ACL Laboratories
Every Sample is a Life™

Test Bulletin

December 2017

Important Reminder

ACL Laboratories Specimen Handling during Inclement Weather

All Winter Temperatures:

- Keep specimens and lock box(es) indoors until leaving your facility for the night. The lock box with specimens should be placed outside at the last possible moment to preserve specimen integrity.

Very cold days; between 0-10° F without wind-chill:

- Keep specimens and lock box(es) indoors until leaving for the night. The lock box with specimens should be placed outside at the last possible moment for specimen integrity.
- Wrap specimens – in a towel or padding for additional insulation.
- Inform ACL Logistics of any early closures or cancellations so we can attempt to minimize the time your specimens will remain outside.

Extreme cold; below 0° F without wind-chill:

- Keep specimens and lock box(es) indoors until leaving for the night. The lock box with specimens should be placed outside at the ***last possible*** moment for specimen integrity.
- Wrap specimens – in a towel or padding for additional insulation.
- Inform Logistics of any early closures or cancellations so we can attempt to minimize the time your specimens will remain outside.
- ACL Logistics will implement an internal process that alters routing in order to reduce the pickup window, minimizing the amount of outside exposure to your specimens. It is imperative that Logistics is notified of any site hour changes.

Extreme Summer Temperatures in Excess of 95° F:

- Keep specimens and lock box(es) indoors until leaving for the night. The lock box with specimens should be placed outside at the last possible moment for specimen integrity.
- Inform ACL Logistics of any early closures or cancellations.

Please call ACL Logistics with any questions or concerns at 1.800.877.7016, option #3.

ACL Laboratories Announces New Drug Level Testing

Effective Wednesday, December 13, 2017, ACL laboratories will begin offering testing for the following new tests. The concentration of the drug as well as levels of antibodies to the drug will be included in the report.

Test Name	New Test Order Code
Infliximab (Remicade)	INFLIX
Adalimumab (Humira)	ADALIM
Vedolizumab (Entyvio)	VEDOLZ

Please visit ACL Laboratories Directory of Services for additional information, as well as specimen collection requirements (https://www.acllaboratories.com/test-catalog/).

Change in Performing Laboratory

Effective Wednesday, December 13, 2017, ACL Laboratories will be utilizing our reference laboratory partner ARUP for the following tests previously performed by Prometheus Laboratories.

Test Name	Current Test Order Code	New Test Order Code
Thiopurine Drug Metabolites	P6MP	THIOMT
TPMT Genetics	TMPTG	TPMTGN
TPMT Enzyme	TPMTE	TPMTRB
Celiac Genetics	CELGEN	CELHLA

There will be no change to the methodology utilized by ARUP.

Please visit ACL Laboratories Directory of Services for additional information, as well as specimen collection requirements (https://www.acllaboratories.com/test-catalog/).

Effective Wednesday, December 13, 2017, ACL Laboratories will be utilizing our reference laboratory partner ARUP for the following tests previously performed by Prometheus Laboratories.

Current Test Name	Current Test Order Code	New Test Name	New Test Order Code
Crohn's Prognostic	CROHNS	Crohn's Prognostic Panel	CRODIS
IBD sgi Diagnostic	IBDSGI	IBD Differentiation Panel	IBDPNL

Inflammatory Bowel Disease (IBD) can be subdivided into Crohn's disease (CD) and ulcerative colitis (UC). Both present with symptoms of diarrhea and abdominal pain. It can be difficult to differentiate between CD and UC, but the definitive diagnosis can usually be established by a combination of radiographic, endoscopic and histologic criteria.

Serologic, genetic and inflammation markers have been investigated as a possible means to help differentiate between IBD versus non-IBD and CD versus UC, as well as to assess the probability of disease complications.

Studies have shown neuronal specific antibodies (pANCA) and anti-Saccharomyces cerevisiae IgA and IgG antibodies (ASCA) can be used to differentiate ulcerative colitis from Crohn's disease in many patients suspected of IBD. In addition, anti-Glycan markers can be useful to predict disease phenotype/risk in Crohn's disease.

Systematic reviews have found there is insufficient evidence of clinical utility for many of the additional markers that are included in the Prometheus Laboratories test panels. These new tests, offered by ARUP, contain the established markers that offer the best clinical utility.

Reference: *American Journal of Gastroenterology*, 107:1760-1761, 2012

ACL Laboratories Discontinues Three Culture Test Order Codes that include Gram Stains – Test Order Codes ENPCS, URCS and GCCS

Effective Wednesday, December 13, 2017, ACL Laboratories will deactivate three test order codes that automatically include a Gram Stain as part of the test order. The tests are identified below.

Test Name	ACL Test Order Code
Culture, Enteric Path with Smear	ENPCS
Urine Culture and Smear	URCS
Culture/Smear, GC	GCCS

Please note that ACL currently offers and will continue to offer an enteric pathogen, urine and gonorrhea culture that does ***not*** include a Gram Stain.

