



SPECIALTY LABORATORIES

2211 Michigan Avenue
Santa Monica, CA 90404

800-421-4449

New from *Specialty*

effective September 24, 2002 or as noted

1500 Complement C3 & C4 Panel

Component	Method	Reference Range
Complement 3	NEPH	85-200 mg/dL
Complement 4	NEPH	14-53 mg/dL
Specimen Requirement	1.0 (0.5) mL Serum; Ambient, Refrigerated, or Frozen	
CPT Code	86160x2	
Clinical Utility	Quantitation of C3 and C4 is used to detect individuals with deficiencies or those with inflammatory disease.	

5361 Gleevec™ Resistance Mutation Analysis

Component	Method	Reference Range
T3151 Mutation	PCR/MALDI-TOF	Not Detected
Specimen Requirement	8 mL Whole Blood; Refrigerate but do not freeze. Stability: Refrigerated 72 hrs	
Collection Instructions	Neither heparinized bone marrow nor ACD bone marrow is acceptable. Refrigerate but do not freeze. Ship on a cold pack by overnight courier to arrive at Specialty within 72 hours of collection. Specimens will be stabilized upon receipt in department.	
CPT Code	83891, 83902, 83898, 83894, 83904, 83912	
Clinical Utility	This test assays for presence of the ABL kinase domain mutation, T315I, on BCR/ABL RNA transcripts. The patient must be positive for the BCR/ABL translocation, either by quantitative PCR (to monitor minimal residual disease) or by FISH (for diagnosis of CML) in order for this result to be meaningful.	

7420NY HIV-1 Phenoscript Assay for New York

Component	Method	Reference Range
3TC Lamivudine (Epivir)		Technical Cut-off: 3.0 Clinical Cut-off: 5.5
Abacavir (Ziagen)		Technical Cut-off: 2.5 Clinical Cut-off: 8.0
Amprenavir (Agenerase)		Technical Cut-off: 2.5 Clinical Cut-off: 7.0
AZT Zidovudine (Retrovir)		Technical Cut-off: 3.5 Clinical Cut-off: 4.5
d4T Stavudine (Zerit)		Technical Cut-off: 3.0 Clinical Cut-off: 3.0
ddC Zalcitabine (Hivid)		Technical Cut-off: 3.5 Clinical Cut-off: 3.5
ddI Didanosine (Videx)		Technical Cut-off: 2.0 Clinical Cut-off: 2.5
Delavirdine (Rescriptor)		Technical Cut-off: 2.5 Clinical Cut-off: 10.0
Efavirenz (Sustiva)		Technical Cut-off: 2.0 Clinical Cut-off: 5.0
Indinavir (Crixivan)		Technical Cut-off: 2.5 Clinical Cut-off: 20.0
Lopinavir+Ritonavir (Kaletra)		Technical Cut-off: 2.5 Clinical Cut-off: 10.0
Nelfinavir (Viracept)		Technical Cut-off: 2.5 Clinical Cut-off: 3.0
Nevirapine (Viramune)		Technical Cut-off: 2.0 Clinical Cut-off: 6.5

Saquinavir (Fortovase)

Technical Cut-off: 2.5
 Clinical Cut-off: 11.0

Specimen Requirement 4.0 mL Plasma EDTA; Frozen

CPT Code 87903, 87904

Notes The numerical values in this report correspond to the patient resistance index followed by the estimated contribution to response. The patient resistance index represents the fold difference in drug susceptibility between the test virus and a drug sensitive control virus. The estimated contribution to response is described as either Likely, patient sample is sensitive to drug; Unlikely, patient sample is highly resistant to drug; Possible, patient sample shows some development of resistance but is not above the cut-off used to define complete resistance or clinical non-response. **This Panel does not include Tenofovir.**

6100 Platelet Glycoprotein (Direct and Indirect) Autoantibodies

Component	Method	Reference Range
Platelet Glycoprotein Ia/IIa (Indirect) Autoabs	EIA	Not Detected
Platelet Glycoprotein Ib/IX (Indirect) Autoabs	EIA	Not Detected
Platelet Glycoprotein IIb/IIIa (Indirect) Autoabs	EIA	Not Detected
Platelet-Assoc Glycoprotein Ia/IIa (Direct) Autoabs	EIA	Not Detected
Platelet-Assoc Glycoprotein Ib/IX (Direct) Autoabs	EIA	Not Detected
Platelet-Assoc Glycoprotein IIb/IIIa (Direct) Autoabs	EIA	Not Detected

