

May 27, 2010

Dear Colleague:

Our May communication to you brings very exciting news of a new test offering available in July – **FcGammaRIIa & FcGammaRIIIa Mutation Analysis (5388)**. Combined FcγRIIa/FcγRIIIa polymorphisms are shown to be prognostic factors for disease progression in metastatic colorectal cancer in patients treated with cetuximab plus irinotecan. These polymorphisms have also been found to predict rituximab response in patients with follicular lymphoma. Human Fcγ receptors on hematopoietic cells are involved in several important biological responses, including phagocytosis, release of inflammatory mediators, antibody-dependent cellular toxicity, enhancement of antigen presentation, and platelet activation. The efficacy of Fcγ receptor function displays inter-individual heterogeneity due to genetic polymorphisms of FcγR subclasses including FcγRIIa (CD32a), FcγRIIIa (CD16a). These polymorphisms have been associated with immune –related disorders and furthermore serve as markers for therapeutic efficacy and side-effects of treatment with monoclonal antibodies.

We are also pleased to inform you of *Specialty's* recent New York approval for **Fentanyl & Norfentanyl Urine w/Reflex Confirmation (4175U)**. This also applies to panel **Expanded Drugs Of Abuse Screen Ur + Fentanyl W/Reflex Conf (4472U)**. This will enable our New York clients and those serving New York residents to have these testing provided within our facility. In addition, please note that **EBV Nuclear Ag (EBNA) IgM Abs (2271)** and **F-Actin IgA Autoabs (5924)** are now FDA approved tests.

Please also see this important reminder from our Billing Department:

You are likely aware of Medicare's requirement for physician and non-physician practitioners to be enrolled in the Medicare Provider Enrollment, Chain and Ownership System (PECOS). We are currently receiving warning messages that certain ordering/referring providers are not enrolled in PECOS. Under the current rule, claims will be denied and payments will stop on January 1, 2011. If that occurs, your facility could potentially be responsible for payment. Please work with your physician and clients to ensure that they are enrolled.

We thank you for choosing *Specialty* and look forward to your continued support. For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.

Respectfully Yours,



Christopher Lockhart, M.D.
Laboratory Director

New Tests (*Specialty*):

3750 Respiratory Allergy Profile Region XI

(Available Immediately)

Component	Method	Reference Range/Units
<i>Dermatophagoides pteronyssinus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Dermatophagoides farinae</i> IgE	ImmunoCAP	<0.35 kU/L
Cat epithelium/dander IgE	ImmunoCAP	<0.35 kU/L
Dog dander IgE	ImmunoCAP	<0.35 kU/L
Bermuda grass IgE	ImmunoCAP	<0.35 kU/L
Timothy grass IgE	ImmunoCAP	<0.35 kU/L
Cockroach, German IgE	ImmunoCAP	<0.35 kU/L
<i>Penicillium chrysogenum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Cladosporium herbarum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Aspergillus fumigatus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Alternaria alternata/tenuis</i> IgE	ImmunoCAP	<0.35 kU/L
Grey alder IgE	ImmunoCAP	<0.35 kU/L
Mountain juniper/cedar IgE	ImmunoCAP	<0.35 kU/L
Oak IgE	ImmunoCAP	<0.35 kU/L
Elm IgE	ImmunoCAP	<0.35 kU/L
Olive IgE	ImmunoCAP	<0.35 kU/L
Cottonwood IgE	ImmunoCAP	<0.35 kU/L
Box elder IgE	ImmunoCAP	<0.35 kU/L
Mulberry IgE	ImmunoCAP	<0.35 kU/L
Short (common) ragweed IgE	ImmunoCAP	<0.35 kU/L
Mugwort IgE	ImmunoCAP	<0.35 kU/L
Saltwort, Russian thistle IgE	ImmunoCAP	<0.35 kU/L
Pigweed IgE	ImmunoCAP	<0.35 kU/L
Sheep sorrel IgE	ImmunoCAP	<0.35 kU/L
IgE Total	ImmunoCAP	0 – 6 weeks < 5.2 IU/mL 7 weeks – 3 months < 9.2 IU/mL 4 – 6 months < 16.4 IU/mL 7 – 9 months < 22.6 IU/mL 10 – 12 months < 29.2 IU/mL 13 months – 2 years < 51.7 IU/mL 3 years < 72.0 IU/mL 4 years < 90.0 IU/mL 5 years < 108.0 IU/mL 6 years < 126.0 IU/mL 7 years < 142.0 IU/mL 8 years < 160.0 IU/mL 9 years < 176.0 IU/mL 10 years < 192.0 IU/mL >10 years < 114.0 IU/mL

Specimen/Stability Serum 6.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
 Schedule Sunday- Saturday
 Report Same day
 CPT Code 86003x24, 82785
 Regulatory Status FDA Approved
 Always Statement