Test Name	ACL Test Order Code
Culture, Enteric Pathogen	ENPC
Urine Culture	URC
Culture, GC	GCC

In addition, a stand-alone Gram Stain may be ordered on any specimen type.

Test Name	ACL Test Order Code
Gram (Stain) Smear	GRAS

The clinical utility of a Gram Stain from these specimen types is quite limited and as such, ACL Laboratories receives very few orders for these cultures. Because there are some situations in which a Gram Stain may be beneficial from these specimen types, providers may place an order for a separate Gram Stain ***in addition to*** the order for the specific culture. Some examples of situations in which a Gram Stain may be beneficial from these specimens and how to order the testing are provided below.

Clinical Utility	Tests to Order	ACL Test Order Codes
When *Campylobacter* spp. is suspected	Culture, Enteric Pathogen ***AND*** Gram Smear	ENPC and GRAS
Patient diagnosis is sterile pyuria Staining may aid in determining empiric coverage	Urine Culture ***AND*** Gram Smear	URC and GRAS
Presumptive diagnosis of gonorrhea from a male urethral specimen	Culture, GC ***AND*** Gram Smear	GCC and GRAS

Please contact ACL Laboratories Client Services for additional information regarding this change 1.800.877.7016.

ACL Laboratories Implements New Test – Lung Cancer Fusion Panel by Next Gen Sequencing (NGS) (Test Order Code LUNGFS)

Effective Wednesday, December 13, 2017, ACL Laboratories will implement a new multiplex assay test order code LUNGFS. ACL's new assay Lung Cancer Fusion Panel is based on NGS Quantidex NGS RNA LUNG CANCER panel from Asuragen. This assay is validated on FFPE tumor samples, with minimum 30% tumor cells. The new assay is capable of detecting 107 of the most common known fusions, as well as fusions with unknown partner gene.

Gene and variant
ALK – fusions of exons 19-22
ROS1 – fusions of exons 31-37
NTRK1 – fusions
NTRK3 – fusions
MET – skipping exon 14
RET – fusions of exons 8-13

For additional information, as well as specimen collection requirements visit ACL Laboratories Directory of Services (https://www.acllaboratories.com/test-catalog/).

FibroMeter Liver Fibrosis Test Update

Effective immediately, ACL Laboratories will be unable to offer the FibroSPECT test (Test Order Code FSPECT) as the reference laboratory has discontinued this testing.

Effective Wednesday, December 13, 2017, Test Order Code FSPECT will be inactivated.

The FibroMeter Liver Fibrosis test, performed by ARUP Laboratories is a suitable replacement test. This test, however, is currently not available as an orderable test and will need to be ordered as a Miscellaneous Test until an orderable code is announced in January 2018.

FibroMeter is a blood test used to aid in the evaluation and management of liver fibrosis. This is a non-invasive test that evaluates the level of fibrosis in the liver using algorithms based on several blood biomarkers and patient demographic information. The calculated scores include the following:

- Fibrosis score (FibroMeter)
- Cirrhosis score (CirrhoMeter)
- Necroinflammatory activity score (InflaMeter)

The corresponding Metavir Classification scores are also reported:

- F0 – F4 for fibrosis/cirrhosis
- A0 – A3 for activity grade

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/.

Referral Testing Order Code Modifications

Paraneoplastic Autoantibody Evaluation (Test Order Code PARNEO)

Cleveland Clinic Laboratories has added two new reflexes to this testing panel – Leucine-Rich Glioma Inactivated Protein-1 (LGI1) IgG (Test Order Code LG1RFX) and Contactin-Associated Protein-Like-2 (CASPR2)-IgG, Serum (Test Order Code CASRFX). Reflex testing will be performed at an additional charge, when applicable.

PARNEO Reflex Tests

Test(s) that may or may not be performed, at an additional charge, depending on the result and interpretation of the initial test(s) are identified below.

ACL Test Order Code	Reporting Name	Available Separately	Always Performed
PARGAD	Glutamic Acid Decarboxylase (GAD65) Antibody	Yes. Test Order Code GADCAB	No
PNEOWB	Paraneoplastic Autoantibody, Western Blot Confirmation	No	No
MUSMOD	AChR Receptor (Muscle) Modulating Antibody	No	No
AMPHIP	Amphiphysin Western Blot	No	No
NMDCBA	N-Methyl-D-Aspartate Receptor Antibody Cell Binding Assay	No	No
AMPCBA	AMPA-Receptor Antibody Cell Binding Assay	No	No
GABCBA	Gamma-Amino Butyric acid-type B Receptor Antibody Cell Binding Assay	No	No
NMDIFA	NMDA-RECEPTOR AB IFA	No	No
AMPIFA	AMPA-Receptor Antibody IFA	No	No
GABIFA	Gamma-Amino Butyric acid-type B Receptor Antibody IFA	No	No
NMOA4	NMO Aquaporin 4 IgG, Serum	Yes	No
NMTRFX	NMO/AQP4 Titer Serum	No	No
CRMP	CRMP-5-IgG Western Blot	No	No
LG1RFX	Leucine-Rich Glioma Inactivated Protein-1 (LGI1) IgG	No	No
CASRFX	Contactin-Associated Protein-Like-2 (CASPR2)-IgG, Serum	No	No