Specimen One Whole Blood; ambient; Specimen Volume depends on platelet count:
 <20,000 = 40 mL
 21,000-50,000 = 30 mL
 51,000-150,000 = 20 mL
 >150,000 = 10 mL

Specimen Two 2 (1) mL Serum; Ambient, Refrigerated, Frozen; Two 1 mL aliquots of serum
 CPT Code 86022x6

Clinical Utility Comprehensive assessment of Platelet Glycoprotein Autoantibodies in patients with suspected autoimmune thrombocytopenic purpura.

6102 Platelet Glycoprotein (Indirect) Autoabs

Component	Method	Reference Range
Platelet Glycoprotein Ia/IIa (Indirect) Autoabs	EIA	Not Detected
Platelet Glycoprotein Ib/IX (Indirect) Autoabs	EIA	Not Detected
Platelet Glycoprotein IIb/IIIa (Indirect) Autoabs	EIA	Not Detected

Specimen Requirement 2 (1) mL serum; Ambient, Refrigerated, Frozen; Two 1 mL aliquots of serum

CPT Code 86022 x 3

Clinical Utility Detection of platelet autoantibodies in serum of patients with suspected autoimmune thrombocytopenic purpura.

6104 Platelet-Associated Glycoprotein (Direct) Autoabs

Component	Method	Reference Range
Platelet-Assoc Glycoprotein Ia/IIa (Direct) Autoabs	EIA	Not Detected
Platelet-Assoc Glycoprotein Ib/IX (Direct) Autoabs	EIA	Not Detected
Platelet-Assoc Glycoprotein IIb/IIIa (Direct) Autoabs	EIA	Not Detected

Specimen Requirement Whole Blood; Ambient; Specimen Volume depends on platelet count:
 <20,000 = 40 mL
 21,000-50,000 = 30 mL
 51,000-150,000 = 20 mL
 >150,000 = 10 mL

CPT Code 86022 x 3

Clinical Utility Detection of autoantibodies on platelet surface in patients with suspected autoimmune thrombocytopenic purpura.

8080 West Nile Virus Detection [IFA]

Component	Method	Reference Range
West Nile Virus IgG	IFA	<1:40
West Nile Virus IgM	IFA	<1:40
Specimen Requirement	1 (0.5) mL serum; Ambient	
CPT Code	86790 x 2	
Clinical Utility	There is known cross-reactivity by other flaviviruses with IFA. Comparison of the titer in the WNV assay with other flavivirus-specific assays allows differentiation of the virus. Positive specimens will be forwarded to the CDC.	
Notes	Also available on CSF, see test code 8080C West Nile Virus Detection [IFA] CSF	

Test Changes

effective September 24, 2002 or as noted				
Test Code	Test Name	Specific	Change	Also Affected
3104	Aldosterone	Reference Range	Supine: <16 ng/dL	3113 Aldosterone/Renin Ratio
3844	Amylase	Reference Range Stability	Amylase <101 U/L Delete the pediatric reference ranges Ambient 3 days Refrigerated 7 days Frozen 2 months	3846 Amylase Isoenzymes
1081	Antiphospholipid Syndrome EvaluatR™	Specimen	Citrated Plasma not accepted for Beta2 GPI testing	
8831	<i>Brucella abortus</i> IgG, IgM & IgA (effective 8-20-02)	Reference Range	Negative: <=0.8 Index Indeterminate: 0.81 - 1.19 Index Positive: >=1.20 Index	8836 <i>Brucella abortus</i> IgG Antibodies
7438SW	<i>Chlamydia trachomatis</i> / <i>N. gonorrhoeae</i> rRNA Ur-Sure® PLUS Swab	Alternate Spec	Thin Prep Swab in Cytyc PreservCyt 4 (1) mL Ambient or Refrigerated; Do not freeze	2932SW <i>Neisseria gonorrhoeae</i> rRNA [TMA] Swab 7437SW <i>Chlamydia trachomatis</i> rRNA Detection [TMA] Swab
3454	Cholesterol Evaluation	Reference Range	LDL (calc) Optimal: <100 mg/dL Near or above optimal: 100-129 mg/dL Borderline high: 130-159 mg/dL High: 160-189 mg/dL Very high: >189 mg/dL	
3350	Cholesterol, Total	Reference Range	Total Cholesterol Desirable: <200 mg/dL Borderline high: 200-239 mg/dL High: >239 mg/dL	3454 Cholesterol Evaluation 3445 Lipoprotein Electrophoresis 1538 Cardiovascular Disease Risk AssessR™ 5921 LDL Subfractions
1605	Complement C2	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citrated Plasma not accepted 6.0-32.5 mg/L	

