

September 2006

Dear Colleague:

This client letter details changes in tests available from *Specialty* as well as a listing of discontinued tests. Among the notable changes in this letter is the introduction of a new third generation test **3133 Cyclic Citrullinated Peptide 3rd Generation (CCP3) IgG Antibody** for detection of rheumatoid arthritis. This test has a 5% increase in sensitivity compared to the previous second generation test.

Also of significance are new changes to the **4168 Kidney Stone Risk AssessR™** test for evaluating a patient's propensity to form urinary tract calculi. The 24 hour urine collection kit for this test was re-developed to allow patients to collect the 24 hour sample at home, self aliquot the specimen samples, and send directly to *Specialty* for analysis. Now only two specimen samples instead of three are needed and we have eliminated patient handling of caustic acid and basic solutions.

The **new graphic color report for 4168 Kidney Stone Risk AssessR™** readily illustrates contributing factors that increase a patient's risk for developing kidney stones. There is also a patient-specific interpretation which summarizes this information. This new report complements our Stone-A-Lyzer color-report and is intended to help physician's better communicate clinical information of value to their patients.

For additional information, please visit our Web site at [www.specialtylabs.com](http://www.specialtylabs.com) or contact Client Services at 800-421-4449.



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Vice President and Laboratory Director

## Discontinued and Changed Assays at *Specialty*

Effective date as noted

### DISCONTINUED:

#### 5420 NATURAL KILLER CELL FUNCTION

Effective: IMMEDIATELY

Reason reagent unavailable

#### 5422 Natural Killer Cell EvaluatR™

Effective: IMMEDIATELY

Reason reagent unavailable

Note: 1872: Natural Killer Cell Quantitation by flow cytometry is available

### DISCONTINUED Send out:

#### S46880 Alpha-Thalassemia Gene Rearrangement

Effective: 10/17/06

Reason Send out discontinued, new test available in-house

### Test Changes

#### 3952 Chromogranin-A (effective immediately)

Ref Range < 160 ng/mL

Specimen Strict Frozen only. Ambient, refrigerated, hemolysed, lipemic and icteric samples will be rejected

#### 3951 Chromogranin-A End-Point Titer (effective immediately)

Ref Range < 160 ng/mL

Specimen Strict Frozen only. Ambient, refrigerated, hemolysed, lipemic and icteric samples will be rejected

#### 5784 Blood Culture, Aerobic (effective immediately)

Alternate specimens 3 mL (1) Bone Marrow ACD; Ambient 48 Hour

#### 2410 Viral Culture (effective immediately)

Alternate Specimen Bone Marrow 1.0 mL (0.5)

#### 3521 Vitamin D, 25-Hydroxy (Calciferol) (effective immediately)

CPT Code 82307

#### 3523 Vitamin D, 1, 25-Dihydroxy & 25-Hydroxy (effective immediately)

CPT Code 82307, 82652

- 2473**      ***Giardia / Cryptosporidium* Antigen Detection**  
(effective immediately)  
Specimen    Stool in Formalin  
                 Unpreserved stool is not acceptable
- 1592U**      **Monoclonal Gammopathy Evaluation, 24-hr Urine**  
(effective immediately)  
Name change to add 24-hr urine and "U" after test code
- 1481**      **Hyaluronic Acid**  
(effective immediately)  
Alternate Specimen Plasma 1 mL (0.5) , EDTA
- 5116**      **Hemoglobin**  
(effective immediately)  
Stability Ambient 48 hrs, Refrigerated 4 days
- 5779**      **Fungus Culture: Yeast Screen**  
(effective immediately)  
CPT Codes, add 87206 for stain, change 87102 for culture
- 1062**      **Lymphocyte Antigen & Mitogen Proliferation Analysis**  
(effective immediately)  
Specimen volume 50 (30) mL  
Note: Panel is not available for infants due to large whole blood volume requirement. For infants, if a specific antigen or mitogen test is needed, please refer to the individual panel component for specimen requirement volume(s).
- 1648**      **Lymphocyte Antigen Proliferation Analysis**  
(effective immediately)  
Specimen volume 20 (14) mL  
Note: For infants or pediatric patients, 15.0 mL whole blood ACD is required. If insufficient volume is sent, test will not be performed.
- 3133**      **Cyclic Citrullinated Peptide 3<sup>rd</sup> Generation (CCP3) IgG Antibody**  
(effective immediately)  
Test name change: Replaces second generation test Cyclic Citrullinated Peptide (CCP) IgG Antibody with third generation test. Same high clinical specificity levels as CCP2.  
  
