SPECIALTY LABORATORIES
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April/May, 2005

Dear Colleague:

In this client letter we are pleased to introduce a DNA-based rapid detection assay for Group B Strep with 7-days/week set up and 1 day TAT. This rapid TAT is particularly valuable for expectant mothers experiencing preterm labor and others near term who may not have received recent prenatal screening.

We are also introducing new assays for detection and quantification of BK (Polyomavirus) virus DNA, specifically for monitoring patients with renal allografts or bone marrow transplants who are immunocompromised and have evidence of renal failure or findings on renal biopsy which indicate the presence of tubulointerstitial nephritis. We have a new assay for Hyaluronic Acid to help monitor liver fibrosis in patients with chronic hepatitis. Finally, we are also making available frequently requested panels for Lead [whole blood] with Zinc Protoporphyrin [OSHA panel], and Aerobic Bacterial Identification reflex to Susceptibility. We are also reactivating Lymphocyte Mitogen Proliferation Analysis following a re-validation of the assay to improve performance.

We have received notice from BD Diagnostics confirming a recently published study [posted on our Website www.specialtylabs.com] that sending samples in frozen PPT tubes may cause elevated HIV-1 viral load results, particularly in patients with viral loads close to the assay's lower limit of detection. This effect applies specifically to Roche Amplicor HIV-1 Monitor 1.5 and Ultrasensitive tests. We will be attaching a disclaimer to results received in frozen PPT tubes pending proper client notification (see Test Changes) that frozen PPT tubes are no longer acceptable for HIV RNA PCR testing. Note that plasma samples collected from PPT tubes may be split into appropriate aliquot tubes and these aliquots may be frozen prior to shipment. Samples collected in PPT tubes may still continue to be shipped overnight ambient or refrigerated.

Also of note, interfering substances sometimes prevent us from providing you a result for metanephrine testing in urine. This occurs when drugs used to treat hypertension and their metabolites in urine produce data peaks in HPLC similar to those produced by the metanephrines making it difficult to interpret results. Because it may not be possible to take patients off their medication, it may be useful for physicians to consider alternate testing. Our experience shows substantially fewer cases of interference with metanephrine testing on plasma. Other alternate testing options available from *Specialty* are catecholamines in either urine or plasma specimens, or vanillylmandelic acid (VMA) in urine. If you would like more information or alternate testing options, please contact Client Services or visit our Website (www.specialtylabs.com).

There was an inadvertent transposition of information on last month's client letter. The reference ranges for 5-Aminolevulinic Acid should be as follows:

4159U **5-Aminolevulinic Acid, 24-hr Urine**

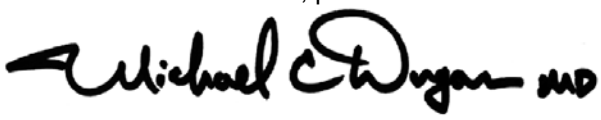
Component	Method	Reference Range	Units
Aminolevulinic Acid, 24hr	Ion Exchange Chromatography/ Spectroscopy	Less than 7.5	mg/24 hr

4159UR **5-Aminolevulinic Acid, Random Urine**

Component	Method	Reference Range	Units
Aminolevulinic Acid, random	Ion Exchange Chromatography/ Spectroscopy	Less than 4.5	mg/L

Clients visiting *Specialty* who see our extensive automation and detailed quality assurance program frequently ask "how are we doing on our Proficiency Testing?" Proficiency Testing is one of our key quality indicators among many monitored. *Specialty* is pleased to report stellar performance on both CAP and NY proficiency testing over the past year with pass rates of 98.55% and 99.1%, respectively (99.4% and 99.33% in Q1-2005 since we relocated). We are also pleased to note that our internal measures of turn around time (TAT) have remained very stable throughout the relocation and set-up in our new facility, excepting only a few areas affected mainly by reagent backorders. For further information regarding our quality assurance program or to request a client tour of our facility, please contact your regional sales representative or visit our 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, May 17, 2005 or as noted

2951 Aerobic Bacterial Identification reflex to Susceptibility (effective 05/17/05)

Component	Method	Reference Range	Units
Preliminary Culture	Culture		
Bacterial Identification	Biochem		

