

August 3, 2010

**Dear Colleague:**

Our July communication to you comes in the form of two separate communications. In addition to the test updates that follow, we are sending you a letter that is specific to the new Pain Management offerings that we referenced in our June letter. These new assays are intended to address a variety of needs specific to the monitoring of pain management prescriptions and available as of today, August 3, 2010. All of the testing and reporting details are available on the Home Page of our website. We encourage you to contact us for both technical and operational assistance in accessing these assays.

This letter also introduces a number of gene-based assays utilizing saliva as the specimen type. These tests are denoted with "S" at the ending of the orderable test code and offer an alternative collection method. Testing for **Alpha-1-Antitrypsin GenotypR™ (1515S)**, **DPD 5-FU GenotypR™ (5383S)**, **Factor II (PT) GenotypR™ (5371S)**, **1966S**, **Factor V (Leiden) GenotypR™ (1966S)**, **Hemochromatosis GenotypR™ (5369S)**, **MTHFR GenotypR™ (4562S)**, **Plasminogen Activator Inhibitor (PAI-1) GenotypR™ (5375S)**, **TPMT GenotypR™ (5353SNY)**, and **Warfarin Sensitivity DetectR™ (5055S)** fall into this newly available category.

Please pay particular attention to the Test Change section of this letter. There are a number of tests that have Specimen/Stability revisions including the addition of acceptable sample types and/or extended stability times. In coming months, we will continue to enhance these criteria intended to reduce specimen rejection and avoid patient re-collection.

Also of note, we are introducing informational requirement changes to some of our ER/PgR test menu. Based on ASCO/CAP guidelines for these assays it is required that ordering clients supply us with information including: Type of Fixation, Duration of Fixation, Time to Fixation and Type of Tissue Processing. We have provided in this letter a complete list of tests affected and the data fields that will be used to collect the required information.

As always, we genuinely 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*):

**1515S      Alpha-1-Antitrypsin GenotypR™ - Saliva      (Available August 10)**

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Alpha-1-Antitrypsin</b>	<b>PCR</b>	<b>Mutation not detected</b>

Specimen/Stability	Saliva: Ambient 10 days
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.
Schedule	Monday-Friday
Report	Next day
CPT Code	83891, 83900, 83909, 83912, 83914x2
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 detects the Pi gene mutations Z and S from saliva.
Clinical Utility	Alpha-1-antitrypsin deficiency is an autosomal recessive disorder resulting in increased risk for early-onset of obstructive lung disease and/or cirrhosis of the liver. Although over 70 European alleles in the Pi gene have been reported, 95% of patients are alpha-1-antitrypsin deficient and are either homozygous for the Z allele or are compound heterozygotes for the Z and the S allele.

**5383S      DPD 5-FU GenotypR™ - Saliva      (Available August 10)**

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>DPD 5-FU</b>	<b>PCR</b>	<b>Mutation not detected</b>

Specimen/Stability	Saliva: Ambient 10 days
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.
Schedule	Monday-Friday
Report	Next day
CPT Code	83891, 83898, 83909, 83912, 83914
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 detects the DPYD gene mutation, IVS14+1 G>A from saliva.
Clinical Utility	Partial or complete deficiency of DPD activity has been associated with an increased risk for severe adverse reactions when treated with pyrimidine-based chemotherapeutic agents, such as 5-fluorouracil (5-FU). This test can also be used to confirm the clinical diagnosis of dihydropyrimidine dehydrogenase (DPD) deficiency in affected patients and for the detection of the IVS14+1 G>A mutation in asymptomatic carriers.

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

## 5371S Factor II (PT) GenotypR™ - Saliva (Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Factor II (PT)</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83898, 83909, 83912, 83914	
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 detects the Factor II (Prothrombin) G20210A mutation from saliva.	
Clinical Utility	The G20210A mutation in the Prothrombin Factor II gene is the second most common inherited risk factor occurring in approximately 2% of Caucasians. Presence of the mutation is associated with an elevation of prothrombin levels to about 30% above normal in heterozygotes and to 70% above normal in homozygotes.	

## 1966S Factor V (Leiden) GenotypR™ - Saliva (Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Factor V (Leiden)</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83898, 83909, 83912, 83914	
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 detects the Factor V Leiden (R506Q) mutation from saliva.	
Clinical Utility	The Factor V Leiden (R506Q) mutation in the Factor V gene is one of the most common causes of inherited thrombophilia. This mutation causes resistance to degradation of activated Factor V protein by activated protein C (APC).	

