

January 28, 2009

**Dear Colleague:**

We are pleased to announce standardization of some of the protein chemistry tests at Specialty Laboratories, utilizing state-of-the-art Roche Integra 800 analyzers. This new analyzer utilizes different methodologies, such as turbidimetric and colorimetric methods. It is a high-throughput and fully-automated analyzer with better performance than other similar instruments on the market. In addition, introduction of the Integras in our laboratory will improve the turn-around time for our clients. Affected tests include **Antistreptolysin O Antibodies, Complement C3 & C4, C-Reactive Protein, Hemoglobin A1c, Lactic Acid Plasma** and **Rheumatoid Factor**.

We would also like to take this opportunity to remind you of our molecular PCR assays for evaluation of the JAK2 gene. **JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13 [5394]** is a qualitative RNA-based sequencing assay that detects 5% of mutant cells within a background of normal cell populations. The test detects the exon 14 V617F somatic point mutation in a highly-conserved residue of the pseudokinase domain of the JAK2 (Janus kinase) tyrosine kinase gene. The V617F mutation was found in greater than 80% of patients with polycythemia vera (PV), and 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis (MF). Patients that are negative for the V617F mutation get reflexed to **JAK2 Exons 12 and 13 Mutations, Qualitative, Plasma [5392]** for the analysis of additional mutations in exons 12 and 13. Patients with JAK2 exon 12 mutation have been documented to present with isolated erythrocytosis and distinctive bone marrow morphology or had reduced serum erythropoietin levels. Mutations in exon 13 have been reported; however, their impact on JAK2 kinase activity is currently unknown. A negative test result does not rule out a diagnosis of PV, as rare cases of PV have been reported to lack JAK2 mutations. A JAK2 mutation-positive test result rules out a diagnosis of reactive thrombocytosis or myelofibrosis in patients suspected of having ET or MF.

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,



Christopher Lockhart, M.D.  
Laboratory Director

# New Tests:

**4975 Hemoglobin A1c w/MPG**

**(Available Feb. 24)**

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Hemoglobin A1c</b>	<b>Turbidimetric</b>	<b>&lt; 6.0 %</b>
<b>Mean Plasma Glucose (MPG)</b>	<b>Calculated</b>	
Specimen/Stability	Whole Blood EDTA 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months	
Alternate Specimen	Whole Blood Lithium Heparin 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months	
Collection	Please ship EDTA whole blood in lavender-top Vacutainer® tube rather than in aliquot tube. Note: fasting is not required.	
Schedule	Monday-Saturday	
Report	Same day	
CPT Code	83036	
Clinical Utility	In the erythrocyte, the relative amount of HbA converted to stable HbA1c increases with the average concentration of glucose in the blood. The conversion to stable HbA1c is limited by the erythrocyte's life span of approximately 100-120 days. As a result, HbA1c reflects the average blood glucose level during the preceding 2-3 months. HbA1c is thus suitable to monitoring long-term glucose control in individuals with diabetes mellitus. The approximate relationship between HbA1c and mean plasma glucose (MPG) during the preceding 2 to 3 months was analyzed by studies standardized to DCCT/NGSP.	
Notes	Specimens containing high amounts of HbF (>10%) may yield lower than expected HbA1c values.	

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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.**

# Test Changes:

## 4870U **Copper 24Hr Urine**

Effective Immediately  
Specimen/Stability Urine 24hr 2.0 (1.0) mL: Ambient 5 days, Refrigerated 5 days, Frozen 14 days

## 4870UR **Copper Urine Random**

Effective Immediately  
Specimen/Stability Urine 2.0 (1.0) mL: Ambient 4 days, Refrigerated 4 days, Frozen 14 days

## 4868W **Cadmium Whole Blood**

Effective Immediately  
Specimen/Stability Whole Blood EDTA Trace Metal 2.0 (1.0) mL: Ambient 7 days, Refrigerated 14 days, Frozen 1 month  
Also affected DOS Code 4500I

## 4868UR **Cadmium Urine Random**

Effective Immediately  
Specimen/Stability Urine 5.0 (2.0) mL: Refrigerated 14 days, Frozen 1 month  
Also affected DOS Codes 4500I, 4500UR1

