

April 17, 2007

Dear Colleague:

This client letter details recent changes that have occurred in tests available from *Specialty* as well as a listing of discontinued tests. A new section in this communication will be titled "**SENDOUT REPLACEMENTS**". These are current send out tests that are going to be brought in-house. Please note the effective dates that the **replacements** will go into effect and update accordingly. The replacement tests will also be listed in the NEW TEST client letter along with the test code that the in-house test is replacing.

A significant addition in **Streptococcus Group B DNA DetectR™** testing is the approval of liquid cytology samples. Three acceptable media have been added and are detailed on the following pages. The stability ranges from 21-28 days ambient or refrigerated. We here at specialty hope these additional media types will meet your needs in Group B testing and encourage clients to voice their needs concerning sample collection issues. We will work diligently to institute value added services as warranted and look forward to helping our clients in any way possible.

Specimens for **First Trimester Screening** should be obtained between 10 weeks 3 days and 13 weeks 6 days gestation (crown-rump measurements 35-79mm). The Nuchal Translucency (NT) measurement must be provided by the patient's NT certified sonographer along with the blood specimen. Accurate NT measurements are necessary for valid screening results. An NT measurement provided by an NT certified sonographer must be received before Specialty can report these results. A copy of the sonographer's certification must be submitted with the first specimen sent from each sonographer for our files. Information on how to obtain NT certification and the Nuchal Translucency Quality Review Program (NTQR) can be obtained at <http://www.ntqr.org>. By submitting an NT certification, sonographer's authorize Specialty Laboratories to provide their specific NT measurement data to NTQR for quality monitoring. An updated requisition is now available for First Trimester Screening. Please contact client relations to obtain the updated requisition.

For our NY Clients, if a test is not available in NY the following statement will be in the NOTES section of the Web as well as Client Letters: "NOT APPROVED FOR NY PATIENTS UNTIL FURTHER NOTICE". There are instances where approval has been obtained and the Web is in the update process. If in doubt, a call to Client Relations is guaranteed to definitively answer questions you may have regarding NY availability.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.



Michael C. Dugan, M.D.
Vice President and Laboratory Director

Sendout Replacements:

S50698 Urothelial Cancer (FISH)

Replaced by **#5841 UroVysion™**
Effective Immediately

S51155 Urovysion FISH

Replaced by **#5841 UroVysion™**
Effective Immediately

S49203 Clonazepam & Metabolite Urine

Replaced by **#4939U Clonazepam and 7-Amino Clonazepam Urine**
Effective Immediately

S49520 Bile Acids, Total Only

Replaced by **#6820 Total Bile Acid**
Effective Immediately

S46905 Nicotine & Metabolite

Replaced by **#4190U Nicotine and Metabolites Urine**
Effective 4/24/2007

S40445 Nicotine & Cotinine

Replaced by **#4190 Nicotine and Cotinine Serum**
Effective 4/24/2007

S50087 Nicotine & Metabolite Screen Serum GC/MS Confirmation

Replaced by **#4190 Nicotine and Cotinine Serum**
Effective 4/24/2007

S50833 Fentanyl (Sublimaze) Serum

Replaced by **#4302 Fentanyl and Norfentanyl Confirmation Serum**
Effective 4/24/2007

S50832 Fentanyl (Sublimaze) Urine

Replaced by **#4302U Fentanyl and Norfentanyl Confirmation Urine**
Effective 4/24/2007

S43912 Meperidine and Normeperidine Urine

Replaced by **#4300U Meperidine and Normeperidine Urine**
Effective 4/24/2007

S51180 Thyroglobulin Tumor Marker

Replaced by **#3255 Thyroglobulin Serum**
Effective Immediate

Discontinued

No Tests

Test Changes:

2418	Cytomegalovirus Culture	Effectively Specimen	Immediately 10 (1)mL Urine, Ambient 72 hrs, Refrigerated 7 days, Frozen 2 months
5708	Anaerobic Bacterial Culture	Effectively Collection	Immediately 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. Amies liquid HealthLink Transporter with gel is also acceptable. Unacceptable culturette types: 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 Specialty's "Guidelines for Shipping Infectious Substances." 5. Refer to Appendix B for detailed collection instructions.
5046	MSI DetectR™	Effectively Note Also Affected	Immediately This test is now available for NY patients 5046BK
9640	Streptococcus group B DNA DetectR™	Effectively Alternate Sample	Immediately TriPath CytoRich solution TPCRS 1.5(0.5) AR* Ambient - 21 Day(s) / Refrigerated - 21 Day(s)
	Alternate Sample	ThinPrep Vial TPVDI 1.5(0.5) AR* Ambient - 21 Day(s) / Refrigerated - 21 Day(s)	
	Alternate Sample	Tripath SurePath Vial TSPV 1.5(0.5) AR* Ambient - 28 Day(s) / Refrigerated - 28 Day(s)	

