

October 25, 2006

Dear Colleague:

*Specialty* continues a tradition of “helping doctors help patients” by introducing eleven new assays in the areas of maternal testing, oncology, allergy testing, therapeutic drug monitoring and drugs of abuse (DOA) confirmation this month. For allergists, gastroenterologists and pediatricians we think you will find our new food allergen panel especially helpful. This panel evaluates IgE responses to the six most common food allergens (milk, eggs, peanuts, wheat, soybean, and fish) with a 95% PPV to the specific food allergen challenge.

- **3746 Food Allergy EvaluatR™**

In the area of oncology, **BCL1 DetectR™** identifies the BCL1/JH fusion gene product of the t(11;14)(q13;q32) translocation which appears in approximately 95% of Mantle Cell Lymphomas (MCL).

- **5048 BCL1 DetectR™**

As part of our comprehensive drug screening and confirmation offering, we have recently completed validations of several serum and urine confirmatory tests that can be found on the following pages. For therapeutic drug monitoring, Carbamazepine with 10,11 epoxides is now available.

- **4115 Carbamazepine & Metabolites (10,11 Epoxides)**

Maternal serum-based testing for **First Trimester Screening** is now available with a calculation of adjusted risk provided for common chromosomal abnormalities. This is a new non-invasive screening test that combines serum-based PAPP-A and total beta HCG assays with ultrasound measurements of the fetus to identify risks for Down's Syndrome, Trisomy-18 and Trisomy-21. In November 2005 the *New England Journal of Medicine* cited first trimester screening as the most accurate noninvasive screening method available.

- **3095 First Trimester Screening**

On the horizon, several new molecular based DetectR™ assays will be available to clients shortly (details to follow in another client letter), including Micro Satellite Instability (MSI) and B-Cell & T-Cell Gene Rearrangement DetectR™.

We are confident these new assays will assist you in caring for your patients. A comprehensive listing of all new tests can be found on the following pages for your review as well.

For additional information, please visit our Web site at [www.specialtylabs.com](http://www.specialtylabs.com) or contact Client Services at 800-421-4449.



Michael C. Dugan, M.D.  
Vice President and Laboratory Director

# New Assays Available from *Specialty*

Effective date as noted

## 5048 BCL1 DetectR™ (available 11/14/06)

Component	Method	Reference Range / Units
BCL1 DetectR™	PCR	By Report

Specimen/Stability 5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week  
 Alternate Specimens 1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week  
 Clinical Utility The BCL1/JH t(11;14)(q13;q32) translocation occurs in approximately 95 percent of Mantle Cell Lymphomas (MCL). The t(11;14) translocation at the Major Translocation Cluster (MTC) locus has been reported in 50%-70% of Mantle Cell Lymphomas (MCL), 10%-20% of B Prolymphocytic Leukemia (B-PLL), 20%-25% of Multiple Myeloma (MM), 2%-5% of Chronic Lymphocytic Leukemia (CLL), Plasma Cell Leukemia (PCL) and Splenic Lymphoma with Villous Lymphocytes (SLVL).  
 Schedule Wednesday  
 Reported 6 days  
 CPT Code 83891, 83900, 83896x2, 83912, 83894  
 Note Not offered to NY patients until further notice.

## 3746 Food Allergy EvaluatR™ (available immediately)

Component	Method	Reference Range / Units
Egg IgE	FEIA by ImmunoCAP®	<0.35 kU/L
Milk IgE	FEIA by ImmunoCAP®	<0.35 kU/L
Peanut IgE	FEIA by ImmunoCAP®	<0.35 kU/L
Fish IgE	FEIA by ImmunoCAP®	<0.35 kU/L
Soybean IgE	FEIA by ImmunoCAP®	<0.35 kU/L
Wheat IgE	FEIA by ImmunoCAP®	<0.35 kU/L

Specimen/Stability 1.0mL (650uL) Serum (red top), Ambient 7 days, Refrigerated 14 days, Frozen 30 days  
 Clinical Utility Food specific IgE levels (kU/L) that provide 95% Positive Predictive Values (PPV) for clinical reactivity to the specific food allergen challenge.  
 Schedule Sunday-Saturday  
 Report Same day  
 CPT Code 86003x6

