SPECIALTY LABORATORIES
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Test Updates

September 25, 2009

Dear Colleague:

Specialty Laboratories is pleased to announce a new assay, **PT and PTT-LA Mixing Studies [3890]** to help differentiate between congenital or acquired factor deficiencies and acquired inhibitors, such as lupus anticoagulant or factor-specific inhibitors. **PT and PTT-LA Mixing Studies** are performed only on samples with prolonged PT or PTT-LA values and require very specific collection instructions. Please be sure to review the collection instructions in detail. **Lupus Anticoagulant AssessR™ [1910], Lupus Anticoagulant: Screen 1 [5963]** and **Lupus Anticoagulant: Screen 3 [5962]** have several new components that include mixing studies with interpretation.

There are several other test changes of note, including **Cytomegalovirus Culture [2418], FLT3 & NPM1 GenotypR™ [5038], Alpha-Thalassemia GenotypR™ [5220], von Willebrand Multimers [1906], and Selenium Urine Random [4875UR],** with new collection instructions that should be communicated to the staff responsible for specimen collection to ensure appropriate care.

Please note that **HCV RNA, Quantitative Real-Time PCR [7577],** has new specimen requirements, with a preferred specimen of frozen plasma in EDTA shipped on dry ice and alternative specimens of frozen serum or frozen plasma in a PPT Tube. Specimens will no longer be acceptable if plasma is still an original collection tube, EVEN IF SEPARATED BY CENTRIFUGATION. Specimens collected using heparin as the anticoagulant are unsuitable for this test.

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,

Christopher Lockhart, M.D.
Laboratory Director

New Tests (*Specialty*):

3220 Insulin-Like Growth Factor 1 (IGF-1) (Available Immediately)

Component	Method	Reference Range/Units
IGF-1	**CL**	**By report ng/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 7 days, Frozen 2 months
Collection Instructions	Avoid freeze/thaw cycles.
Schedule	Tuesday-Saturday
Report	Same day
CPT Code	84305
Note	Also known as Somatomedin-C. Please provide patient age on Specialty's Test Requisition Form to allow reporting of age-specific reference ranges.
Clinical Utility	Low IGF-1 is most helpful in discrimination between normal and GH-deficiency when the deficiency is severe or the bone age is greater than 12 years. In Laron dwarfism, GH is normal, but a mutation in the receptor causes low concentrations of IGF-1. IGF-1 concentrations are elevated in acromegaly.

3541 Vitamin D, 25-hydroxy Total [LC-MS-MS] (Available Immediately)

Component	Method	Reference Range/Units
Vitamin D, 25-OH, Total	**CALC**	**20 – 100 ng/mL**
Vitamin D, 25-OH, D2	**LC-MS-MS**	**ng/mL**
Vitamin D, 25-OH, D3	**LC-MS-MS**	**ng/mL**

Specimen/Stability	Serum 0.3 (0.2) mL: Ambient 21 days, Refrigerated 21 day, Frozen 21 days
Collection Instructions	Serum is the only acceptable specimen type. Do not use any additives. Serum in centrifuged SST that is less than 24 hours from collection is acceptable. Red top tube (with serum not separated) is not acceptable.
Schedule	Monday-Saturday
Report	Same day
CPT Code	82306
Note	25-OHD3 (cholecalciferol) indicates both endogenous production and supplementation. 25-OHD2 (ergocalciferol) is an indicator of exogenous sources such as diet or supplementation. Therapy is based on measurement of Total 25-OHD, with levels <20 ng/mL indicative of Vitamin D deficiency while levels between 20 ng/mL and 30 ng/mL suggest insufficiency. Optimal levels are >30 ng/mL.
Clinical Utility	The measurement of circulating levels of 25-hydroxyvitamin D3 and 25-hydroxyvitamin D2 (25OHD) is important in the diagnosis and management of disorders of calcium metabolism. Low levels of 25OHD are indicative of vitamin D deficiency associated with hypocalcemia, hypophosphatemia, secondary hyperparathyroidism, elevated alkaline phosphatase, and osteomalacia in adults and rickets in children. In patients suspected of vitamin intoxication, elevated levels of 25OHD distinguish this disorder from other disorders that cause hypercalcemia.
Always Statement	25-OHD3 indicates both endogenous production and supplementation. 25-OHD2 is an indicator of exogenous sources such as diet or supplementation. Therapy is based on measurement of Total 25-OHD, with levels <20 ng/mL indicative of Vitamin D deficiency while levels between 20 ng/mL and 30 ng/mL suggest insufficiency. Optimal levels are >30 ng/mL.