## 4873W **Mercury Whole Blood**

Effective Immediately  
Specimen/Stability Whole Blood EDTA Trace Metal 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
Alt Specimen WB EDTA 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
WB NaHep Trace Metal 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
Also affects DOS Code 4080W

## 4867W **Arsenic Whole Blood**

Effective Immediately  
Specimen/Stability Whole Blood EDTA Trace Metal 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
Alt Specimen WB EDTA 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
WB NaHep Trace Metal 2.0 (0.5) mL: Ambient 7 days, Refrigerated 31 days, Frozen 2 months  
Also affects DOS Code 4080W

## 2102 ***Treponema pallidum* IgM Abs [IFA]**

Effective February 24  
Reporting Weakly reactive results will be reported as "1+ Weakly reactive".  
Also affects DOS Codes 2102C, 2104, 2104C, 2104T

# Test Changes: (cont'd)

<b>5660</b>	<b>Fungus Susceptibility: MIC Panel</b>	Effective Component	Immediately Ketoconazole MIC (no longer available)
<b>5661AM</b>	<b>Fungus Susceptibility Custom MIC: Amphotericin B</b>	Effective Note Also affects	Immediately Specific cut-offs have not been established. As a guideline, an MIC value of >1.0 ug/mL is probably resistant to Amphotericin B. DOS Code 5660
<b>3360</b>	<b>Valproic Acid</b>	Effective Specimen/Stability	Immediately Serum 1.0 (0.2) mL: Ambient 5 days, Refrigerated 5 days, Frozen 2 months
<b>7876</b>	<b><i>Rickettsia rickettsii</i> &amp; <i>R. typhi</i> IgG &amp; IgM Abs Eval</b>	Effective Specimen/Stability Also affected	Immediately Serum 1.0 (0.5) mL: Refrigerated 5 days, Frozen 2 months NOTE: Plasma is no longer acceptable Ambient stored specimens no longer acceptable DOS Codes 7871, 7881, 7886, 7891, 7896, 7901, 7906, 7911
<b>1191</b>	<b>Endomysial IgA Autoabs</b>	Effective Specimen/Stability Also affected	Immediately Serum 1.0 (0.4) mL: Refrigerated 7 days, Frozen 2 months NOTE: Ambient stored specimens are no longer acceptable DOS Codes 1075, 1076, 1077
<b>1162</b>	<b>Reticulin IgA Autoabs</b>	Effective Specimen/Stability Also affected	Immediately Serum 1.0 (0.4) mL: Refrigerated 7 days, Frozen 2 months NOTE: Ambient stored specimens are no longer acceptable DOS Codes 1075, 1076, 1077
<b>3334</b>	<b>Homocysteine</b>	Effective Name Ref Range Also affects	February 24 Homocysteine Cardiovascular Male: < 11.4 umol/L Female: < 10.4 umol/L DOS Codes 1537, 4994, 5971, 5973, 5990
<b>7711</b>	<b><i>Borrelia burgdorferi</i> IgG &amp; IgM Abs IB [CDC Criteria]</b>	Effective Specimen/Stability Also affects	Immediately Serum 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 2 months DOS Codes 7711B, 7711BNY

# Test Changes: (cont'd)

## 4920 Flurazepam (Dalmane®)

Effective February 24  
Component Flurazepam (reporting only metabolite)  
All other components remain the same  
Note Flurazepam is assayed as its primary metabolite, Desalkylflurazepam.

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

Effective February 24  
Note If the JAK2 V617F result is negative, panel will automatically reflex to JAK2 Exons 12 & 13 (test code 5392) for an additional charge (CPT codes 83904, 83912).

