PHYSICIANS LABORATORY SERVICES
www.physlab.com

TECHNICAL BULLETIN

Volume #10 Issue #1 January 2012

NEW TESTING OFFERED AT PLS – EFFECTIVE JANUARY 1, 2012

Gastrointestinal Distress Panel – Test #1304

PERFORMED: VARIOUS DAYS PERFORMING LAB: PLS OMAHA CPT: 86003x12, 83516x4

Physicians Laboratory announces the release of a Gastrointestinal Distress (GI) Panel designed as a second line test for diagnosing recurrent GI symptoms such as abdominal pain, cramping, bloating, constipation, diarrhea, nausea and reflux. These symptoms can be caused by an IgE mediated response to certain foods or from untreated celiac disease. The panel includes IgE specific allergens for 12 allergens and specific antibodies associated with celiac disease:

- Peanut
- Shrimp
- Sesame seed
- Walnut
- Scallop
- Wheat
- Deaminated Gliadin IgG/IgA
- Tissue transglutaminase IgG and IgA
- Hazelnut
- Cow's Milk
- Gluten
- Codfish
- Soybean
- Corn

Ruling these allergen/antibodies out as triggers is as important as identifying them as causative agents. When a positive agent is identified, modification of the diet has improved the quality of life in the majority of patients.

CCP (Cyclic Citrullinated Peptide) - Test #9290

PERFORMED: TWICE PER WEEK PERFORMING LAB: PLS LINCOLN CPT: 86200

Cyclic citrullinated peptide (CCP), IgG antibodies are present in about 69-83% of patients with rheumatoid arthritis (RA) and have specificities of 93-95%. These autoantibodies may be present in the preclinical phase of disease and are associated with future RA development. Patients with weak positive results should be monitored and testing repeated periodically to assess progression of disease. Anti-CCP antibodies are locally produced in inflamed joints of patients with rheumatoid arthritis. In adults, a CCP test is usually ordered along with an RF test when a patient has previously undiagnosed inflammatory arthritis or has been diagnosed with undifferentiated arthritis. A CCP test may also be ordered as a follow-up to a negative RF test when clinical signs, such as symmetrical joint pain and inflammation, lead the physician to suspect RA.

Indications for testing

- A clinical indication of RA but with negative or equivocal RF assays
- As a confirmatory test in the presence of a positive RF test
- Monitoring disease activity and prognosis
- A presumptive diagnosis of patients considered at high risk

Reference Interval:
19 Units or less: Negative
20-39 Units: Weak positive
40-59 Units: Moderate positive
60 Units or Greater: Strong positive

Cardiolipin IgG/IgM - Test # 546

PERFORMED: TWICE PER WEEK PERFORMING LAB: PLS LINCOLN CPT: 86147x2

Most patients with antiphospholipid antibody syndrome (APS) have medium or high levels of anticardiolipin IgG and/or IgM antibodies. Anticardiolipin antibodies occur in higher prevalence in patients with systemic lupus erythrematosis (SLE) or lupus like illnesses, infectious diseases, drug induced lupus syndromes and with advanced age. Antiphospholipid syndrome (APS) is an autoimmune disorder in which autoantibodies are directed against phospholipid-protein complexes. APS is characterized by arterial and venous thrombosis (up to 10% of affected patients), thrombocytopenia, cerebrovascular accidents and/or recurrent fetal miscarriage. All positive results should be repeated on two or more occasions and at least 12 weeks apart to confirm persistence.

Cardiolipin Antibody, IgG	0-14 GPL: Negative 15-19 GPL: Indeterminate 20-80 GPL: Low to Medium positive 81 GPL or above: High positive	**Cardiolipin Antibody, IgM**	0-12 MPL: Negative 13-19 MPL: Indeterminate 20-80 MPL: Low to Medium Positive 81 MPL or above: High positive

Epstein Barr Virus (EBV) Panel – Test #327

PERFORMED: TWICE PER WEEK PERFORMING LAB: PLS LINCOLN CPT: 86665x2, 86664, 86663

EBV infections are prevalent in most populations and primary infections often occur in young children and may be asymptomatic or accompanied by nonspecific minor illness. In persons infected in adolescence, infection is often manifested as infectious mononucleosis (IM). IM is characterized by fever, sore throat, myalgias, lymphadenopathy and hepatosplenomegaly. Initial diagnosis is typically performed using the heterophile agglutination test (monospot). EBV serology can be used to differentiate heterophile negative infections from IM-like illnesses such as CMV, toxoplasmosis, etc. Approximately 90% of the adult population will have been infected with EBV sometime in the past and will be positive for anti-VCA-IgG and anti-EBNA.
Antibodies to EBNA develop 6-8 weeks after primary infection and remain present for life. Presence of EA-D antibodies indicates recent primary infection, chronic infection or reactivation with EBV.