## 5369S Hemochromatosis GenotypR™ - Saliva (Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Hemochromatosis</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83900, 83909, 83912, 83914x3	
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 detects the HFE gene mutations, C282Y, H63D and S65C from saliva.	
Clinical Utility	The mutations in the HFE gene are the major cause of hereditary hemochromatosis.	

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

## 4562S MTHFR GenotypR™ - Saliva

(Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>MTHFR</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83900, 83909, 83912, 83914x2	
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 detects the MTHFR C677T and A1298C mutations from saliva.	
Clinical Utility	Hyperhomocysteinemia is a risk factor for arterial disease and venous thrombosis. Homocysteine levels are affected by nutritional and genetic factors. Since MTHFR is involved in methylation of homocysteine to methionine, individuals with MTHFR gene mutations that reduce enzyme activity may develop hyperhomocysteinemia and thus be at elevated risk for vascular disease.	

## 5375S Plasminogen Activator Inhibitor (PAI-1) GenotypR™ - Saliva

(Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>PAI-1</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83898, 83909, 83912, 83914	
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 detects the 4G/5G polymorphism in the promoter region of the plasminogen activator inhibitor-1 (PAI-1) gene.	
Clinical Utility	Deep vein thrombosis and coronary artery disease are associated with increased PAI-1 levels.	

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

## 5353SNY TPMT GenotypR™ - Saliva [NY] (Available Immediately)

This test is available for the testing of patient samples from New York State.

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>TPMT</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83900, 83901, 83909, 83912, 83914x3	
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	Test detects the wild-type TPMT*1 and TPMT*2, *3A, *3B and *3C variants. This test is available for the testing of patient samples from New York State. Informed consent is required. Consent form is available on our website: <a href="http://www.specialtylabs.com">www. specialtylabs.com</a> .	
Clinical Utility	Test identifies patients at risk for toxicity from thiopurine drugs.	

## 5055S Warfarin Sensitivity DetectR™ - Saliva (Available August 10)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>Warfarin Sensitivity</b>	<b>PCR</b>	<b>Mutation not detected</b>
Specimen/Stability	Saliva: Ambient 10 days	
Collection Instructions	Collect saliva in REF OG-310 Oragene DNA self-collection kit. Follow the kit's collection instructions. Ship at room temperature.	
Schedule	Monday-Friday	
Report	Next day	
CPT Code	83891, 83900, 83901, 83909, 83912, 83914x3	
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 detects the CYP2C9*2 430C>T, CYP2C9*3 1075A>C and VKORC1 – 1639G>A mutations from saliva.	
Clinical Utility	Mutations in CYP2C9 and VKORC1 genes are estimated to account for 40-63% of the variability in therapeutic warfarin dosage required.	

# Test Changes:

- 1081 Antiphospholipid Syndrome EvaluatR™**  
Effective Immediately  
Specimen/Stability (1) Serum 2.0 (1.0) mL: Refrigerated 7 days, Frozen 2 months  
Specimen/Stability (2) Plasma Citrated 2.0 (1.0) mL: Frozen 14 days  
**Note: Increased refrigerated stability for serum.**  
Also Affected DOS Code 1082
- 1083 Beta-2-Glycoprotein I (Beta-2-GPI) IgG, IgM & IgA Autoabs**  
Effective Immediately  
Specimen/Stability Serum 1.0 (0.6) mL: Ambient 14 days, Refrigerated 28 days, Frozen 28 days  
**Note: Ambient specimens now accepted. Increased refrigerated stability; decreased frozen stability**  
Also Affected DOS Codes 1182, 1183, 1184
- 1615 Complement C1q**  
Effective Immediately  
Specimen/Stability Plasma EDTA 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 2 months  
Collection Instructions Reject Criteria: Gel barrier tubes are not acceptable as they interfere with assay methodology. **(NEW)**
- 1776 Antiphospholipid Evaluation**  
Effective Immediately  
Specimen/Stability Serum 5.0 (3.0) mL: Refrigerated 7 days, Frozen 2 months  
**Note: Increased refrigerated stability.**  
Also Affected DOS Code 1080S
- 3092 Alpha-Fetoprotein Quad Screen, 2.5 MoM**  
Effective Immediately  
Specimen/Stability Serum 5.0 (3.0) mL: Ambient 2 days, Refrigerated 5 days, Frozen 2 months  
**Note: Ambient specimens now accepted.**
- 3296 Plasminogen Activator Inhibitor-1**  
Effective Immediately  
Specimen/Stability Plasma Citrated (Platelet Poor) 1.0 (0.5) mL: Frozen 3 months  
Reference Range Males: <47.2 IU/mL **(NEW)**  
Females: <40.8 IU/mL **(NEW)**  
Also Affected DOS Codes 5973, 5991
- 3371 Cardiolipin IgG, IgM & IgA Autoabs**  
Effective Immediately  
Specimen/Stability Serum 1.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months  
Alt Specimen Plasma Heparinized 1.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months  
Plasma EDTA 1.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months  
**Note: Increased refrigerated stability.**  
Also Affected DOS Codes 3372, 3373, 3374, 5963, 5976

