

Dear Colleague:

New Tests

In the next phase of our AmeriPath™/Specialty test integration roll out, Specialty is introducing 2 new oncology related FISH assay panels. These new test panels are intended for the further evaluation of chromosome alterations associated with:

- Acute Myeloid Leukemia (AML) / High Grade Myelodysplastic Syndromes (MDS)
- Low Grade Myelodysplastic Syndromes (MDS)

Also new next month is **UGT1A1 GenotypR™**, a pharmacogenomic test intended for evaluating patients being considered for irinotecan -- a drug used to treat metastatic colorectal cancer. We are also introducing new sample-specific fungal cultures that reflect changes in CPT coding for these tests.

Welcome to National Medical Director, Robert Kisabeth, M.D.

Specialty Laboratories is pleased to welcome noted pathologist and former Medical Director at Mayo Medical Laboratories, Robert Kisabeth, M.D. Dr. Kisabeth previously served as Senior Vice President of Medical Affairs, Mayo Collaborative Services and Assistant Professor of Laboratory Medicine, Mayo Clinic College of Medicine. Prior to joining Mayo, Dr. Kisabeth was Vice President of Duckworth Pathology Group, President of Medical Express Laboratories, and President and Chief Operating Officer of National Laboratory Center. Dr. Kisabeth is Board Certified in both Clinical and Anatomic Pathology and will direct the initiative to provide **expanded Consultant Services** for AmeriPath/Specialty.

Reactivation of BCR/ABL1 (Philadelphia Chromosome)

We are reactivating #5834 BCR/ABL1 Gene Rearrangement (Philadelphia Chromosome) by FISH to address continued client requests for BCR/ABL1 testing without the 9q34 deletion which involved an additional charge. Please keep in mind, however, that our new Test #5862 Chronic Myeloid Leukemia (CML) by FISH includes BCR/ABL1 by FISH and an ancillary test for the 9q34 deletion involving the argininosuccinate synthetase gene locus, which is intended to increase both the clinical sensitivity of FISH testing and specificity of the BCR/ABL1 by FISH. In addition, the CML by FISH test with the added probe provides information that may be pertinent to prognosis in relation to selected therapy. Note that BCR/ABL has been changed to BCR/ABL1 in the latest nomenclature guidelines and this change will be reflected in our test names.

Other Test Changes

Herpes Simplex Virus Type 1 & 2 IgG Abs, #9446 has been improved to reduce cross reactivities between HSV 1 and HSV 2 antibodies.

Specialty encourages all clients to provide the requested sample volume (3 mL serum; 2 mL absolute minimum) for Methylmalonic Acid testing serum. All QNS (insufficient) samples received for **Methylmalonic Acid testing** will be run at dilution and results will be accompanied by the **disclaimer** below:

Sample volumes less than 1.2 mL are analyzed following dilution (addition of drug-free serum) to compensate for the volume needed for the assay. Dilution results in analytical values below that expected for serum or urine, which are then corrected via a calculation accounting for the dilution. This is reasonably accurate, but results on dilutions have a greater level of imprecision than undiluted samples. High levels of Methylmalonic Acid (MMA) are indicative of B12 deficiency, but precision for high samples may be similarly affected by dilution, and could erroneously indicate normal levels of MMA in certain borderline circumstances. Submission of an additional sample may be helpful for confirming correct serum levels of MMA. Note that impaired renal function may also affect serum MMA levels.

CIGNA Health Care

Specialty Laboratories is pleased to announce participation with CIGNA HealthCare members effective March 1, 2006. Specialty has signed a multi-year agreement to provide esoteric and reference testing services for CIGNA HealthCare members. Under the agreement, Specialty will be a participating provider in CIGNA HealthCare's HMO, POS, OAP, PPO and indemnity networks and may actively market its services to CIGNA HealthCare members and physicians in certain states. Please contact your local sales representative or Specialty Laboratories' Sales Department at 1-800-421-7110 for specific details.

If you are planning to attend **Digestive Disease Week** in May, please stop by the AmeriPath booth to find out more about Specialty's comprehensive test menu in gastroenterology, including our new pharmacogenomic assays.