The panel consists of the following tests:

- Epstein-Barr Virus Antibody to Viral Capsid Antigen, IgG (VCA IgG),
  - Clarify or confirm equivocal or negative Monospot test, especially in patients at risk for splenic rupture (contact sports)
- Epstein-Barr Virus Antibody to Viral Capsid Antigen IgM (VCA IgM)
  - Presence of VCA IgM antibodies indicates recent primary infection with Epstein-Barr virus (EBV).
- Epstein-Barr Virus Antibody to Nuclear Antigen, IgG (EBNA, IgG)
  - Confirm previous infection with EBV.
- Epstein-Barr Virus Antibody to Early D Antigen, IgG (EA-D)
  - Confirm chronic active mononucleosis, post-transplant lymphoproliferative disease and nasopharyngeal carcinoma.

EBV Panel Interpretation				
VCA IgG	VCA IgM	EA-D	EBNA IgG	Interpretation
-	-	-	-	No previous exposure, susceptible
+	+	+	-	Current or recent infection
+	-	-	+	Past infection, EBNA becomes positive 2-4 months post infection, present for life.
+	+	-	-	Recent infection with loss of EA-D which is positive for 1-2 weeks post infection, but may persist for up to 6 months.
+	-	+	+	Past infection with possible reactivation of infection or subclinical infection. Up to 20% of the population has persistently detectable EA-D IgG values.

Bordetella Pertussis & Parapertussis by Real Time PCR – Test #8201

PERFORMED: VARIOUS DAYS PERFORMING LAB: PLS OMAHA CPT: 87801

Physicians Laboratory is pleased to announce the Molecular Diagnostics Department will perform real-time PCR assays for Bordetella Pertussis and Parapertussis effective 01/01/2012.

To detect fastidious organisms that are significant by their presence even in the asymptomatic individual, PCR is the method of choice for direct detection of *B. pertussis* and *B. parapertussis* in clinical specimens. The diagnostic sensitivity of PCR for pertussis syndrome has been reported to be 93-95%.

This assay is appropriate for diagnosis of pertussis syndrome in children with consistent epidemiological and clinical features of disease. The test is also appropriate in the adult with persistent cough in whom pertussis is suspect.

Place nasopharyngeal swabs in M4 transport media and refrigerate for transport. Collect samples as early in the course of clinical illness as possible.

Connective Tissue Disease Profile – Test #8210

PERFORMED: WEDNESDAY PERFORMING LAB: PLS LINCOLN CPT: 86225, 86235x6, 86038

Effective, January 1, 2012, test number #2099 will be replaced by #8210 Connective Tissue Disease Profile. Single Stranded DNA is not included in the new CTD panel. Clinically, the presence of anti-ssDNA is highly nonspecific and thus not useful for diagnostic purposes. All of the individual components of the new CTD panel are performed at the PLS - Lincoln location and can be ordered as individual tests. The new test numbers and CPT codes are as follows:

#8210	Connective Tissue Disease Profile			
	#8207	Double Stranded DNA (dsDNA), IgG	CPT 86225	***(REPLACES TEST #1720)***
	#8163	Smith ENA, IgG	CPT 86235	
	#8208	Ribonucleic Protein (RNP), IgG	CPT 86235	***(NEW TEST)***
	#7616	SSA (Ro), IgG	CPT 86235	
	#7617	SSB (La), IgG	CPT 86235	
	#1750	Scleroderma (Scl-70), IgG	CPT 86235	
	#2098	Chromatin, IgG	CPT 86235	
	#8209	Centromere, IgG	CPT 86038	***(NEW TEST)***

Syphilis TrepSure EIA – Test #8200

PERFORMED: MONDAY-FRIDAY PERFORMING LAB: PLS LINCOLN CPT: 86780

Syphilis is caused by the spirochete Treponema and diagnostic testing traditionally is performed using a non-treponemal or treponemal based test. Currently, Physicians Laboratory Services uses the RPR (Rapid Plasma Reagin, non-treponemal) to screen for syphilis, but effective January 1, 2012 will change to an EIA based anti-treponemal (TrepSure) methodology. The RPR test can produce false negative and false positive results due to non-specificity. The TrepSure has increased sensitivity and is superior at detecting early and late stage syphilis infection versus RPR. All positive TrepSure tests will be reflexed to the non-treponemal RPR test. The CDC has endorsed the protocol for screening for syphilis and the results are interpreted as:

- Negative TrepSure would be consistent with no infection
- Positive TrepSure and positive RPR would be consistent with an active infection.
- A positive TrepSure and negative RPR would be consistent with very early or late disease or a past treated infection.