Test Code	Test Name	Specific	Change	Also Affected
1610	Complement C5	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citratd Plasma not accepted 67-175 mg/L	
1976	Complement C6	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citratd Plasma not accepted 60-135 mg/L	
1978	Complement C7	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citratd Plasma not accepted 42-108 mg/L	
1980	Complement C8	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citratd Plasma not accepted 85-193 mg/L	
1982	Complement C9	Specimen Reference Range	Serum (0.5) mL- two aliquots, Frozen Citratd Plasma not accepted 75-310 mg/L	
3164	Estrogen <i>(effective 10/08/02)</i>	Reference Range	Male: <200 pg/mL	
1266	Gliadin IgG & IgA Antibodies	Stability	3 days Ambient, 2 weeks Refrigerated	1261 Gliadin IgG Antibodies 1286 Gliadin IgA Antibodies 1076 Celiac Disease Autoantibodies Evaluation 1077 Celiac Disease EvaluatR™
3352	HDL Cholesterol	Reference Range	>40 mg/dL	3454 Cholesterol Evaluation 1538 Cardiovascular Disease Risk AssessR™
7741	<i>Helicobacter pylori</i> IgG, IgM & IgA Antibodies	Stability	3 days Ambient, 2 weeks Refrigerated	7761 <i>Helicobacter pylori</i> IgG Abs 7986 <i>Helicobacter pylori</i> IgA Abs 7736 <i>Helicobacter pylori</i> IgM Abs
4974	Hemoglobin A2, Quantitative	Reference Range	New range 2.4 - 3.5%.	4984 Hemoglobin Variant reflex to Electrophoresis 4970 Beta-Thalassemia and Hemoglobinopathy Screen
3984	Inhibin A	Reference Range	Male or Female: <10 pg/mL Early Follicular: <28 pg/mL Late Luteal: <90 pg/mL Polycystic Ovary Syndrome: <16 pg/mL Post Menopausal: <10 pg/mL	
3356	Isohemagglutinin Titer	Stability	Ambient - not acceptable Refrigerated - 7 days Frozen - 2 months	
5921	Low Density Lipoprotein Subfractions	Reference Range	Subfractions 4-7: <1 mg/dL	
5963	Lupus Anticoagulant: Screen 1	Specimen	Two specimens required. 3.0 (1.5) mL Citratd Plasma; Frozen 1.0 (0.5) mL Serum; Refrigerated or Frozen	5976 Lupus Anticoagulant: Screen 2
5420	Natural Killer Cell Function	Specimen	The only acceptable specimen is ACD whole blood, ambient. Ship to arrive within 24 hr after collection.	1652 CFIDS with NK Cell Function

