June, 2005

Dear Colleague:

This month Specialty Laboratories is pleased to introduce new tests that supplement or clarify existing testing. The new AFB Identification by DNA Probe provides an automatic reflex to HPLC when commercial probes fail to identify the specific organism as a convenience for physicians who prefer this algorithmic testing sequence. We have also created a separate test code for West Nile Virus RNA testing on CSF to facilitate reporting.

We have augmented our immunohistochemistry (IHC) stain menu to meet specific ancillary needs for our clients in Anatomic Pathology. Specific IHC stains are available by request ("stain only", if preferred), or our pathologists may select them as part of diagnostic consultations on tumors of unknown origin or other related differential diagnoses. Myeloperoxidase is helpful in identifying tumors of myeloid origin such as extramedullary myeloid tumors (chloromas), or distinguishing AML from ALL in bone marrow biopsies lacking accompanying aspirate samples for flow cytometry. Villin is very useful in distinguishing mucinous colonic adenocarcinomas from mucinous carcinomas arising in other sites such as lung (mucinous broncho-alveolar carcinomas), breast, ovary, or prostate. CK5/6 is helpful in distinguishing mesothelioma from adenocarcinoma. A complete IHC stain test menu is available by request or on our Web site.

In response to client requests, we have reactivated our Acetylcholine Receptor Modulating Autoantibodies assay. *Specialty* was the first commercial laboratory to introduce AChR autoantibody testing for myasthenia gravis. The AChR modulating autoantibodies, present in up to 90% of MG, may be the only AChR autoantibodies present in mild, recent onset or ocular-restricted MG.

PPT clarification:

The stability of plasma in a spun ambient PPT tube is 2 days, or 3 days if the PPT tube is refrigerated. If shipping is to be delayed, then client should remove plasma from the PPT tube and send plasma frozen in separate plastic tubes to ensure sample stability. BD (Becton, Dickinson and Company) has confirmed that freezing of PPT tubes often results in problematic false positives at the lower limits of detection for quantitative RNA assays using both standard and ultrasensitive Amplicor™ methods. This is under further investigation by the manufacturer, but is presumably due to cellular changes in latently infected white blood cells from samples which have no otherwise detectable viral RNA in plasma.

Again, it is acceptable to freeze plasma that has been collected in a PPT tube as long as the plasma is removed from the PPT tube and transferred to another plastic tube before freezing.

Hyaluronic Acid Update

Note that test code #1481 Hyaluronic Acid introduced in a previous client letter incorrectly listed EDTA plasma rather than Heparinized plasma as an alternate specimen to serum for this assay. Because the sample stability when refrigerated is only 72 hours, we strongly recommend that specimens for this assay be **shipped FROZEN**.

Lead Testing Supplemental Patient Information Form

Specialty has created a form for clients to submit the supplemental information necessary for reporting heavy metal (lead) values to various states. This form should accompany the specimens and bill of lading when clients submit electronic orders. The *Specialty* Heavy Metal manual requisition already requests the necessary information. For a copy of this form, please contact your Sales Representative or Client Services or visit the *Specialty* Web site at www.specialtylabs.com.

For additional information, please contact Client Services at 800-421-4449.

Michael C. Dugan, M.D.

Vice President and Laboratory Director

New from Specialty

Effective Tuesday, June 21, 2005 or as noted

2939 AFB Identification by DNA Probe w/ Reflex HPLC

Component Method Reference Range Units

Final Report DNA Probe Not identified

Specimen/Stability Pure Culture Agar Slant or Pure Culture Broth; Ambient

Ambient - 7 days

Collection Instructions 1. Culture on Lowenstein-Jensen (L-J), 7H11 agar slant or broth

based media (BACTEC, MGIT, etc.)

2. Wrap parafilm around the screw cap of slant or lid of broth or

culture plate and wrap in paper towel.

Clinical Utility This assay is a rapid DNA probe test which utilizes the technique

of nucleic acid hybridization for the identification of *M. tuberculosis* complex,

M. avium-intracellulare complex (MAC), M. kansasii, and M. gordonae isolated from culture.

Schedule Monday-Friday
Turnaround Time 2-10 days

CPT Code 87149, 87560, 87550 x 2

Notes Send PURE culture only. If the specimen submitted is mixed, there will be a

separate charge for each organism that requires *Mycobacterium* identification. 2. Specimens received that are contaminated with bacteria may delay results. 3. Slow growing *Mycobacteria* may require additional time for identification. 4. If *M. tuberculosis* is identified, susceptibility testing is performed at an additional charge. For other organisms, susceptibility testing will be performed upon request. Call Client Services for details. 5. Organisms that cannot be identified by commercial

probes will be reflexed to HPLC for an additional charge.

Immunohistochemistry Stains (effective immediately)

IHC197 Myeloperoxidase

IHC198 Villin

IHC199 Cytokeratin 5/6 (CK5/6)

IHC200 DBA44 (Hairy Cell Leukemia)

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/neu) in selected tumor types.

Collection Notes Shipping on cold pack is recommended during the warm weather months. Ship by

overnight courier to Specialty.