Specimen/Stability	Pure Culture Agar Slant Ambient – 7 Days, Refrigerated – 48 hours
Collection Instructions	1. Source of specimen is required. Indicate the exact site where the specimen was obtained. 2. Acceptable specimens: Pure culture of an actively growing bacteria either grown on a slant or culture plate. Unacceptable specimens: Mixed cultures, growth in liquid media, frozen. 3. Ship specimen at ambient temperature within 24 hours of collection. See *Specialty's* "Guidelines for Shipping Infectious Substances."
Clinical Utility	The assay provides complete identification of bacterial isolates submitted.
Schedule	Sunday – Saturday
Turnaround Time	7-14 days
CPT Code	87077
Notes	1. Send PURE culture only. If the specimen is mixed, there will be no workup pending clarification with the client. There will be separate charges for each organism that requires identification. 2. Specimens received that are contaminated with other bacteria may delay test results. 3. Indicate on the requisition form if the isolates submitted are suspicious for organisms that can cause laboratory acquired infections such as *Francisella* or *Brucella*. 4. Antimicrobial susceptibility testing on significant pathogens will be performed at an additional charge.

8148 BK (Polyomavirus) DNA DetectR™ (effective 05/17/05)

Component	Method	Reference Range	Units
BK Virus DNA	RT-PCR	Not Detected	

Specimen/Stability 2 (1.0) mL EDTA or ACD Plasma
Refrigerated 7 days; Frozen – 30 days

Collection Instructions Collect whole blood in EDTA K3 or ACD-A tube. Mix well. Centrifuge and separate plasma. Place plasma in plastic tube for shipping. Ship on cold pack or frozen on dry ice (preferred) by overnight courier.

Alternate Specimens Urine, ACD or EDTA whole blood. See Web site for collection/shipping instructions.

Clinical Utility BK virus-associated nephropathy has become increasingly recognized as the cause of renal dysfunction and kidney allograft loss in transplant patients. The BK virus can reactivate and cause disease in states of immunodeficiency, most frequently in renal and bone marrow transplant patients. BK virus disease is associated with hemorrhagic and non-hemorrhagic cystitis, ureteral stenosis, tubulointerstitial nephritis, compromised allograft function, and allograft failure. The diagnosis of the BK virus has relied heavily on biopsy-based evidence. This PCR-based assay can aid in the diagnosis of BKV reactivation and nephropathy.

Schedule Tuesday, Friday

Turnaround Time 1-5 days

CPT Code 87798

Notes This assay will detect specific BK (Polyomavirus) DNA down to 200 copies/mL.

8149 BK (Polyomavirus) DNA UltraQuant® (effective 05/17/05)

Component	Method	Reference Range	Units
BK Virus DNA Quant	RT-PCR	less than 200 copies/mL	

Specimen/Stability 2 (1.0) mL EDTA or ACD Plasma
Refrigerated 7 days; Frozen – 30 days

Collection Instructions Collect whole blood in EDTA K3 or ACD-A tube. Mix well. Centrifuge and separate plasma. Place plasma in plastic tube for shipping. Ship on cold pack or frozen on dry ice (preferred) by overnight courier.

Alternate Specimens Urine, ACD or EDTA whole blood. See Web site for collection/shipping instructions.

Clinical Utility BK virus-associated nephropathy has become increasingly recognized as the cause of renal dysfunction and kidney allograft loss in transplant patients. The BK virus can reactivate and cause disease in states of immunodeficiency, most frequently in renal and bone marrow transplant patients. BK virus disease is associated with hemorrhagic and non-hemorrhagic cystitis, ureteral stenosis, tubulointerstitial nephritis, compromised allograft function, and allograft failure. The diagnosis of the BK virus has relied heavily on biopsy-based evidence. This new quantitative PCR-based assay can aid in the diagnostic and therapeutic management of BKV nephropathy. Recent studies demonstrated that cidofovir may be useful in treating interstitial nephritis. Quantitative viral load testing may be useful for early diagnosis of reactivated BKV infection and for monitoring the response to specific therapy.