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, April 18, 2006 or as noted

5874 Acute Myeloid Leukemia/ High Grade Myelodysplasia by FISH (effective 4/25/06)

Component	Method	Reference Range	Units
AML/MDS, high grade	FISH		
Specimen/Stability	3.0 (1.0) mL Heparinized Bone Marrow; Ambient 72 hrs	By report	
Alternate Specimen	5.0 (3.0) mL Heparinized Whole Blood; Ambient 72 hrs		
Collection Instructions	This test requires SODIUM HEPARINIZED specimens. Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze. Ship by overnight courier.		
Clinical Utility	For the detection of chromosome abnormalities associated with AML/High-Grade MDS: t(8;21), inv(16)/t(16;16), t(9;22), -5/5q deletion, -7/7q deletion, trisomy 8, 11q23 rearrangements, 20q deletion.		
Performance Schedule	Set-up: Sun-Sat	Reported: within 7 days	
CPT Code	88237, 88271x12, 88275x8		

5322W Fungus Culture -- Blood or Bone Marrow (effective 5/2/06)

Component	Method	Reference Range	Units
Preliminary Culture 1	Culture	By report	
Preliminary Culture 2	Culture	By report	
Fungus Culture - Final	Culture	By report	
Specimen/Stability	10.0 (5.0) mL ACD or Heparinized Whole Blood; Ambient 48 hrs		
Alternate Specimens	Blood Culture Bottle, Whole Blood Isolator Tube, ACD Bone Marrow		
Unacceptable specimens	EDTA blood or bone marrow, Leaking containers, Frozen specimens		
Collection Instructions	Provide type (blood or bone marrow) and source of specimen on requisition as set up and processing are dependent upon this information. Ship ambient overnight.		
Clinical Utility	Assay includes the direct examination of specimens for detection of fungal elements, isolation, and identification of fungi in culture. Aids in the diagnosis of fungal related infections.		
Performance Schedule	Set-up: Sun-Sat	Reported: within 31 days	
CPT Code	87103		
Notes	There will be no fungal stain reported on whole blood and bone marrow. If culture is positive, it will reflex to #5323 Fungus ID Mould, or #5324 Fungus ID Yeast, or #5633 Fungus ID by DNA Probe (<i>Histoplasma</i> , <i>Blastomyces</i> , <i>Coccidioides</i>) at an additional charge. Also available, #5322 Fungus Culture & Stain -- Skin, Hair or Nail and #5322M Fungus Culture & Stain -- Miscellaneous.		

5322M Fungus Culture and Stain-- Miscellaneous (effective 5/2/06)

Component	Method	Reference Range	Units
Fungal Stain	Stain	By report	
Preliminary Culture 1	Culture	By report	
Preliminary Culture 2	Culture	By report	
Fungus Culture -- Final	Culture	By report	
Specimen/Stability	Miscellaneous Specimen in sterile container or tube		
Alternate Specimens	1.0 mL Pure Culture Broth; Ambient 24 hrs, Refrigerated 7 days 2.0 (1.5) mL CSF; Ambient 48 hrs Culturette/Swab; Ambient 48 hrs, Refrigerated 7 days 1.0 mL Tissue in small amount of sterile saline; Ambient 48 hrs 5.0 mL Urine; Ambient 48 hrs		
Unacceptable specimens	Leaking containers, Frozen specimens		
Collection Instructions	Provide type information and source of specimen on requisition as set up and processing are dependent upon this information. Ship ambient overnight.		
Clinical Utility	Assay includes the direct examination of specimens for detection of fungal elements, isolation, and identification of fungi in culture. Aids in the diagnosis of fungal related infections.		
Performance Schedule	Set-up: Sun-Sat	Reported: within 31 days	
CPT Code	87102, 87206		
Notes	If culture is positive, it will reflex to #5323 Fungus ID Mould, or #5324 Fungus ID Yeast, or #5633 Fungus ID by DNA Probe (<i>Histoplasma</i> , <i>Blastomyces</i> , <i>Coccidioides</i>) at an additional charge. Also available, #5322 Fungus Culture & Stain -- Skin, Hair or Nail and #5322B Fungus Culture -- Blood.		

