

December, 2005

Dear Colleague:

2005 New Test Summary

Specialty introduced more than 80 new tests during 2005, including:

- AmpliChip™ CYP450 (FDA-approved test for 2 genes: CYP2D6 & CYP2C19)
- Anti-Mullerian Hormone
- Connexin 26 GenotypR™
- Celiac Disease GenotypR™
- Heat Shock Protein 70 Autoantibodies (Anti-68 kd)
- Serum and urine confirmation drug testing for opiates
- Ashkenazi Jewish GenotypR™ - Carrier Panel and carrier, diagnostic and fetal studies for 8 diseases
- *Mycobacterium avium* and *M. tuberculosis* DNA DetectR™ assays
- *Streptococcus* Group B DNA DetectR™
- YKL-40 (Human Cartilage Glycoprotein 39)

2006 CPT Coding

We have received the list of new codes that will go into effect in January 2006 and have listed the resultant CPT code changes to our test menu. If you have any questions about the new codes, please contact our Coding Specialist, Sandra Jones at ext. 6756.


Alpha-Fetoprotein Maternal

Please note that the maternal serum AFP tests are not diagnostic and AFP alone has limited application for screening purposes. Alpha-Fetoprotein Maternal, 2.0 MoM #3108 and Alpha-Fetoprotein Maternal, 2.5 MoM #3090 should only be used to screen for Neural Tube Defects. AFP Quad Screen (#3092) is preferred when screening for fetal anomalies. Although *Specialty* has traditionally offered AFP maternal serum testing and Triple Screens with cut-offs at either 2.5 MoM or 2.0 MoM, it should be noted that the Triple Screen 2.5 MoM #3091 is accepted as a screening standard which minimizes the number of false-positive screening results. The 2.0 MoM AFP Maternal Serum and Triple Screen panels are more sensitive but less specific; hence, positive screens on these tests will result in follow up of additional patients.

Testosterone Panel Changes

Specialty's testosterone panels employ two different methods to determine free testosterone levels. The standard RIA panel is a rapid test suited for adult males who, in most cases, do not require determination of very low free testosterone levels. The testosterone panels employing dialysis are intended for quantifying the lower free testosterone levels generally found in pediatric and female patients as well as in adult males when clinically indicated. Two new panels using the ultrasensitive dialysis method in determining Bioavailable and Weakly Binding testosterone will soon be available.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Services at 800-421-4449.



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

New from *Specialty*

Effective Tuesday, December 13, 2005 or as noted

5854 Cytogenetics - MLL(11q23) [FISH]

Component	Method	Reference Range	Units
MLL(11q23) Interpretation	FISH		By Report
Specimen/Stability	3 (1.0) mL Bone Marrow Ambient 72 hours		
Alternate Specimen Collection Instructions	3 (1.0) mL Whole Blood, Sodium Heparin Do not refrigerate or freeze. Ship by overnight courier to arrive at <i>Specialty</i> within 24 hours of collection.		
Clinical Utility	For the detection of 11q23 rearrangements associated with various translocations involving the MLL gene seen with Myeloid/lymphoid or mixed- lineage leukemias		
Performance Schedule	Set up: Sunday - Saturday	Resulted: 7 days	
CPT Code	88237, 88271, 88275, 88291		

8315UR *Histoplasma* Antigen Urine [effective 12-20-05]

Component	Method	Reference Range	Units
Histoplasma Ag	EIA		
		Negative <8.0 U	
		Borderline 8.0-10.0 U	
		Positive >10.0 U	
Specimen/Stability	10 (1.0) mL Urine Ambient 3 days; Refrigerated 14 days; Frozen 2 months		
Clinical Utility	Support the diagnosis of Histoplasmosis.		
Performance Schedule	Set up: Wednesday	Resulted: Next day	
CPT Code	87385		

IHC204 SMMS-1 (Smooth Muscle Myosin, Heavy Chain) [IHC]

Component	Method	Reference Range	Units
SMMS-1	IEF		By report
Specimen/Stability	Formalin-fixed paraffin embedded tissue Ambient or Refrigerated		
Collection Instructions	Shipping on cold pack recommended during warm months.		
Clinical Utility	IHC stains are 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/ <i>neu</i>) in selected tumor types.		
Performance Schedule	Set up: Monday-Sunday	Resulted: Next day	
CPT Code	88342		
Notes	Diagnostic code required for third party reimbursement. Please send copy of pathology report and other applicable tests.		
Order Codes	1857 IHC Stain & Diagnostic Interpretation: Pathologist Chooses 1-3 Stains 1859 IHC Stain & Diagnostic Interpretation: Pathologist Chooses 1-6 Stains 1854 IHC Stain & Interpretation: Client Chooses Stains 1856 IHC Stain Only: Client Chooses Stains		

Test Changes

Blood Bank Tests -- Specimen Stability

For all serum and plasma sample types, ambient is no longer acceptable; Refrigerated stability is 7 days. Frozen stability is unchanged at 2 months.