Schedule Tuesday, Friday

Turnaround Time 1-5 days

CPT Code 87799

Notes BK (Polyomavirus) DNA UltraQuant® will quantify viral load within a defined range of Less than 200 to more than 10,000,000,000 copies/mL. Extremely elevated viral loads are possible,especially in urine samples

1481 Hyaluronic Acid (effective 05/17/05)

Component	Method	Reference Range	Units
Hyaluronic Acid	EIA	Less than 75.0	ng/mL

Specimen/Stability 1 (0.5) mL Serum
Refrigerated -7 Days; Frozen 30 days

Alternate Specimen 1 (0.5) mL EDTA Plasma
Refrigerated -7 Days; Frozen 30 days

Clinical Utility Hyaluronic Acid levels may be used to help assess the degree of liver fibrosis and cirrhosis in chronic liver disease.

Schedule Wednesday

Turnaround Time 1-8 days

CPT Code 83520

4863I Lead, OSHA Panel with Zinc Protoporphyrin (effective 05/17/05)

Component	Method	Reference Range	Units
Lead, Industrial	GF-AAS	Less than 40	ug/dL
~		OSHA Industrial Reference Range for Lead:	
~		Exposure . . . . . < 40 ug/dL	
		Toxic . . . . . > 40 ug/dL	
Zinc Protoporphyrin, Industrial	HF	Less than 101	ug/dL
~		OSHA occupational threshold for Zinc Protoporphyrin: 100 ug/dL blood at hematocrit of 42%	

Specimen/Stability 3 (1.5) mL EDTA Whole Blood Trace Metal, Foil Wrapped
Ambient -7 Days; Refrigerated 14 days

Alternate Specimens Heparinized Whole Blood Tan or Trace Metal, Foil Wrapped
EDTA Whole Blood, Foil Wrapped

Collection Instructions Collection material such as alcohol swabs should be lead-free. Use powder-free gloves or rinse the powder off with tap water. Clean skin with the lead-free alcohol swab prior to puncture. Avoid hemolysis. Avoid worksite collection. Protect from light: use foil wrapping or amber tubes.

Schedule Sunday - Saturday

Turnaround Time 1-2 days

CPT Code 83655, 84202

Notes *Specialty* is approved by OSHA to perform this assay.

9640 *Streptococcus*, Group B DNA DetectR™ (effective 05/17/05)

Component	Method	Reference Range	Units
Group B Strep DNA	RT-PCR	Not Detected	

Specimen/Stability Swab
Refrigerated – 7 Days, Frozen – 30 Days

Collection Instructions Collect swab samples from vaginal, cervical, urethral or rectal sources or prenatal vaginal/rectal sites. Place in one of the following validated transport media:
- Copan-LQ Amies or Copan-Amies without charcoal
- BBL-Amies with charcoal or BBL-Amies without charcoal
- BBL-LQ Stuart
- Healthlink-Amies with charcoal
- StarPlex-Modified Amies

Shipping Instructions Ship refrigerated on cold pack or frozen on dry ice by overnight courier.

Clinical Utility *Streptococcus agalactiae* is the leading cause of neonatal infections. Approximately 15-35% of healthy adult women are intermittently colonized by GBS. Invasive infections in pregnant women involve bacteremia, urinary tract infections, chorioamnionitis, endometritis, and wound infections. Infant infection may result in sepsis and meningitis, leading to death or long-term disabilities such as hearing loss, impaired vision, developmental problems, and cerebral palsy. The CDC recommends prenatal screening for GBS colonization of all pregnant women at 35-37 weeks gestation, allowing opportunity for implementation of selective intrapartum chemoprophylaxis or immunoprophylaxis.

Schedule Sunday - Saturday

Turnaround Time 1 day

CPT Code 87798

Notes The lower limit of detection is 14 CFU/reaction. Due to intermittent colonization, this PCR assay may provide a more sensitive prenatal screening detection than culture alone.

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
3129U	05/17/05	Cortisol, Free 24 Hour UltraQuant®	Name Cortisol, Free 24h Urine UltraQuant® Stability Ambient – 48 h, Refrigerated 7 d, Frozen 2 m Collection Instructions Acetic and boric acid are acceptable additives. Add 12.5 mL of 50% acetic acid or 5 g of boric acid at the start of a 24 hour collection. Measure the total volume, mix the specimen and transfer the aliquot to a clean, leakproof screw cap tube. Record the total volume on specimen container and requisition form.	

