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
   Effective Immediately
   Specimen 10 (1)mL Urine, Ambient 72 hrs, Refrigerated 7 days, Frozen 2 months

5708  Anaerobic Bacterial Culture
   Effective Immediately
   Collection 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™
   Effective Immediately
   Note This test is now available for NY patients
   Also Affected 5046BK

9640  Streptococcus group B DNA DetectR™
   Effective Immediately
   Alternate Sample 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-PDGFRA)
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
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
Abstinence/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
Abstinence/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
Normeperidine  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.......
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