2447T	Hepatitis C Virus Ab by RIBA (Blood Bank)	3021BT	HIV-1 Abs by IB reflex HIV-2 Abs IB + bands (Blood Bank)
2447BT	Hepatitis C Virus Ab RIBA + bands (Blood Bank)	9921BT	HIV-2 Abs reflex to IB + bands [Blood Bank]
3012BT	HIV-1 Antibodies by IB + bands (Blood Bank)	9921T	HIV-2 IgG Abs with reflex IB [Blood Bank]
3012T	HIV-1 Antibodies by IB (Blood Bank)	7780T	HTLV-I/II Abs by IB (Blood Bank)
3013BT	HIV-1 Abs by IB + bands reflex HIV-2 Abs EIA (Blood Bank)	7780BT	HTLV-I/II Abs by IB + bands (Blood Bank)
		7782B	HTLV-I/II Abs IB + bands Reflex RIPA (Blood Bank)

Other Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected																																																																														
3930	01-10-06	Alkaline Phosphatase	<p><u>Reference Range</u></p> <table border="1"> <thead> <tr> <th></th> <th>Males U/L</th> <th>Females U/L</th> </tr> </thead> <tbody> <tr><td>0 - 30 days</td><td>45 - 270</td><td>45 - 270</td></tr> <tr><td>1 - 11 months</td><td>55 - 300</td><td>55 - 300</td></tr> <tr><td>1 - 3 years</td><td>90 - 270</td><td>90 - 270</td></tr> <tr><td>4 - 6 years</td><td>110 - 320</td><td>110 - 320</td></tr> <tr><td>7 - 9 years</td><td>110 - 400</td><td>110 - 400</td></tr> <tr><td>10 - 11 years</td><td>60 - 430</td><td>60 - 460</td></tr> <tr><td>12 - 13 years</td><td>65 - 440</td><td>50 - 460</td></tr> <tr><td>14 - 15 years</td><td>80 - 460</td><td>30 - 290</td></tr> <tr><td>16 - 18 years</td><td>40 - 230</td><td>25 - 120</td></tr> <tr><td>> 18 years</td><td>25 - 100</td><td>25 - 100</td></tr> </tbody> </table>		Males U/L	Females U/L	0 - 30 days	45 - 270	45 - 270	1 - 11 months	55 - 300	55 - 300	1 - 3 years	90 - 270	90 - 270	4 - 6 years	110 - 320	110 - 320	7 - 9 years	110 - 400	110 - 400	10 - 11 years	60 - 430	60 - 460	12 - 13 years	65 - 440	50 - 460	14 - 15 years	80 - 460	30 - 290	16 - 18 years	40 - 230	25 - 120	> 18 years	25 - 100	25 - 100	<p>3996 Alkaline Phosphatase Isoenzymes</p> <p>5317 Metabolic Panel, Comprehensive</p> <p>5318 Hepatic Function Panel</p>																																													
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3996	01-10-06	Alkaline Phosphatase Isoenzymes	<p><u>Reference Range</u></p> <p>No change to intestinal isoenzyme range</p> <table border="1"> <thead> <tr> <th rowspan="2">Age</th> <th colspan="2">Bone %</th> <th colspan="2">Liver %</th> </tr> <tr> <th>Male</th> <th>Female</th> <th>Male</th> <th>Female</th> </tr> </thead> <tbody> <tr><td>< 1 yo</td><td>10 - 90</td><td>10 - 90</td><td>10 - 50</td><td>10 - 50</td></tr> <tr><td>1 - 5 yo</td><td>30 - 80</td><td>30 - 80</td><td>10 - 50</td><td>10 - 50</td></tr> <tr><td>6 - 10 yo</td><td>20 - 90</td><td>20 - 90</td><td>10 - 40</td><td>10 - 40</td></tr> <tr><td>11 - 15 yo</td><td>40 - 90</td><td>20 - 90</td><td>10 - 40</td><td>10 - 40</td></tr> <tr><td>16 - 18 yo</td><td>40 - 