

May 27, 2009

Dear Colleague:

Specialty Laboratories is pleased to announce the immediate availability of a new molecular diagnostic assay, **MPL W515 & MPL S505 Mutation Analysis, Qual, Plasma [5398]**, for sporadic and familial chronic myeloproliferative diseases (polycythemia vera, essential thrombocythemia and primary myelofibrosis) in patients with a negative JAK2 test result. The MPL W515 & S505 mutations are also available as a reflex from a negative JAK2 test by ordering **JAK2 V617F Mutation, QI, w/Rfx Exons 12, 13 & MPL W515, S505, [5396]**. The W515L and W515K mutations in the myeloproliferative leukemia gene (MPL) are important, because only about half of essential thrombocythemia or primary myelofibrosis patients are positive for JAK2.

Please note that our **FLT3 & NPM1 GenotypR™ [5038]** and **FLT3 & NPM1 GenotypR™ - Paraffin Block [5038BK]** are now approved by the Wadsworth Center for use on patients from New York State.

Coagulation testing often requires special attention for good results. When sending samples for coagulation studies, please be sure to **provide platelet-poor plasma by spinning the specimen twice**. After the first spin, draw off the plasma into another tube and spin a second time, to assure a platelet concentration of $<10 \times 10^9/L$. Remember, the only anticoagulant acceptable for coagulation studies is Sodium Citrate. For your convenience, we have attached a copy of our protocol for obtaining platelet-poor plasma. For a full description of specimen preparation for coagulation studies, please go to the Specialty Labs Web site or refer to our Directory of Services.

In addition, Specialty Laboratories would like to re-emphasize the specimen volume requirement for **ThinPrep** vials submitted for our **Human Papillomavirus High Risk DetectR™** assays [1821, 1822, 1824, and 1827]. To avoid insufficient volume rejection, please submit **a minimum of 4.0 mL (8.0 mL preferred, if repeat testing is required)**. Adherence to specimen requirements will assure maximum sensitivity of the assay.

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):

5396 JAK2 V617F Mutation, QI, w/Rfx Exons 12, 13 & MPL W515, S505
(Available June 23)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
JAK2 V617F	PCR/Sequencing	By report
JAK2 Exons 12 & 13 (if needed)	PCR/Sequencing	By report
MPL W515 & S505 (if needed)	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.	
	Bone Marrow ACD 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.	
	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	Wednesday	
Report	2-9 days	
CPT Code	83891, 83902, 83898, 83904, 83912	
Notes	If the JAK2 V617F result is negative, then exons 12 and 13 will be performed for an additional charge (CPT codes: 83904x2, 83912). If exons 12 and 13 are negative then MPL W515 and S505 will be performed for an additional charge (CPT code: 83904x2, 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). The test identifies the JAK2 exon 14 V617F point mutation, mutations in JAK2 exons 12 to 13 and MPL W515 and S505 mutations.	

New Tests (Specialty): (cont'd)

5398 MPL W515 & MPL S505 Mutation Analysis, Qual, Plasma (Available June 23)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
MPL W515 & S505	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. Bone Marrow ACD 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. 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	Wednesday 2-9 days	
CPT Code	83891, 83898, 83902, 83904x2, 83912	
Notes	This test is not approved for the testing of patient samples from New York State.	
Clinical Utility	Diagnose sporadic and familial chronic myeloproliferative diseases (polycythemia vera, essential thrombocythemia and idiopathic myelofibrosis) in patients with a negative JAK2 test result. MPL W515 mutations are present in patients with idiopathic myelofibrosis or essential thrombocythemia at a frequency of approximately 5% and 1%, respectively. The S505 mutation is usually detected in patients with familial essential thrombocythemia.	

Test Changes:

2419 AFB Culture & Stain

Effective Immediately
Collection Instructions 1. Collect specimen in a sterile, leak-proof container.
2. For respiratory specimens, collect three sputum samples from deep productive coughs in consecutive 8 to 24 hour intervals per CDC guidelines (at least one should be an early morning specimen).
3. Place tissue and needle biopsies in Middlebrook broth (available from Specialty) or in sterile saline.
4. Culturette and nasopharyngeal swab collections may result in a potential decline in sensitivity of Mycobacterium isolation in culture. The yield of material is limited, and due to the hydrophobicity of Mycobacteria, the organisms may be entrapped within the fiber matrix and not readily transition into solution or onto media. False negative cultures are possible, especially if few pathogens are present.
5. If gastric aspirate cannot be shipped immediately add 100mg of sodium bicarbonate as a buffer to neutralize any acid detrimental to Mycobacteria.
6. Refrigerate all samples within 1 hour of collection time except for whole blood samples. **(NEW)**
7. Ship specimens on cold pack within 24 hours of collection. Whole blood is shipped at ambient temperature.
Also affected DOS Codes 2417, 5320

5394 JAK2 V617F Mutation, Qual PCR, Plasma w/Reflex Exons 12, 13

Effective Immediately
CPT Code 83891, 83902, 83898, 83904, 83912
If reflexed to exons 12, 13 add CPT codes 83904x2, 83912

5392 JAK2 Exons 12 & 13 Mutation, Qualitative, Plasma

Effective Immediately
CPT Code 83891, 83902, 83898, 83904x2, 83912

9721 Mumps IgM Abs

Effective June 23
Report Comment The clinical diagnosis must be interpreted in conjunction with the clinical signs and symptoms of the patient.
Also Affected DOS Code 9711

1584UR Protein Electrophoresis (PEP) Evaluation Urine

Effective June 23
Report Comment Normal urine protein concentration is very low (4-19 mg/dL) and urine PEP typically shows only a faint band of albumin if detected. Other protein fractions (% of total protein) are reported only when noted or when total protein concentration is increased.
If abnormal, urine scan will follow under separate cover.
Also Affected DOS Code 1580U

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.