- 4170 Cocaine and Metabolites Confirmation, Serum**
 Effective Immediately
 Specimen 5.0(2.5)mL Serum, Refrigerated 72 hrs, Frozen 2 Months
 Note Serum is the only acceptable sample. SST tubes are not acceptable.
 Also Affected 4171, 4172
- 4185 Opiates Confirmation Serum**
 Effective Immediately
 Specimen 5.0(2.5)mL Serum, Refrigerated 72 hrs, Frozen 2 Months
 Note Serum is the only acceptable sample. SST Tubes are not acceptable.
 Also Affected 4491, 4493, 4495, 4492, 4496
- 5836 HER-2/neu [FISH], Breast Cancer**
 Effective Immediately
 CPT 88367x2
 Also Affected 5842
- 5884 DEL(4)(Q12) By FISH (FIP1L1-CHIC2-PDGFR)**
 Effective Immediately
 Test Name DEL(4)(Q12) By FISH (FIP1L1-PDGFR)
- 7675C Toxoplasma Igm Antibodies CSF**
 Effective Immediately
 Ref. Range <0.50
 Also Affected 2263C
- 1580U Electrophoresis, Protein Urine**
 Effective Immediately
 Ref. Range Albumin: 100%, Alpha 1: 0%, Alpha 2: 0%, Beta: 0%, Gamma: 0%
 Note Normal urine protein concentration is very low (<140 mg/24 hours) and urine PEP typically shows only a faint band of albumin if detected. Other protein fractions (% of total protein) are reported only when noted or when total protein concentration is increased.
 Also Affected 1595U
- 1322 Creatinine Clearance**
 Effective Immediately
 CPT 82575

5500

PCA3 Profiler™

Effective Immediately
Collection Instructions

To guarantee correct urine sample preparation and submission, the PCA3 Profiler Bag Kit is available and can be ordered by phoning Client Relations at 800-421-4449 and requesting kit #P12501.

Two APTIMA Urine Transport tubes are required for testing.

1. Conduct a DRE as described below immediately prior to urine collection: Apply pressure on the prostate, enough to depress the surface approximately 1cm, from the base to the apex and from the lateral to the median line for each lobe. Perform exactly three strokes for each lobe.

2. Following the DRE, direct the patient to provide first-catch urine (approximately 20-30 mL of the initial urine stream) in an appropriately labeled urine collection cup. This must be the first voided urine specimen following the DRE. Use a collection cup free of any preservatives.

Note: If the patient is unable to provide the requested volume of urine, at least 2mL is required to run the PCA3 assay.

3. Invert the sample 5 times to re-suspend the cells in urine. Remove the cap of the APTIMA urine specimen transport tubes and transfer 2mL of the collected urine into 2 tubes using the disposable transfer pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.

4. Re-cap the APTIMA urine transport tubes tightly and invert 5 times to mix.

Note: Urine must be transferred into the urine specimen transport tube within 4 hours of collection.

Storage prior to shipping: Urine samples in APTIMA Urine Transport Tubes must be stored refrigerated (preferred) or if shipping delayed, frozen.

3127

Disaccharidases

Effective Immediately
CPT Code 84311x4

4939U

Clonazepam & 7-Amino Clonazepam Urine

Effective Immediately
Reference Range <5 ng/mL for both components

4866R

Magnesium RBC

Effective Immediately
Specimen

Primary	3.0(2.0) mL	RBC from WB EDTA Trace Metal
Alternate	3.0(2.0) mL	RBC from WB Heparin
Alternate	3.0(2.0) mL	RBC from WB EDTA
Alternate	3.0(2.0) mL	RBC from WB Sodium Heparin Trace Metal

