



# SPECIALTY LABORATORIES

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Dear Colleague:

This client letter contains several new or improved assays and changes related to CPT codes, reflex testing, several updated reference ranges and instructions on processing specimens in PPT tubes.

Among the highlights, we are pleased to introduce the "*Streptococcus pneumoniae* IgG Antibodies, 23 Serotypes" assay for determining the efficacy of immunization with the 23-valent Pneumococcal Vaccine. This assay measures IgG antibodies to all 23 *S. pneumoniae* polysaccharide serotypes contained in the vaccine, including serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F. The quantitative value obtained is calibrated against the USFDA Pneumococcal Reference Standard 89SF. All serum samples are also pre-treated with Pneumococcal Cell-Wall Polysaccharide (C-Ps) to remove anti-C-Ps-specific cross-reactivity. With the introduction of the *S. pneumoniae* 23 serotype assay, we are also replacing our other *S. pneumoniae* panels: "*Streptococcus pneumoniae* IgG Antibodies, 12 and 4 Serotypes" with the "*Streptococcus pneumoniae* IgG Antibodies, 14 and 7 Serotypes", respectively.

Cartilage Oligomeric Matrix Protein (COMP) is an important new assay for evaluating cartilage degradation and risk for continued erosion in inflammatory joint diseases. COMP is a useful adjunct to Cyclic Citrullinated Peptide (CCP), Rheumatoid Factor Abs and C-Reactive Protein (CRP) in assisting with treatment decisions for rheumatoid arthritis and evaluating patients with suspected inflammatory or degenerative joint diseases.

This time of year is when CPT code changes from Medicare become fully implemented. Very few of the CPT code changes this year concern assays offered by *Specialty*. The changes which have occurred involve more specific delineation of the quantitative and semi-quantitative nature of immunohistochemistry assays as well as identification of protein electrophoresis on non-serum specimens. A list of recommended CPT code changes is attached. The revised NCD/LMRP listings are now posted on the Web and copies are available through Client Services.

As part of our on-going effort to resolve any issues which may cause delays, we have also attached the instructions for processing samples in the PPT tubes that *Specialty* provides. We have recently received a number of tubes that were not centrifuged prior to shipment, and we were unable to perform the requested tests on these samples.

For additional information on testing or other specimen collection guidelines, please contact Client Services at 800-421-4449.

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



## New from *Specialty*

**Effective Tuesday, May 4, 2004 or as noted**

### 3130 Cartilage Oligomeric Matrix Protein (COMP)

Component	Method	Reference Range	Units
COMP	EIA	< 15	U/L
<b>Specimen/Stability</b>	1.0 (0.5) mL Serum; Ambient, Refrigerated or Frozen Ambient – 7 days; Refrigerated – 14 days; Frozen – 2 months		
<b>Clinical Utility</b>	COMP serum levels can be used to evaluate cartilage degradation in inflammatory joint diseases and to help guide treatment decisions. Results less than or equal to 15 U/L suggests decreased risk for cartilage degradation; results greater than 15 U/L suggests increased risk for aggressive cartilage destruction.		
<b>Schedule</b>	Thursday (additional set-ups will be scheduled as test volume grows)		
<b>Turnaround Time</b>	1-8 days		
<b>CPT Code</b>	83520		

### 1014 Rheumatoid Arthritis COMPrehensive

Component	Method	Reference Range	Units
COMP	EIA	< 15	U/L
Cyclic Citrullinated Peptide IgG	EIA	< 20	Units
Rheumatoid Factor Autoantibodies	NEPH	< 20	IU/mL
C-Reactive Protein	NEPH	< 5	mg/L
<b>Specimen/Stability</b>	3.0 (1.0) mL Serum; Ambient, Refrigerated or Frozen Ambient – 7 days; Refrigerated – 14 days; Frozen – 2 months		
<b>Clinical Utility</b>	Used for differential diagnosis or rheumatoid arthritis and to help guide treatment decisions.		
<b>Schedule</b>	Thursday		
<b>Turnaround Time</b>	1-8 days		
<b>CPT Code</b>	83520x2, 86431, 86140		

