

January/February, 2005

Dear Colleague:

Specialty Laboratories has completed the Company's relocation to Valencia, California ahead of schedule. Clinical testing and new test development are now being performed at *Specialty's* new state-of-the-art reference laboratory and headquarters facility, approximately 30 miles north of our former locations in Santa Monica, California. The new custom-designed facility, measuring 198,000 square feet, is nearly twice the total size of the former configuration, significantly increasing available space for future growth, efficiency enhancement and operational flexibility. *Specialty's* new clinical laboratory incorporates highly advanced mechanical, structural and architectural features to support stringent quality control, rigorous specimen management, and optimized work-flow. We expect that these changes will translate into important benefits for our clients and their patients, including the exceptional speed and analytical quality of test results. As intended, we accomplished this very complex move without service disruptions to our clients.

New Address and Contact Information for Specialty Laboratories:

27027 Tourney Road
 Valencia, CA 91355-5386
 Phone: 800-421-7110
 Phone: 661-799-6543
 Web site: www.specialtyabs.com

Client Services
 Phone: 800-421-4449
 Fax: 661-799-5252
 E-Mail: specialty@specialtylabs.com

Automated Phone Services at 800-421-7110	
Press 1	If you know your party's 4-digit extension
Press 2	For Specimen Pick-up (24 hr)
Press 3	For Client Services (or 800-421-4449 direct)
Press 4	For Clinical Trials Information
Press 5	For Patient Billing and Collections
Press 6	For Government Billing
Press 7	For Accounts Payable
Press 8	For Client Billing and Collections
Press 9	For Employment Opportunities
For Operator assistance, please stay on the line.	

Service	Phone	Fax
Client Services	800-421-4449	661-799-5252
Client Services (Spanish speaking)	800-421-4449, x49010	661-799-5252
SRC	800-841-2685	661-799-5277
Support Systems	800-421-7110, x6770	661-799-5281
LORRA/Send Outs	800-421-7110 x6440	661-799-5276
	661-799-6440 Direct	
Client Supply	800-421-7110 x6690	661-799-5251
Distribution (Specimen Pick-up)	800-421-7110 press 2	661-799-5275
IT Product Support (Client Hotline)	800-421-7110 x1580	661-799-5257

Address and telephone information can also be found in the Specialty Laboratories 2005 Directory of Services, which will be shipped later this month. For copies of the Directory of Services please contact your *Specialty* Representative or Client Services.

Please note that after assessing stability, we have increased the stability limits of all whole blood-based DNA tests in Molecular Genetics from 72 hours to 7 days. This will avoid unnecessary cancellations. The affected test codes are: 1515, 1705, 1966, 4555, 4558, 4559, 4560, 5356, 5357, 5362, 5369, 5371, 5375 and all related custom panels.

For additional information, 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, February 15, 2005 or as noted

2487 Hepatitis Delta Virus IgG Antibodies (effective 12/30/04)

Component	Method	Reference Range	Units
Hepatitis Delta Virus IgG Antibodies	EIA	Negative	
Specimen/Stability	1 (0.5) mL Serum Ambient – 7 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s) Alternate: Plasma Heparinized		
Clinical Utility	Hepatitis Delta virus can only replicate in HBV infected individuals. HDV 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, Friday		
Turnaround Time	2-5 days		
CPT Code	86692		

2488 Hepatitis Delta Virus IgG & IgM Antibodies (effective 12/30/04)

Component	Method	Reference Range	Units
Hepatitis Delta Virus IgG Antibodies	EIA	Negative	
Hepatitis Delta Virus IgM Antibodies	EIA	Negative	
Specimen/Stability	1 (0.5) mL Serum Ambient – 7 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s)		
Clinical Utility	Hepatitis Delta virus can only replicate in HBV infected individuals. HDV 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, Friday		
Turnaround Time	2-8 days		
CPT Code	86692, 86692-59		

Immunohistochemistry Stains

IHC194	AE1/AE3
IHC195	p57
IHC193	Plasma Cell
IHC196	Thrombomodulin
Specimen Req	Formalin-fixed, paraffin-embedded tissue; Ambient
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.
Collection Notes	Shipping on cold pack is recommended during the warm weather months. Ship by overnight courier to <i>Specialty</i> .
Schedule	Monday-Sunday
Turnaround Time	1-3 days
CPT Code	88342 times the number of stains selected
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