## 3270UR Epinephrine Urine Random (available immediately)

Component	Method	Reference Range / Units
Epinephrine Urine	HPLC	Not Established
Epinephrine/Creatinine Ratio	Calc	<16.2 ug/g Creat

Specimen/Stability 10.0 (6.0)mL Urine, Refrigerated 14 days, Frozen 2 months  
 Clinical Utility Evaluate hypertension, especially if paroxysmal; evaluate orthostatic hypotension; diagnose pheochromocytoma; preoperative evaluation of suspected childhood adrenal neoplasms (i.e. neuroblastoma); evaluate suspected multiple endocrine neoplasia (MEN) syndromes.  
 Schedule Tuesday – Saturday  
 Report 2 days  
 CPT Code 82384, 82570  
 Note Ship Refrigerated or on cold pack---Ambient is not acceptable.  
 Collection Instructions If possible, patient should discontinue all drugs at least 1 week prior to collection. Some medications known to interfere with the assay include: Alpha-methyl dopa (Aldomet), Isoproterenol, Labetalol, Mandelamine, Metaclopramide, Acetaminophen (high concentrations only), Cimetidine, and Catecholamine-containing drugs, MAO inhibitors, Diuretics and Vasodilators. Acid additive (HCl, Nitric or Acetic acid) is acceptable but not necessary if the specimen is refrigerated during collection and transport.

## 4115 Carbamazepine & Metabolites (10,11 Epoxides)

(available 11/03/06)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Carbamazepine	LCMS/MS	4.0-12.0 ug/mL
10,11 Epoxide	LCMS/MS	0.20-2.0 ug/mL
Specimen/Stability	1.2 (0.6)mL, Serum, Ambient 15 days, Refrigerated 15 days, Frozen 2 months	
Alternate Specimen	1.2 (0.6)mL, EDTA Plasma, Ambient 15 days, Refrigerated 15 days, Frozen 2 months	
Clinical Utility	Carbamazepine has anticonvulsant properties which have been found useful in the treatment of psychomotor epilepsy and as an adjunct in the treatment of partial epilepsies, when administered in conjunction with other anticonvulsant drugs to prevent the possible generalization of the epileptic discharge.	
Schedule	Wednesday	
Report	8 days	
CPT Code	80156x2	
Collection Notes	Ship refrigerated or on cold pack. Use red top tubes for serum and EDTA lavender for plasma. Serum Separator Tubes are not acceptable.	

## 2495 Hepatitis Delta Virus IgG Antibody

(available immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Hepatitis Delta Virus IgG Antibody	EIA	Negative
Specimen/Stability	1.0 (0.5)mL, Serum, Ambient 7 days, Refrigerated 14 days, Frozen 2 months	
Alternate Specimen	1.0 (0.5)mL, Heparinized Plasma, Ambient 7 days, Refrigerated 14 days, Frozen 2 months	
Clinical Utility	Hepatitis Delta Virus can only replicate in HBV infected individuals. HBV can convert an asymptomatic or mild chronic HBV infection into severe or rapidly progressive disease. In HBV carriers with HDV superinfection, chronic HDV infection will lead to severe chronic hepatitis and cirrhosis.	
Schedule	Wednesday and Friday	
Report	2 days	
CPT Code	86692	
Note	This assay is available for a limited time only.	

## 3129UR Cortisol, Free Urine Random

(available immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Cortisol, Free Urine Random	LS/MS/MS	not established ug/L
Specimen/Stability	10.0 (5.0)mL, Urine, Ambient 2 days, Refrigerated 7 days, Frozen 2 months	
Clinical Utility	Assess adrenal function; particularly useful in the diagnosis of Cushing syndrome. Recent data suggests that urinary free cortisol concentrations can be significantly altered in patients taking inhaled corticosteroids. (J Clin Endocrinol Metab 2002; 87:4541-6)	
Schedule	Monday, Wednesday, Friday	
Report	same day	
CPT Code	82530	
Collection Instructions	Acetic and boric acid are acceptable additives. Add 2mL of 50% acetic acid or 1 g of boric acid to collection. Mix well. Send 10mL of random urine in a leak proof container.	