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

3890 PT and PTT-LA Mixing Studies (Available November 3)

Component	Method	CPT code	Reference Range/Units
PT	**CLOT DET**	**85610**	**10.4 – 13.5 seconds**
PT 1:1 Immediate Mix	**CLOT DET**	**85611**	
PTT-LA	**CLOT DET**	**85730**	**30.0 – 42.0 seconds**
PTT-LA 1:1 Immediate Mix	**CLOT DET**	**85732**	
PTT-LA 1:1 Incubated Mix	**CLOT DET**	**85732**	
Mixing Study Interpretation			

Specimen/Stability	Plasma Citrated 2.0 (1.0) mL: Frozen 14 days
Collection Instructions	Please follow collection and processing instructions very carefully. Presence of >10,000 platelets may cause the neutralization of heparin if present in plasma. Specimens with high platelet count, upon freezing, release PF4, which is a powerful neutralizer of heparin and will result in inaccurate heparin monitoring by the APTT test. 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. Do not overfill. 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 is no current data to support a recommendation for adjusting the citrate concentration. 5. The needle gauge could be between 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. Stable for 2 months at -20 C and 6 months at -70 C. 12. Specimen must remain frozen at all times. Ship to *Specialty* within 24 hours on dry ice. 13. 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.
Schedule	Monday-Friday
Report	Next day
CPT Code	85610, 85611, 85730, 85732x2
Note	PT/PTT-LA mixing studies are performed only on samples with prolonged PT or PTT-LA values.
Clinical Utility	Helps differentiate between congenital or acquired factor deficiencies and acquired inhibitors such as lupus anticoagulant or factor-specific inhibitors.

Test Changes:

2418 Cytomegalovirus Culture

Effective	Immediate
Collection Instructions	1. Specimens should be collected early in the acute phase of infection. The chance of viral recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many viruses. 2. Source of specimen is required. Please include on requisition. 3. Place the following specimens into: a. sterile leak proof container: CSF, body fluids, urine, semen, saliva, biopsy or tissues and bone marrow. b. viral transport media (M4, etc.): respiratory samples (bronchial, lung, throat, nasal, sputum). 4. Unacceptable specimens: stool, whole blood, wooden swabs and calcium alginate. 5. **(NEW)** All specimens except bone marrow, fluids and semen held more than 72 hours must be frozen at -70C (not -20C) or on dry ice. Do not freeze at -20C. Virus looses infectivity. 6. Ship specimens on cold pack or on dry ice. 7. *Specialty* provides M4 transport media (M4) and dacron-tipped swabs with plastic or fine-wire shafts available for use with M4. Please call Client Services, 800-421-4449 to request media.

5038 FLT3 & NPM1 GenotypR™

Effective	Immediate
Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days
Alt Specimen	Whole Blood ACD 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days Whole Blood Heparin 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days Bone Marrow ACD 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days Bone Marrow EDTA 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days Bone Marrow Heparin 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days Cell Pellet: Ambient 6 months **(NEW)** **Note: Cell pellet now accepted.**

5220 Alpha-Thalassemia GenotypR™

Effective	October 27
Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days
Alt Specimen	Whole Blood ACD 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days Whole Blood Heparin 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days **Note: Increased ambient and refrigerated stability.**

1906 von Willebrand Multimers

Effective	October 27
FDA 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.
Also affected	DOS Codes 1905, 5981

4875UR Selenium Urine Random

Effective	October 27
Collection Instructions	**(NEW)** Collect urine in an acid washed plastic container. Acidify with hydrochloric or nitric acid (1 mL of concentrated acid for each 100 mL of urine). Avoid worksite collection. Send aliquot in a *Specialty* transfer tube.