# Test Changes: (cont'd)

<b>3984</b>	<b>Inhibin A</b>	
Effective	Immediately	
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 2 days, Refrigerated 5 days, Frozen 2 months Plasma Heparinized 1.0 (0.5) mL: Ambient 2 days, Refrigerated 5 days, Frozen 2 months Plasma EDTA 1.0 (0.5) mL: Ambient 2 days, Refrigerated 5 days, Frozen 2 months	
	<b>Note: Ambient specimens now accepted.</b>	
<b>4950</b>	<b>Fluoxetine &amp; Norfluoxetine</b>	
Effective	Immediately	
Method	LC-MS-MS (NEW)	
<b>1092</b>	<b>Thyroid Stimulating Immunoglobulins</b>	
Effective	August 17	
Specimen/Stability	Serum 3.0 (1.0) mL: Refrigerated 21 days, Frozen 60 days	
	<b>Note: Ambient specimens are no longer accepted. Increased refrigerated stability.</b>	
Reference Range	Negative (NEW)	
Regulatory Status	FDA Modified	
Always Statement	A positive result is one in which the Specimen to Reference Ratio (%) (SRR%) is $\geq 140\%$ of the Reference Control. Thyroid Stimulating Immunoglobulins (TSI) can engage the TSH receptors resulting in hyperthyroidism in Graves' disease patients. TSI results can be useful in monitoring the clinical outcome of Graves' disease as well as assessing the potential for hyperthyroidism from maternal-fetal transfer. NOTE: A serum TSH level greater than 350 micro-International Units/mL can interfere with the TSI bioassay and potentially give false positive results.	
Also Affected	DOS Codes 1091, 3060	
<b>1136</b>	<b>Glomerular Basement Membrane IgG Autoabs</b>	
Effective	August 24	
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 14 days, Refrigerated 28 days, Frozen 28 days	
	<b>Note: Increased ambient and refrigerated stability; decreased frozen stability</b>	
<b>1726</b>	<b>Rapidly Progressive Glomerulonephritis Evaluation</b>	
Effective	August 24	
Specimen/Stability	Serum 3.0 (2.0) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 28 days	
	<b>Note: Decreased frozen stability</b>	

# Test Changes: (cont'd)

## 1817 ER/PR/HER-2/KI-67/DNA Cell Cycle Analysis, Breast Cancer

Effective August 24  
Component ER Intensity **(ADD)**  
Component PR Intensity **(ADD)**  
Component Time to Fixation **(ADD)**

All other components remain the same

Always Statement ER clone 1D5 and PR clone PGR636, Her-2/neu polyclonal c-erbB-2 and Ki-67 clone MIB1 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

Also Affected DOS Codes 1839

## 1818 ER, PR, DNA CCA, HER-2/*neu* w/Reflex FISH, Breast Cancer

Effective August 24  
Component ER Intensity **(ADD)**  
Component PR Intensity **(ADD)**  
Component Time to Fixation **(ADD)**

All other components remain the same

Always Statement ER clone 1D5, PR clone PGR636 and HER-2/neu polyclonal c-erbB-2 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

Also Affected DOS Codes 1819, 1840, 1842

## 1830 ER, PR (Estrogen & Progesterone Receptors), Breast Cancer

Effective August 24  
Component ER Intensity **(ADD)**  
Component PR Intensity **(ADD)**  
Component Type of Fixation **(ADD)**  
Component Duration of Fixation **(ADD)**  
Component Time to Fixation **(ADD)**  
Component Type of Tissue Processing **(ADD)**

All other components remain the same

Always Statement ER clone 1D5, PR clone PGR636 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

## 1831 ER (Estrogen Receptor), Breast Cancer

Effective August 24  
Component ER Intensity **(ADD)**  
Component Type of Fixation **(ADD)**  
Component Duration of Fixation **(ADD)**  
Component Time to Fixation **(ADD)**  
Component Type of Tissue Processing **(ADD)**

All other components remain the same

Always Statement ER clone 1D5 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.



