

Test Bulletin

ACL Laboratories Implements Advanced Technology in Hematology Laboratory Testing

Wednesday, March 21, 2018, ACL Laboratories has implemented new advanced technology in Hematology laboratory testing at four sites – ACL's Central Laboratories in Illinois and Wisconsin, Advocate Christ Medical Center in Illinois, and Aurora St. Luke's Medical Center in Wisconsin. The advanced technology will allow these sites to report an automated 6 part differential. The automated 6 part differential will include the usual neutrophils, lymphocytes, monocytes, eosinophils and basophils, as well as an immature granulocyte population. The immature granulocyte population includes metamyelocytes, myelocytes, and promyelocytes. In addition, the presence or absence of nucleated red blood cells (NRBCs) will be reported on all samples with orders for CBC analysis (CBCA and CBCNO).

Samples flagged by the analyzer for possible increased immature granulocytes (>3%) as well as other abnormalities will continue to have a manual slide review and manual differential performed, if deemed necessary. In addition, any sample with NRBCs will have a manual slide review for confirmation on the first occurrence. These changes only apply to the automated differential. There are no changes to the manual differential. The manual differential will continue to report metamyelocytes, myelocytes, and promyelocytes as separate cell types.

Over the next 12 to 18 months, ACL Laboratories plans to implement the advanced technology at the remainder of ACL's hospital laboratory sites throughout Illinois and Wisconsin.

ACL joins many large laboratories and health care systems using the advanced technology to report a 6 part automated differential and automated NRBCs. Below is a partial list of those laboratories.

- Massachusetts General Hospital
- North Shore Hospital
- Brigham and Women's Hospital
- Tufts Medical Center
- Johns Hopkins
- University of Maryland
- Boston Children's Hospital
- Banner Health System
- MD Anderson Cancer Center
- Houston Methodist Hospitals

- Texas Children's Hospital, Houston, TX
- University of lowa
- University of Washington
- Cleveland Clinic
- University Hospitals Health System
- The Ohio State University Medical Center
- OhioHealth
- Nationwide Children's Hospital

- Vanderbilt University Medical Center
- Northwestern Memorial Hospital
- Northshore University Health
 System
- University of Chicago
- Rush University Medical Center
- Allina Health
- University of Wisconsin Hospitals and Clinics
- Wisconsin Diagnostic Laboratories

Table of Contents

ACL Laboratories Implements Advanced Technology in Hematology Laboratory Testing – 1

ACL Laboratories Discontinues Performing Anaerobe Culture on Kidney Stone Specimens – **2**

Myasthenia Gravis Reflex Testing Update - 2

ACL Laboratories Revises Humoral Immunity Panel - 2

Revised Parathyroid Hormone Assay - 3

Infliximab Testing Update - 3

ACL Laboratories Announces New Test – Neutrophil Oxidative Burst (Test Order Code NOXB) – **3**

ACL Laboratories Introduces Two New Multiplex Assays — GPARX and NORVRX – ${\bf 3}$

Wisconsin Public Health Follow-up and Testing Recommendations for Individuals with Parotitis – Wisconsin PNH Testing Update – Benzodiazepines Quantitation (Test Order Code BNZCFB) – Complete Atopic Dermatitis Panel (Test Order Code CATOP) – Glucagon (Test Order Code GLUCAG) – Mycophenolic Acid (Test Order Code MYCOPH) – Platelet Autoantibodies – Serotonin, Serum (Test Order Code SERTON) – Vitamin B2 (Test Order Code VITB2) –

ACL Laboratories Discontinues Performing Anaerobe Culture on Kidney Stone Specimens

Effective Wednesday, March 21, 2018, ACL Laboratories will only perform Culture, Aerobic with Smear (Test Order Code ROCS) on kidney stone specimens. Kidney Stone(s) will be removed from the appropriate specimen pick lists for Culture, Anaerobic/Aerobic w Smear (Test Order Code AANC) and Extend Hold Anaerobe/Aerobe Cult/Smr (Test Order Code SPROCS).

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 www.acllaboratories.com/test-catalog/.

Myasthenia Gravis Reflex Testing Update

Effective Wednesday, March 21, 2018, ACL Laboratories will update testing for Myasthenia Gravis which will include reflex testing to MuSK Antibody when indicated. This new test, Myasthenia Gravis Panel 2 with Reflex (Test Order Code MGPNL2) has been developed as a primary referral test algorithm in the differential diagnosis of autoimmune and non-autoimmune etiology, monitoring of disease progression, and screening for the presence of thymoma.

