>
</table>
Change in Toxicology Testing—Thin Layer Chromatography Discontinued
ACL Laboratories will be eliminating Thin Layer Chromatography testing effective Wednesday, March 16, 2016.

Due to ongoing changes in the health care and laboratory industries along with recent instrumentation issues, ACL Laboratories will no longer perform Thin Layer Chromatography (TLC) testing on Urine Drug panels (Test Order Codes UCOMP, UDINV). Improved technology is available through our reference laboratory partners. ACL will be sending drug panel screening testing to Mayo Medical Laboratories, who utilize Gas Chromatography/Mass Spectrophotometry (GCMS) methodology to screen for 95 drug analytes. Confirmation testing will be by request only and will be sent to Cordant Health Solutions with an additional charge.

It is important that you continue to receive quality testing services. As a result, ACL has made these changes so there is no interruption in your test ordering practices.

The table below summarizes the changes. Please note the Drug Screen Basic test (Test Order Code TOXSU) is performed at ACL’s hospital-based Rapid Response Laboratories, offering 24 hour turnaround time and including many common drugs screened.

<table>
<thead>
<tr>
<th>Test Order Code</th>
<th>Test Description</th>
<th>New Testing</th>
<th>Current Testing</th>
<th>TAT</th>
<th>Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOXSU</td>
<td>Drug Screen Basic—Includes: Amphetamine, Barbiturates, Benzodiazepine, Cocaine, Opiate, Phencyclidine, THC</td>
<td>No change</td>
<td>EIA testing</td>
<td>24 hours</td>
<td>Urine Random, 10.0 mL</td>
</tr>
<tr>
<td>UCOMP</td>
<td>Drug Screen Complete—Includes: Amphetamine, Barbiturates, Cocaine Benzodiazepine, Ethanol, Methadone, Opiate, Phencyclidine, THC</td>
<td>EIA testing performed by ACL Laboratories, GCMS testing performed by Mayo Medical Laboratories</td>
<td>EIA testing and TLC (Thin Layer Chromatography)</td>
<td>24 hour EIA 4-5 days GCMS</td>
<td>Urine, Random 45.0 mL</td>
</tr>
<tr>
<td>UDINV</td>
<td>Drug Investigation—Includes: Amphetamine, Barbiturates, Benzodiazepine, Cocaine, Ethanol, Methadone, Opiate, Phencyclidine, THC Positive EIA screen results except for Benzodiazepine, Ethanol, THC will auto-reflex to a confirmation and be sent to Cordant Health Solutions</td>
<td>EIA testing performed by ACL Laboratories, GCMS testing performed by Mayo</td>
<td>EIA testing and TLC (Thin Layer Chromatography)</td>
<td>48 hour EIA 4-5 days GCMS</td>
<td>48 hour EIA 4-5 days GCMS Urine, Random 45.0 mL</td>
</tr>
</tbody>
</table>

EIA: Enzymatic Immunoassay

Testing for ADAMTS13 Antibody is available

Effective immediately, testing for ADAMTS13 Antibody is available from the Blood Center of Wisconsin (Test Order Code ADAMAB). The supply shortage of commercial reagent for this assay has been resolved. All testing for the reflexive algorithm ADAMTS13 Evaluation is also now available (Test Order Code ADAMEV).

The ADAMTS13 Antibody assay provides evidence of an auto-immune mechanism for ADAMTS13 deficiency. The results are used to aid in the diagnosis of thrombotic thrombocytopenic purpura (TTP).

Zika Virus Announcement

January 28, 2016

The Centers for Disease Control and Prevention (CDC) recently issued a travel alert for Zika virus for those traveling to Central America, South America, the Caribbean, Polynesia, and Mexico. The major concern with Zika virus infection is for pregnant women and maternal-fetal transmission of Zika virus which is suspected of causing microcephaly in the fetus during pregnancy.

Specimen Collection and Transport

**Serum and CSF for Serology**

- Acute and convalescent samples, if available, should be sent together

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>3 to 10 days post onset of symptoms</td>
</tr>
<tr>
<td>Convalescent</td>
<td>2-3 weeks after acute sample</td>
</tr>
</tbody>
</table>

- At least 0.5 ml of serum or 1.0 ml of CSF is required for serology testing. Whole blood will not be accepted. Serum or CSF must be submitted in plastic screw cap tubes 13 mm in diameter (2.0 ml microtube).