S51867 BRAF Mutation Analysis [16767]

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

Discontinued Tests:

Effective Immediately:

- 3520 Vitamin D, 1, 25-Dihydroxy**
Recommended replacement: S51661 – Vitamin D, 1, 25-Dihydroxy, LC/MS/MS [4861]
- 3523 Vitamin D, 1, 25-Dihydroxy & 25-Hydroxy**
Recommended replacement: 3521 – Vitamin D, 25-Hydroxy (Calcifediol) and S51661 – Vitamin D, 1, 25-Dihydroxy, LC/MS/MS [4861]
- S49260 Ketosteroids Fractionated-17 (GC) 24Hr [8567]**
Recommended replacement: S51864 - 17 Ketosteroids, Fractionated, Urine [4932X]
- S50983 17-Ketosteroid Fractionation Profile Random, Urine [84349]**
Recommended replacement: S51864 - 17 Ketosteroids, Fractionated, Urine [4932X]
- S49282 Hydroxyproline Total 25Hr Urine [14209N]**
Recommended replacement: No replacement
- S49311 Hydroxyproline, Total, Random Urine [37407N]**
Recommended replacement: No replacement
- S48848 Hydroxyproline Free 24Hr Urine [3483N]**
Recommended replacement: No replacement
- S48950 Hydroxyproline Free Random Urine [6681]**
Recommended replacement: No replacement

Effective Immediately New York Clients:

- S51614NY T3 Reverse [70188] [NY]**
Recommended replacement: 3236 – Triiodothyronine, Reverse (RT3)
- S51610NY Copper RBC [1330R] [NY]**
Recommended replacement: No replacement
- S51605NY Zinc RBC [6354X] [NY]**
Recommended replacement: No replacement

Discontinued Tests: (cont'd)

Effective June 10:

7230 **Connexin 26 GenotypR™**
Recommended replacement: No replacement

The following allergens are being discontinued by the manufacturer. Panels will be discontinued immediately with no replacements.

RK212	Allergen – Abachi Wood Dust IgE
RO202	Allergen – <i>Artemisia salina</i> Fish Feed IgE
RF334	Allergen – Bovine Lactoferrin IgE
RW206	Allergen – Camomile IgE
M5G	Allergen – <i>Candida albicans</i> IgG
RF295	Allergen – Carambola IgE
RE208	Allergen – Chinchilla Epithelium IgE
K85	Allergen – Chloramin T IgE
D2G	Allergen – <i>Dermatophagoides farinae</i> IgG
RF285	Allergen – Elk/Moose Meat IgE
RF276	Allergen – Fennel Fresh IgE
RFX12	Allergen – Food Mix IgE – Vegetable & Grain: RFX12
RFX19	Allergen – Food Mix IgE – Vegetables: RFX19
RT203	Allergen – Horse Chestnut IgE
RF348	Allergen – Litchi IgE
RM227	Allergen – <i>Malassezia</i> spp. IgE
RI203	Allergen – Mediterranean Flour Moth IgE
RK211	Allergen – Methyltetrahydrophthalic Anhydride IgE
RE203	Allergen – Mink Epithelium IgE
PAX4	Allergen – Occupational Mix IgE: PAX4
RT223	Allergen – Oil Palm IgE
RT219	Allergen – Paloverdes IgE
RRX5	Allergen – Regional Mix IgE: RRX5
RW211	Allergen – rPar j 2 (Recombinant)0 IgE
RF351	Allergen – rPen a 1; Tropomyosin from Shrimp IgE
RK206	Allergen – Savinase IgE
RM223	Allergen – Staphylococcal Enterotoxin C IgE
RM225	Allergen – Staphylococcal Enterotoxin D IgE

May 27, 2009

Dear Client,

In order to maintain continuous quality of coagulation testing performed at *Specialty*, we routinely perform platelet counts on random specimens submitted for testing. **Recently a specimen submitted by your facility did not meet the below outlined requirements** and we would like you to review the following procedure. Strict adherence to these NCCLS recommended guidelines is imperative for accurate and useful APTT test results. We thank you in advance for your attention to this matter, and look forward to providing you with accurate, timely, and quality results in the future.

The presence of >10,000 platelets may cause the neutralization of heparin, if present in plasma. Specimens with high platelet counts, upon freezing, release PF4, which is a powerful neutralizer of heparin and will result in inaccurate heparin monitoring by the APTT test.

Instructions for obtaining 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 value 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 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.