Test Code	Effective Date	Test Name	Specific Change	Also Affected
2421	03/30/05	Cytomegalovirus Antigen Detection	Specimen 2 Smears/slides Alternate Specimens 2 Buffy Coat smears 1 Culturette/Swab 1 Swab in M4 Transport Media 1 Sterile Container/Tube Collection Instructions 1. For all sample submissions, the source of specimen is required; please include on requisition. 2. Smear or slide: For whole blood samples: centrifuge either Heparin or ACD anticoagulated peripheral blood. Collect buffy coat and smear on two or more slides. Acetone fix. Only smears from buffy coat will be accepted. Do not submit whole blood or smears made from whole blood due to low mononuclear cell concentration in peripheral blood. 3. Smear or slide: Bone Marrow: Prepare smear on two slides and acetone fix. 4. Smear or slide: Tissue: Prepare tissue or organ touch prep slides by gently touching tissue to clean dry slides. Submit minimum of 2 slides acetone fixed. Tissue may also be submitted as specified below. 5. Submit the following in a sterile, leak proof container: Bronchoalveolar lavage (BAL), saliva, and urine. For biopsy tissues and throat swab, place in viral transport media or M4 media 6. Unacceptable specimens: stool specimens, wooden swabs, and calcium alginate swabs. 7. Specimens received at *Specialty* more than 72 hours from time of draw must be frozen at -70C (not -20C) or on dry ice. 8. A shell vial will be set up on urine specimens. Final result will be released 48 hours after incubation. 9. Ship specimens refrigerated or on dry ice.	
2960	04/05/05	Fecal Leukocytes	Alternate Specimens 1 g (mL) Stool in SAF or EcoFix Refrigerated 48 hours. Ship within 24h or collection	
9448	03/30/05	Herpes Simplex Virus 1 & 2 Differentiation IgG Antibodies	Name Herpes Simplex Virus 1 & 2 Differentiation IgG Abs [IB]	
9884A	5/17/05	HIV-1 RNA Quantitation [Roche Amplicor]	Stability Plasma PPT tubes: Ambient 48h, Refrigerated 72hr Frozen PPT tubes will no longer be accepted. EDTA Plasma separated from PPT tube and shipped frozen in separate plastic tubes is acceptable.	9884ASR HIV-1 RNA Quant by Roche Amplicor with serial reporting 9884FPNY HIV-1 RNA Quant by Roche New York Prognostic and FPNS serial reporting 7482A HIV-1 RNA Ultrasensitive by Roche reflex to GenotypR™ PLUS and 7482ASR serial reporting 7482FPNY HIV-1 RNA Quant by Roche reflex to HIV GenotypR™ Plus New York 7484A HIV-1 RNA Quant by Roche reflex to HIV GenotypR™ PLUS 7485A HIV-1 RNA Quant by Roche Ultrasensitive and 7485ASR serial rept 9874A HIV-1 RNA Quantitation [Roche] reflex to Ultrasensitive and 9874ASR serial reporting 9874AFN HIV-1 RNA Quant by Roche reflex to Ultrasensitive New York and 9874AFNS serial reporting

Test Code	Effective Date	Test Name	Specific Change	Also Affected
1060	04/12/05	Lymphocyte Mitogen Proliferation Analysis	Notes Test not available for New York clients	1062 Lymphocyte Antigen & Mitogen Proliferation Analysis 1640 Lymphocyte Mitogen Proliferation Analysis, PHA 1641 Lymphocyte Mitogen Proliferation Analysis, PWM 1642 Lymphocyte Mitogen Proliferation Analysis, Con A
2472	05/17/05	Rotavirus Antigen Detection	Specimen 1 g (mL) unpreserved stool Alternate Specimen Stool on Culturette/Swab Only unpreserved stool is acceptable. Eliminate stool in Cary-Blair as acceptable sample.	
3521	03/28/05	Vitamin D, 25 Hydroxy (Calciferol)	Method CL	*Method change is only for Vitamin D, 25 Hydroxy in following panels:* 3523 Vitamin D, 1,25-Dihydroxy & 25 Hydroxy 3525 Vitamin A & Vitamin D, 25-Hydroxy

Sendout Changes

Discontinue Sendouts S50563 and S50554 for BK Virus and replace with 8148 BK (Polyoma) Virus DNA DetectR™ or 8149 BK (Polyoma) Virus DNA UltraQuant®.

See attached summary of other sendout changes. Please call Client Services at 800-421-4449 for more information.