5365 Maternal Cell Contamination Detection in Fetal and Cord Blood Samples

Component	Method	Reference Range	Units
Maternal Cell Contamination	STR Analysis	Negative	
Specimen/Stability	5 (3.0) mL EDTA Whole Blood (maternal)		
Collection Instructions	Ambient – 7 Days; Refrigerated acceptable but not preferred EDTA is the preferred anticoagulant, but ACD (A or B) is also acceptable. Do not freeze. Refrigerated specimens are also acceptable but not preferred. Heparinized whole blood is not acceptable. Ship by overnight courier to arrive at <i>Specialty</i> within one week of collection. Specimens will be stabilized upon departmental receipt. Note that fetal (amniotic fluid, amniotic fluid culture, CVS) or cord blood specimen requirements are described in the primary test, either 5358 or 5363.		
Clinical Utility	This assay uses simultaneous testing of maternal and fetal samples by short tandem repeat (STR) analysis to detect maternal cell contamination (MCC), a potential source of error, in DNA-based prenatal diagnosis and analysis of cord blood. We perform prenatal and cord blood diagnosis of cystic fibrosis (# 5358) and Fragile X syndrome (# 5363); this ancillary assay confirms that the results reported reflect only the fetal/cord blood genotype and are not confounded by the presence of maternal DNA in the PCR template.		
Schedule	As needed; prenatal and associated MCC studies are performed upon demand		
Turnaround Time	2 days after receipt of fetal/cord blood and maternal template DNAs		
CPT Code	83894x2, 83901x4, 83912		
Notes	This is a required ancillary test to be added on to 5358 and 5363 and any additional future assays that include prenatal or cord blood analysis of a single gene. UWFTP reporting is requested.		

Test Changes

Effective Tuesday, February 15, 2005 or as noted

<u>Test Code</u>	<u>Test Name</u>	<u>Specific Change</u>	<u>Also Affected</u>
1410	Acetylcholine Receptor Binding Autoantibodies (effective 1-18-05)	<u>CPT Code</u> 84238	1025 Myasthenia Gravis Eval.
2935	AFB Identification <i>Mycobacterium</i> spp rRNA [GenProbe®] (effective 1-18-05)]	<u>CPT Code</u> 87149	
1842	Breast Cancer Basic ER/PR, with HER-2/ <i>neu</i> IHC reflex to FISH Tissue (effective 1-20-05)	<u>Name Change</u> ER, PR, HER-2/ <i>neu</i> reflex FISH, Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1839	Breast Cancer ER, PR, Ki67, HER-2 Reflex to FISH (effective 1-20-05)	<u>Name Change</u> ER, PR, Ki-67, HER-2/ <i>neu</i> reflex to FISH, Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1830	Breast Cancer Estrogen & Progesterone Receptor (effective 1-20-05)	<u>Name Change</u> ER, PR (Estrogen and Progesterone Receptors), Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1831	Breast Cancer Estrogen Receptor (effective 1-20-05)	<u>Name Change</u> ER (Estrogen Receptor), Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1846	Breast Cancer HER-2/ <i>neu</i> (effective 1-20-05)	<u>Name Change</u> HER-2/ <i>neu</i> [IHC], Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
5836	Breast Cancer HER-2/ <i>neu</i> [by FISH Only] (effective 1-20-05)	<u>Name Change</u> HER-2/ <i>neu</i> [FISH], Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1845	Breast Cancer MIB-1 (ki-67) (effective 1-20-05)	<u>Name Change</u> Ki-67 (MIB-1), Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.
1819	Breast Cancer Profile 3 with HER-2/ <i>neu</i> (effective 1-20-05)	<u>Name Change</u> ER, PR, DNA CCA, HER-2/ <i>neu</i> [IHC], Breast Cancer	See also specimen change for test code 5400 DNA Cell Cycle Analysis.