REFERENCE RANGES for Allergen IgE tests:

IgE (kU/L)	Interpretation
< 0.35	Class 0 - Below Detection
0.35 - 0.69	Class 1 - Low
0.70 - 3.49	Class 2 - Moderate
3.50 - 17.49	Class 3 - High
17.50 - 49	Class 4 - Very High
50 - 99	Class 5 - Very High
>=100	Class 6 - Very High

Note: Omalizumab (Xolair, Genentech; humanized IgG1 antihuman IgE Fc) treatment does not significantly interfere with the accuracy of total IgE on the ImmunoCAP (Phadia) platform. J Allergy Clin Immunol 2006;117:759-66).

New Tests (*Specialty*): (cont'd)

3751

Respiratory Allergy Profile Region XV

(Available Immediately)

Component	Method	Reference Range/Units
<i>Dermatophagoides pteronyssinus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Dermatophagoides farinae</i> IgE	ImmunoCAP	<0.35 kU/L
Cat epithelium/dander IgE	ImmunoCAP	<0.35 kU/L
Dog dander IgE	ImmunoCAP	<0.35 kU/L
Bermuda grass IgE	ImmunoCAP	<0.35 kU/L
Timothy grass IgE	ImmunoCAP	<0.35 kU/L
Cockroach, German IgE	ImmunoCAP	<0.35 kU/L
<i>Penicillium chrysogenum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Cladosporium herbarum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Aspergillus fumigatus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Alternaria alternata/tenuis</i> IgE	ImmunoCAP	<0.35 kU/L
Mountain juniper/cedar IgE	ImmunoCAP	<0.35 kU/L
Oak IgE	ImmunoCAP	<0.35 kU/L
Elm IgE	ImmunoCAP	<0.35 kU/L
Olive IgE	ImmunoCAP	<0.35 kU/L
Cottonwood IgE	ImmunoCAP	<0.35 kU/L
Box elder IgE	ImmunoCAP	<0.35 kU/L
Mulberry IgE	ImmunoCAP	<0.35 kU/L
Short (common) ragweed IgE	ImmunoCAP	<0.35 kU/L
Mugwort IgE	ImmunoCAP	<0.35 kU/L
Saltwort, Russian thistle IgE	ImmunoCAP	<0.35 kU/L
Pigweed IgE	ImmunoCAP	<0.35 kU/L
IgE Total	ImmunoCAP	0 – 6 weeks < 5.2 IU/mL
		7 weeks – 3 months < 9.2 IU/mL
		4 – 6 months < 16.4 IU/mL
		7 – 9 months < 22.6 IU/mL
		10 – 12 months < 29.2 IU/mL
		13 months – 2 years < 51.7 IU/mL
		3 years < 72.0 IU/mL
		4 years < 90.0 IU/mL
		5 years < 108.0 IU/mL
		6 years < 126.0 IU/mL
		7 years < 142.0 IU/mL
		8 years < 160.0 IU/mL
		9 years < 176.0 IU/mL
		10 years < 192.0 IU/mL
		>10 years < 114.0 IU/mL

Specimen/Stability Serum 6.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
 Schedule Sunday- Saturday
 Report Same day
 CPT Code 86003x22, 82785
 Regulatory Status FDA Approved
 Always Statement

REFERENCE RANGES for Allergen IgE tests:

IgE (kU/L)	Interpretation
< 0.35	Class 0 - Below Detection
0.35 - 0.69	Class 1 - Low
0.70 - 3.49	Class 2 - Moderate
3.50 - 17.49	Class 3 - High
17.50 - 49	Class 4 - Very High
50 - 99	Class 5 - Very High
>=100	Class 6 - Very High

Note: Omalizumab (Xolair, Genentech; humanized IgG1 antihuman IgE Fc) treatment does not significantly interfere with the accuracy of total IgE on the ImmunoCAP (Phadia) platform. J Allergy Clin Immunol 2006;117:759-66).

New Tests (*Specialty*): (cont'd)

3752

Respiratory Allergy Profile Region XVI

(Available Immediately)

