

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](http://www.specialtylabs.com) or contact Client Relations at 800-421-4449.

Respectfully Yours,



Basel Kashlan, MD, FCAP  
Laboratory Director

# New Tests (*Specialty*):

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

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
JAK2 V617F	PCR/Sequencing	By Report
Specimen/Stability Alt Specimen	Whole Blood EDTA 5.0 (3.0) mL: Ambient 72 hours, Refrigerated 72 hours 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 Report	Monday, Wednesday, Thursday 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 Clinical Utility	This test identifies the JAK2 exon 14 V617F point mutation and other mutations in exon 14. 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)**

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
JAK2 V617F	PCR/Sequencing	By Report
Specimen/Stability Alt Specimen	Whole Blood EDTA 5.0 (3.0) mL; Ambient 72 hours, Refrigerated 72 hours 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 Report	Monday, Thursday 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)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
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)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
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)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
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:

<b>1820</b>	<b>Human Papillomavirus DetectR™</b>	Effectively Specimen/Stability	Immediately 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 <b>Note: Increased ThinPrep stability</b> DOS Codes 1821, 1822, 1824
	Also Affected		
<b>1821R</b>	<b>Human Papillomavirus High Risk DetectR™ Anal/Rectal</b>	Effectively Specimen/Stability	Immediately 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 <b>Note: Increased ThinPrep stability</b> DOS Codes 1822R
	Also Affected		
<b>2941</b>	<b>Fungus Stain: Skin, Hair or Nail</b>	Effectively Specimen/Stability	Immediately 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 <b>Note: Increased ambient and refrigerated stability for smear/slides and tissue specimens</b>
<b>3959</b>	<b>Insulin-Like Growth Factor Binding Protein (IGFBP-3)</b>	Effectively Collection Instructions	Immediately Gross hemolysis and gross lipemia are unacceptable. Samples will be rejected <b>(NEW)</b>
<b>4877R</b>	<b>Zinc RBC</b>	Effectively Specimen/Stability	Immediately 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 <b>Note: Non-trace metal whole blood EDTA specimens now Accepted</b>

# Test Changes: (cont'd)

<b>5322</b>	<b>Fungus Culture &amp; Stain – Skin, Hair or Nail</b>	
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	
	<b>Note: Increased ambient and refrigerated stability</b>	
<b>5323</b>	<b>Fungus Identification Mould, Culture</b>	
Effective	Immediately	
Specimen/Stability	Pure Culture Agar Slant: Ambient 7 days	
	<b>Note: Increased ambient stability</b>	
<b>7581</b>	<b>Herpes Simplex Virus DNA DetectR™</b>	
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	
	<b>Note: Frozen M4 and Viral Transport Media now accepted.</b>	
Also Affected	DOS Code 9496	
<b>1510</b>	<b>Albumin</b>	
Effective	September 21	
Reference Range	3.6 – 5.1 g/dL <b>(NEW)</b>	
Also Affected	DOS Codes 5314, 5317, 5318	
<b>1623</b>	<b>IgG Subclass 1, 2, 3 &amp; 4</b>	
Effective	September 21	
Name	IgG Total w/Subclass 1, 2, 3 & 4 <b>(NEW)</b>	
<b>1862</b>	<b>ANCA (Antineutrophil Cytoplasmic Autoantibodies), Total</b>	
Effective	September 21	
Name	ANCA (Antineutrophil Cytoplasmic Autoabs), Total w/ANA <b>(NEW)</b>	

# Test Changes: (cont'd)

## 3454 Cholesterol Evaluation

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

## 5110 Complete Blood Count & Differential

Effective September 21  
Reference Range Lymphocytes  
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)

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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](http://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 15<sup>th</sup>

- 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-Fcεr Autoantibody (2103)**  
Recommended replacement: S52240-Histamine Release (Chronic Urticaria) (16838)  
Test performed by Quest Diagnostics, San Juan Capistrano