# Test Changes: (cont'd)

## 1832 PR (Progesterone Receptor), Breast Cancer

Effective	August 24
Component	PR Intensity <b>(ADD)</b>
Component	Type of Fixation <b>(ADD)</b>
Component	Duration of Fixation <b>(ADD)</b>
Component	Time to Fixation <b>(ADD)</b>
Component	Type of Tissue Processing <b>(ADD)</b>

All other components remain the same

Always Statement PR clone PGR636 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

## 1833 ER, PR, KI-67, p53, HER-2/*neu* w/Reflex FISH, Breast Cancer

Effective	August 24
Component	ER Intensity <b>(ADD)</b>
Component	PR Intensity <b>(ADD)</b>
Component	Time to Fixation <b>(ADD)</b>

All other components remain the same

Always Statement ER clone 1D5 and PR clone PGR636, Her-2/*neu* polyclonal c-erbB-2, Ki-67 clone MIB1 and p53 clone DO7 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

## 1845 KI-67 (MIB-1), Breast Cancer

Effective	August 24
Always Statement	Ki-67 clone MIB1 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.

## 1846 HER-2/*neu* [IHC], Breast Cancer

Effective	August 24
Always Statement	Her-2/ <i>neu</i> polyclonal c-erbB-2 from DAKO used with polymer detection system, heat induced epitope retrieval with DAKO platform. Positive and negative controls are included with every run.
Also Affected	DOS Codes 5842, 5846

## 3024 Colorectal Cancer Monitor

Effective	August 24
Specimen/Stability	Serum 2.0 (0.7) mL: Ambient 5 days, Refrigerated 7 days, Frozen 2 months

**Note: Ambient specimens now accepted. Increased refrigerated stability.**

# Test Changes: (cont'd)

<b>3120</b>	<b>CA 19-9</b>	August 24
Effective		
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months	
	<b>Note: Ambient specimens now accepted. Increased refrigerated stability.</b>	
Also Affected	DOS Code 3120SR	
<b>3131</b>	<b>Adenosine Deaminase</b>	August 24
Effective		
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 30 days, Frozen 30 days	
Alt Specimen	CSF 1.0 (0.5) mL: Ambient 3 days, Refrigerated 30 days, Frozen 30 days Pleural Fluid 1.0 (0.5) mL: Ambient 3 days, Refrigerated 30 days, Frozen 30 days	
	<b>Note: Decreased ambient stability</b>	
<b>3143</b>	<b>Beta-2-Microglobulin Serum</b>	August 24
Effective		
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days, Frozen 30 days	
	<b>Note: Decreased ambient, refrigerated and frozen stability.</b>	
Reference Range	< 2.6 mg/L <b>(NEW)</b>	
Also Affected	DOS Code 3143SR	
<b>3143U</b>	<b>Beta-2-Microglobulin Urine</b>	August 24
Effective		
Specimen/Stability	Urine Additive 4.0 (1.0) mL: Refrigerated 7 days, Frozen 56 days	
	<b>Note: Frozen specimens now accepted. Decreased refrigerated stability.</b>	
Reference Range	< 0.24 mg/L <b>(NEW)</b>	
Also Affected	DOS Codes 4500I, 4500URI	
<b>3163</b>	<b>Progesterone</b>	August 24
Effective		
Reference Range	Females: see below Male: < 1.4 ng/mL <b>(NEW)</b>	
Always Statement	Female >= 18 Years: Follicular Phase < 1.0 ng/mL <b>(NEW)</b> Luteal Phase 2.6 – 21.5 ng/mL <b>(NEW)</b> Postmenopausal < 0.4 ng/mL <b>(NEW)</b> Pregnancy: 1 <sup>st</sup> Trimester 4.1 – 34.0 ng/mL <b>(NEW)</b> 2 <sup>nd</sup> Trimester 24.0 – 76.0 ng/mL <b>(NEW)</b> 3 <sup>rd</sup> Trimester 52.0 – 302.0 ng/mL <b>(NEW)</b>  Female < 18 Years: Progesterone reference ranges established on post-pubertal patient population. Reference range not established for pre-pubertal patients using this assay.	
Also Affected	DOS Code 2016	