Notice to Wisconsin Clients Ordering Drug Testing for Patients with Title 19 MDWI (Medicaid of WI)

Medicaid of WI (Title 19) mandates that only one drug screening test can be ordered per member per day for several drug test/panels. Please review the list of tests that are impacted to ensure you are not ordering tests out of compliance with Medicaid of WI. Implications, if not followed, pose a risk with billing, and could result in billing the client/physician for any additional testing, if ruling is not followed.

Medicaid of WI Ruling:
Only one of three presumptive drug tests may be submitted per day per member.

Presumptive Drug Tests

Test Name	Test Order Code	Drugs or Drug Classes	CPT Code
Drug Management Panel 1	DMPNL1	Methadone Metabolite, Methadone, Naloxone, Codeine, Morphine, Hydrocodone, Hydromorphone, Norhydrocodone, Oxycodone, Oxymorphone, and Noroxycodone	80358, 80361, 80365, Medicare G0480-90
Drug Management Panel 2	DMPNL2	Propoxyphene, Gabapentin, Pregabalin, Tramadol, O-Desmethyl tramadol, Meperidine, Normeperidine, Acetyl Fentanyl, Acetyl Norfentanyl, Fentanyl, Norfentanyl, Carisoprodol, and Meprobamate	80354, 80355, 80362, 80366, 80367, 80369, 80373, Medicare G0480-90
10 Drug Medical Panel & Alcohol	UEIA8	Amphetamine, Benzodiazepine, Ethanol, Opiate, THC Screen, Barbiturates, Cocaine, Methadone, and Phencyclidine	80307
Drug Abuse Panel-Drug Management	DMABUS	Amphetamines, Cocaine, PCP, Marijuana, and 6-Acetylmorphie	80307-90
Drug Screen-Complete	UCOMP	Amphetamine, Benzodiazepine, Ethanol, Opiate, THC, Barbiturates, Cocaine, Methadone, and Phencyclidine	80307
Amphetamines	AMPCFB	Amphetamine, Methylenedioxyamphetamine, Methylenedioxyethylamphetamine, Methamphetamine, Methylenedioxymethamphetamine	80324, 80359, Medicare G0480-90
Barbiturates-Drug Management	DMBARB	Prescribed Medications	80345, Medicare G0480-90

Medicaid of WI Ruling:
Only one of four definitive drug tests may be submitted per day, per member.

Definitive Drug Tests

Test Name	Test Order Code	Drugs or Drug Classes	CPT Code
Benzodiazepine-Drug Management	DMBENZ	7-Aminoclonazepam, 7-Aminoflunitrazepam, Alpha Hydroxy Alprazolam, Midazolam, Desalkyflurazepam, Lorazepam, Nordiazepam, Oxazepam, Alpha Hydroxy Triazolam, and Temazepam	80346, Medicare G0480-90
Buprenorphine and Metabolites, Confirmation/ Quantitation, Urine	UBUPM	Buprenorphine and Metabolite, Norbuprenorphine Quantitation, Buprenorphine Quantitation, Glucuronide, Norbuprenorphine glucuronide	80348, Medicare G0480-90
Carisoprodol-Drug Management	DMCARS	Meprobamate (Carisoprodal metabolite)	80369
Fentanyl-Drug Management	DMFENT	Fentanyl, Norfentanyl	80354, Medicare G0480-90
Gabapentin-Drug Management	DMGABA	Gabapentin	80355
Opiates-Drug Management	DMOPI	Naloxone, Codeine, Morphine, Hydrocodone, Hydromorphone, Norhydrocodone, Oxycodone, Oxymorphone, and Noroxycodone	80361, Medicare G0480-90
Meperidine-Drug Management	DMMEP	Merperidine, Norpeperidine	80362, Medicare G0480-90
Methadone-Drug Management	DMMETD	Methadone, EDDP (methadone metabolite)	80358, Medicare G0480-90
Oxycodone-Drug Management	REF720	Oxycodone, Oxymorphone, Noroxycodone	83925
Propoxyphene and Metabolite Quantitation	PRPCFB	Propoxyphene	80367, Medicare G0480-90
THC Confirmation/Quant	THCCFB	Marijuana metabolite: 9-Carboxytetrahydrocannabinol (THC)	80349, Medicare G0480-90
Tramadol-Drug Management	DMTRAM	Tramadol, Des-Methyl Tramadol	80373