SPECIALTY LABORATORIES
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Test Updates

August 25, 2010

Dear Colleague:

As Specialty continues to enhance our test offerings and service levels to our customers, we firmly believe that direct feedback is vital to meeting your needs and expectations. Many of you will be receiving a short survey early in September. Your responses provide not only feedback on our current performance but the blueprint for future enhancement activities. The survey will take only 10-12 minutes to complete. It was prepared in collaboration with our independent research partner, Burke, Inc., who will compile the results. We thank you in advance for your participation and look forward to your responses.

Recently we have noted that clarification of the ordering method for Antimicrobial Susceptibilities would be beneficial. If an antimicrobial susceptibility is required for a bacterial isolate being ordered for test **Bacterial Identification, Aerobic Organism ID [S49971],** please also request test **Antimicrobial Susceptibility Holding Code [S52229].** This will alert the laboratory to order and proceed with the susceptibility panel *appropriate* for the identified bacteria.

We are also pleased to inform you that **Histoplasma Antigen Urine [8315UR]** is now **New York approved** and available for New York patients. Please update your records accordingly.

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*):

5395 JAK2 V617F Mutation, Qual, PCR (Available September 6)

Component	Method	Reference Range/Units
JAK2 V617F	**PCR/Sequencing**	**By Report**

Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL: Ambient 72 hours, Refrigerated 72 hours
Alt Specimen	Whole Blood ACD 5.0 (3.0) mL: Ambient 72 hours, Refrigerated 72 hours Bone Marrow EDTA 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours Bone Marrow ACD 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours
Collection Instructions	Follow standard whole blood collection procedure. Collect 3-5 mL whole blood samples in an EDTA tube. ACD tube is also acceptable, but not preferred. Heparin is not acceptable. For Bone Marrow collect 2-3 mL in an EDTA tube. ACD tube is also acceptable, but not preferred. Heparin is not acceptable. Ship immediately to maintain sample stability. Ship refrigerated at 4 degrees C.
Schedule	Monday, Wednesday, Thursday
Report	Within 5 days
CPT Code	83891, 83902, 83898, 83904, 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	This test identifies the JAK2 exon 14 V617F point mutation and other mutations in exon 14.
Clinical Utility	Diagnose polycythemia vera (PV), essential thrombocythemia (ET) and idiopathic myelofibrosis (MF).

5394 JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13 (Available Immediately)

Component	Method	Reference Range/Units
JAK2 V617F	**PCR/Sequencing**	**By Report**

Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL; Ambient 72 hours, Refrigerated 72 hours
Alt Specimen	Whole Blood ACD 5.0 (3.0) mL; Ambient 72 hours, Refrigerated 72 hours Bone Marrow EDTA 3.0 (2.0) mL; Ambient 72 hours, Refrigerated 72 hours Bone Marrow ACD 3.0 (2.0) mL; Ambient 72 hours, Refrigerated 72 hours
Collection Instructions	Follow standard whole blood collection procedure. Collect 3-5 mL whole blood samples in an EDTA tube. ACD tube is also acceptable but not preferred. Heparin is not acceptable. Collect 2-3 mL bone marrow sample in an EDTA tube. ACD tube is also acceptable but not preferred. Heparin is not acceptable. Ship immediately to maintain sample stability. Ship refrigerated at 4 degrees C.
Schedule	Monday, Thursday
Report	Within 3 days
CPT Code	83891, 83902, 83898, 83904, 83912
Notes	This test identifies the exon 14 V617F point mutation and mutations in exons 12 to 13 of JAK2 gene (Janus Kinase 2). The somatic point mutation, V617F, in exon 14 of JAK2 gene is detected in most patients (>80%) with polycythemia vera (PV) and in 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome. If the JAK2 V617F result is negative, then exons 12, 13 will be performed for an additional charge (CPT codes: 83904x2, 83912).
Clinical Utility	Diagnose polycythemia vera (PV), essential thrombocythemia (ET), and idiopathic myelofibrosis (MF).