Component	Method	Reference Range/Units
<i>Dermatophagoides pteronyssinus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Dermatophagoides farinae</i> IgE	ImmunoCAP	<0.35 kU/L
Cat epithelium/dander IgE	ImmunoCAP	<0.35 kU/L
Dog dander IgE	ImmunoCAP	<0.35 kU/L
Timothy grass IgE	ImmunoCAP	<0.35 kU/L
Cockroach, German IgE	ImmunoCAP	<0.35 kU/L
<i>Penicillium chrysogenum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Cladosporium herbarum</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Aspergillus fumigatus</i> IgE	ImmunoCAP	<0.35 kU/L
<i>Alternaria alternata/tenuis</i> IgE	ImmunoCAP	<0.35 kU/L
Grey alder IgE	ImmunoCAP	<0.35 kU/L
Mountain juniper/cedar IgE	ImmunoCAP	<0.35 kU/L
Oak IgE	ImmunoCAP	<0.35 kU/L
Elm IgE	ImmunoCAP	<0.35 kU/L
Common silver birch IgE	ImmunoCAP	<0.35 kU/L
Cottonwood IgE	ImmunoCAP	<0.35 kU/L
Box elder IgE	ImmunoCAP	<0.35 kU/L
Mugwort IgE	ImmunoCAP	<0.35 kU/L
Saltwort, Russian thistle IgE	ImmunoCAP	<0.35 kU/L
Pigweed IgE	ImmunoCAP	<0.35 kU/L
Sheep sorrel IgE	ImmunoCAP	<0.35 kU/L
IgE Total	ImmunoCAP	0 – 6 weeks < 5.2 IU/mL
		7 weeks – 3 months < 9.2 IU/mL
		4 – 6 months < 16.4 IU/mL
		7 – 9 months < 22.6 IU/mL
		10 – 12 months < 29.2 IU/mL
		13 months – 2 years < 51.7 IU/mL
		3 years < 72.0 IU/mL
		4 years < 90.0 IU/mL
		5 years < 108.0 IU/mL
		6 years < 126.0 IU/mL
		7 years < 142.0 IU/mL
		8 years < 160.0 IU/mL
		9 years < 176.0 IU/mL
		10 years < 192.0 IU/mL
		>10 years < 114.0 IU/mL

Specimen/Stability Serum 6.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
 Schedule Sunday- Saturday
 Report Same day
 CPT Code 86003x21, 82785
 Regulatory Status FDA Approved
 Always Statement

REFERENCE RANGES for Allergen IgE tests:

IgE (kU/L)	Interpretation
< 0.35	Class 0 - Below Detection
0.35 - 0.69	Class 1 - Low
0.70 - 3.49	Class 2 - Moderate
3.50 - 17.49	Class 3 - High
17.50 - 49	Class 4 - Very High
50 - 99	Class 5 - Very High
>=100	Class 6 - Very High

Note: Omalizumab (Xolair, Genentech; humanized IgG1 antihuman IgE Fc) treatment does not significantly interfere with the accuracy of total IgE on the ImmunoCAP (Phadia) platform. J Allergy Clin Immunol 2006;117:759-66).

New Tests (*Specialty*): (cont'd)

3753

Respiratory Allergy Profile Region XVII

(Available Immediately)

Component	Method	Reference Range/Units	
<i>Dermatophagoides pteronyssinus</i> IgE	ImmunoCAP	<0.35 kU/L	
<i>Dermatophagoides farinae</i> IgE	ImmunoCAP	<0.35 kU/L	
Cat epithelium/dander IgE	ImmunoCAP	<0.35 kU/L	
Dog dander IgE	ImmunoCAP	<0.35 kU/L	
Timothy grass IgE	ImmunoCAP	<0.35 kU/L	
Cockroach, German IgE	ImmunoCAP	<0.35 kU/L	
<i>Penicillium chrysogenum</i> IgE	ImmunoCAP	<0.35 kU/L	
<i>Cladosporium herbarum</i> IgE	ImmunoCAP	<0.35 kU/L	
<i>Aspergillus fumigatus</i> IgE	ImmunoCAP	<0.35 kU/L	
<i>Alternaria alternata/tenuis</i> IgE	ImmunoCAP	<0.35 kU/L	
Mountain juniper/cedar IgE	ImmunoCAP	<0.35 kU/L	
Oak IgE	ImmunoCAP	<0.35 kU/L	
Elm IgE	ImmunoCAP	<0.35 kU/L	
Grey alder IgE	ImmunoCAP	<0.35 kU/L	
Cottonwood IgE	ImmunoCAP	<0.35 kU/L	
Common silver birch IgE	ImmunoCAP	<0.35 kU/L	
Box elder IgE	ImmunoCAP	<0.35 kU/L	
White ash IgE	ImmunoCAP	<0.35 kU/L	
Walnut tree pollen IgE	ImmunoCAP	<0.35 kU/L	
Short (common) ragweed IgE	ImmunoCAP	<0.35 kU/L	
Pigweed IgE	ImmunoCAP	<0.35 kU/L	
Sheep sorrel IgE	ImmunoCAP	<0.35 kU/L	
Nettle IgE	ImmunoCAP	<0.35 kU/L	
IgE Total	ImmunoCAP	0 – 6 weeks	< 5.2 IU/mL
		7 weeks – 3 months	< 9.2 IU/mL
		4 – 6 months	< 16.4 IU/mL
		7 – 9 months	< 22.6 IU/mL
		10 – 12 months	< 29.2 IU/mL
		13 months – 2 years	< 51.7 IU/mL
		3 years	< 72.0 IU/mL
		4 years	< 90.0 IU/mL
		5 years	< 108.0 IU/mL
		6 years	< 126.0 IU/mL
		7 years	< 142.0 IU/mL
8 years	< 160.0 IU/mL		
9 years	< 176.0 IU/mL		
10 years	< 192.0 IU/mL		
>10 years	< 114.0 IU/mL		