Schedule Monday-Sunday

Turnaround Time 1-4 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

1856 IHC Stain Only: Client Chooses Stains

8160C West Nile Virus RNA DetectR™ CSF

(effective 04/27/05)

Component Method Reference Range Units

West Nile Virus RNA PCR Not Detected

Specimen/Stability 1 (0.5) mL CSF; Ambient, Refrigerated or Frozen

Ambient - 4 days, Refrigerated - 4 days, Frozen - 2 months

Clinical Utility Detects the presence of West Nile virus RNA in cerebral spinal fluid to aid in the

diagnosis of infections due to West Nile virus meningoencephalitis.

Schedule Sunday, Wednesday

Turnaround Time 3-5 days CPT Code 87798

Notes See also Meningoencephalomyelitis (MEM) Panels. #2272. 2273C. #2274C.

Test Reactivations

1413 Acetylcholine Receptor Modulating Autoantibodies

(effective immediately)

ComponentMethodReference RangeUnitsACHR Modulating AbsRIALess than 20%

RIA Less than 20 %
Reference Range Comment:

Less than 20% Negative 20 - 40% Indeterminate

Greater than 40% Positive; suggestive of

myasthenia gravis

Specimen/Stability 2 (0.8) mL Serum; Ambient, Refrigerated or Frozen

Ambient - 7 days, Refrigerated - 14 days, Frozen - 2 months

CPT Code 83519

Allergens: Reactivation of IgG Assays for which IgE counterparts are available

(effective immediately)

RF288G Blueberry IgG RF300G Goat Milk IgG RF303G Halibut IgG

RF287G Red Kidney Bean IgG

F87G Melon IgG F210G Pineapple IgG F214G Spinach IgG

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
5708	05/03/05	Anaerobic Bacterial Culture	Collection Instructions 1. Source of specimen is required. Indicate the exact site where the specimen was obtained. 2. Acceptable culturette types: Amies gel with or without charcoal labeled with either a 'PLUS' in the product description or specified as anaerobic or other clearly identified anaerobic collection products. Unacceptable culturette types: Amies liquid media culturettes or any culturette not clearly labeled as either 'PLUS' or anaerobic. 3. Acceptable specimen sources: Deep wounds, aspirates, body fluids, tissue. Unacceptable specimens: Specimens with normal anaerobic flora such as stool, frozen specimens, dry swabs. 4. Ship specimen at ambient temperature within 24 hours of collection. See also Specialty's "Guidelines for Shipping Infectious Substances" on our website www.specialtylabs.com.	
7570	06/21/05	<i>Borrelia burgdorferi</i> DNA DetectR™	Alternate Specimens Whole blood and urine are no longer acceptable. The clinical appropriateness of whole blood and urine for the detection of <i>B burgdorferi</i> has been questioned and testing on these sample types is discouraged. Please refer to CDC Publication MMWR 54(05):125.	

Test Code	Effective Date	Test Name	Specific Change	Also Affected
3304	06/17/05	Catecholamines, Fractionated Plasma	Reference Range Epinephrine: 0 – 364 days <150 pg/mL 1 - 5 yr old <120 pg/mL >5 yr old <84 pg/mL	3270 Epinephrine Plasma
			Norepinephrine: 0 - 364 days	
			Dopamine: 0 - 364 days <150 pg/mL	
			Total Catecholamines: 0 - 364 days <800 pg/mL 1 - 5 yr old <720 pg/mL >5 yr old <504 pg/mL	
5110	04/27/05	Complete Blood Count & Differential	<u>Temperature/Stability</u> Ambient 48 hrs: Refrigerated 4 days	
1320U	05/06/05	Creatinine 24 hr Urine	<u>Stability</u> Ambient 4 days; Refrigerated 4 days; Frozen 2 months	
1440	05/03/05	Fetal Fibronectin	Stability Refrigerated 72 hrs; Frozen 2 months	
5322	06/07/05	Fungus Culture & Stain	<u>Specimen/Stability</u> Frozen CSF is not acceptable. Ambient CSF is preferred; refrigerated CSF will be accepted.	
4168	05/03/05	Kidney Stone Risk AssessR™	<u>Stability</u> Ambient 3 days; Refrigerated 14 days; Frozen 2 months	
3315U	04/14/05	Metanephrines, Fractionated Total 24 hr Urine	Name Change Metanephrines, Fractionated 24 hr Urine	
3315UR	04/14/05	Metanephrines, Fractionation Random Urine	Name Change Metanephrines, Fractionated Urine Random	
3240	05/02/05	Myositis AssessR™	Collection Instructions Collect serum in a red-top tube. Separate serum within 4 hours of collection. Split serum into two transfer tubes, 3 mL in each, and ship by overnight courier. Second tube is needed for possible repeats.	3242 Myositis AssessR™ Plus Jo-1 Autoantibodies
8160	06/21/05	West Nile Virus RNA DetectR™	Alternate Specimen Serum is the acceptable specimen. If submitting CSF for this panel, please order West Nile Virus RNA DetectR™ #8160C.	

Sendout Changes (effective immediately)

Discontinue Sendout S49811 and use #1413 Acetylcholine Receptor Modulating Autoabs Discontinue Sendout S43980 and use #3304 Catecholamines, Fractionated Plasma Discontinue Allergen Sendouts as indicated below:

S50783	use #RF288G	Blueberry IgG
S50781	use #RF300G	Goat Milk IgG
S50785	use #RF303G	Halibut IgG
S50789	use #RF287G	Kidney Bean IgG
S50793	use #F87G	Melon IgG
S50775	use #F210G	Pineapple IgG
S50773	use #F214G	Spinach IgG

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