Note: Cyclic Citrullinated Peptide Third Generation (CCP3) IgG Antibody is more efficient at discriminating rheumatoid arthritis (RA) patients than either the perinuclear autoantibody test or the test for rheumatoid factor. Approximately 74% of patients with RA are positive for anti-CCP3 IgG, while only about 4% of random blood donors and disease control subjects are positive. CCP3 IgG has improved clinical sensitivity of 5% over CCP2 IgG in discriminating RA patients.
- 3318UR**      **Vanillylmandelic Acid Urine Random**  
(effective immediately)  
Specimen volume, 5 (2.5) mL

- 5868 FISH Burkitt Lymphoma**  
(effective immediately)  
Add CPT Code 88291
- 5872 FISH Follicular Lymphoma**  
(effective immediately)  
Add CPT Code 88291
- 5866 FISH MALT Lymphoma**  
(effective immediately)  
Add CPT Code 88291
- 5870 FISH Mantle Cell Lymphoma**  
(effective immediately)  
Add CPT Code 88291
- 5864 FISH Multiple Myeloma**  
(effective immediately)  
Add CPT Code 88291
- 5874 FISH AML/ High Grade Myelodysplastic**  
(effective immediately)  
Add CPT Code 88291
- 5878 FISH Myelodysplastic Syndrome, Low Grade**  
(effective immediately)  
Add CPT Code 88291
- 7760 *Giardia lamblia* Antigen Detection**  
(effective immediately)  
Add alternate specimen:  
Stool SAF Fixative STSAF 2.0 (1.0) AR Ambient 14 days, Refrigerated 14 days  
Stool ECOFIX STECO 2.0 (1.0) AR Ambient 14 days, Refrigerated 14 days
- 1901 Apolipoprotein A-1**  
(effective immediately)  
New reference range:128-276 mg/dL
- 1900 Apolipoprotein Evaluation**  
(effective immediately)  
New reference range:128-276 mg/dL
- 3116 Antidiuretic Hormone (ADH)**  
(effective immediately)  
Reference range: <7 pg/mL

**9474C**     ***Herpes Simplex Virus DNA UltraRapid® CSF***  
(effective immediately)

Stability: 24 hr ambient, 24 hr refrigerated, Frozen 2 months.

**9474**     ***Herpes Simplex Virus DNA UltraQuant®***  
(effective immediately)

Stability: Whole Blood: Ambient 4 days for both EDTA and ACD whole blood

Fluid: Ambient 24 hr, Refrigerated 24 hr, Frozen 2 months

Urine: Frozen or mixed with equal volume of 95% ethanol: Ambient 48 hrs Refrigerated 48 hrs, Frozen 2 months

**7440SW**     ***Chlamydia trachomatis/N. gonorrhoeae rRNA PLUS [TMA]***  
**w/ rfx Confirm**  
(effective immediately)

Stability:

Specimen 1: Gen-Probe (Aptima) Swab, GENPA 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

Alternate: Gen-Probe (Apt) Vag Swab, GENPV 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

**7437SW: *Chlamydia trachomatis* rRNA Detection [TMA]**  
(effective immediately)

Stability:

Specimen 1: Gen-Probe (Aptima) Swab, GENPA 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

Alternate: Gen-Probe (Apt) Vag Swab, GENPV 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

**7438SW**     ***Chlamydia trachomatis/N. gonorrhoeae rRNA PLUS [TMA]***  
(effective immediately)

Stability:

Specimen 1: Gen-Probe (Aptima) Swab, GENPA 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

Alternate: Gen-Probe (Apt) Vag Swab, GENPV 1.0 (1.0) ARF Ambient 60 days, Refrigerated 60 days, Frozen 90 days

