

November 26, 2008

Dear Colleague:

We are pleased to announce the availability of two new assays for an expanded evaluation of mutations in the JAK2 gene in the work-up of myeloproliferative disorders. The **JAK2 Exons 12 & 13 Mutation, Qualitative, Plasma [5392]** is a PCR Sequencing test that identifies mutations in exons 12 and 13 of the JAK2 gene (Janus Kinase 2). JAK2 exon 12 and 13 mutations define a distinctive myeloproliferative syndrome without the presence of the V617F mutation.

For a better evaluation of the JAK2 gene, the **JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13 [5394]** provides a reflex test to exon 12 & 13 mutations, if the JAK2 V617F exon 14 mutation is negative. By ordering this reflex test, clients can get a more timely and complete evaluation of their patients with polycythemia vera (PV), essential thrombocythemia (ET) or myelofibrosis.

Beginning December 1st, *Specialty* will again be performing the **Vitamin D, 25-Hydroxy Total [LC/MS/MS] assay [3541]** at our Valencia California facility. This sensitive and specific test performed by liquid chromatography with tandem mass spectrometry and a 4 day turnaround time provides the information endocrinologists need when evaluating patients for vitamin D deficiency and when monitoring treatment. To ensure your **Vitamin D, 25-Hydroxy Total** assays are performed immediately upon receipt at *Specialty*, please be sure your CPU interface orders **test code 3541**.

For more flexibility diagnosing antiphospholipid syndrome and Lupus, the individual test components of the Antiphospholipid Evaluation [1776] are now available separately: **Phosphatidylinositol IgG Autoabs [1777], Phosphatidylinositol IgM Autoabs [1778], Phosphatidylinositol IgA Autoabs[1779], Phosphatidylethanolamine IgG Autoabs[1792], Phosphatidylethanolamine IgM Autoabs[1793], Phosphatidylethanolamine IgA Autoabs[1794], Phosphatidylcholine IgG Autoabs [1752], Phosphatidylcholine IgM Autoabs[1753], Phosphatidylcholine IgA Autoabs[1754]**.

The **Lp-PLA2 [3470]** assay will be discontinued immediately, due to unexpected performance characteristics of the reagents. No alternative tests are available.

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:

5392 JAK2 Exons 12 & 13 Mutation, Qualitative, Plasma
(Available Dec. 2nd)

Component	Method	Reference Range/Units
JAK2 Exons 12 & 13	PCR/Sequencing	By report
Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL; Ambient 72 hours, Refrigerated 72 hours.	
Alternate	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. Plasma EDTA 3.0 (2.0) mL; Frozen 30 days. Plasma ACD 3.0 (2.0) mL; Frozen 30 days.	
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. For plasma, collect blood in sterile tube containing EDTA anticoagulant (Lavender-top). ACD tube is also acceptable but not preferred. Heparin is not acceptable. Separate plasma from the cells by centrifugation within 2 hours after collection. Transfer the plasma to a separate plastic screw-cap vial, and ship frozen.	
Shipping Instruction	Ship immediately to maintain sample stability. Ship whole blood and bone marrow samples at room temperature or refrigerated at 4 degrees C. Plasma samples should be shipped frozen immediately after separation.	
Schedule	Monday, Thursday	
Report	5 days	
CPT Code	83891, 83902, 83898, 83904, 83912	
Notes	The test identifies mutations in exons 12 and 13 of the JAK2 gene (Janus Kinase 2). The test does not detect the exon 14 V617F mutation. If patient's V617F mutation status is not known, please order test code 5394 (JAK2 V617F Mutation, Qualitative PCR, Plasma with Reflex to Exons 12, 13). The V617F mutation 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.	
Clinical Utility	This test is not approved for the testing of patient samples from New York State. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome without the V617F mutation. Patients with JAK2 exon 12 mutation presented with an isolated erythrocytosis and distinctive bone marrow morphology or had reduced serum erythropoietin levels. JAK2 exon 12 mutations are rare when compared with V617F mutation, and it is always heterozygous according to publications.	

New Tests: (cont'd)

5394 JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13 (Available Dec. 2nd)

Component	Method	Reference Range/Units
JAK2 V617F	PCR/Sequencing	By report
Specimen/Stability Alternate	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. Plasma EDTA 3.0 (2.0) mL; Frozen 30 days. Plasma ACD 3.0 (2.0) mL; Frozen 30 days.	
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. For plasma, collect blood in sterile tube containing EDTA anticoagulant (Lavender-top). ACD tube is also acceptable but not preferred. Heparin is not acceptable. Separate plasma from the cells by centrifugation within 2 hours after collection. Transfer the plasma to a separate plastic screw-cap vial, and ship frozen.	
Shipping Instruction	Ship immediately to maintain sample stability. Ship whole blood and bone marrow samples at room temperature or refrigerated at 4 degrees C. Plasma samples should be shipped frozen immediately after separation.	
Schedule Report	Monday, Thursday 5 days	
CPT Code	83891, 83902, 83898, 83904, 83912	
Notes	The 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 code(s): 83904, 83912). This test is not approved for the testing of patient samples from New York State.	
Clinical Utility	Diagnose polycythemia vera (PV), essential thrombocythemia (ET), and idiopathic myelofibrosis (MF).	