1818	Breast Cancer Profile 3 with HER-2/ <i>neu</i> Reflex to FISH (effective 1-20-05)	<u>Name Change</u> ER, PR, DNA CCA, HER-2/ <i>neu</i> reflex to FISH, Breast Cancer	<i>See also specimen change for test code 5400 DNA Cell Cycle Analysis.</i>
1840	Breast Cancer Profile Basic with ER/PR, HER-2/ <i>neu</i> (effective 1-20-05)	<u>Name Change</u> ER, PR, HER-2/ <i>neu</i> [IHC], Breast Cancer	<i>See also specimen change for test code 5400 DNA Cell Cycle Analysis.</i>
1832	Breast Cancer Progesterone Receptor (effective 1-20-05)	<u>Name Change</u> PR (Progesterone Receptor), Breast Cancer	<i>See also specimen change for test code 5400 DNA Cell Cycle Analysis.</i>
3976	Creatine Phosphokinase (effective 1-20-05)	<u>Name Change</u> Creatine Kinase	
1203	DNA Autoantibodies, Double-Stranded [Crithidia]	<u>Specimen Requirement</u> Serum is the only acceptable specimen	
5400	DNA Cell Cycle Analysis, Breast Cancer	<u>Specimen Requirement</u> Formalin-fixed, paraffin-embedded tissue is the only acceptable specimen; unstained slides are not acceptable.	5400T DNA Cell Cycle Analysis, Non-Breast 1818, 1819, 181830, 1831, 1832, 1833, 1839, 1840, 1842, 1845, 1846, 5836, 5846
1833	ER/PR/Ki67/p53 & HER-2 Reflex to FISH, Breast Cancer (effective 1-20-05)	<u>Name Change</u> ER, PR, Ki-67, p53, HER-2/ <i>neu</i> reflex to FISH, Breast Cancer	<i>See also specimen change for test code 5400 DNA Cell Cycle Analysis.</i>
5846	HER-2/ <i>neu</i> [IHC] Reflex to FISH (effective 1-20-05)	<u>Name Change</u> HER-2/ <i>neu</i> [IHC] Reflex to FISH, Breast Cancer	<i>See also specimen change for test code 5400 DNA Cell Cycle Analysis.</i>
1368	HLA-A, B, C DetectR™	<u>Stability</u> 7 days	1376 HLA-A DetectR™ 1377 HLA-B DetectR™ 1378 HLA-C DetectR™ 1379 HLA-DR DetectR™ 1369 HLA-A, B,C,DR DetectR™
3184SR	Human Chorionic Gonadotropin with Serial Reporting (effective 1-20-05)	<u>Name Change</u> Human Chorionic Gonadotropin, Beta, with Serial Reporting	3184C Human Chorionic Gonadotropin Beta CSF 3184F Human Chorionic Gonadotropin Beta Fluid
4168	Kidney Stone Risk AssessR™	<u>Collection Instructions</u> Urine should be refrigerated during collection; ship on cold pack. Collection kits are available that contain pre-measured NaOH and HCl for convenient pH adjustment. Please call Client Supply at 800-421-7110 ext. 6690 or fax supply request to 661-799-5251 to have the collection kits sent to you. The collections kits are designed for a minimum urine volume of 500 mL; volumes smaller than this should be collected according to the procedure specified in the Directory of Services.	
5922	Liver Cytosol (Lc-1) Autoantibodies	<u>Collection Instructions</u> Serum is the only acceptable sample.	
5317	Metabolic Panel, Comprehensive	<u>Specimen</u> Sample must be protected from light in foil-wrap or amber tube.	5318 Hepatic Function Panel

Discontinued Tests

Effective Tuesday, February 1, 2005 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
Rf228	Allergen – Milk, powder, Alfare, Nestle IgE	Reagents not available.	F2 Cow Milk IgE F14 Soybean IgE (soy-based milk powder)
MX3 E213	Allergen Mix – Molds & Yeasts Mix Allergen – Parrot Feathers IgE	Reagents not available. Reagents not available.	Request as individual assay: E70 Allergen – Goose Feathers E78 Allergen – Budgerigar Feathers E85 Allergen – Chicken Feathers (same as above)
EX72	Allergen – Animal Epidermals & Proteins Mix IgE	Reagents not available.	(same as above)
EX73	Allergen – Animal Epidermals & Proteins Mix IgE	Reagents not available.	(same as above)
2458	Hepatitis Delta Virus Total Antibodies (effective 12-30-04)		2487 Hepatitis Delta Virus IgG Antibodies [replacement]
2465	Hepatitis Delta Virus Total & IgM Antibodies (effective 12-30-04)		2488 Hepatitis Delta Virus IgG & IgM Abs [replacement]
S47955	HER-2/ <i>neu</i> IHC Frozen	Frozen samples no longer referred	1846 HER-2/ <i>neu</i> [IHC], Breast Cancer

Send Out Test Changes

Test Code	Test Name	Deactivated	Previous Specimen/Stability Requirements	Replacement code	New Requirements
S49499	Toxic-shock syndrome antibody panel (52050)	12/28/2004	Serum-Amb14day/Ref. 3 months/ Frz 12 months	S50727	Serum-Ref. 7 days
A48640	Alt- Amphetamine Meconium Confirmation (5703)	1/14/2005	n/a	dup for A50071	No Change
A48750	Alt-C3 Functional Activity	1/13/2005	n/a	dup for S49542	No Change
S49107	Secretin Antibodies Plasma	1/14/2005	n/a	Test no longer available	n/a
S48578	Vitamin B ₃ 24hr Urine	1/8/2005	n/a	Test no longer available	n/a
S42735	Ceftriaxone (Rocephin)	12/16/2004	n/a	Test no longer available	n/a
S49166	Factor VIII Gene Analysis (Hemophilia A)	12/8/2004	Whole Blood EDTA Amb-14 days	S50736	Whole Blood (EDTA, ACD) Amb. 72 hrs/Ref. 14 days

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