SPECIALTY LABORATORIES
27027 Tourney Road 800•421•7110
Valencia, CA 91355 www.specialtylabs.com

Test Updates

June 25, 2010

Dear Colleague:

Specialty Laboratories is pleased to announce upcoming enhancements to our specimen transport and tracking capabilities. During the next few months we will transition to newly designed specimen transport bags, tubes and caps that we supply to you. Among the benefits of these new items, our transport bags will now have a bar code for use by most couriers. This will allow us to track specimen bags you send to us and more easily determine the location of a specimen. More information about these new items will soon be available on our website *www.specialtylabs.com*, and will also be available through our client supply process. These new items have been tested to ensure they meet the same high standards as the items we currently supply.

Our process improvement team in Logistics and Specimen Processing has also determined that missing specimens can be significantly reduced when a manifest is included with every shipment to *Specialty*. A summary sheet of submitted specimens and patients allows our processing staff to immediately isolate problems. The sooner an issue is identified, the more likely we are able to resolve it and complete ordered testing. A sample template can be made available upon request.

Our analytical staff is pleased to inform you that our test [7510] Influenza A H1N1 (2009) Real-Time RT-PC is now FDA approved. Please update your records appropriately.

Specialty will shortly be introducing a new comprehensive program for drug testing in the field of Pain Management. Specialized drug testing for medications prescribed for pain is needed for:

- Physician compliance with state licensure and DEA regulatory requirements
- Pain Management Clinics that monitor pain medication compliance
- Detecting substance abuse in patients prescribed pain medications

Profiles will include specimen validity testing (SVT) to insure that valid drug testing specimens have been submitted. Our custom medMatch™ reports for pain management testing will clearly provide the physician with an accurate status of the patient's compliance to drug therapy. A separate client letter with details on this program will soon be provided. Please watch for it in upcoming weeks.

We thank you for choosing *Specialty* and look forward to your continued support. For additional information, please visit our Web site at *www.specialtylabs.com* or contact Client Relations at 800-421-4449.

Respectfully Yours,

Basel Kashlan

Basel Kashlan, MD, FCAP
Laboratory Director

New Tests (*Specialty*):

2946 Extended-Spectrum Beta-Lactamase Conf (ESBL) Detection (Available July 8)

Component	Method	Reference Range/Units
ESBL	**DISC-DIFF**	**No ESBL(s) Detected**

Specimen/Stability	Pure Bacterial Isolate (slant or plate): Ambient 7 days, Refrigerated 7 days
Collection Instructions	1- Indicate the organism identification. 2- Acceptable specimens: Pure culture of an actively growing bacteria either grown on a slant or culture plate. 3- Unacceptable specimens: Growth in liquid media, frozen, nonviable organisms. 4- Refer to Appendix B for detailed collection instructions. 5- Ship specimen at ambient temperature within 24 hours of collection. See *Specialty's* "Guidelines for Shipping Infectious Substances".
Schedule	Sunday-Saturday
Report	Within 5 days
CPT Code	87184
Regulatory Status	FDA Approved
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- Test results may be delayed if the specimen is mixed or contaminated with other bacteria. 3- Organisms other than Enterobacteriaceae, nonviable organisms, and frozen samples are unacceptable for this test.
Clinical Utility	To determine if a pure culture is susceptible to beta-lactamase drugs. In vitro susceptibility testing may suggest susceptibility when specialized testing demonstrates a pure culture is a beta-lactamase producer. Results are useful in selecting optimal therapy.