Glucose Tolerance Testing

Glucose tolerance testing consists of a baseline glucose followed by administration of a glucose load. Normal responses are measured typically at 1 or 2 hours post dose. Currently our laboratory also tests for serum glucose at 30 minutes post dose, but the ADA does not have accepted or recognized standards for a "normal" value and it frequently is not collected. For these reasons, our laboratory will no longer routinely test the 30 min glucose on tolerance panels.

Test #1142 Glucose Tolerance 2 + ½ Hour is no longer offered (**Refer to test #2323: Fasting, 2 Hr)**

Test #2321 Glucose Tolerance 3 + ½ Hour is no longer offered (**Refer to test #142 GTT 3 Hr**: **Fasting, 1Hr, 2Hr, 3Hr**)

Exposure Panel & HIV TESTING

Tests available at Physicians Laboratory Services:

#680 HIV	(Recommended for screening) – Cannot be performed STAT Specimen Requirements: 1.0 mL (0.5 mL) Serum Performed Mon-Fri. Reported 2-3 days.
#4680 HIV – RAPID	(Recommended for exposures when anti-retroviral therapy may be indicated) **HIV RAPID will be performed STAT** Specimen Requirements: 5.0 mL Whole Blood EDTA Performed Daily. Reported Immediately.
#3680 EXPOSURE PANEL – STAT #4680 HIV (RAPID) #945 Hepatitis C #568 Hepatitis B Surface Antibody #565 Hepatitis B Surface Antigen	(Recommended for exposures when anti-retroviral therapy may be indicated) **HIV RAPID will be performed STAT** Specimen Requirements: 3.0 mL Serum & 5.0 mL Whole Blood EDTA.
#2680 EXPOSURE PANEL – ROUTINE #680 HIV #945 Hepatitis C #568 Hepatitis B Surface Antibody #565 Hepatitis B Surface Antigen	(Recommended for exposures when anti-retroviral therapy **is not** indicated) **HIV **will not** be performed STAT** Specimen Requirements: 3.0 mL Serum & 5.0 mL Whole Blood EDTA.

HIV is the only test that needs to be ordered stat if anti-retroviral therapy is being considered, as the CDC recommends that treatment begins within 4 hours of exposure. If the source blood is unknown, the decision to start anti-retroviral therapy would be independent of test results. If the source blood can be tested, the rapid assay will provide information which will help direct therapy.

Hepatitis testing can be performed routinely (same day) as directed therapies do not have the narrow window encountered with HIV. Currently, the CDC does not recommend prophylactic therapy for Hepatitis C exposure. If the exposed individual has been immunized for Hepatitis B and has a documented positive response, testing for Hepatitis B markers is unnecessary and only HIV and Hepatitis C testing should be ordered.

Anti-Thyroglobulin Antibodies & TPO – Changes to Reference Ranges

Physicians Laboratory Services is changing to a new platform for testing thyroid antibodies. The new method employs purified TPO and TG antigen eliminating cross reactivity of other auto antibodies resulting in greater specificity. Due to this modification in testing, the reference ranges for thyroid peroxidase antibodies (TPO) and thyroglobulin antibodies have significantly changed.

To ensure a smooth transition to the reference values, our laboratory will issue patient reports that include results from both platforms through the month of January to provide a new baseline for any patients that are being monitored for disease progression/regression.

TPO **Test #7163**	CURRENT NORMAL RANGE <10 IU/mL	NEW NORMAL RANGE <100 U
Anti-Thyroglobulin **Test #7162**	CURRENT NORMAL RANGE Negative < 100 IU/mL Positive ≥ 100 IU/mL	NEW NORMAL RANGE Negative < 0.6 U Weak Positive 0.6 – 1.0 U Positive > 1.0 U

Call Dr. Greg Post (402)326-0617 or Patsi Tobey (402)488-7710 with questions.