Specimen/Stability	Serum 6.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
Schedule	Sunday- Saturday
Report	Same day
CPT Code	86003x23, 82785
Regulatory Status	FDA Approved
Always Statement	REFERENCE RANGES for Allergen IgE tests:

IgE (kU/L)	Interpretation
< 0.35	Class 0 - Below Detection
0.35 - 0.69	Class 1 - Low
0.70 - 3.49	Class 2 - Moderate
3.50 - 17.49	Class 3 - High
17.50 - 49	Class 4 - Very High
50 - 99	Class 5 - Very High
>=100	Class 6 - Very High

Note: Omalizumab (Xolair, Genentech; humanized IgG1 antihuman IgE Fc) treatment does not significantly interfere with the accuracy of total IgE on the ImmunoCAP (Phadia) platform. J Allergy Clin Immunol 2006;117:759-66).

New Tests (*Specialty*): (cont'd)

3606 Sucrase

(Available June 1)

Component	Method	Reference Range/Units
Sucrase	S	25.0 – 69.9 uM/min/gram protein

Specimen/Stability	Tissue 5.0 (2.0) mg: Frozen 31 days
Collection Instructions	Place 5 mg (2 mg) small bowel biopsy in a polypropylene screw cap collection tube and freeze within 2 hours of collection. Keep frozen on dry ice. Store at -50 to -90 degrees C.
Schedule	Tuesday - Saturday
Report	Next day
CPT Code	84311
Regulatory Status	Laboratory Developed Test
Always Statement	Units are reported as uM/min/gram protein
Clinical Utility	Lactase, maltase, palatinase and sucrase are mucosal disaccharidases that are present in normal small intestine and fetal colon. A decrease in the enzyme activity of these disaccharidases has been noted in colonic adenomas, adenocarcinomas and malabsorption. Decreased disaccharidase activity is a good indicator of mucosal injury with the exception of lactase.

3608 Palatinase

(Available June 1)

Component	Method	Reference Range/Units
Palatinase	S	5.0 – 26.3 uM/min/gram protein

Specimen/Stability	Tissue 5.0 (2.0) mg: Frozen 31 days
Collection Instructions	Place 5 mg (2 mg) small bowel biopsy in a polypropylene screw cap collection tube and freeze within 2 hours of collection. Keep frozen on dry ice. Store at -50 to -90 degrees C.
Schedule	Tuesday - Saturday
Report	Next day
CPT Code	84311
Regulatory Status	Laboratory Developed Test
Always Statement	Units are reported as uM/min/gram protein
Clinical Utility	Lactase, maltase, palatinase and sucrase are mucosal disaccharidases that are present in normal small intestine and fetal colon. A decrease in the enzyme activity of these disaccharidases has been noted in colonic adenomas, adenocarcinomas and malabsorption. Decreased disaccharidase activity is a good indicator of mucosal injury with the exception of lactase.

3610 Maltase

(Available June 1)

Component	Method	Reference Range/Units
Maltase	S	100.0 – 224.4 uM/min/gram protein

Specimen/Stability	Tissue 5.0 (2.0) mg: Frozen 31 days
Collection Instructions	Place 5 mg (2 mg) small bowel biopsy in a polypropylene screw cap collection tube and freeze within 2 hours of collection. Keep frozen on dry ice. Store at -50 to -90 degrees C.
Schedule	Tuesday - Saturday
Report	Next day
CPT Code	84311
Regulatory Status	Laboratory Developed Test
Always Statement	Units are reported as uM/min/gram protein
Clinical Utility	Lactase, maltase, palatinase and sucrase are mucosal disaccharidases that are present in normal small intestine and fetal colon. A decrease in the enzyme activity of these disaccharidases has been noted in colonic adenomas, adenocarcinomas and malabsorption. Decreased disaccharidase activity is a good indicator of mucosal injury with the exception of lactase.