2947 Modified Hodge Test (Available July 8)

Component	Method	Reference Range/Units
Hodge Test	**DISC-DIFF**	**Phenotypic test negative for carbapenemases**

Specimen/Stability	Pure Bacterial Isolate (slant or plate): Ambient 7 days, Refrigerated 48 hours
Collection Instructions	1- Indicate the organism identification. 2- Acceptable specimens: Pure culture of an actively growing bacteria either grown on a slant or culture plate. 3- Unacceptable specimens: Mixed cultures, growth in liquid media, frozen, nonviable organisms. 4- Refer to Appendix B for detailed collection instructions. 5- Ship specimen at ambient temperature within 24 hours of collection. See Specialty's "Guidelines for Shipping Infectious Substances".
Schedule	Sunday-Saturday
Report	Within 5 days
CPT Code	87184
Regulatory Status	FDA Approved
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- Test results may be delayed if the specimen is mixed or contaminated with other bacteria. 3- Organisms other than Enterobacteriaceae, nonviable organisms, and frozen samples are unacceptable for this test. 4- Antimicrobial susceptibility testing on significant pathogens will be performed at client's request and an additional fee will be charged.
Clinical Utility	The assay provides identification if bacterial isolates submitted are Hodge Test Positive. *Klebsiella pneumoniae* carbapenemase (KPC)-producing organisms can be a difficult therapeutic challenge, due to their broad spectrum of resistance to beta-lactams. The profile of KPC beta-lactam resistance is similar to that of extended-spectrum beta-lactamases (ESBLs) with the addition of resistance to the carbapenems (imipenem, meropenem, doripenem, and ertapenem). In addition, KPC producers may be cross-resistant to a wide range of antibiotic classes including the aminoglycosides, fluoroquinolones, and sulfa drugs.

New Tests (*Specialty*): (cont'd)

5353S TPMT GenotypR™ - Saliva (Available July 1)

Component	Method	Reference Range/Units
TPMT	**PCR**	**Mutation not detected**

Specimen/Stability	Saliva: Ambient 10 days
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instruction. Ship at room temperature.
Schedule	Monday-Friday
Report	Next day
CPT Code	83891, 83900, 83901, 83914x3, 83909, 83912
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Note	Test detects the wild-type TPMT*1 and TPMT*2, *3A, *3B and *3C variants.
Clinical Utility	Test identifies patients at risk for toxicity from thiopurine drugs.

Test Changes:

4866R Magnesium RBC

Effective	Immediately
Specimen/Stability	RBC from WB EDTA TM 2.0 (1.0) mL: Refrigerated 72 hours
Alt Specimen	RBC from WB NaHEP TM 2.0 (1.0) mL: Refrigerated 72 hours WB EDTA Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours WB NaHEP Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours WB EDTA Lavender Top 2.0 (1.0) mL: Refrigerated 72 hours **Note: Whole Blood specimens collected in lavender top tubes now accepted.**

7510 Influenza A H1N1 (2009) Real-Time RT-PCR

Effective	Immediately
Specimen/Stability	Swab Viral Transport 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Alt Specimen	M4 Transport Media/Swab 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days Universal Transport Media 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Collection Instructions	Collect nasal swab, nasopharyngeal swab, or nasal aspirate in 3 mL viral transport media, V-C-M media (green-cap) tube or equivalent (UTM) universal transport media or multimicrobe media (M4). Use only sterile swabs: Dacron, nylon, or rayon with plastic shafts. Label the container with two unique patient identifiers. Ship overnight at 2-8 degrees celsius. Reject Criteria: Sputum, Bronchial lavage or Throat swabs. DO NOT USE calcium alginate swabs. **Note: Throat swabs are no longer accepted.**
Regulatory Status	FDA Approved
Also Affected	DOS Codes Reflex of 7505

1148 Humoral Immune Status Survey (Pneumo 14)

Effective	July 27
Specimen/Stability	Serum 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 7 days, Frozen 30 days **Note: Decreased frozen stability.**
Also Affected	DOS Codes 1147, 1147P, 1148P, 1149, 1149P

1245 IgE

Effective	July 27
Specimen/Stability	Serum 2.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days **Note: Increased refrigerated stability.**
Also Affected	DOS Codes 3701, 3703, 3705, 3719, 3747, 3749, 3750, 3751, 3752, 3753

Test Changes: (cont'd)