### 4891 Leptin

Component	Method	Reference Range	Units
Leptin	EIA	Adult Males: 1.0 - 35.3	ng/mL
		Adult Females: 3.6 - 72.4	ng/mL
<b>Specimen/Stability</b>	1.0 (0.5) mL Serum; Refrigerated or Frozen Refrigerated – 7 days; Frozen – 2 months		
<b>Alternate Specimen</b>	1.0 (0.5) mL EDTA or Heparinized Plasma; Refrigerated or Frozen Refrigerated – 7 days; Frozen – 2 months		
<b>Clinical Utility</b>	Leptin is a protein hormone produced predominantly in the adipocytes. Small amounts are synthesized in the epithelium of the stomach and in the placenta. Leptin plays an important role in the regulation of body weight through the hypothalamic centers of hunger, body temperature and energy expenditure. Increased leptin levels are seen in obese individuals. The fact that elevated leptin levels fail to alter the obese state of these individuals may be related to a "leptin resistance" and an inability of leptin to enter the cerebral spinal fluid to reach sites in the hypothalamus to regulate appetite. Leptin levels have been shown to change under certain endocrine conditions. For example, when leptin levels are expressed per body adiposity, females have higher leptin levels than do males. This may be related to the distribution of adipose tissue where omental fat vs. subcutaneous fat, which differs between genders, may have different leptin production rates. Its role in metabolism, insulin sensitivity, and endocrine function are still under investigation.		
<b>Schedule</b>	Wednesday		
<b>Turnaround Time</b>	1-8 days		
<b>CPT Code</b>	83520		

## Immunohistochemistry Markers (new or not previously listed in Directory of Services)

Test Code	Name of Marker	Methodology	Reference Range
IHC 140	ALK (Alkprotein)	IHC	By report
IHC186	Bcl-6	IHC	By report
IHC187	CD1a	IHC	By report
IHC34	CD21	IHC	By report
IHC 148	CMV	IHC	By report
IHC 177	EBV-LMP	IHC	By report
IHC188	E-Cadherin	IHC	By report
IHC189	Factor XIIIa	IHC	By report
IHC 89	Gastrin	IHC	By report
IHC190	Myogenin	IHC	By report
IHC191	MyoD1	IHC	By report
IHC 57	OC125 (CA125)	IHC	By report
IHC08	p53	IHC	By report
IHC192	p63	IHC	By report

### The following information applies to all the markers listed above.

Specimen/Stability	Formalin-fixed, paraffin-embedded Tissue Block; Paraffin Block Ambient – 60 Months; Refrigerated (during summer months)
<b>Collection Instructions</b>	Ship using a cold pack during summer months
<b>Clinical Utility</b>	Useful for identification of antigens present in paraffin-embedded tissues. Properly selected panels may aid in the identification of tumor type and subclassification. Additional markers may be useful in assessing proliferation (Ki67) or prognosis (e.g., bcl-2 or HER-2/neu) in selected tumor types.
<b>Schedule</b>	Monday-Sunday
<b>Turnaround Time</b>	2-4 days
<b>CPT Code</b>	88342
Notes	Diagnostic code required for third party reimbursement. Please send copy of pathology report and other applicable test results. Markers can be ordered individually or in combination; by request, <i>Specialty's</i> pathologists can select stain(s) to support or rule out a differential diagnosis. Stains not yet listed may be available. Please contact <i>Specialty</i> Anatomic Pathology/Oncology, 1-888-567-5225, for additional information or to speak with a pathologist.

## 2388 *Streptococcus pneumoniae* IgG Antibodies, 23 Serotypes

Component	Method	Reference Range	Units
<i>S. pneumoniae</i> Type 1 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 2 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 3 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 4 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 5 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 6B Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 7F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 8 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 9N Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 9V Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 10A Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 11A Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 12F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 14 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 15B Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 17F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 18C Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 19A Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 19F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 20 Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 22F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 23F Antibodies	IAA	>1.0	ug/mL
<i>S. pneumoniae</i> Type 33F Antibodies	IAA	>1.0	ug/mL

**2388      *Streptococcus pneumoniae* IgG Antibodies, 23 Serotypes (continued)**

<b>Specimen/Stability</b>	3.0 (1.0) mL Serum; Ambient, Refrigerated or Frozen
<b>Clinical Utility</b>	Ambient – 7 days; Refrigerated – 14 days; Frozen – 2 months Determination of IgG antibody concentrations to 23 different <i>Streptococcus pneumoniae</i> polysaccharide-serotypes. A Post-/Pre-immunization ratio of greater than 4 is considered a good responder against that particular serotype.
<b>Schedule</b>	Tuesday, Thursday, Saturday
<b>Turnaround Time</b>	2-4 days
<b>CPT Code</b>	86609x23
<b>Notes</b>	All serum specimens are pre-treated with Pneumococcal Cell-Wall Polysaccharide (C-PS) to remove anti-C-PS specific antibody. Also available, 2388P <i>Streptococcus pneumoniae</i> IgG Antibodies, 23 Serotypes Pre/Post. Pre- and Post-immunization sera MUST be sent together. Please label the tubes "Pre" and "Post" so that the sera can be tested simultaneously.