90</td><td>20 - 60</td><td>10 - 50</td><td>30 - 80</td></tr> <tr><td>> 18 yo</td><td>16 - 56</td><td>16 - 56</td><td>44 - 84</td><td>44 - 84</td></tr> </tbody> </table> <table border="1"> <thead> <tr> <th rowspan="2">Age</th> <th colspan="2">Bone U/L</th> <th colspan="2">Liver U/L</th> </tr> <tr> <th>Male</th> <th>Female</th> <th>Male</th> <th>Female</th> </tr> </thead> <tbody> <tr><td>< 1 yo</td><td>10 - 270</td><td>10 - 270</td><td>10 - 150</td><td>10 - 150</td></tr> <tr><td>1 - 5 yo</td><td>30 - 240</td><td>30 - 240</td><td>10 - 150</td><td>10 - 150</td></tr> <tr><td>6 - 10 yo</td><td>20 - 360</td><td>20 - 360</td><td>10 - 160</td><td>10 - 160</td></tr> <tr><td>11 - 15 yo</td><td>30 - 405</td><td>15 - 405</td><td>10 - 180</td><td>10 - 180</td></tr> <tr><td>16 - 18 yo</td><td>20 - 205</td><td>5 - 75</td><td>5 - 115</td><td>10 - 95</td></tr> <tr><td>> 18 yo</td><td>5 - 58</td><td>5 - 58</td><td>5 - 93</td><td>5 - 93</td></tr> </tbody> </table>	Age	Bone %		Liver %		Male	Female	Male	Female	< 1 yo	10 - 90	10 - 90	10 - 50	10 - 50	1 - 5 yo	30 - 80	30 - 80	10 - 50	10 - 50	6 - 10 yo	20 - 90	20 - 90	10 - 40	10 - 40	11 - 15 yo	40 - 90	20 - 90	10 - 40	10 - 40	16 - 18 yo	40 - 90	20 - 60	10 - 50	30 - 80	> 18 yo	16 - 56	16 - 56	44 - 84	44 - 84	Age	Bone U/L		Liver U/L		Male	Female	Male	Female	< 1 yo	10 - 270	10 - 270	10 - 150	10 - 150	1 - 5 yo	30 - 240	30 - 240	10 - 150	10 - 150	6 - 10 yo	20 - 360	20 - 360	10 - 160	10 - 160	11 - 15 yo	30 - 405	15 - 405	10 - 180	10 - 180	16 - 18 yo	20 - 205	5 - 75	5 - 115	10 - 95	> 18 yo	5 - 58	5 - 58	5 - 93	5 - 93	
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1000	12-13-05	ANALyzer®	<p><u>Reference Range for SSA, SSB, RNP/Sm, Sm, Scl-70, RiboP</u></p> <p>Negative <5.0</p> <p>Borderline 5.0 – 10.0</p> <p>Positive > 10.0</p> <p><u>Method</u></p> <p>EIA/LIA (Line Immunoblot Array)</p> <p><u>Stability</u></p> <p>Ambient 7 d, Refrigerated 14 d, Frozen 2 Months</p> <p><u>Component Name Change</u></p> <p>RNP/Sm</p>	<p>1004 Rheumatic Evaluation</p> <p>1005 ANALyzer® without ANA</p> <p>1006 ANALyzer® without RF</p> <p>1118 ANA reflex to ANALyzer®</p> <p>1104 Parietal Cell Total Autoabs</p> <p>1121 ANA reflex to Profile</p> <p>1126 ANA, Profile #2</p> <p>1127 ANA, dsDNA, SS-A/SS-B, ENA, Scl-70 Autoabs</p> <p>1007 SS-A & SS-B IgG Autoabs</p> <p>1204 SS-A IgG Autoantibodies</p> <p>1205 SS-B IgG Autoantibodies</p> <p>1210 Extractable Nuclear Ag (ENA) IgG Autoabs</p> <p>1235 Scl-70 IgG Autoabs</p> <p>1215 U1 RNP/snRNP Autoabs</p> <p>1220 Sm (Smith) IgG Autoabs</p> <p>1271 Ribosomal P Protein IgG Autoantibodies</p>																																																																														
3138	11-09-05	Anti-Mullerian Hormone AssessR™	<p><u>CPT Code</u></p> <p>83520 (quantitative code)</p>																																																																															

