ACL Laboratories
Every Sample is a Life™

Test Bulletin

January 2018

New Reporting Format For Measles And Varicella Immunity Testing

Effective Wednesday, January 24, 2018, ACL Laboratories will no longer report Rubeola Immunity IgG (Test Order Code MEAI) and VZV Immunity IgG (Test Order Code VARIC) testing with numeric values and an appended immunity interpretation comment. ACL will now convert the numeric results for both of these tests to the appropriate immune status of the patient and report "Immune" or "Not Immune".

Re-standardization of Insulin (Test Order Code INSUFR) Testing

Effectively immediately, ACL Laboratories insulin testing has been standardized to the World Health Organization (WHO) 1st IRP 66/304 Standard. As a result of this re-standardization, patient results may be lower than previously reported. The reference interval for insulin is not impacted as a result of this change and will remain 3 – 28 mUnits/mL. The manufacturer is not recommending a review of previously generated results.

Insulin testing is not generally used in isolation in clinical practice. Additional laboratory testing is typically performed along with insulin, including glucose, HbA1c, C-peptide, and proinsulin.

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/.

Hypersensitivity Pneumonitis II Test Modification

Effective Wednesday, January 24, 2018, Hypersensitivity Pneumonitis II (Test Order Code HYPNE2) result for Pigeon Droppings IgG will be removed from the patient report. It was being reported as "Test component is no longer available" due to a test modification completed by Cleveland Clinic Laboratories.

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/.

Revised Parathyroid Hormone Assay

Effective Wednesday, February 19, 2018, ACL Laboratories will implement 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) will reflect 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/.

FibroMeter Liver Fibrosis Test Update

Effective Wednesday, January 24, 2018, ACL Laboratories will offer a new test, FibroMeter Liver Fibrosis (Test Order Code LIVERF).

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/.

ACL Laboratories Announces New Allergen Testing Minimum Specimen Requirements

Effective immediately, ACL Laboratories announces new specimen volume requirements for allergen tests. All individually orderable allergen tests now have the following requirements:

	New Requirement	New Minimum Requirement
Individual Allergen Test	0.5 mL	0.3 mL

Allergen groups or panels now have the following requirements:

Test Code	Group/Panel Test Name	New Requirement	New Minimum Requirement
CEREAL	Allergen, Food, Cereal Group IgE ImmunoCAP	1.0 mL	0.5 mL
FOODRL	Allergen, Food, Food Panel 20 IgE ImmunoCAP	2.5 mL	1.3 mL
FOODS	Allergen, Food, Foods Profile IgE, ImmunoCAP	1.8 mL	0.9 mL
GRASS	Allergen, Grass Panel IgE – ImmunoCAP	1.0 mL	0.5 mL
INHALE	Allergen, Inhalants Group IgE – ImmunoCAP	2.0 mL	1.0 mL
INSCT	Allergen, Insect Group IgE ImmunoCAP	1.0 mL	0.5 mL
NUTPNL	Allergen, Food, Nut Panel IgE ImmunoCAP	1.5 mL	0.7 mL
SEAFDR	Allergen: Seafood Profile ImmunoCAP	1.0 mL	0.5 mL
SHLFSH	Allergen, Food, Shellfish Panel IgE – ImmunoCAP	1.5 mL	0.6 mL
WEEDS	Allergen, Weed, Weed Group IgE ImmunoCAP	1.0 mL	0.5 mL

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/.

2018 CPT Code Changes

ACL Test Order Code	Test Description	2017 CPT Code(s)	2018 CPT Code(s)
TPMTGN	TMPT Genotyping 4 Variants	81401	81335
5FLUO	5-FU 5-Mutations	81400 81401	81400 81346
BBHBBB	Beta Globin Gene Sequencing	81404	81364
MBABPN	Mosquito Borne Antibody Panel	86790 x6	86790 x5 86794
MQBPNL	Mosquito Borne Panel by PCR	87798 x3	87798 x2 87662

Potential Interference of High dose Biotin Supplements on Laboratory Tests

The use of mega-doses of biotin containing supplements (> 300 times the recommended daily dose) is increasing due to claims of their potential to improve hair, nails, and skin. It was first reported in 2016 that mega-doses of biotin could interfere with certain immunoassay laboratory tests that incorporate biotin and streptavidin into their design. This biotin interference has the potential to affect patient laboratory results, producing either falsely high or low results, depending on laboratory test system, thus increasing the potential for misdiagnosis. It should be noted that the vast majority of laboratory tests are NOT impacted by biotin interference.

A limited number of assays used at ACL Laboratories incorporate biotin in their assay architecture but the level of biotin ingestion required to trigger significant interference is very high and unlikely to occur for the majority of patients. Based on the assay design employed, there is the potential for extremely high biotin concentrations to impact the following tests:

Lower/False Negative Results:

- Hepatitis B Surface Antigen, Troponin I, Sex-hormone binding globulin, Thyroglobulin

Higher/False Positive Results:

- Hepatitis A Total, Testosterone, DHEA-Sulfate, Folate

To date, there have been no published scientific reports confirming the inference with these assays on the instrument platforms in use within ACL Laboratories.

Biotin is cleared rapidly by the kidneys, and is generally at levels that will NOT cause interference within 12 hours. In order to minimize interference and ensure accurate results, it is recommended that patients taking mega-dose biotin supplements notify their physician and should wait 8 – 12 hours after their last dose prior to having laboratory testing. Further, physicians need to be aware of this potential source of interference, especially if the laboratory results are inconsistent with the patient clinical presentation.

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/.

FIBRINOGEN Changes

Effective Wednesday, January 24, 2018, ACL Laboratories will implement changes to the fibrinogen test. The changes will involve the ability to flag as critical a sample that has no coagulation detected. The new test order codes and the location and appearance of the test results are identified in the chart below.

New Test Order Codes:

Test Name/ Description	Current Panel/Individual Test Order Code/ Result	New Test Panel/ Individual Test Order Code/Result
Fibrinolysis Panel	COAGC • APTT • PTINR • DDIMER • PLTC • FBGN	COAGC • APTT • PTINR • DDIMER • PLTC • FIBGN
Fibrinogen	FBGN	FIBGN
Critical Value:	FBGN: <90	FBGN: <90 FIBGN: NCGD

The Fibrinogen currently has a numeric critical value for a result between 40 and 89 that will remain the same. Additionally, a result entered as NCGD [no clot detected] will trigger a critical flag. Both results will be handled per ACL's critical results notification procedure and called immediately to the provider.

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 Implements Individual CSF Test Order Codes for Detection of Viral Targets CMV, EV, VZV and HSV

Effective Wednesday, January 24, 2018, ACL Laboratories will implement unique test order codes for detection of viral targets in CSF samples. The following test order codes will be implemented:

Test Order Code	Test Description
CSFHSV	Herpes Simplex Virus 1 and 2 by PCR (CSF)
CSFVZV	Varicella-Zoster Virus by PCR (CSF)
CSFEV	Enterovirus by PCR (CSF)
CSFCMV	Cytomegalovirus by PCR (CSF)

An ACL CSF testing menu is needed to provide more ordering options as well as to improve specimen tracking, and reporting (calls for critical results).

With implementation of the new CSF specific test order codes, CSF will be removed as a source for test order codes Herpes Simplex Virus 1 and 2 by PCR (Test Order Code HSVPCR), Varicella-Zoster Virus by PCR (Test Order Code VZVP), Enterovirus by RT PCR (Test Order Code ERTPCR), and Cytomegalovirus by PCR (Test Order Code CMVQL).