Myasthenia Gravis Panel 2 with Reflex (Test Order Code MGPNL2) includes:

- Acetylcholine Receptor Blocking Ab
- Acetylcholine Receptor Binding Ab
- Acetylcholine Receptor Modulating Ab

If Acetylcholine Receptor Blocking is < 15% inhibition, Acetylcholine Receptor binding is <0.30 nmol/l, and Acetylcholine Receptor modulating is < 32% binding inhibition, then MuSK Antibody (RFMUSK) will be performed at an additional charge.

Current Test Order Code	Current Test Description	New Test Order Code	New Test Description
ARABR	Acetylcholine Receptor Antibody Reflexive Panel	MGPNL2	Myasthenia Gravis Panel 2 with Reflex
ACBLR	Acetylcholine Receptor Blocking AB	MGPNL2	Myasthenia Gravis Panel 2 with Reflex
MUSK	MuSK Antibody	RFMUSK	MuSK Antibody

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 www.acllaboratories.com/test-catalog/.

ACL Laboratories Revises Humoral Immunity Panel

Effective Wednesday, March 21, 2018, Humoral Immunity Panel (Test Order Code HUMORL) is being discontinued by Cleveland Clinic Laboratories. The recommended replacement test is Humoral Immunity Panel 1 (Test Order Code HUMIPR) which is performed at ARUP Laboratories. The components of this panel include:

- Diptheria Ab, IgG
- Tetanus Ab, IgG
- Streptococcus Pneumoniae Ab, IgG (14 Serotypes)
- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- Immunoglobulin G Subclass 1,2,3,4

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 www.acllaboratories.com/test-catalog/.

Revised Parathyroid Hormone Assay

Effective immediately, ACL Laboratories implemented a revised method for parathyroid hormone (PTH) testing. This method is used for both intact PTH (Test Order Code INTAC) and intraoperative PTH (Test Order Code PTHIO). See below for reference range changes for intact PTH.

Test Order Code	Test Description	Current Reference Range	New Reference Range
INTAC	Intact PTH	14-72 pg/mL	19-88 pg/mL

Note: The revised method also requires a change in the specimen transport temperature to FROZEN. ACL's Directory of Services (DOS) reflects this change.

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 www.acllaboratories.com/test-catalog/.

Infliximab Testing Update

Effective Wednesday, March 21, 2018, Infliximab Activity & Neutralizing Antibody (Test Order Code IFXNEU) will be inactivated. Infliximab (Remicade) Concentration and Anti-Infliximab Antibody (Test Order Code INFLIX) is the replacement test.

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 www.acllaboratories.com/test-catalog/.

ACL Laboratories Announces New Test – Neutrophil Oxidative Burst (Test Order Code NOXB)

Effective Wednesday, March 21, 2018, ACL Laboratories will offer Neutrophil Oxidative Burst testing. The neutrophil oxidative burst test aids in the diagnosis of Chronic Granulomatous Disease (CGD). This test will be performed by flow cytometry at Ann and Robert H. Lurie Children's Hospital of Chicago.

Chronic Granulomatous Disease (CGD) is characterized by defective microbial killing. The underlying defect is a mutation in one of the four known components of the Nicotinamide Adenine Dinucleotide Phosphate (NADPH) oxidase system leading to an inability to generate toxic oxygen radicals that play a major role in granulocyte/ monocyte mediated killing of phagocytosed organisms.

The CGD flow assay determines the ability of polymorphonuclear leukocyte (PMN) cells to generate an oxidative burst by indirectly measuring the increase in fluorescence generated by the oxidation (by O2-) of a laser sensitive dye, dihydrorhodamine 123. X-Linked CGD patients' PMN's display negligible fluorescence while the PMN's obtained from carriers of the X-linked form of CGD have two populations of fluorescent (normal) and non-fluorescent (abnormal active X chromosome) cells. Autosomal recessive (AR) forms of CGD display intermediate levels of fluorescence while AR-carriers appear practically normal in the assay.

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 www.acllaboratories.com/test-catalog/.