1777 Phosphatidylinositol IgG Autoabs (Available Immediately)

Component	Method	Reference Range/Units
Phosphatidylinositol IgG	EIA	<10 U/mL
Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

New Tests: (cont'd)

1778 Phosphatidylinositol IgM Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylinositol IgM	EIA	< 10 U/mL

Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.
Shipping Instruction	Ship refrigerated.
Schedule	Thursday
CPT Code	83520
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.
Notes	This test is not approved for the testing of patient samples from New York State.

1779 Phosphatidylinositol IgA Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylinositol IgA	EIA	< 15 U/mL

Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.
Shipping Instruction	Ship refrigerated.
Schedule	Thursday
CPT Code	83520
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.
Notes	This test is not approved for the testing of patient samples from New York State.

1792 Phosphatidylethanolamine IgG Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylethanolamine IgG	EIA	< 10 U/mL

Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.
Shipping Instruction	Ship refrigerated.
Schedule	Thursday
CPT Code	83520
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.
Notes	This test is not approved for the testing of patient samples from New York State.

New Tests: (cont'd)

1793 Phosphatidylethanolamine IgM Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylethanolamine IgM	EIA	<10 U/mL
Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

1794 Phosphatidylethanolamine IgA Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylethanolamine IgA	EIA	<2.0 Index
Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

1752 Phosphatidylcholine IgG Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylcholine IgG	EIA	<10 U/mL
Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

New Tests: (cont'd)

1753 Phosphatidylcholine IgM Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylcholine IgM	EIA	<10 U/mL

Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

1754 Phosphatidylcholine IgA Autoabs (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phosphatidylcholine IgA	EIA	<2.0 Index

Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 60 days.	
Shipping Instruction	Ship refrigerated.	
Schedule	Thursday	
CPT Code	83520	
Clinical Utility	Phospholipids autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyelin are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases.	
Notes	This test is not approved for the testing of patient samples from New York State.	

Test Changes:

2388	<i>Streptococcus pneumoniae</i> IgG Antibodies, 23 Serotypes
Effective	Immediately
CPT Code	86317 for each serotype
Also affected	DOS Codes 1047, 1047P, 1049, 1049P, 1087, 1087P, 1088, 1088P, 1143, 1143P, 1146, 1146P, 1147, 1147P, 1148, 1148P, 1149, 1149P, 2384, 2384P, 2386, 2386P, 2388P
5510	StoneRisk® Diagnostic Profile
Effective	Immediately
Collection Instruction	Use only Quest 24-hour Urine Collection kits specific for renal stone formation diagnosis. Follow instructions in the kit. <ol style="list-style-type: none">1) Upon completion of 24-hour collection in the large orange collection container, tighten the cap on the container and mix contents in the container vigorously for one minute. A good mix will assure accurate test results.2) Carefully fill the two plastic white vials with urine collected in the large orange container. The two white vials must be filled within two to four hours of completion of 24-hour collection. Fill and cap vials one at a time. Cap both vials tightly, write patients name on each vial and place in zip-lock bags provided. <u>DO NOT REMOVE ABSORBENT SHEETS.</u>3) Complete the patient information section.4) Place specimen in mail-back box and mail to the laboratory. <u>DO NOT MAIL LARGE ORANGE COLLECTION CONTAINER.</u> For High Urine Output Patient with a high urine output (greater than 3.8L) will require more than one large container. Collect urine in the first container until it is ¾ full and then begin filling the second container to complete the 24-hour collection. Carefully follow steps 1-4 for each jug and mark one as box 1 of 2 the other box 2 of 2.
Note	Urine must only be collected and stored in the large orange collection container. Do not remove sponge from the orange collection container. Do not remove wool from white container. Do not collect the first urination at the beginning of 24-hour collection. During collection process store orange container in a cool location.
Also affected	DOS Codes 5515, 5520, 5530, 5525
3530	Vitamin E (Alpha & Gamma Tocopherol)
Effective	Immediately
CPT Code	Alpha Tocopherol – 84446; Gamma-Tocopherol – 84591.
Also Affected	DOS Code 3524

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.

Discontinued Tests:

Effective Immediately:

3470 **Lp-PLA2**
Replaced by: No replacement

S51557 **Penta Screen [15934X]**
Replaced by: No replacement