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

4354 Specific Gravity, Urine (Available September 6)

Component	Method	Reference Range/Units
Specific Gravity	**Refract**	**1.002 – 1.030**

Specimen/Stability	Urine 5.0 (1.0) mL: Ambient 30 days, Refrigerated 30 days, Frozen 30 days
Collection Instructions	Collect random urine with no additives
Schedule	Tuesday, Thursday, Saturday
Report	Same day
CPT Code	81099
Regulatory Status	Laboratory Developed Test
Clinical Utility	Specific gravity is the ratio of the density of the solution to the density of water and is determined by measuring the refractive index of the solution using a refractometer. Specific gravity is used in conjunction with measurement of the creatinine concentration in the specimen to help assess the validity of a urine specimen being tested for the presence of drugs.

4191 Leflunomide Metabolite (Available September 28)

Component	Method	Reference Range/Units
Teriflunomide	**LC-MS-MS**	**By Report ng/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 5 days, Refrigerated 14 days, Frozen 30 days
Alt Specimen	Plasma Heparin 1.0 (0.5) mL: Ambient 5 days, Refrigerated 14 days, Frozen 30 days
Collection Instructions	Collect specimen in plain red top tube. Avoid separator tubes. Ship at room temperature.
Schedule	Tuesday, Friday
Report	Within 2 days
CPT Code	80299
Regulatory Status	Laboratory Developed Test
Always Statement	Mean steady state plasma concentrations of teriflunomide from patients on daily dosages of 5, 10, or 25 mg of leflunomide were 8,800 18,000, and 63,000 ng/mL, respectively. It is recommended that women of childbearing potential who discontinue leflunomide therapy undergo the cholestyramine drug elimination procedure. This procedure includes verification that plasma levels of teriflunomide are less than 20 ng/mL by two separate tests at least 14 days apart.
Clinical Utility	Leflunomide is an immunosuppressant medication used in the treatment of rheumatoid arthritis. Leflunomide is rapidly and extensively metabolized to teriflunomide, which is the active form of the medication. Steady state plasma concentrations in patients receiving recommended daily dosages: up to 63,000 ng/mL. It is recommended that all women of childbearing potential who discontinue leflunomide and women receiving treatment who wish to become pregnant undergo the cholestyramine drug elimination procedure. This procedure includes verification that plasma levels of teriflunomide are less than 20 ng/mL by two separate tests at least 14 days apart.

4304 Pregabalin (Available September 28)

Component	Method	Reference Range/Units
Pregabalin	**LC-MS-MS**	**By Report mcg/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
Alt Specimen	Plasma Citrate 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days Plasma EDTA 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days Plasma Heparin 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
Collection Instructions	Ship at room temperature.
Schedule	Tuesday, Thursday, Saturday
Report	Within 3 days
CPT Code	80299
Regulatory Status	Laboratory Developed Test
Always Statement	Therapeutic and toxic ranges have not been established. Expected concentrations in patients taking recommended daily dosages: up to 10 mcg/mL.
Clinical Utility	Pregabalin is an anti-epileptic drug. It works by slowing down impulses in the brain that cause seizures. Pregabalin also affects chemicals in the brain that send signals across the nervous system. Pregabalin is used to control seizures and to treat fibromyalgia.

Test Changes:

1820 Human Papillomavirus DetectR™

Effective	Immediately
Specimen/Stability	Brush Qiagen (Digene): Ambient 14 days, Refrigerated 21 days, Frozen 3 months AutoCyte PREP Tube 2.0 (1.0) mL: Ambient 28 day, Refrigerated 6 months Tissue: Frozen 2 months ThinPrep Vial 8.0 (4.0) mL: Ambient 3 months, Refrigerated 3 months SurePath Vial 3.0 (2.0) mL: Ambient 28 days, Refrigerated 6 months **Note: Increased ThinPrep stability**
Also Affected	DOS Codes 1821, 1822, 1824

1821R Human Papillomavirus High Risk DetectR™ Anal/Rectal

Effective	Immediately
Specimen/Stability	Anal/Rectal Brush Qiagen (Digene): Ambient 14 days, Refrigerated 21 days, Frozen 3 months ThinPrep Vial 8.0 (4.0) mL: Ambient 3 months, Refrigerated 3 months **Note: Increased ThinPrep stability**
Also Affected	DOS Codes 1822R