ACL Laboratories Introduces Two New Multiplex Assays — GPARX and NORVRX

Effective Wednesday, March 21, 2018, ACL Laboratories will implement two new multiplex assays — Gastrointestinal Parasites Panel by PCR (Test Order Code GPARX) and Norovirus GI/GII by RT-PCR (Test Order Code NORVRX). These tests will replace current Test Order Codes GPARPN and NORVRS.

Specimen collection requirements, test methodology and transport conditions will remain the same.

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 www.acllaboratories.com/test-catalog/.

Wisconsin Public Health Follow-up and Testing Recommendations for Individuals with Parotitis

The following information pertains to Wisconsin only.

The State of Wisconsin Department of Health Services Division of Public Health recently sent a memo titled "Public Health Follow-up and Testing Recommendations for Individuals with Parotitis".

Recommendations

Below are additional details for ordering and collecting specimens for submission to ACL Laboratories.

The clinician must first contact the patient's local health department. The local health department will determine the risk, and if the patient requires further state laboratory testing. If the clinician has already spoken with their local public health department, see below for ordering and collection information.

Ordering Instructions

If **both** tests are required, place two orders.

Test Name	Test Order Code	Notes that must be added to order
Reference Lab Test Miscellaneous	CREF	Mumps to WSLH
Reference Lab Test Miscellaneous	CREF	Influenza and other respiratory pathogens to WSLH

If only Influenza/respiratory pathogen test is required, place one order:

Test Name	Test Order Code	Notes that must be added to order
Reference Lab Test Miscellaneous	CREF	Influenza and other respiratory pathogens to WSLH

Note: Do **not** order Mumps Virus RNA, Qualitative, Real-Time PCR (Test Order Code PCRMUM) as this test is performed by one of ACL Laboratories Reference Laboratories and has a 6-7 day turnaround time for test results. Additionally, do not order Respiratory Pathogen Panel (Test Order Code RPPNL) or Influenza Rapid Antigen A/B (Test Order Code FLUAG) – as these are performed by ACL Laboratories.

Collection Instructions

Each test requires separate specimen collection using the Universal Transport Media (UTM):

Test	Specimen/Swab Type	Transport
Mumps	Buccal Swab in UTM	Refrigerated
Influenza and other respiratory pathogens	Nasopharyngeal Swab in UTM	Refrigerated

If you have any questions regarding this communication please contact ACL Laboratories Client Services Department at 1.800.877.7016.

Wisconsin PNH Testing Update

The following information only pertains to sites that previously were sending PNH specimens to the St. Lukes Flow Cytometry Department.

Effective Wednesday, March 21, 2018, a new test for Paroxysmal Hemoglobinuria (Test Order Code PNHMK) will be implemented in Wisconsin *only*. **Note**: This **does not** apply to Illinois clients who should continue to order PNH Analysis (Test Order Code TXPNH).

ACL Laboratories Flow Cytometry Technical Advisory Team has determined that due to sensitivity issues with current testing methodology, and the difficulty obtaining true positive samples to validate a new method, ACL will be referring PNH samples to Wisconsin Diagnostic Laboratories for testing. This decision was made to ensure patients with very small amounts of the measured clone will be detected.

The specimen stability has been extended from 24 hours to 48 hours, but specimens can still only be collected Monday through Thursday. Results from a CBC with automated or manual differential performed within the first 24 hours of the PNH sample collection must be included with the specimen.

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 www.acllaboratories.com/test-catalog/.

Benzodiazepines Quantitation (Test Order Code BNZCFB)

Effective Wednesday, March 21, 2018, ARUP Laboratories (ARUP), the performing laboratory, has updated the specimen requirements and added two new additional result components for Benzodiazepines Quantitation (Test Order Code BNZCFB).