New Tests (*Specialty*): (cont'd)

3614 Lactase

(Available June 1)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Lactase	S	15.0 – 45.5 uM/min/gram protein
Specimen/Stability	Tissue 5.0 (2.0) mg: Frozen 31 days	
Collection Instructions	Place 5 mg (2 mg) small bowel biopsy in a polypropylene screw cap collection tube and freeze within 2 hours of collection. Keep frozen on dry ice. Store at -50 to -90 degrees C.	
Schedule	Tuesday - Saturday	
Report	Next day	
CPT Code	84311	
Regulatory Status	Laboratory Developed Test	
Always Statement	Units are reported as uM/min/gram protein	
Clinical Utility	Lactase, maltase, palatinase and sucrase are mucosal disaccharidases that are present in normal small intestine and fetal colon. A decrease in the enzyme activity of these disaccharidases has been noted in colonic adenomas, adenocarcinomas and malabsorption. Decreased disaccharidase activity is a good indicator of mucosal injury with the exception of lactase.	

8328 *Histoplasma* Total Antibody

(Available June 14)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Histoplasma Total Ab	EIA	<0.90 Index
Specimen/Stability	Serum 1.0 (0.3) mL: Ambient 48 hours, Refrigerated 2 weeks, Frozen 2 months	
Schedule	Thursday	
Report	Same day	
CPT Code	86698	
Regulatory Status	FDA Approved	
Always Statement	Reference Ranges for Histoplasma Total Ab: Negative: < 0.90 Index Equivocal: 0.90 – 1.10 Index Positive: > 1.10 Index	
Clinical Utility	This test is indicated for testing persons having symptoms of respiratory disease, as an aid in the presumptive laboratory diagnosis of histoplasma infection. The test is not approved for testing blood or plasma donors.	

1182 Beta-2-Glycoprotein (Beta-2-GPI) IgG Autoabs

(Available July 6)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Beta-2-GPI IgG Autoabs	EIA	<21 Units
Specimen/Stability	Serum 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months	
Schedule	Sunday - Saturday	
Report	Same day	
CPT Code	86146	
Regulatory Status	FDA Approved	
Clinical Utility	Beta-2-GPI autoantibodies are found in patients with antiphospholipid syndrome (APS) and are associated with increased risk of venous and arterial thrombosis and thrombocytopenia. Beta-2-GPI autoantibodies are found only in patients with autoimmune diseases, while cardiolipin autoantibodies can be transiently found in infectious diseases.	

New Tests (*Specialty*): (cont'd)

1183 Beta-2-Glycoprotein (Beta-2-GPI) IgM Autoabs (Available July 6)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Beta-2-GPI IgM Autoabs	EIA	<21 Units
Specimen/Stability	Serum 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months	
Schedule	Sunday - Saturday	
Report	Same day	
CPT Code	86146	
Regulatory Status	FDA Approved	
Clinical Utility	Beta-2-GPI autoantibodies are found in patients with antiphospholipid syndrome (APS) and are associated with increased risk of venous and arterial thrombosis and thrombocytopenia. Beta-2-GPI autoantibodies are found only in patients with autoimmune diseases, while cardiolipin autoantibodies can be transiently found in infectious diseases.	

1184 Beta-2-Glycoprotein (Beta-2-GPI) IgA Autoabs (Available July 6)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Beta-2-GPI IgA Autoabs	EIA	<21 Units
Specimen/Stability	Serum 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months	
Schedule	Sunday - Saturday	
Report	Same day	
CPT Code	86146	
Regulatory Status	FDA Approved	
Clinical Utility	Beta-2-GPI autoantibodies are found in patients with antiphospholipid syndrome (APS) and are associated with increased risk of venous and arterial thrombosis and thrombocytopenia. Beta-2-GPI autoantibodies are found only in patients with autoimmune diseases, while cardiolipin autoantibodies can be transiently found in infectious diseases.	

5388 FcGammaRIIa & FcGammaRIIIa Mutation Analysis (Available July 12)

This test is not approved for the testing of patient samples from New York State.

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
FcGammaRIIa & RIIIa	PCR	Mutation not detected
Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days	
Alt Specimen	Whole Blood ACD (A or B) 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days	
Collection Instructions	EDTA is the preferred anticoagulant, but ACD (A or B) is also acceptable. Heparin is not acceptable. Ship ambient. Frozen specimens are not acceptable.	
Schedule	Wednesday	
Report	Within 3 days	
CPT Code	83891, 83898, 83896x2, 83912	
Regulatory Status	Laboratory Developed Test	
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.	
Note	Test detects the FcGammaRIIa and FcGammaRIIIa V158F genomic variants. This test is not approved for the testing of patient samples from New York State.	
Clinical Utility	FcGammaRIIa H131R and FcGammaRIIIa V158F variants have been associated with immune-related disorders and serve as markers for therapeutic efficacy and side-effects of treatment with monoclonal antibodies. These variants have been found to predict rituximab response in patients with follicular lymphoma. Combined FcGammaRIIa/FcGammaRIIIa variants are also shown to be prognostic factors for disease progression in metastatic colorectal cancer, in patients treated with cetuximab plus irinotecan.	