# Test Changes: (cont'd)

## 3234 Triiodothyronine (T3), Free

Effective	August 24	
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months	
	<b>Note: Ambient specimens now accepted. Increased refrigerated stability.</b>	
Reference Range	< 1 Year	Not established
	1 -9 Years	3.4 – 5.1 pg/mL <b>(NEW)</b>
	10 – 13 Years	3.4 – 4.8 pg/mL <b>(NEW)</b>
	14 – 18 Years	2.9 – 4.6 pg/mL <b>(NEW)</b>
	> 18 Years	2.3 – 4.2 pg/mL (same)

## 4185UR Opiates Confirmation Urine

Effective	August 24	
Component	Oxymorphone <b>(ADD)</b>	
Always Statement	Limit of quantitation	
	Codeine	100 ng/mL
	Hydrocodone	100 ng/mL
	Hydromorphone	100 ng/mL
	Morphine	100 ng/mL
	Oxycodone	50 ng/mL
	Oxymorphone	50 ng/mL <b>(NEW)</b>
	All other components remain the same	
Also Affected	DOS Codes 4186UR, Reflex of DOS Codes 4129U, 4250U, 4470U, 4472U	

## 4866R Magnesium RBC

Effective	August 24
Reference Range	4.0 – 6.4 mg/dL <b>(NEW)</b>
Also Affected	DOS Code 4165

## RF333 Allergen – Linseed IgE

Effective	August 24
Name	Allergen – Linseed (Flaxseed) IgE <b>(NEW)</b>

## 4903P Vancomycin, Peak & Trough

Effective	August 31	
Reference Range	Peak:	30.0-40.0 ug/mL (same)
	Trough:	10.0-20.0 ug/mL <b>(NEW)</b>
Always Statement	REFERENCE RANGE for Vancomycin:	
	Peak Therapeutic Level:	30.0-40.0 ug/mL
	Trough Level:	10.0-20.0 ug/mL
	Vancomycin trough concentrations should be at least 10.0 ug/mL. For invasive infections or when bacterial isolates exhibit vancomycin MICs between 1.0 and 2.0 mcg/mL, trough concentrations of 15.0 to 20.0 ug/mL should be considered. When MICs are greater than or equal to 2.0 mcg/mL, alternate therapies should be considered.	
Also Affected	DOS Code 4903	

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.

**S52168 - Cytomegalovirus (CMV) Genotype [14980X]**

Test performed at Quest Diagnostics, San Juan Capistrano

**S52219NY - AccuType™ CP, Clopidogrel CYP2C19 Genotype (1-5) [NY]**

Test performed at Quest Diagnostics, San Juan Capistrano

**S52036NY - HCV Genotype, LIPA [37811X] [NY]**

Test performed at Quest Diagnostics, Chantilly

**S52165 - JC Virus Qualitative Reflex to JC Virus DNA Quant [43336]**

Test performed at Focus Diagnostics

**S52220 - Antimicrobial Susceptibility, *Haemophilus*, MIC Panel [51275]**

Test performed at Focus Diagnostics

**S52221 - Antimicrobial Susc, *Streptococcus pneum*, MIC Panel [51435]**

Test performed at Focus Diagnostics

**S52222 - Antimicrobial Susc, *Staphylococcus*, MIC Panel [51310]**

Test performed at Focus Diagnostics

Please call client relations at 800-421-4449 or visit our website at [www.specialtylabs.com](http://www.specialtylabs.com) for ordering information.

# Performing Lab Updates:

- S51351 GlycoMark® [19599]**  
Test now performed at Quest Diagnostics, San Juan Capistrano
- S51361 Carbamazepine, Free [37512X]**  
Test now performed at Quest Diagnostics, Chantilly

# Discontinued Tests:

## Effective Immediately:

- S42530 Thyrotropin Releasing Hormone [36588X]**  
No replacement
- S51940 Allergen - Flaxseed IgE [87910E]**  
Recommended replacement-RF333 Allergen – Linseed IgE  
Test performed at Specialty Laboratories

## Effective August 15th

- S41350 Tissue Immunofluorescence**  
Recommended replacement: S46335 - Cutaneous Immunofluorescence, Biopsy [8041]  
Test performed at Mayo Medical Laboratories
- 1813 Breast Cancer Profile with KI-67**  
Recommended replacement: 1817 – ER/PR/HER-2/KI-67/DNA Cell Cycle Analysis,  
Breast Cancer  
Test performed at Specialty Laboratories