1705	Narcolepsy EvaluatR™
Effective	Immediately
Clinical Utility	Narcolepsy is a lifelong neurological disorder characterized by excessive daytime sleepiness, and pathologic intrusion of rapid-eye-movement sleep (REM) into wakefulness, and is often associated with cataplexy. It affects 1/200-1/500 individuals in the United States. Narcolepsy is strongly associated with the human leukocyte antigen (HLA) alleles DQB1*0602 and DQA1*0102, suggesting a possible autoimmune etiology. Approximately 85-95% of individuals with narcolepsy have DQB1*0602 and DQA1*0102 as compared to 25% of the general Caucasian population. While the HLA-DQB1*0602, DQA1*0102 alleles are associated with narcolepsy they are not sufficient to cause narcolepsy. Other genetic and non-genetic factors are involved. The value of HLA typing in patients suspected of having an HLA associated disease depends on a presumptive diagnosis of the disease based on clinical and other laboratory findings.
2362	Ova & Parasite: Comprehensive Exam with Coccidia Evaluation
Effective	Immediately
Specimen	Remove stool from the Alternate sample list
4867U	Arsenic 24HR Urine
Effective	Immediately
Collection	Avoid worksite collection. Avoid seafood consumption for 48 hr prior to sample collection. Collect urine in an acid- washed plastic container. Acidify with acetic or nitric acid (1 mL of concentrated acid for each 100mL urine). Do not use hydrochloric acid. Send aliquot in a Specialty transfer tube.
Also Affected	4867UR
4861U	Lead 24 Hour Urine
Effective	Immediately
Collection	Avoid worksite collection. Avoid seafood consumption for 48 hr prior to sample collection. Collect urine in an acid- washed plastic container. Acidify with acetic or nitric acid (1 mL of concentrated acid for each 100mL urine). Do not use hydrochloric acid. Send aliquot in a Specialty transfer tube.
Also Affected	4861UR
4962	Clomipramine & Desmethylclomipramine
Effective	Immediately
Alternate Sample	Plasma ACD 3.0(2.0) ARF Ambient - 7 Day(s) / Refrigerated - 14 Day(s) / Frozen - 2 Month(s)
8137	Hepatitis B Virus DNA Ultraquant™
Effective	Immediately
Interpretation	Results will also be reported in IU/mL (Ref. Range <95IU/mL) Approximately 5.26 copies = 1 IU
Also Affected	2479

- 4190 Nicotine and Cotinine Serum**
 Effective Immediately
 Ref. Range Nicotine
 Unexposed/non-Tobacco user <2 ng/mL
 Passive/Exposure <2 ng/mL
 Abstinenet/Use >2 weeks <2 ng/mL
 Active Tobacco user >30 ng/mL
 Cotinine
 Unexposed/non-Tobacco user <2 ng/mL
 Passive/Exposure <8 ng/mL
 Abstinenet/Use >2 weeks <2 ng/mL
 Active Tobacco user >200 ng/mL
- 9446 Herpes Simplex Virus 1 & 2 IgG Antibodies**
 Effective Immediately
 Name Herpes Simplex Virus Types 1 & 2
 IGG(HerpeSelect®) & IGM ABS [EIA]
 Also Affected 8051, 9451, 9461
- 4300U Meperidine and Normeperidine Urine**
 Effective Immediately
 Ref.Range Meperidine Cut-off <50 ng/mL
 Normeperididne Cut-off <50 ng/mL
- 4302U Fentanyl and Norfentanyl Urine**
 Effective Immediately
 Ref.Range Fentanyl Cut-off <0.1 ng/mL
 Norfentanyl Cut-off <0.1 ng/mL
- 4302 Fentanyl and Norfentanyl Serum**
 Effective Immediately
 Ref.Range Fentanyl 1-3 ng/mL
 Norfentanyl By Report
- 5830 Genetic Diseases [FISH]**
 Effective Immediately
 Add the following to list of syndromes covered: **1p36** and **Sotos syndrome (5q35)**

Continued on next page.....

3521

Vitamin D 25 Hydroxy

Effective Immediately

Interpretive guidelines for Vitamin D (25-hydroxy):

>100 ng/mL (>250 nmol/L)	Potential Vitamin D toxicity
32 - 100 ng/mL (80 - 250 nmol/L)	Vitamin D sufficiency
20 - 32 ng/mL (50 - 80 nmol/L)	Mild Vitamin D insufficiency
10 - 20 ng/mL (25 - 50 nmol/L)	Moderate Vitamin D insufficiency
7-10 ng/mL (17.5 - 25 nmol/L)	Marked Vitamin D insufficiency
<7 ng/mL (<17.5 nmol/L)	Vitamin D deficiency

Effective

5/22/2007

Ref. Range

20-100 ng/mL (50.0-250 nmol/L)

Note:

Ranges observed in selected populations vary considerably and a significant portion of asymptomatic persons, particularly elderly and those with limited sun exposure will have Vitamin D insufficiency associated with elevated intact parathyroid hormone (intact PTH) levels and elevated risk of osteoporosis. Serum levels above 32 ng/mL (80 nmol/L) have been recommended for optimizing bone health whereas levels below 10 ng/mL (25 nmol/L) are associated with a significant risk of osteomalacia.

Also Affected

3523