New Tests (*Specialty*): (cont'd)

3515W Vitamin B1 (Thiamine) Whole Blood

(Available July 12)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Vitamin B1 WB	HPLC	87-280 nmol/L

Specimen/Stability	Whole Blood EDTA 1.0 (0.5) mL: Refrigerated 24 hours, Frozen 30 days
Collection Instructions	Protect from light; use foil wrapping or amber tubes. Ship frozen.
Schedule	Monday, Wednesday, Friday
Report	Next day
CPT Code	84425
Regulatory Status	Laboratory Developed Test
Clinical Utility	Vitamin B1 helps to maintain the health of mucous membranes such as those lining the intestines. Thiamine diphosphate (also referred to as "thiamine pyrophosphate") is the physiologically active form of Vitamin B1 thus the monitoring of this diphosphate should be preferred to the analysis of total thiamine.

Test Changes:

2271	Epstein-Barr Virus Nuclear Ag (EBNA) IgM Abs
Effective	Immediately
Regulatory Status	FDA Approved (NEW)
2364	Rapid Plasma Reagin (RPR)
Effective	Immediately
Always Statement	Reactive results for this nontreponemal test are not confirmed. All reactive nontreponemal tests should be confirmed using a standard treponemal test unless the patient has had a known/documented prior syphilis infection.
Also Affected	DOS Codes 2366, 2366C
3114	Angiotensin Converting Enzyme (ACE)
Effective	Immediately
Collection Instructions	Grossly hemolyzed samples will be rejected. (NEW)
3131	Adenosine Deaminase
Effective	Immediately
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days
Alt Specimen	CSF 1.0 (0.5) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days Pleural Fluid 1.0 (0.5) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days Note: Ambient and frozen specimens now accepted; increased refrigerated stability.
4094U	Propoxyphene Confirmation Urine
Effective	Immediately
Specimen/Stability	Urine 4.0 (2.0) mL: Ambient 14 days, Refrigerated 14 days, Frozen 30 days Note: Increased ambient, refrigerated and frozen stability.
4101U	Phencyclidine (PCP) Screen Urine w/Reflex Confirmation
Effective	Immediately
Specimen/Stability	Urine 5.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days Note: Increased ambient, refrigerated and frozen stability.

Test Changes: (cont'd)

4109U Methadone Screen Urine w/Reflex Confirmation

Effective Immediately
Specimen/Stability Urine 5.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
Note: Increased ambient and frozen stability.

4127U Propoxyphene Screen Urine w/Reflex Confirmation

Effective Immediately
Specimen/Stability Urine 5.0 (4.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
Note: Increased ambient, refrigerated and frozen stability.

4183U Phencyclidine (PCP) Confirmation Urine

Effective Immediately
Specimen/Stability Urine 4.0 (2.0) mL: Ambient 14 days, Refrigerated 14 days, Frozen 30 days
Note: Increased ambient, refrigerated and frozen stability.

4185UR Opiates Confirmation Urine

Effective Immediately
Specimen/Stability Urine 10.0 (5.0) mL: Ambient 14 days, Refrigerated 14 days, Frozen 30 days
Note: Increased ambient and decreased frozen stability.
Also Affected DOS Codes 4179U, 4186UR, 4187UR, 4490UR, 4492UR

4192U Methadone Confirmation Urine

Effective Immediately
Specimen/Stability Urine 4.0 (2.0) mL: Ambient 14 days, Refrigerated 14 days, Frozen 30 days
Note: Increased ambient and frozen stability.

4250U Opiates Screen Urine w/Reflex Confirmation

Effective Immediately
Specimen/Stability Urine 10.0 (5.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 30 days
Note: Increased ambient and decreased frozen stability.

5924 F-Actin IgA Autoabs

Effective Immediately
Regulatory Status FDA Approved (**NEW**)

Test Changes: (cont'd)