## 1305UR Protein, Total & Creatinine Urine random W/Ratio

(available immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Protein Total Urine Random	S	4-19 mg/dL
Creatinine Urine Random	S	not established mg/dL
Protein/Creatinine Ratio	Calc	not established n/a
Specimen/Stability	5.0 (3.0)mL, Urine, Ambient 4 days, Refrigerated 4 days, Frozen 2 months	
Schedule	Sunday thru Saturday	
Report	2 days	
Note	This is a calculation based result utilizing random urine total protein and random urine creatinine.	
CPT Code	84156, 82570	

**4183U Phencyclidine (PCP) Confirmation Urine**  
(available 11/03/06)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
PCP Urine	LCMS-MS	<25 ng/mL

Specimen/Stability 4.0 (2.0)mL, Urine, Ambient 5 days, Refrigerated 5 days, Frozen 2 weeks  
 Clinical Utility Phencyclidine (PCP) is classified as a hallucinogen and has many of the same effects as Lysergic Acid Diethylamide (LSD), but can be much more dangerous. It acts as a hallucinogen, stimulant, depressant and anesthetic all at the same time.  
 Schedule Thursday  
 Report same day  
 CPT Code 83992  
 Collection Instructions Collect random urine in leak proof container. No additive required.

**4252 Cocaine Metabolites Screen Serum W/Reflex Confirmation**  
(available 11/03/06)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Cocaine Metabolites Screen Serum	EIA	Negative

Specimen/Stability 5.0 (2.5)mL, Serum, Refrigerated 2 days, Frozen 14 days  
 Clinical Utility This panel is useful for confirmation of screen positive results. Cocaine is metabolized mainly to benzoylecgonine and ecgonine methylester. Cocaethylene is an indication of concurrent cocaine and alcohol consumption. Hydroxybenzoylecgonine is a metabolite mainly present in meconium. Serum half-life of cocaine is 1-5 hours. Benzoylecgonine appears in circulation 15-30 minutes after cocaine administration. Elimination half-life of benzoylecgonine is 5-6 hours. Benzoylecgonine will be detectable in urine after 2-3 hours and urine remains positive for 2-3 days (longer for chronic abusers) after cocaine use.  
 Schedule Tuesday, Thursday, Saturday  
 Report 1 day (extra time needed for reflex testing)  
 CPT Code 80101  
 Collection Instructions Do not use serum separator tubes. Ship Refrigerated or on a cold pack.  
 Notes Cut off: Index 1.0=100ng/mL. Positive screen results automatically reflex for confirmation (test code 4170) for an additional fee.

**4250 Opiate Screen Serum W/Reflex Confirmation**  
(available immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Opiate Screen Serum	EIA	Negative

Specimen/Stability 5.0 (2.5)mL, Serum, Refrigerated 2 days, Frozen 14 days  
 Clinical Utility This panel is useful for confirmation of screen positive results.  
 Schedule Tuesday, Thursday, Saturday  
 Report 1 day (extra time needed for reflex testing)  
 CPT Code 80101  
 Collection Instructions Do not use serum separator tubes. Ship Refrigerated or on a cold pack  
 Notes Cut off: Index 1.0=100ng/mL. Positive screen results automatically reflex for confirmation (test code 4185) for an additional fee.

**3095 First Trimester Screening**  
(available immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Beta HCG, Total	EIA	mIU/mL
PAPP-A	EIA	By Report

Specimen/Stability 6.0 (3.0)mL, Serum, Ambient 7 days, Refrigerated 7 days, Frozen 2 months  
 Clinical Utility First trimester screening test is performed between 10 weeks 3 days and 13 weeks 6 days of gestation to screen for pregnancies with increased risks for Down's Syndrome or Trisomy 18. Three marker levels and maternal age are used in the calculation of such risks. Two of the markers are biochemical (PAPP-A and HCG total) and the third is an ultrasound measurement of the fetal nuchal translucency (NT). The NT measurement, expressed in mm, is to be provided by a certified ultrasonographer.  
 Schedule Monday - Saturday  
 Report 2 days  
 CPT Code 84702, 83520  
 Collection Instructions All information must be completed on the Maternal Screening Test Requisition form for proper analysis.