5878 Myelodysplastic Syndromes (MDS), Low Grade by FISH (effective 4/25/06)

Component	Method	Reference Range	Units
MDS, low grade	FISH	By report	
Specimen/Stability	3.0 (1.0) mL Heparinized Bone Marrow; Ambient 72 hrs		
Alternate Specimen	5.0 (3.0) mL Heparinized Whole Blood; Ambient 72 hrs		
Collection Instructions	This test requires SODIUM HEPARINIZED specimens. Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze. Ship by overnight courier.		
Clinical Utility	For the detection of chromosome abnormalities associated with Low-Grade MDS: -5/5q deletion, -7/7q deletion, trisomy 8, 11q23 rearrangements, 20q deletion.		
Performance Schedule	Set-up: Sun-Sat	Reported: within 7 days	
CPT Code	88237, 88271x6, 88275x5		

5384 UGT1A1 GenotypR™ (effective 5/16/06)

Component	Method	Reference Range	Units
UGT1A1 GenotypR	PCR CE/Electrophoresis	By Report	
Specimen/Stability	5.0 (3.0) mL EDTA Whole Blood; Ambient 7 days, Refrigerated 7 days		
Collection Instructions	Whole blood samples should be anti-coagulated with potassium EDTA. Do not freeze. Refrigerated specimens are also acceptable but not preferred. Heparinized whole blood is not acceptable.		
Clinical Utility	UGT1A1 GenotypR™ detects the four polymorphisms [(*36 (TA5), *1 (TA6), *28 (TA7) and *37 (TA8)] in the promoter region of the UDP glucuronosyl transferase gene (UGT1A1). The enzyme produced by UGT1A1 is responsible for the metabolism of irinotecan, a drug used in the treatment of patients with metastatic colorectal cancer. Polymorphisms in the UGT1A1 gene can affect an individual's ability to efficiently metabolize irinotecan, and are known to increase that individual's risk for severe toxicity from the drug. By identifying the genetic variants in the gene, physicians can better understand the potential risk of an adverse reaction and customize the dosage of irinotecan to optimize its benefits while minimizing potentially serious side effects.		
Performance Schedule	Set-up: Monday, Thursday	Reported: within 3 days	
CPT Code	83891, 83898, 83909, 83912		
Notes	Shipment should be by overnight courier to arrive at <i>Specialty</i> within 24 hrs of collection. Specimens will be stabilized upon departmental receipt.		

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
5342	immediate	BCR/ABL UltraQuant® Major 210 KD Transcript Bone Marrow	<u>CPT Code</u> 83891, 83898, 83896, 83902, 83912	5344 BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow 5352 BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood 5354 BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood
3121	immediate	CA 125	<u>Stability</u> Refrigerated 7 days, Frozen 2 months	3121F CA 125 Fluid 3121SR CA 125 with serial reporting
4836U	immediate	Calcium, Total 24-hr Urine	<u>CPT Code</u> 82340	See also #4168 Kidney Stone Risk AssessR™
4202	3/28	D-Dimer Quantitative	<u>Reference Range</u> <2.09 mg/L (error in March letter)	
4125U	4/25	Drugs of Abuse Screen Urine	<u>Stability</u> Refrigerated 7 days, Frozen 2 months	4118U Cocaine Metabolites Screen Urine 4106U Amphetamine/Methamphetamine Screen Urine 4132U Cannabinoids Screen Urine 4108U Barbiturates Screen Urine 4111U Benzodiazepine Screen Urine 4113U Methadone Screen Urine 4138U Opiates Screen Urine 4117U Phencyclidine Screen Urine 4149U Propoxyphene Screen Urine
5362	immediate	Fragile X	<u>CPT Code</u> 83891, 83898, 83909, 83912, reflex to Southern blot: 83892x2, 83894, 83896, 83897, 83912	5363 Fragile X Fetal Study