Specimen collection requirements are as follows:

Benzodiazepines Quantitation (Test Order Code BNZCFB)	Current Specimen Collection Requirements	Effective Wednesday, March 21, 2018 – New Specimen Collection Requirements
Collect	One Plain Red 6.0 mL (also acceptable: green (sodium heparin no gel) 4.0 mL or lavender (EDTA) 6.0 mL or two gray (sodium fluoride/ potassium oxalate) 2.0 mL). Separate serum or plasma from cells ASAP or	One plain red 6.0 mL (also acceptable: green (sodium heparin no gel) 4.0 mL or Two lavender (EDTA) 3.0 mL or Two gray (sodium fluoride/ potassium oxalate) 2.0 mL). Separate serum or plasma from cells within 2 hours of collection.
	within 2 hours of collection.	Transfer to an ARUP Standard Transport Tube.
Transport	2.0 mL (min: 1.0 mL) serum or plasma refrigerated	2.0 mL (min: 1.0 mL) serum or plasma refrigerated
Unacceptable Conditions	Specimens exposed to repeated freeze/thaw cycles. Separator tubes. Plasma or whole blood collected in light blue (sodium citrate).	Specimens exposed to repeated freeze/thaw cycles. Separator tubes. Plasma or whole blood collected in light blue (sodium citrate). Hemolyzed specimens.
Stability	Ambient: 1 Week Refrigerated: 2 Weeks Frozen: 3 Years	Ambient: 1 Week Refrigerated: 2 Weeks Frozen: 3 Years
Reporting Time	Final within 5 Days	Final within 6 days

Complete Atopic Dermatitis Panel (Test Order Code CATOP)

Effective Wednesday, March 21, 2018, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements.

Specimen collection requirements are as follows:

Complete Atopic Dermatitis Panel (Test Order Code CATOP)	Current Specimen Collection Requirements	Effective Wednesday, March 21, 2018 – New Specimen Collection Requirements
Collect	Two gold gel 5.0 mL	Two gold gel 5.0 mL (also acceptable: Two Plain Red 4.0 mL)
Transport	5.0 mL (min: 5.0 mL) serum refrigerated	5.0 mL (min: 4.5 mL) serum refrigerated Centrifuge and transfer serum into CCL's Sarstedt non-sterile aliquot tube.
Unacceptable Conditions		Lipemic samples may lead to rejection.
Stability	Ambient: 28 Days Refrigerated: 28 Days	Ambient: 4 Weeks Refrigerated: 4 Weeks
Stability	Frozen: 1 Year	Frozen: 1 Year

Glucagon (Test Order Code GLUCAG)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements and test performance for Glucagon (GLUCAG).

Specimen collection requirements are as follows:

Glucagon (Test Order Code GLUCAG)	Current Specimen Collection Requirements	<i>Effective Immediately</i> – New Specimen Collection Requirements
Patient Preparation	Patient should fast overnight	Patient is not required to fast overnight
Collect	One lavender (EDTA) 3.0 mL Draw in pre-chilled lavender (EDTA) tube. Once collected, leave on ice for 10 minutes, then separate plasma from cells ASAP and freeze.	Collect using one Protease Inhibitor tube (PPACK; Phe- Pro-Arg- chloromethylketone). Protease Inhibitor tubes are available at ACL Storeroom (ARUP # 49662 via CCL). A winged collection set or butterfly needle must be used. Mix Well. Separate from cells within 1 hours of collection.
		Transfer plasma to CCL's standard aliquot tube and freeze immediately.
	2.0 mL (min: 0.5 mL) plasma frozen	1.0 mL (min: 0.5 mL) plasma frozen
Transport		Separate specimens must be submitted when multiple tests are ordered.
Unacceptable	Refrigerated.	Ambient
Conditions	Ambient.	Grossly hemolyzed specimens
Stability	Frozen: 90 Days	Refrigerated: 48 Hours after separation from cells
Stability		Frozen: 3 Months after separation from cells
Performed	Monday and Thursday	Tuesday
Reporting Time	Final within 9 Days	Final within 13 Days

Mycophenolic Acid (Test Order Code MYCOPH)

Effective Immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements for Mycophenolic Acid (Test Order Code MYCOPH).

Specimen collection requirements are as follows:

Mycophenolic Acid (Test Order Code MYCOPH)	Current Specimen Collection Requirements	Effective Immediately – New Specimen Collection Requirements	
Collect	One gold gel 3.5 mL (also acceptable: plain red 4.0 mL and lavender (EDTA) 3.0	Plain Red 4.0 mL (also acceptable: lavender (EDTA) 3.0 mL).	
Conect	mL and green (lithium heparin no gel) 6.0 mL)	Centrifuge and transfer into a CCL standard aliquot tube.	
Transport	1.0 mL (min: 0.5 mL) serum or plasma refrigerated	1.0 mL (min: 0.5 mL) serum or plasma refrigerated	
Unacceptable Conditions		Gel Separator Tube	
	Ambient: 8 Hours	Ambient: 8 Hours after separation from cells	
Stability	Refrigerated: 96 Hours	Refrigerated: 96 Hours after separation from cells	
	Frozen: 11 Months	Frozen: 11 Months after separation from cells	

ACL Laboratories

Platelet Autoantibodies

Effective immediately, Platelet Autoantibodies (Test Order Code PLABBC) is temporarily unavailable due to performing laboratory experiencing reagent issues.