2941 Fungus Stain: Skin, Hair or Nail

Effective	Immediately
Specimen/Stability	Smear/Slides 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Pure Culture Broth 1.0 (1.0): Ambient 24 hours, Refrigerated 72 hours Culturette/Swab 1.0 (1.0): Ambient 24 hours, Refrigerated 72 hours Pure Culture Agar Slant 1.0 (1.0): Ambient 24 hours, Refrigerated 72 hours Hair 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Nails 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Skin 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Sterile Container/Tube 1.0 (1.0): Ambient 14 days, Refrigerated 14 days **Note: Increased ambient and refrigerated stability for smear/slides and tissue specimens**

3959 Insulin-Like Growth Factor Binding Protein (IGFBP-3)

Effective	Immediately
Collection Instructions	Gross hemolysis and gross lipemia are unacceptable. Samples will be rejected **(NEW)**

4877R Zinc RBC

Effective	Immediately
Specimen/Stability	WB EDTA Trace Metal 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours WB Heparin Trace Metal 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours Whole Blood EDTA 3.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours **Note: Non-trace metal whole blood EDTA specimens now Accepted**

Test Changes: (cont'd)

5322 Fungus Culture & Stain – Skin, Hair or Nail

Effective	Immediately
Specimen/Stability	Sterile Container/Tube 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Hair 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Nails 1.0 (1.0): Ambient 14 days, Refrigerated 14 days Skin 1.0 (1.0): Ambient 14 days, Refrigerated 14 days **Note: Increased ambient and refrigerated stability**

5323 Fungus Identification Mould, Culture

Effective	Immediately
Specimen/Stability	Pure Culture Agar Slant: Ambient 7 days **Note: Increased ambient stability**

7581 Herpes Simplex Virus DNA DetectR™

Effective	Immediately
Specimen/Stability	Whole Blood ACD 5.0 (1.0) mL: Ambient 4 days Whole Blood EDTA 5.0 (1.0) mL: Ambient 4 days CSF 2.0 (0.5) mL: Ambient 24 hours, Refrigerated 24 hours, Frozen 2 months Culturette/Swab: Ambient 24 hours M4 Transport Media/Swab: Ambient 7 days, Refrigerated 7 days, Frozen 30 days Plasma EDTA 2.0 (1.0) mL: Frozen 2 months Tissue 0.2 (0.1) g: Frozen 2 months TriPath CytoRich Solution 1.5 (0.5) mL: Ambient 21 days, Refrigerated 21 days ThinPrep Vial 1.5 (0.5) mL: Ambient 21 days, Refrigerated 21 days SurePath Vial 1.5 (0.5) mL: Ambient 21 days, Refrigerated 21 days Viral Transport Media: Ambient 7 days, Refrigerated 7 days, Frozen 30 days **Note: Frozen M4 and Viral Transport Media now accepted.**
Also Affected	DOS Code 9496

1510 Albumin

Effective	September 21
Reference Range	3.6 – 5.1 g/dL **(NEW)**
Also Affected	DOS Codes 5314, 5317, 5318

1623 IgG Subclass 1, 2, 3 & 4

Effective	September 21
Name	IgG Total w/Subclass 1, 2, 3 & 4 **(NEW)**

1862 ANCA (Antineutrophil Cytoplasmic Autoantibodies), Total

Effective	September 21
Name	ANCA (Antineutrophil Cytoplasmic Autoabs), Total w/ANA **(NEW)**

Test Changes: (cont'd)

3454 Cholesterol Evaluation

Effective	September 21
Name	Lipid Panel **(NEW)**

5110 Complete Blood Count & Differential

Effective	September 21
Reference Range	Lymphoctyes 0 – 13 years: 50.0 – 70.0 % (same) > 13 Years: 17.0 – 50.0 % **(NEW)**

All other components remain the same

1536 C-Reactive Protein (CRP) UltraQuant® (Cardiac Risk)

Effective	September 28
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 1 month Plasma EDTA 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 1 month **Note: Reduced ambient and frozen stability.**
Methodology	Nephelometry **(NEW)**
Always Statement	REFERENCE RANGE for CRP UltraQuant® For ages >17 years:

CRP mg/L	Risk
< 1.0	Lower relative cardiovascular risk according to AHA/CDC guidelines.
1.0 – 3.0	Average relative cardiovascular risk according to AHA/CDC guidelines.
3.1 – 10.0	Higher relative cardiovascular risk according to AHA/CDC guidelines. Consider retesting in 1 to 2 weeks to exclude a benign transient elevation in the baseline CRP value secondary to infection or inflammation.
>10 .0	Persistent elevation, upon retesting, may be associated with infection and inflammation according to AHA/CDC guidelines.