**Also Newly Available:**

- 1049      Humoral Immune Evaluation (Pneumo 23)**  
(*S. pneumoniae* types 1, 2, 3, 4, 5, 6b, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) and 1049P Humoral Immune Evaluation (Pneumo 23) Pre/post
- 1088      Humoral Immune Evaluation, (Pneumo 23) plus *Haemophilus influenzae* b**  
(*S. pneumoniae* types 1, 2, 3, 4, 5, 6b, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) and 1088P Humoral Immune Evaluation (Pneumo 23) plus *Haemophilus influenzae* b Pre/post
- 1149      Humoral Immune Status Survey (Pneumo 23)**  
(*S. pneumoniae* types 1, 2, 3, 4, 5, 6b, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) and 1149P Humoral Immune Status Survey (Pneumo 23) Pre/post
- 1047      Humoral Immune Evaluation (Pneumo 7)**  
(*S. pneumoniae* types 4, 6b, 9V, 14, 18C, 19F, 23F) and 1047P Humoral Immune Evaluation (Pneumo 7) Pre/post
- 1087      Humoral Immune Evaluation (Pneumo 7) plus *Haemophilus influenzae* b**  
(*S. pneumoniae* types 4, 6b, 9V, 14, 18C, 19F, 23F) and 1087P Humoral Immune Evaluation (Pneumo 7) plus *Haemophilus influenzae* b Pre/post
- 1147      Humoral Immune Status Survey (Pneumo 7)**  
(*S. pneumoniae* types 4, 6b, 9V, 14, 18C, 19F, 23F) and 1147P Humoral Immune Status Survey (Pneumo 7) Pre/post

## Test Changes

**Effective Tuesday, April 27, 2004 or as noted**

<u>Test Code</u>	<u>Test Name</u>	<u>Specific Change</u>	<u>Also Affected</u>
9941	<i>Aspergillus</i> IgG, IgM & IgA Abs	<u>Reference Range</u> <i>Aspergillus</i> IgG, IgM, IgA <0.81 Index < 0.81                      Negative 0.81 – 1.19                Indeterminate > 1.19                        Positive	9961 <i>Aspergillus</i> IgG 9946 <i>Aspergillus</i> IgM
1266	Gliadin IgG & IgA Autoantibodies	<u>Reference Range</u> IgG <10.0 U/mL IgA <5.0 U/mL	1261 Gliadin IgG 1286 Gliadin IgA 1075 Celiac Disease Eval w/ IgA 1076 Celiac Disease Autoab Eval 1077 Celiac Disease EvaluatR

8132	Hepatitis B Virus GenotypR	<u>Name</u> Hepatitis B Virus Drug Resistance DetectR™ <u>Method</u> Line Probe Assay (LiPA) <u>Components</u> Lamivudine (3TC) Polymerase Codon 180 Polymerase Codon 204 Polymerase Codon 207	
9884A	HIV-1 RNA Quant by Roche <i>Effective 4-6-04</i>	<u>Dynamic Range</u> Upper limit now extended to 10,000,000 copies/mL. Lower limit is unchanged	9884ASR HIV-1 RNA Quant by Roche Serial Report 9874A HIV-1 RNA Quant reflex to Ultrasensitive 9874ASR HIV-1 RNA Quant reflex to Ultrasensitive Serial Rpt 7484A HIV-1 RNA Quant reflex to GenotypR PLUS Also New York codes: 9884FPNY, 9884FPNS, 9884NYP, 9884NYPS, 7482FPNY, 9874AFN, 9874AFNS
7482	HIV-1 RNA UltraQuant® with reflex to GenotypR™ Plus <i>Effective 4-6-04</i>	<u>Reflex Conditions</u> HIV-1 RNA will reflex to HIV GenotypR™ when the viral load is greater than or equal to 1,000 copies/mL	7482SR HIV-1 RNA Ultra-Quant® with reflex to GenotypR™ Plus Serial Report 7482A HIV-1 RNA Ultrasensitive by Roche reflex to GenotypR™ Plus 7482ASR HIV-1 RNA Ultrasensitive by Roche reflex to GenotypR™ Plus Serial Report 7484A HIV-1 RNA Quant reflex to GenotypR PLUS Also New York code: 7482FPNY
9874A	HIV-1 RNA Quant [Roche] reflex to Ultrasensitive <i>Effective 4-6-04</i>	<u>Stability PPT tubes</u> Ambient – 48 hours Refrigerated – 48 hours Frozen – 2 months (preferred)	PPT tubes received ambient or refrigerated within 48 hrs of draw are acceptable for all HIV-1 RNA by PCR panels and reflexes
1143	Humoral Immune Evaluation (pneumo 12) <i>Effective 5/4/04</i>	<u>Name</u> Humoral Immune Evaluation (pneumo 14) <u>Components</u> Add <i>S. pneumoniae</i> types 5, 9V <u>CPT Codes</u> 86774, 86648, 86609x14	1143P Humoral Immune Eval (pneumo 14) Pre/post (double the CPT codes)
1146	Humoral Immune Evaluation (pneumo 12) plus <i>Haemophilus influenza</i> b <i>Effective 5/4/04</i>	<u>Name</u> Humoral Immune Evaluation (pneumo 14) plus <i>Haemophilus influenza</i> b <u>Components</u> Add <i>S. pneumoniae</i> types 5, 9V <u>CPT Codes</u> 86684, 86774, 86648, 86609x14	
1148	Humoral Immune Status Survey (pneumo 12) <i>Effective 5/4/04</i>	<u>Name</u> Humoral Immune Status Survey (pneumo 14) <u>Components</u> Add <i>S. pneumoniae</i> types 5, 9V <u>CPT Codes</u> 82784x3, 82785, 82787x4, 86774, 86648, 86609x14	1148P HISS (pneumo 14) Pre/post (double the CPT codes)
3860	Neuron-Specific Enolase	<u>Method (serum and CSF)</u> EIA <u>Reference Range (CSF only)</u> <10 ng/mL (remove Indeterminate range)	3860C NSE, CSF (range change) 3254 Small Cell Carcinoma Monitor, Lung