9640	Streptococcus Group B DNA DetectR™
Effective	Immediately
Note	This test is not approved by the State of New York for the testing of ThinPrep and SurePath samples.
3541	Vitamin D, 25-Hydroxy Total [LC-MS-MS]
Effective	June 7
Reference Range	Vitamin D, 25-OD Total: 30 – 100 ng/mL (NEW)
Also Affected	DOS Code 3525
4176U	Oxycodone & Metabolite Urine
Effective	June 15
Always Statement	Limit of quantitation
	Oxycodone 50 ng/mL (NEW)
	Oxymorphone 50 ng/mL (NEW)
Also Affected	Reflex of DOS Codes 4422U, 4470U, 4472U
1519	Transferrin
Effective	June 29
Reference Range	188 – 341 mg/dL (NEW)
1600	Complement Functional Activity CH50
Effective	June 29
Specimen/Stability	Serum 1.0 (0.8) mL: Frozen 1 month Note: Reduced frozen stability.
3174	Follicle-Stimulating Hormone
Effective	June 29
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months Note: Ambient now accepted; increased refrigerated stability.
Reference Range	Female see below Male: 1.6 – 8.0 mIU/mL (NEW)
Always Statement	Female >= 18 Years: Follicular 2.5 – 10.2 mIU/mL (same) Mid Cycle Peak 3.1 – 17.7 mIU/mL (NEW) Luteal 1.5 – 9.1 mIU/mL (same) Postmenopausal 23.0 – 116.3 mIU/mL (same) Female < 18 Years: FSH reference ranges established on post-pubertal patient population. Reference range not established for pre-pubertal patients using this assay.
Also Affected	DOS Codes 2016, 2020 (reference range only), 2023 (reference range only)

Test Changes: (cont'd)

3198	Luteinizing Hormone
Effective	June 29
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months Note: Ambient now accepted; increased refrigerated stability.
Reference Range	Female see below Male < 70 Years: 1.5 – 9.3 mIU/mL (NEW) >=70 Years: 3.1 – 34.6 mIU/mL (NEW)
Always Statement	Female >= 18 Years: Follicular 1.9 – 12.5 mIU/mL (same) Mid Cycle Peak 8.7 – 76.3 mIU/mL (same) Luteal 0.5 – 16.9 mIU/mL (same) Postmenopausal 15.9 – 54.0 mIU/mL (same) Female < 18 Years: LH reference ranges established on post-pubertal patient population. Reference range not established for pre-pubertal patients using this assay.
Also Affected	DOS Codes 2016, 2020 (reference range only), 2023 (reference range only)
3228	Thyroxine (T4), Free
Effective	June 29
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months Note: Ambient now accepted; increased refrigerated stability.
Reference Range	< 1 Year Not established 1 – 9 Years 0.9 – 1.6 ng/dL (NEW) 10 – 18 Years 0.9 – 1.4 ng/dL (NEW) > 18 Years 0.8 – 1.8 ng/dL (NEW)
Also Affected	DOS Codes 3072 (reference range only), 3074 (reference range only)
3318U	Vanillylmandelic Acid 24Hr Urine
Effective	June 29
Specimen/Stability	Urine 24 hour 5.0 (2.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 14 days Note: Decreased frozen stability.
3318UR	Vanillylmandelic Acid Urine Random
Effective	June 29
Specimen/Stability	Urine 5.0 (2.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 14 days Note: Decreased frozen stability.

Test Changes: (cont'd)

3522	Folate	June 29
Effective		
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 1 day, Refrigerated 7 days, Frozen 2 months	
	Note: Increased refrigerated stability.	
Reference Range	< 5 Years: Not established	
	5 – 9 Years: > 7.1 ng/mL (NEW)	
	10 – 17 Years: > 8.0 ng/mL (NEW)	
	> 17 Years: > 5.4 ng/mL (NEW)	
Always Statement	Reference Range Interpretation (> 17 Years):	
	Low <3.4 ng/mL (NEW)	
	Borderline 3.4 – 5.4 ng/mL (NEW)	
	Normal > 5.4 ng/mL (NEW)	
Also Affected	DOS Code 3020 (reference range only)	
4129U	Drugs of Abuse Screen Urine w/Reflex Confirmation	June 29
Effective		
Specimen/Stability	Urine 10.0 (5.0) mL: Refrigerated 7 days, Frozen 14 days	
	Note: Decreased frozen stability.	
4175U	Fentanyl Screen Urine w/Reflex Confirmation	June 29
Effective		
Methodology	ELISA (NEW)	
Always Statement	Reporting Limit: 0.3 ng/mL	
	Synonym: Sublimaze®	
	Approximately 6% of dose is excreted in the urine as unchanged drug in 3-4 days.	
	Analysis by Enzyme-Linked Immunosorbent Assay (ELISA)	
4933	Olanzapine	June 29
Effective		
Specimen/Stability	Serum 3.0 (2.0) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days	
	Note: Ambient and refrigerated specimens now accepted; decreased frozen stability.	
Collection Instructions	Serum separator tubes are not acceptable. Ship samples refrigerated.	
4964	Clozapine & Norclozapine	June 29
Effective		
Specimen/Stability	Plasma Heparinized 2.0 (1.0) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days	
Alt Specimen	Plasma EDTA 2.0 (1.0) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days	
	Serum 2.0 (1.0) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days	
	Note: Ambient specimens now accepted; increased refrigerated and decreased frozen stability.	