ACL is recommending the Platelet Autoantibody Profile, Whole Blood and should be ordered as a miscellaneous test. Specimen collection requirements are as follows:

Platelet Autoantibodies	Current Specimen Collection Requirements	Effective Immediately – New Specimen Collection Requirements
Collect	Four yellow (ACD) 10 mL or 40.0 mL of lavender, EDTA	Four 3.0 mL whole blood lavender (EDTA)
Transport	40.0 mL whole blood refrigerated in cardboard rack	12.0 mL whole blood ambient
Unacceptable Conditions	Specimens greater than 3 days old	Specimens other than EDTA whole blood, Hemolysis
Stability	Refrigerated: 3 Days	Ambient: 72 Hours
Name Change/ Order Update	Platelet Autoantibodies (Test Order Code PLABBC)	Platelet Autoantibody Profile, Whole Blood (order as a miscellaneous test)

Serotonin, Serum (Test Order Code SERTON)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements for Serotonin, Serum (Test Order Code SERTON).

Specimen collection requirements are as follows:

Serotonin, Serum (Test Order Code SERTON)	Current Specimen Collection Requirements	<i>Effective Immediately</i> – New Specimen Collection Requirements
Collect	One Plain Red 4.0 mL Centrifuge, aliquot within 1 hour of collection, and freeze ASAP	One gold Gel 3.5 mL Centrifuge, aliquot within 1 hour of collection, and freeze ASAP
Transport	1.0 mL (min:0.3 mL) serum frozen	1.0 mL (min: 0.3 mL) serum frozen
Unacceptable Conditions	Samples collected in gel tubes. Samples other than serum. Ambient Samples. Non-Frozen specimens will not be accepted.	Samples other than serum. Ambient Samples. Non-Frozen specimens will not be accepted.
Stability	Refrigerated: 24 Hours after separation from cells Frozen: 1 Month after separation from cells	Refrigerated: 24 Hours after separation from cells Frozen: 1 Month after separation from cells

Vitamin B2 (Test Order Code VITB2)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements and test performance for Vitamin B2 (Test Order Code VITB2).

Specimen collection requirements and test performance are as follows:

Vitamin B2 (Test Order Code VITB2)	Current Specimen Collection Requirements	Effective Immediately – New Specimen Collection Requirements
Patient Preparation	Overnight fasting is required. Avoidance of vitamin supplements for 24 hours prior to collection is preferred.	Overnight fasting is not required.
Collect	One lavender (EDTA) 3.0 mL Protect from light during collection, storage and shipment. Centrifuge, aliquot and freeze plasma within 4 hours of collection.	One green (sodium heparin no gel) 4.0 mL (also acceptable: one green (lithium heparin no gel) 2.0 mL and one green (lithium heparin gel) 3.0 mL). Protect specimen from light during collection, storage, and shipment.
		Separate plasma from cells within 1 hour of collection and transfer to amber transport tube.
Transport	2.0 mL (min: 0.5 mL) plasma frozen	1.0 mL (min: 0.5 mL) plasma frozen
	Specimen must be frozen.	Specimen must be frozen.
CRITICAL	Protect from light.	Protect from light.
	Separate samples must be submitted when multiple tests are ordered.	Separate samples must be submitted when multiple tests are ordered.
	Hemolyzed specimen	Hemolyzed specimen
Unacceptable	Lipemic specimen	Lipemic specimen
Conditions		Serum, whole blood, body fluids, EDTA preserved tubes
	Ambient: 4 Hours	Ambient: Unacceptable
Stability	Refrigerated: 24 Hours	Refrigerated: 5 Days
	Frozen: 1 Month	Frozen: 1 Month
Performed	Tuesday, Wednesday, Thursday, Friday, and Saturday	Sunday, Wednesday, and Friday
Reporting time	Final within 6 Days	Final within 8 Days