1668 Lymphocyte Enumeration, Basic and NK Cells

Effective	July 27
Reference Range Component	WBC 0 – 13 Years: 6.0 – 17.5 x 10^9/L (same) > 13 years: 4.0 – 11.0 x 10^9/L (same) Total Lymphocyte 0 – 13 years: 50 – 70% (same) > 13 Years: 17 – 50% **(NEW)** Total Lymphocyte 0 – 13 years: 3000 - 12250 /uL (same) > 13 Years: 1210 – 3750 /uL **(NEW)** % CD3 (Mature T Cells) 0 – 13 years: 57 – 85% (same) > 13 Years: 57 – 87% **(NEW)** Absolute CD3 0 – 13 years: 2040 - 6000 /uL (same) > 13 Years: 890 - 2850 /uL **(NEW)** % CD4 (Helper/Inducer) 0 – 13 years: 34 – 57% (same) > 13 Years: 27 – 67% **(NEW)** Absolute CD4 0 – 13 years: 1300 - 4100 /uL (same) > 13 Years: 440 - 2020 /uL **(NEW)** % CD8 (Cytotoxic/Suppressor) 0 – 13 years: 18 – 42% (same) > 13 Years: 16 – 39% **(NEW)** Absolute CD8 0 – 13 years: 750 - 2600 /uL (same) > 13 Years: 280 - 950 /uL **(NEW)** CD4/CD8 Ratio 0 – 13 years: 1.1 – 3.5 (same) > 13 Years: 0.8 – 4.1 **(NEW)** % CD19 (Earliest B Cell) 0 – 13 years: 19 – 26% (same) > 13 Years: 8 – 24% **(NEW)** Absolute CD19 0 – 13 years: 610 - 1830 /uL (same) > 13 Years: 120 - 660 /uL **(NEW)** % Dual CD56/CD16 0 – 13 years: <16% (same) > 13 Years: 3 – 25% **(NEW)** Absolute Dual CD56/16 0 – 13 years: <339 /uL (same) > 13 Years: 70 - 550 /uL **(NEW)**
Also Affected	DOS Codes 1655, 1656, 1656SR, 1657, 1658, 1659, 1668, 1671, 1683, 1684, 1685, 1687, 1688, 1872, 9872, 9872SR

Test Changes: (cont'd)

1795 Leukemia/Lymphoma Flow EvaluatR™

Effective	July 27
Specimen/Stability	Whole Blood Heparin 5.0 (3.0) mL: Refrigerated 48 hours
Alt Specimen	Whole Blood ACD 5.0 (3.0) mL: Refrigerated 72 hours Whole Blood EDTA 5.0 (3.0) mL: Refrigerated 24 hours Bone Marrow Heparin 5.0 (3.0) mL: Refrigerated 48 hours Bone Marrow ACD 5.0 (3.0) mL: Refrigerated 72 hours Bone Marrow EDTA 5.0 (3.0) mL: Refrigerated 24 hours Fluid 80 (50) mL: Refrigerated 72 hours Fine Needle Aspirate 50 (50) mL: Refrigerated 72 hours Tissue: Refrigerated 72 hours **Note: Ambient specimens no longer accepted; Heparin, ACD, Fluid and Tissue increased stability; EDTA decreased stability.**
Collection Instructions	WHOLE BLOOD or BONE MARROW specimens should be submitted along with a SMEAR. TISSUE, LYMPH NODE or SPLEEN thinly sliced or minced in Specialty Tissue Transport Medium. At least 0.5g, but more tissue may be necessary if there is fibrosis or low cellularity. Request and use Specialty Tissue Transport Medium. BODY FLUIDS may contain sodium heparin anticoagulant to prevent clotting. More volume is required with low cellularity. FROZEN SPECIMENS WILL BE REJECTED. A specialized flow viability and count tube is used to evaluate sample acceptability for all samples received. Collect specimen in late afternoon for pick-up and delivery by overnight courier to arrive within 24 hours of collection. New York State Specimen Stability: 48 hours