Test Changes: (cont'd)

5382 Cytochrome P450 2C19 GenotypR™

Effective June 29
Name Cytochrome P450 2C19 (Clopidogrel) GenotypR™

1083 Beta-2-Glycoprotein I (Beta-2-GPI) IgG, IgM & IgA Autoabs

Effective July 6
Reference Range Beta-2-GPI IgG < 21 Units **(NEW)**
Beta-2-GPI IgM < 21 Units **(NEW)**
Beta-2-GPI IgA < 21 Units **(NEW)**
Also Affected DOS Code 1081

1136 Glomerular Basement Membrane IgG Autoabs

Effective July 6
Reference Range < 21 Units **(NEW)**
Always Statement Negative < 21 Units
Weak Positive 21-30 Units
Moderate to Strong Positive > 30 Units
Also Affected DOS Code 1726

The CPT Codes provided are based on AMA Guidelines and are for informational purposes only. CPT Coding is the sole responsibility of the billing party. Please direct any questions regarding CPT Coding to the payer being billed.

New Referral Tests:

The following tests are now available from Quest Diagnostics and may be referred through Specialty Laboratories.

S52159 CellSearch® Circulating Tumor Cells, Prostate [16812]

Test performed at Quest Diagnostics, San Juan Capistrano

S52160 CellSearch® Circulating Tumor Cells, Colon [16811]

Test performed at Quest Diagnostics, San Juan Capistrano

Please call client relations at 800-421-4449 or visit our website at www.specialtylabs.com for ordering information.

Discontinued Tests:

Effective Immediately:

- S52043 HTLV-I/II Antibody, WB (CSF) [61105]**
No replacement
- S52040 Cartilage Oligomeric Matrix Protein (COMP) [157]**
No replacement
- S51728 KRAS Mutation Analysis [16510X]**
Recommended replacement: 5032 – KRAS Mutation Analysis
Test performed at Specialty Laboratories
- S51883 NRAS Mutation Analysis [16818]**
Recommended replacement: 5030 – NRAS Mutation Analysis
Test performed at Specialty Laboratories
- S51674 RAS Mutation Analysis, Cell-Based [16128X]**
Recommended replacement: 5034 – RAS Mutation Analysis, Cell-Based
Test performed at Specialty Laboratories
- S41700NY FENTANYL RANDOM URINE (9176U)**
Recommended replacement: 4175U-Fentanyl screen urine w/reflex confirmation
Test performed at Specialty Laboratories

Effective June 15:

- 8322 *Histoplasma* IgG Abs [EIA]**
Recommended replacement: 8328 – *Histoplasma* Total Antibody [ELISA]
Test performed at Specialty Laboratories
- 8323 *Histoplasma* IgM Abs [EIA]**
Recommended replacement: 8328 – *Histoplasma* Total Antibody [ELISA]
Test performed at Specialty Laboratories
- 8324 *Histoplasma* IgG & IgM Abs [EIA]**
Recommended replacement: 8328 – *Histoplasma* Total Antibody [ELISA]
Test performed at Specialty Laboratories

Discontinued Tests: (cont'd)

Effective July 1:

- S50826 DRUG SCREEN MECONIUM COMPREHENSIVE [941510]**
Recommended replacement: S52037-Drug Screen Panel 9, Meconium (30427X)
Test performed at Quest Diagnostics, Chantilly
- S50870 PHENOBARBITAL [90194]**
Recommended replacement: S52035-Phenobarbital (708X)
Test performed at Quest Diagnostics, Chantilly
- S50902 CALPROTECTIN**
Recommended replacement: S52034-Calprotectin (16796)
Test performed at Quest Diagnostics, San Juan Capistrano
- S49582 INTERLEUKIN 1 – BETA**
Recommended replacement: S52033-Interleukin-1 Beta (1757Z)
Test performed at Quest Diagnostics, San Juan Capistrano
- S42830 PNH CD59 EXPRESSION**
Recommended replacement: S52042- CD55 AND CD59 EXPRESSION, RED CELLS & GRANULOCYTES [19835X]
Test performed at Quest Diagnostics, San Juan Capistrano
- S50710 Anti RNA Polymerase III**
Recommended replacement: S52032-RNA Polymerase III Antibody (19899X)
Test performed by Quest Diagnostics, San Juan Capistrano
- S50878 QUETIAPINE (SEROQUEL) [90069]**
Recommended replacement: S48659- QUETIAPINE [4051SP]
Test performed at National Medical Services

Effective July 6:

- 5394 JAK2 V617F Mutation, Qual PCR, Plasma w/Reflex Exons 12, 13**
Recommended replacement: 5396 – JAK2 V617F Mutation, QI, w/Rfx Exons 12, 13 & MPL W515, S505
Test performed at Specialty Laboratories