Test Changes: (cont'd)

1821R Human Papillomavirus High Risk DetectR™ Anal/Rectal

Effective	October 27
Always Statement	The performance characteristics of this assay(s) have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test when used to test anal/rectal specimens in Digene Transport Medium, ThinPrep or SurePath vials.
Also affected	DOS Code 1822R

4861W Lead Whole Blood

Effective	October 27
Reference Range	0 – 6 years < 5 ug/dL **(NEW)**
	> 6 years < 10 ug/dL (same)
Also Affected	DOS Codes 4080W, 4861CP, 4861X, 4863

5962 Lupus Anticoagulant: Screen 3

Effective	November 3
Component	PT **(NEW NAME)**
Reference Range	10.4 – 13.5 seconds (same)
Component	PT 1:1 Immediate Mix **(NEW NAME)**
Component	PTT-LA **(NEW NAME)**
Reference Range	30.0 – 42.0 seconds **(NEW)**
Component	PTT-LA 1:1 Immediate Mix **(NEW NAME)**
Component	PTT-LA 1:1 Incubated Mix **(NEW)**
Component	Mixing Study Interpretation **(NEW)**
Component	Int'l Normalized Ratio **(REMOVE)**
CPT Codes	85597, 85610, 85611, 85613, 85670, 85730, 85732x2
Note	PT/PTT-LA mixing studies are performed only on samples with prolonged PT or PTT-LA values.

All other components on the panel remain the same.

5963 Lupus Anticoagulant: Screen 1

Effective	November 3
Component	PT **(NEW)**
Reference Range	10.4 – 13.5 seconds (same)
Component	PT 1:1 Immediate Mix **(NEW)**
Component	PTT-LA **(NEW NAME)**
Reference Range	30.0 – 42.0 seconds **(NEW)**
Component	PTT-LA 1:1 Immediate Mix **(NEW NAME)**
Component	PTT-LA 1:1 Incubated Mix **(NEW)**
Component	Mixing Study Interpretation **(NEW)**
CPT Codes	85610, 85611, 85613, 85730, 85732x2, 86147x3
Note	PT/PTT-LA mixing studies are performed only on samples with prolonged PT or PTT-LA values.

All other components on the panel remain the same.

Test Changes: (cont'd)

1910 Lupus Anticoagulant AssessR™

Effective	November 3
Component	PT **(NEW)**
Reference Range	10.4 – 13.5 seconds (same)
Component	PT 1:1 Immediate Mix **(NEW)**
Component	PTT-LA **(NEW NAME)**
Reference Range	30.0 – 42.0 seconds **(NEW)**
Component	PTT-LA 1:1 Immediate Mix **(NEW NAME)**
Component	PTT-LA 1:1 Incubated Mix **(NEW)**
Component	Mixing Study Interpretation **(NEW)**
CPT Codes	85597, 85610, 85611, 85613, 85730, 85732x2
Note	PT/PTT-LA mixing studies are performed only on samples with prolonged PT or PTT-LA values.

All other components on the panel remain the same.

2731 Fungal Abs [CF]

Effective	Immediately
FDA Status	Laboratory Developed Test
Always Statement	**REMOVE**: This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.
Also affected	DOS Codes 2731C, 2511, 2511C, 2526, 2526C, 2581, 2581C

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.

S52017 ***Trichomonas vaginalis* RNA, Qualitative TMA [1955X]**
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:

S50344 ***Yersinia* Abs [41060]**
Recommended replacement: S52085 – *Yersinia enterocolitica* Antibodies (IgG,IgA) [41065]; Performed at Focus Diagnostics

Effective November 3:

3893 **Prothrombin Time Mixing Studies**
Recommended replacement: 3890 – PT and PTT-LA Mixing Studies

3896 **Activated Partial Thromboplastin Time Mixing Studies**
Recommended replacement: 3890 – PT and PTT-LA Mixing Studies