Test Code	Test Name	Specific	Change	Also Affected
3244	Testosterone, Total	Stability Specimen	7 days Refrigerated, 2 months Frozen Serum only	3917 Testosterone, Weakly Bind 3248 Testosterone, Free & Total 3247 Testosterone, Free 3188 Hirsutism Evaluation, Female 3916 Testosterone Bioavailable 2017 Infertility: Endocrine (Male) 2023 Polycystic Ovary Evaluation 2025 Recurrent Spontaneous Abortion: Endocrine
4925	Topiramate (effective 10/08/02)	Collection Reference Range Stability	Red top serum separator tubes are not acceptable. Trough levels are more reproducible than peak levels. Collect specimen for trough level just prior to administration of next dose; collect specimen for peak level approximately 2 hours after the administration of the last oral dose. For DOS #4925P, label each specimen as TROUGH or PEAK. THERAPEUTIC RANGES for Topiramate: Daily Dose (mg) Peak (ug/mL) Trough (ug/mL) 100 1.3 - 2.1 0.7 - 1.4 200 2.9 - 4.5 2.1 - 3.1 400 6.1 - 9.3 4.5 - 6.7 800 13.0 - 23.8 9.0 - 13.4 1200 22.3 - 35.1 14.0 - 21.0 Refrigerated - 48 Hour(s); Frozen - 1 Month Only Refrigerated or Frozen specimens are acceptable.	4925P Topiramate Peak & Trough
3515	Vitamin B1 (Thiamine)	Reference Range	1.2-4.0 ug/dL	
3515W	Vitamin B1 (Thiamine) Whole Blood	Reference Range Note	3.8-12.2 ug/dL Sample requirement - Requires a minimum of 4.0 mL heparinized whole blood to avoid QNS result.	

Late-Breaking News

call Client Services 800-421-4449 for more information

- Omitted from last month's letter was the discontinuation effective 8-20-02 of the following:
 8951SF *Borrelia burgdorferi* IgG Antibodies Synovial Fluid
 8961SF *Borrelia burgdorferi* IgM Antibodies Synovial Fluid
- Effective October 1, 2002 *Specialty* will again offer **1 day turnaround time** on the following assays:
 9474C Herpes Simplex Virus DNA UltraRapid™ CSF
 7584C Epstein-Barr Virus DNA UltraRapid™ CSF
 9430C Cytomegalovirus DNA UltraRapid™ CSF

Discontinued Tests and Evaluations

effective September 24, 2002 or as noted

The following test(s) are no longer available routinely from *Specialty*. Some of these tests have been discontinued because MFC is no longer available or replacement with comparable or better tests. Whenever possible, alternate tests are recommended.

Effective Date	Test Code	Test Name	Alternate Tests
		Fungus Susceptibility Custom MIC & MFC:	Fungus Susceptibility Custom MIC:
8/20/02	5662FC	5-Fluorocytosine	5661FC 5-Fluorocytosine
8/20/02	5662AM	Amphotericin B	5661AM Amphotericin B
8/20/02	5662FL	Fluconazole	5661FL Fluconazole
8/20/02	5662IT	Itraconazole	5661IT Itraconazole
8/20/02	5662KE	Ketoconazole	5661KE Ketoconazole
8/20/02	9446C	Herpes Simplex Virus Types 1 & 2 IgG Abs CSF	
		Also affected: 9515 Herpes Simplex Virus IgG Antibody Index; 9517 Herpes Simplex Virus Encephalitis AccuDx®; 9451C Herpes Simplex Virus SeroDx® Type 1 IgG Abs CSF; 9461C Herpes Simplex Virus SeroDx® Type 2 IgG Abs CSF	
9/24/02	1656NY	Lymphocyte Enumeration, Helper/Inducer without CBC	1656 Lymphocyte Enumeration, Helper/Inducer
9/24/02	1657NY	Lymphocyte Enumeration, Helper/Suppressor without	1657 Lymphocyte Enumeration, Helper/Suppressor
9/24/02	5995	Platelet Autoantibodies, Comprehensive	6100 Platelet Glycoprotein (Direct & Indirect) Autoantibodies
9/24/02	1636	Platelet Autoantibodies Evaluation	6100 Platelet Glycoprotein (Direct & Indirect) Autoantibodies
9/24/02	1631	Platelet IgG, IgM, IgA Autoantibodies	6102 Platelet Glycoprotein (Indirect) Autoantibodies
9/24/02	1630	Platelet-Associated IgG, IgM, IgA Autoantibodies	6104 Platelet-Associated Glycoprotein (Direct) Autoantibodies

Sincerely,



Tom England, Ph.D.
 Vice President of Operations

**For additional information please call Client Services at 1-800-421-4449
 or visit our Web site at www.specialtylabs.com**