Test Code	Effective Date	Test Name	Specific Change	Also Affected
8941	11-29-05	<i>Borrelia burgdorferi</i> IgG & IgM Antibodies	<u>Reference Range</u> Negative <0.8 Borderline 0.8-1.0 Positive > 1.0	8956 <i>B. burgdorferi</i> IgG/IgM + C6 Peptide reflex IB + bands 8941C <i>B. burgdorferi</i> IgG & IgM Antibodies CSF 7716 <i>B. burgdorferi</i> IgG & IgM 7716B <i>B. burgdorferi</i> + bands 7716B NY <i>B. burgdorferi</i> + bands NY 8942 <i>B. burgdorferi</i> IgG & IgM Reflex IB + bands 8938 <i>B. burgdorferi</i> IgG & IgM Reflex IB [Alternate]+ bands 8951 <i>B. burgdorferi</i> IgG Abs 8951C <i>B. burgdorferi</i> IgG CSF 8954 <i>B. burgdorferi</i> + C6 Peptide 7970 <i>B. burgdorferi</i> IgG & IgM Antibody Index 8961 <i>B. burgdorferi</i> IgM Abs 8961C <i>B. burgdorferi</i> IgM CSF 6906 <i>B. burgdorferi</i> Panel 7846 Ehrlichiosis (Granulocytic) & Lyme Disease Eval 8968 <i>Borrelia, Babesia, Anaplasma</i> : Lyme Co-Infection
1651	immediately	Chronic Fatigue & Immune Dysfunction Syndrome Evaluation	<u>CPT Coding Changes 2005</u> 85048, 86359, 86360, 86361, 8814, 88185x2, 86663, 86664, 86665x2, 86790x2	
3851	12-13-05	Creatine Kinase	<u>Stability</u> Ambient 3d Refrigerated 7d, Frozen 2 months	
5356	01-16-06	Cystic Fibrosis GenotypR™ Carrier Study (CF70)	<u>Mutations</u> The benign polymorphism D1270N will be removed. The G622D mutation will be added.	5357 Cystic Fibrosis 70 GenotypR™: Diagnostic Study 5358 Cystic Fibrosis 70 GenotypR™ Fetal Study w/ reflex to MCC
9436	11-13-05	Cytomegalovirus IgG & IgM Antibodies	<u>Reference Range</u> Negative <0.8 Borderline 0.8 -1.0 Positive > 1.0 <u>Method</u> CMV IgM replace MAC EIA with EIA Note: Not to be used for donor screening.	9436C Cytomegalovirus IgG & IgM Antibodies CSF [EIA] 9431 Cytomegalovirus IgG Abs 9431C Cytomegalovirus IgG CSF 8560 CMV IgG Ab Index 2486 Cytomegalovirus IgM Abs 2486C Cytomegalovirus IgM CSF 9901 TORCH IgG/IgM Abs Eval 9911 TORCH IgG Abs Eval 2231 TORCH IgM Abs Eval 2772 MEM Panel
4125	12-13-05	Drugs of Abuse Screen, Serum	<u>Reference Range</u> Change from "detected/not detected" to "positive/negative" for all 9 drugs on panel	
7741	12-13-05	<i>Helicobacter pylori</i> IgG, IgM & IgA	<u>Reference Range</u> Negative <0.8 Borderline 0.8 -1.0 Positive > 1.0 <u>Specimen</u> Primary = Serum Alternate = EDTA Plasma <u>Stability</u> Ambient 7d, Refrigerated 14d, Frozen 2 months	7986 <i>Helicobacter pylori</i> IgA Antibodies 7736 <i>Helicobacter pylori</i> IgM Antibodies 7761 <i>Helicobacter pylori</i> IgG Antibodies
8051	11-29-05	Herpes Simplex Virus 1 & 2 IgG & IgM Antibodies	<u>Reference Range and Units</u> Negative <0.8 Index Borderline 0.8-1.0 Index Positive > 1.0 Index <u>Specimen</u> Primary = Serum Alternate = EDTA Plasma <u>Stability</u> Ambient 7d, Refrigerated 14d, Frozen 2 months	9471 HSV 1 & 2 IgM Abs 9446 HSV 1 & 2 IgG Abs 9451 HSV Type 1 IgG Abs 9461 HSV Type 2 IgG Abs 9901 TORCH IgG/gM Abs Eval 9911 TORCH IgG Abs Eval 2231 TORCH IgM Abs Eval 9496 HSV 1 & 2 AccuDx® 2772 MEM Panel