AHA/CDC Scientific Statement, Circulation 2003;107:499-511.

For ages < or = 17 years:
AHA/CDC recommendations for cardiovascular risk assessment do not apply to non-adults.

Also Affected	DOS Code 1537 (methodology and always statement only)

1537 Treatable Ischemia PredictR™

Effective	September 28
Specimen/Stability	Serum 5.0 (2.0) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 1 months **Note: Reduced frozen stability.**

Test Changes: (cont'd)

1900 Apolipoprotein Evaluation

Effective	September 28
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 1 month **Note: Reduced ambient and frozen stability.**

1901 Apolipoprotein A-1

Effective	September 28
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 10 days, Frozen 3 month **Note: Reduced ambient and refrigerated stability, increased frozen stability.**
Methodology	Nephelometry **(NEW)**
Reference Range	Male: 94-176 mg/dL **(NEW)** Female: 101-198 mg/dL **(NEW)**
Also Affected	DOS Codes 1900, 1904 (methodology and reference range only)

1903 Apolipoprotein B

Effective	September 28
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 9 days, Frozen 1 month **Note: Reduced ambient, refrigerated and frozen stability.**
Methodology	Nephelometry **(NEW)**
Reference Range	Male: 52-109 mg/dL **(NEW)** Female: 49-103 mg/dL **(NEW)**
Also Affected	DOS Codes 1900, 1904 (methodology and reference range only)

1904 Apolipoprotein A-1 & B

Effective	September 28
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 9 days, Frozen 1 month **Note: Reduced ambient, refrigerated and frozen stability.**
Always Statement	APOB/APOA1 RATIO BASED CHD RISK Male: Below average risk: Less than 0.29 Average risk: 0.29 – 1.30 Above average risk: Greater than 1.30 Female: Below average risk: Less than 0.25 Average risk: 0.25 – 1.00 Above average risk: Greater than 1.00
Also Affected	DOS Codes 1900 (always statement only)

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.

S52229 **Antimicrobial Susceptibility Holding Code (51265)**
Test performed by Focus Diagnostics

S52234 **Lipoprotein Fractionation, Ion Mobility with Reflex to Direct LDL (16129X)**
Test performed by 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

S51672 Vitamin B1, Whole Blood (5042X)
Recommended replacement: 3515W-Vitamin B1 (Thiamine) Whole Blood
Test performed by Specialty Laboratories

7505 Influenza A&B RT-PCR w/Reflex to Influenza A H1N1 (2009)
Recommended replacement: S52074 – Influenza A/B RT-PCR Rfx to Influenza A H1N1(09)RT-PCR [42699]
Test performed at Focus Diagnostics

7510 Influenza A H1N1 (2009) Real-Time RT-PCR
Recommended replacement: S51866 – Influenza A H1N1 (2009) Real Time RT-RCP [46585]
Test performed at Focus Diagnostics

7515 Influenza Virus Type A and B RNA, Qual Real-Time PCR
Recommended replacement: S52073 – Influenza A and B RNA, Qual. Real-Time RT-PCR [42684]
Test performed at Focus Diagnostics

Effective September 15th

S43680 Rabies Ab Titer
Recommended replacement: S52235-Rabies Vaccine Response End-Point Titer
Test performed by K-State Rabies Laboratory

S51062 Ethyl Glucuronide Urine (9361U)
Recommended replacement: S52236-Ethyl Glucuronide and Ethyl Sulfate (16604)
Test performed by Quest Diagnostics, Chantilly

S51614NY T3 Reverse (70188) (NY)
Recommended replacement: S52239N-T3 Reverse (NY) (967)
Test performed by Quest Diagnostics, San Juan Capistrano

S51261 Functional Anti-Fcer Autoantibody (2103)
Recommended replacement: S52240-Histamine Release (Chronic Urticaria) (16838)
Test performed by Quest Diagnostics, San Juan Capistrano