**2932SW**     ***Neisseria gonorrhoeae RRNA [TMA]***  
(effective immediately)

Stability:

Specimen 1: Gen-Probe (Aptima) Swab, GENPA 1.0 (1.0) ARF Ambient - 60 Day(s)/Refrigerated - 60 Day(s)/Frozen - 90 Day(s)

Alternate: Gen-Probe (Apt) Vag Swab, GENPV 1.0 (1.0) ARF Ambient - 60 Day(s)/Refrigerated - 60 Day(s)/Frozen - 90 Day(s)

## Kidney Stone Risk AssessR™ (effective immediately)

### Specimen collection instructions:

The following collection instructions are designed for patient performed collection and aliquoting

1. Complete the top portion of the Patient Information Form. Also, print your name clearly on the two Specimen Containers
2. On the morning of your first 24-hour collection, urinate into the toilet and record the date and time on the Patient Information Form
3. The next time you urinate, remove the lid of the Urine Collection Container and urinate directly into the container.
4. Replace the lid and store the container in the refrigerator or in a cooler filled with ice. It is important to keep the Urine Collection Container refrigerated throughout the collection process. Be sure the retractable spout is closed so that urine is not spill when handling the container.
5. Continue to urinate (as needed) into the Urine Collection Container until the following day.
6. The first urination of the following morning is the last urine to be collected. Record the date and time of this last collection on the Patient Information Form. You have now collected all the urine needed for this process.
7. Determine how much total urine was collected by reading the number on the side of the container corresponding to the fill amount in the container. This number is listed in milliliters (ML). Write this number of Total Volume Collected on the Patient Information Form.
8. Be sure the retractable spout is closed and shake the contents vigorously. Mixing the contents well ensures that the Specimen Containers include a representative sample of all the urine collected.
9. Open the retractable spout and carefully pour the urine into the two Specimen Containers up to the fill line (60 ml). Place the lids over the containers and securely tighten them for shipping to the laboratory. One of the containers includes a piece of glass wool that must remain in the container with the urine.
10. After filling the two Specimen Containers, you no longer need the remaining urine in the orange Urine Collection Container. Dispose of the remaining urine and the orange urine collection container. This does NOT need to be sent with the Specimen Containers to the laboratory.

### Specimen Shipping Instructions

Hospital or medical office clients can send the specimen containers via their usual courier to Specialty Laboratories.

11. After filling the two Specimen Containers to the fill line (60 ml) and replacing the lids tightly, shake the containers vigorously. Be sure your name and your physician's name are written clearly on the two container labels where indicated.
12. Place the Specimen Containers into the foam-lining and then into the plastic bag that was included with the Shipping Box. Seal the plastic bag and place it securely in the Shipping Box.
13. Enclose the completed Patient Information Form with the Shipping Box.
14. Place the Shipping Box into the FedEx® package and follow the FedEx® shipping instructions. Be sure to complete the top-half of the FedEx® packing slip and call 1-800-GO-FEDEX to have the package picked-up from your home.

Urine should be refrigerated during collection.

Please call Client Supply at 800-421-7110 ext.6690 or fax supply request to 661-799-5251 to have the collection kits sent to you.

**Note:** The Kidney Stone Risk AssessR™ now has an easy to interpret graphical report with interpretation and comments as needed. Analytes that result in an increased propensity to form stones are listed across the top band with decreased propensity listed across the bottom band.

### **Effective 9/19/06**

Kidney Stone Risk AssessR™ report will include two new components, an interpretation and comment field.

**8091**

**Poliovirus Antibodies**

**(effective 10/10/06)**

Reference Range: greater than or equal to 1:8

Clinical Utility: "Detection of poliovirus antibodies due to immunization or previous exposure to polio or other enteroviruses. Cross-reaction with other enteroviruses are known. Less than 2% of tested individuals have less than 1:8 titer. If an acute polio infection is suspected, paired sera samples, at least three weeks apart, would demonstrate at minimum, a four-fold rise in titer. Best indication of immunity to poliovirus is the neutralization antibody test."