Test Code	Effective Date	Test Name	Specific Change	Also Affected
5322	5/2	Fungus Culture & Stain	<u>Name Change</u> Fungus Culture & Stain -- Skin, Hair or Nail <u>Specimen</u> Skin sources, hair or nail clipping in sterile, leakproof container. Ship ambient or refrigerated, not frozen. <u>CPT Code</u> 87101 <u>Notes</u> If culture is positive, it will reflex to #5323 Fungus ID Mould or #5324 Fungus ID Yeast or #5633 Fungus ID by DNA Probe (<i>Histoplasma, Blastomyces, Coccidioides</i>) at an additional charge. Please provide specimen type as set up and processing are dependent on this information.	
1398	5/2	Glucose-6 Phosphate Dehydrogenase (G-6-PDH)	<u>Reference Range & Units</u> 7-20 U/g Hb (now based on hemoglobin not hematocrit)	
5842	3/21	HER-2/ <i>neu</i> [IHC] and Gene Amplification [FISH]	<u>CPT Code</u> 88367 (error in previous CPT listing), 88360	
2426	3/23	Herpes Simplex Virus 1 & 2 Antigen Detection	<u>Specimen</u> Although mentioned in Collection Instructions, urine is not an acceptable sample type.	
7581	3/2	Herpes Simplex Virus DNA DetectR™	<u>Alternate Specimen Stability</u> Viral Transport Media/Swab M4 Transport Media/Swab Ambient 7 days, Refrigerated 7 days	
7420	5/31	HIV-1 Phenoscript™	<u>Component</u> Saquinovir trade name should be Invirase® ddC Zalcitabine is no longer part of panel <i>Changes below do not apply to 7420NY HIV-1 Phenoscript, New York</i> FTC Emtricitabine (Entriva®) is new RT Inhibitor drug included in analysis. <u>Reference Range</u> Entriva clinical cutoff 5.5	
9842	3/2	HIV p24 Antigen, Qualitative	<u>Alternate Specimen</u> 2.0 (1.0) mL Plasma Ambient 72 hours, Refrigerated 7 days, Frozen 2 months	
1760	5/2	Kappa/Lambda Light-Chain Free Serum	<u>Name Change</u> Myeloma EvaluatR™ (Serum Free Light Chains)	
4168	4/18	Kidney Stone Risk AssessR™	<u>CPT Code</u> 24 hr urine creatinine 82570. 24 hr urine calcium 82340 24 hr urine magnesium 83735 24 hr urine citrate 82507 24 hr urine oxalate 83945 24 hr urine osmolality 83935 24 hr urine chloride 82436 24 hr urine potassium 84133 24 hr urine sodium 84300 24 hr urine uric acid 84560 24 hr urine phosphorus 84105 pH urine 81002	4836U
2422	4/18	<i>Legionella pneumophila</i> Antigen Detection	<u>Specimen</u> Urine is not an acceptable specimen <u>Notes</u> <i>Legionella</i> detection by DFA is not appropriate for urine samples. #9501 <i>Legionella pneumophila</i> Antigen Urine is a more sensitive assay.	
3125U	4/18	Monoclonal Gammopathies Urine	<u>Stability</u> Refrigerated 7 days, Frozen 1 month	3125C Monoclonal Gammopathies, CSF

Test Code	Effective Date	Test Name	Specific Change	Also Affected
4562	3/21	MTHFR C677T/A1298C GenotypR™	<u>CPT Code</u> 83891, 83892x4, 83896x10, 83903x2, 83908x2, 83912 (error in previous CPT listing)	4555 Thrombotic Risk AssessR™ for Obstetric Complications
1705	4/4	Narcolepsy EvaluatR™	<u>Method</u> Inno-LiPA <u>CPT Code</u> 83891, 83894x2, 83896x2, 83900, 83909, 83912	
5250	4/18	Occult Blood [Hemocult]	<u>CPT Code</u> 82272	
7745	5/2	<i>Pneumocystis carinii</i> Antigen Detection	<u>Nomenclature Change</u> <i>Pneumocystis jiroveci (carinii)</i> Ag Detection	
4925	5/2	Topiramate	<u>Interpretation</u> Dosage Expected Peak Concentration (± 20%) 50 mg b.i.d. 3.6 (2.9 - 4.3) ug/mL 100 mg b.i.d. 6.8 (5.4 - 8.1) ug/mL 200 mg b.i.d. 13.1 (10.4 - 15.7) ug/mL 400 mg b.i.d. 25.7 (20.5 - 30.8) ug/mL Pediatric patients have 50% higher clearance and shorter elimination half-life than adults. Consequently, plasma levels for the same dosage will be lower than for adults.	
3510	immediate	Vitamin B12-HoloTC AssessR™	<u>CPT Code</u> 0103T (2006 category III code)	
3318U	4/25/06	Vanillylmandelic Acid 24 hr Urine	<u>Stability</u> Ambient 7 days, Refrigerated 14 days, Frozen 2 months	3318UR Vanillylmandelic Acid Urine Random

Test Discontinuations

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/Date	Alternate or Replacement Tests
4925P	Topiramate Peak & Trough	No therapeutic level established for Trough	4925 Topiramate
S50484	DPD Genotype	In house test available	5383 DPD 5-FU GenotypR™

Please visit our website at www.specialtylabs.com or call Client Services at 800-421-4449 for more information.