5937	Protein S Antigen, Total	<u>Method</u> LIA (Latex Immunoassay) <u>Reference Range</u> 70-140 %	5938 Protein S Evaluation 5973 Thrombotic Risk Evaluation 3
3941	PTH, Intact Only	<u>Specimen</u> Serum is the preferred specimen; Heparinized plasma is acceptable. EDTA plasma is not acceptable	
3217	Renin, Direct	<u>Reference Range</u> 2.4 – 29 uU/mL Supine 3.3 – 41 uU/mL Upright	
2386	<i>Streptococcus pneumoniae</i> IgG Antibodies, 12 Serotypes	<u>Name</u> <i>Streptococcus pneumoniae</i> IgG Antibodies, 14 Serotypes <u>Components</u> (Serotypes 1, 3, 4, 5, 6b, 7F, 8, 9N, 9V, 12F, 14, 18C, 19F, 23F) <u>CPT Codes</u> 86609x14	2386P <i>Streptococcus pneumoniae</i> IgG Abs, 14 Serotypes, Pre/post (double the CPT codes)
1030	Transglutaminase IgG & IgA Autoantibodies	<u>Reference Range</u> IgG < 6.0 U/mL IgA <4.0 U/mL	1027 Transglutaminase IgG 1029 Transglutaminase IgA 1075 Celiac Disease Eval w/ IgA 1077 Celiac Disease EvaluatR
3361	Valproic Acid, Free <i>Effective 4-6-04</i>	<u>Reference Range</u> 5.0 – 20.0 ug/mL	
3503	Vitamin K1	<u>Reference Range</u> 0.15 – 3.5 ng/mL	

## Discontinued Tests

**Effective Tuesday, May 4, 2004 or as noted**

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a “replacement,” contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to alternate tests or sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

Test Code	Test Name	Reason	Alternate or Replacement Tests
S48913	Leptin Sendout	In-house assay now available	4891 Leptin
5311C	Potassium CSF	Low volume	5311 Potassium (serum)
2370	<i>Streptococcus pneumoniae</i> IgG 4 Serotypes and <i>S. pneumoniae</i> IgG 4 Pre/Post	7-serotype panel available	2384 <i>Streptococcus pneumoniae</i> IgG 7 Serotypes and 2384P <i>S. pneumoniae</i> IgG 7 Pre/Post
2370P	Factor XIIIa sendout	In-house assay now available	IHC189 Factor XIIIa IHC
S48881	Humoral Immune Evaluation	New <i>S. pneumo</i> with 7-serotypes	1047 Humoral Immune Eval (7 serotype)
1043	Humoral Immune Eval Pre/Post		1047P Hum Immune Eval 7 Pre/Post
1043P	Humoral Immune Evaluation plus <i>Haemophilus influenzae</i> b	New <i>S. pneumo</i> with 7-serotypes	1087 Hum Immune Eval + Hib (7 serotype)
1086	Hum Immune Eval + <i>Hib</i> Pre/Post		1087P Hum Immune Eval + Hib 7 Pre/Post
1086P	Humoral Immune Status Survey (pneumo 4)	New <i>S. pneumo</i> with 7-serotypes	1147 HISS (7 serotype)
1048	HISS pneumo 4 Pre/Post		1147P HISS 7 Pre/Post

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