**Serum, CSF and Tissue for Nucleic Acid Amplification and Viral Culture**

- For virus isolation or nucleic acid amplification testing, tissue specimens, serum or CSF may be submitted. Tissue specimens should be approximately 1 cm³, quickly frozen at -70 c and shipped on dry ice.

**Illinois**

- If a physician suspects a case of Zika virus, the physician must contact the local health department for approval to test and a case number. County phone numbers can be found at http://www.idph.state.il.us/local/alpha.htm.
- The physician then fills out the Communicable Diseases Laboratory Test Requisition. This form can be downloaded at http://dph.illinois.gov/forms under Clinical Testing. This completed form must accompany the specimen.
- Currently, testing is only available at the CDC. Submit specimens(s) that have been pre-approved for Zika virus testing to Illinois Department of Public Health (IDPH). IDPH will forward them to CDC for testing.

**Wisconsin**

- If a physician suspects a case of Zika virus, please contact Diep (Zip) at 608.267.0249 (phone)/608.261.4976 (fax) or diep.hoangjohnson@dhs.wisconsin.gov. Once Zip approves testing, she will provide your laboratory with a form that must be completed and accompany the specimen.
- Please submit specimen(s) that have been approved for Zika virus testing by the Wisconsin Department of Health Services (WDHS) to the Wisconsin State Laboratory of Hygiene (WSLH) and ACL Laboratories will forward them to the CDC for testing.

**Resources:**

For information on Zika virus infection, please click on the CDC websites below:

Pan American Health Organization (PAHO) information on Zika virus infection and pregnancy fact sheet:

**VAP Assay Update**

Effective immediately, the VAP assay, ACL Test Order Code VAP, is no longer available. On February 28th, the company that provided the VAP assay, Atherotech Diagnostics, closed permanently without any advance notice. Results will be provided on the VAP orders received by Atherotech prior to February 28. The VAP assay was proprietary. Therefore, there is not an exact replacement test at this time.

ACL Laboratories performs a Direct LDL (ACL Test Order Code LDLDIR), which is used to assess a patient’s risk for heart disease or to follow response to therapy to lower cholesterol. Direct LDL is ordered whenever calculation of LDL cholesterol may not be accurate because the patient’s triglycerides are significantly elevated. Elevated levels of LDL, as measured with the Direct LDL test, indicate a greater risk of developing heart disease. Decreasing levels show a response to lipid-lowering lifestyle changes and/or drug therapies and indicate a decreased risk of heart disease. Furthermore, the direct LDL cholesterol assay has been correlated with the CDC-accepted reference method. Thus, results can be related to the epidemiologic data that have been generated for the assessment of CHD risk and the monitoring of therapy to reduce that risk.

The NMR LipoProfile performed at Cleveland Clinic Laboratory is also available.

<table>
<thead>
<tr>
<th>Old Test Order Code</th>
<th>New Test Order Code</th>
<th>Test Description</th>
<th>Tube Type</th>
<th>Preferred Volume</th>
<th>Minimum Volume</th>
<th>Units</th>
<th>Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAP</td>
<td>N/A</td>
<td>VAP Cholesterol</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>LDLDIR</td>
<td>N/A</td>
<td>Direct LDL Cholesterol</td>
<td>Gold Gel</td>
<td>1.0 mL</td>
<td>0.5 mL</td>
<td>mg/dl</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>N/A</td>
<td>NMRLPO</td>
<td>NMR LipoProfile w/Lipid Panel</td>
<td>Serum – Red top (gel tubes unacceptable)</td>
<td>2.0 mL</td>
<td>2.0 mL</td>
<td>mL</td>
<td>Refrigerated*</td>
</tr>
</tbody>
</table>

*Refer to our Directory of Services for more information. [www.aclaboratories.com/test-catalog/](http://www.aclaboratories.com/test-catalog/)

Please accept our apologies for any inconvenience this change may have caused. If you have any questions, please contact Client Services at phone number 1.800.877.7016 and one of our representatives will be happy to assist you.