## 7473 Hepatitis C Virus SubtypR®

Effective February 10  
Method LIPA (Line Probe Assay)

## 1540 Rheumatoid Factor

Effective February 24  
Ref Range < 14 IU/mL  
Specimen/Stability Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 30 days  
Alt Specimen Plasma EDTA 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 30 days  
Plasma Heparanized 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 30 days  
Also affects DOS Codes 1000, 1005, 1010, 1014, 1126, Reflex of panels 1118, 1121

## 1535 C-Reactive Protein (CRP) (Inflammation)

Effective February 24  
Ref Range/Units < 0.8 mg/dL  
Specimen/Stability Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 30 days  
Alt Specimen Plasma EDTA 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 30 days  
Plasma Heparin 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 30 days  
Plasma Citrated 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 30 days  
Plasma Fluoridated 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 30 days  
Also affects DOS Code 1014

# Test Changes: (cont'd)

## 2376 Antistreptolysin O Antibodies (ASO)

Effective February 24  
Ref Range < 18 years: < 150 IU/mL  
> or = 18 years: < 201 IU/mL  
Methodology Turbidimetric  
Specimen/Stability Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 30 days  
Also affects DOS Code 1726

## 5510 StoneRisk® Diagnostic Profile

Effective February 3  
Note Patient weight is no longer needed. It is not necessary to provide, when available.  
Also affects DOS Codes 5515, 5520

## 1500 Complement C3 & C4

Effective February 24  
Ref Range C3: 90 – 180 mg/dL  
C4: 16 – 47 mg/dL  
Specimen/Stability Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 30 days  
Also affects DOS Codes 1000, 1004, 1005, 1006, 1021, 1094, 1126, 1501, 1504, 1726, 5023, Reflex of panels 1118, 1121

## 4128 Lactic Acid Plasma

Effective February 24  
Ref Range/Units 4 – 16 mg/dL  
Methodology Colorimetric  
Specimen/Stability Plasma Fluoridated 1.0 (0.5) mL: Refrigerated 7 days, Frozen 90 days  
Note Ambient stored specimens no longer acceptable  
Collection Instructions Venous specimens should be collected without the use of a tourniquet or immediately after a tourniquet has been applied. The patient should avoid any exercise of the arm or hand before or during collection of the specimen. Lactate levels increase rapidly with physical exercise. Thirty minutes at rest is usually sufficient for lactate to return to pre-exercise level. The collected blood should be well mixed and separated from the cells within 3 hours.

## 4972 Hemoglobin A1c

Effective February 24  
Ref Range < 6.0 %  
Methodology Turbidimetric  
Specimen/Stability Whole Blood EDTA 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months  
Alt Specimen Whole Blood Lithium Heparin 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months  
Collection Instructions Please ship EDTA whole blood in lavender-top Vacutainer® tube rather than in aliquot tube.  
Fasting is not required.  
Also affects DOS Code 4972SR

# Test Changes: (cont'd)

**2211**

## **Epstein-Barr Virus EvaluatR™**

Effective	February 3					
Interpretive Guidelines	Marker	Susceptible	Primary	Acute	Past	Reactivation
	VCA IgM	-	+	+/-	-	+/-
	VCA IgG	-	+/-	+	+	+
	EA IgG	-	+/-	+	-	+/-
	EBNA IgG	-	-	+/-	+	+

The VCA IgM antibody may be detectable at very low level in some reactivated EBV infections, but is normally absent. In immunocompromised or immunosuppressed individuals, detectable EA IgG may help to identify reactivation of infection. For all other cases, the significance of a positive EA IgG antibody must be assessed with clinical findings.

Also affects

DOS Codes 2211E, 2211SB

**3876**

## **Insulin Antibodies**

Effective	Immediate
Ref Range	< 0.4 U/mL
FDA Status	Approved
Also Affects	DOS Codes 1031, 1032

# Discontinued Tests:

## Effective Immediately:

**3553 S-100B AccuQuant® Serum**

Replaced by: No replacement

**3553C S-100B AccuQuant® CSF**

Replaced by: No replacement

**5661KE Fungus Susceptibility Custom MIC: Ketoconazole**

Replaced by: No replacement

**5390 JAK2 GenotypR™**

Suggested replacement: 5394 – JAK2 V617F Mutation, Qual PACR, Plasma w/Rfx Exons 12, 13

**S51557 Penta Screen [15934X]**

Replaced by: No replacement