7480 HIV-1 GenotypR™ PLUS (Rev Trans & Prot Inhib)

Effective	July 27
Component	Amprenavir (APV)/Fosamprenavir (FPV) **Change name to** Fosamprenavir (FPV) Trade Names: Lexiva or Telzir
Component	APV/r or FPV/r **Change name to** FPV/r Trade names: Lexiva/Telzir; boosted All other components remain the same
Also Affected	DOS Codes 7480NY, Reflex of 7482 & 7482A,

8132 Hepatitis B Virus Drug Resistance DetectR™

Effective	July 27
Component	Polymerase Codon 233 **(REMOVE)** All other components remain the same

Test Changes: (cont'd)

4202 D-Dimer Quantitative

Effective: July 27

Reference Range: <0.50 mcg/mL FEU **(NEW)**

Collection Instructions: Instructions for platelet-poor plasma:

1. Draw a plain red-top tube to remove tissue fluid contamination. Discard this tube.
2. Draw blood into a buffered citrate collection tube (light blue top) filled to proper level.
3. The blood-to-anticoagulant ratio should be 9:1; inadequate filling of the collection device will decrease this ratio and may lead to inaccurate results.
4. Adjust the final citrate concentration in the blood of patients who have hematocrit values above 0.55 (55%). For hematocrits below 20%, there are no current data to support a recommendation for adjusting the citrate concentration.
5. The needle gauge could be 19-22. For pediatric patients a 21-23 gauge needle may be used.
6. Invert gently 6 times to mix. Process immediately.
7. Centrifuge for 15 min at 2500 x g.
8. Remove plasma using a plastic pipette to transfer into a new tube.
9. Repeat centrifugation at 2500 x g for 15 minutes to assure complete platelet removal.
10. Dispense the plasma into 2 or more plastic tubes using a plastic transfer pipette. Label tubes appropriately.
11. Freeze immediately at -70 C.
12. Specimen must remain frozen at all times. Ship to Specialty within 24 hours on dry ice.
13. Specimen Stability for Platelet Poor Plasma is Frozen at <-18 degrees C for 4 weeks. **(NEW)**
14. Specimen should not be submitted if:
    * it is hemolyzed
    * microclots are present
    * the tube is less than 90% filled
    * a specimen with hematocrit >55% is collected without anticoagulant adjustment.

Always Statement: The D-Dimer test is used frequently to exclude an acute PE or DVT. In patients with a low to moderate clinical risk assessment and a D-Dimer result < 0.5 mcg/mL, the likelihood of a PE or DVT is very low. However, a thromboembolic event should not be excluded solely on the basis of the D-Dimer level. Increased levels of D-Dimer are associated with a PE, DVT, DIC, malignancies, inflammation, sepsis, surgery, trauma, pregnancy, and advancing patient age. [JAMA 2006 11:295(2): 199-207]

The CPT Codes provided are based on AMA Guidelines and are for informational purposes only. CPT Coding is the sole responsibility of the billing party. Please direct any questions regarding CPT Coding to the payer being billed.

New Referral Tests:

The following tests are now available from Quest Diagnostics and may be referred through Specialty Laboratories.

S52084 **HPV (Human Papillomavirus) Genotypes 16 and 18 [19865X]**
Test performed at Quest Diagnostics, San Juan Capistrano

S52161 **HPV, High Risk, Hybrid Capture II w/Ref Genotypes 16, 18 [19863X]**
Test performed at Quest Diagnostics, San Juan Capistrano

Please call client relations at 800-421-4449 or visit our website at www.specialtylabs.com for ordering information.

Discontinued Tests:

Effective Immediately:

S51322 **IGF II (Insulin Like Growth Factor II) [20707X]**
Recommended replacement: S52155 – IGF-II (Insulin Like Growth Factor II) [500228]
Test performed at Esoterix Endocrinology

S42525 **Growth Hormone Releasing Hormone [141770P]**
No replacement

S48999 **Hydroxycorticosterone – 18 [16741P]**
No replacement

RO212 **Allergen – Streptavidin IgE**
No replacement