

January 26, 2010

Dear Colleague:

Specialty Laboratories is pleased to announce the immediate availability of **HE4, Ovarian CA Monitoring [2040]**; an FDA-cleared adjunct to the evaluation of disease progression in patients with epithelial ovarian cancer. It may be a beneficial compliment to **CA-125 [3121]** testing by increasing the correlation of clinical status by 8% over a single marker alone<sup>1</sup>. Elevated HE4 levels are associated with ovarian cancer, but are not disease-specific. A change in HE4 level of  $\geq 25\%$  is considered significant, suggesting a recurrence or disease progression, while a decrease of this magnitude suggests therapeutic response.

Clopidogrel (Plavix<sup>®</sup>) is widely used to treat patients who have had a previous cardiovascular event and to prevent stent thrombosis following stent implantation. This anti-platelet drug, however, is less effective in the 30% of Caucasians, 40% of Africans, and >55% of East Asians who have a reduced-function mutation in the CYP2C19 gene.<sup>2, 3</sup> Patients with CYP2C19\*1 (wild type) alleles metabolize clopidogrel efficiently (extensive metabolizers) and respond normally to clopidogrel therapy. **Cytochrome P450 2C19 GenotypR™ [5382]** test evaluates 7 polymorphisms (681G> (\*2), 636G>A(\*3), 1A>G(\*4), 1297C>T(\*5), 395G>A(\*6), IVS5+2T>A(\*7), and 358T>C(\*8)). Physicians may choose to treat patients with these mutations with a higher clopidogrel dose or a different anti-platelet agent, such as prasugrel, which does not require activation by CYP2C19.

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

1. Allard J, Somers E, Thiel R, et al. Use of a novel biomarker HE4 for monitoring patients with epithelial ovarian cancer. Paper presented at: 44th Annual Meeting of the American Society of Clinical Oncology; May/June 2008; Chicago, IL. Available at: [http://www.asco.org/ASCO/Abstracts+&+Virtual+Meeting/Abstracts?&vmview=abst\\_detail\\_view&confID=55&abstractID=33888#](http://www.asco.org/ASCO/Abstracts+&+Virtual+Meeting/Abstracts?&vmview=abst_detail_view&confID=55&abstractID=33888#). Accessed July 22, 2008.

2. Myrand SP, Sekiguchi K, Man MZ, et al. Pharmacokinetics/genotype associations for major cytochrome P450 enzymes in native and first- and third-generation Japanese populations: comparison with Korean, Chinese, and Caucasian populations. *Clin Pharmacol Ther.* 2008;84:347-361.

3. Dandara C, Masimirembwa CM, Magimba A, et al. Genetic polymorphism of CYP2D6 and CYP2C19 in east- and southern African populations including psychiatric patients. *Eur J Clin Pharmacol.* 2001;57:11-17.

# New Tests (*Specialty*):

2040 HE4, Ovarian CA Monitoring

(Available March 4)

<b>Component</b>	<b>Method</b>	<b>Reference Range/Units</b>
<b>HE4, Ovarian CA Monitoring</b>	<b>EIA</b>	<b>&lt;151 pM</b>
Specimen/Stability	Serum 0.5 (0.1) mL: Ambient 5 days, Refrigerated 7 days, Frozen 28 days	
Collection Instructions	Remove serum from the clot or red cells as soon as possible after clotting and separation. SST is acceptable. Transport at room temperature. Rejection criteria: hemolysis, specimens with heavy particulate matter, lipemia, icteric samples.	
Schedule	Tuesday, Friday	
Report	Same day	
CPT Code	86305	
Regulatory Status	FDA approved	
Always Statement	Sixty percent of patients with a positive change (>25% over previous test value) showed disease progression. Seventy-five percent of the patient serial samples with no significant change in HE4 value correlated with no progression. <sup>1</sup> The HE4 results should be interpreted in conjunction with other established diagnostic tests or procedures. This test is performed using the Fujirebio EIA method. Values obtained from different assay methods cannot be used interchangeably. HE4 levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease. <sup>1</sup> HE4 EIA Product Insert, Product Number 404-10US.	
Clinical Utility	The HE4 EIA assay is an enzyme immunoassay for the quantitative determination of human HE4 antigen in serum. HE4 is a biomarker for ovarian cancer.	

# Test Changes:

<b>9620</b>	<b>Nuclear Matrix Proteins (NMP)</b>
Effective	Immediately
Specimen/Stability	Urine Additive 10 (5) mL: Ambient 4 days, Refrigerated 7 days, Frozen 56 days
	<b>Note: Ambient specimens are now accepted.</b>
Collection Instructions	Collect a single void of urine between midnight and noon. Stabilize sample immediately. Stabilized urine collected with the NMP22 Urine Collection Kit should be blue/green in color. Stabilized samples may remain at room temperature for up to 96 hrs before being processed. Keep sample away from direct sunlight. Transport specimens refrigerated.
<b>4168</b>	<b>Kidney StoneRisk AssessR™</b>
Effective	Immediately
Specimen/Stability #1	Urine 24 Hour 10 (5) mL: Ambient 72 hours, Refrigerated 14 days, Frozen 60 days
Specimen/Stability #2	Urine HCl Additive 10 (5) mL: Ambient 24 hours, Refrigerated 7 days
Collection Instructions	<b>(NEW)</b> For specimen #2, pour aliquot of urine from a well-mixed 24 Hour collection into a clean, acid-washed, detergent-free leak proof container. Adjust pH to <3 with 6N HCl. Record the total 24 hour volume in mL on the specimen container and Specialty's Test Requisition Form
<b>2454</b>	<b>Hepatitis B Surface Antigen with Reflex to Confirmation</b>
Effective	Immediately
Collection Instructions	<b>(NEW)</b> Certain reactive HBSAg results are confirmed by neutralization and can require up to 2 mL of additional specimen. Sample requirement must be met to prevent a QNS (Quantity Not Sufficient) result.
Note	Certain Retest zone reactive specimens for Hepatitis B Surface Antigen are confirmed by Neutralization for an additional charge (CPT Code 87341). Add 2 days to turnaround time.
Also affected	DOS Codes 2461, 2463, 2464, 7756, 7757, 7758, 9928
<b>4161</b>	<b>Stone Analysis, Non-Kidney Stones</b>
Effective	March 7
Name	Stone Analysis
Specimen/Stability	Stone: Ambient 12 months, Refrigerated 12 months, Frozen 12 months
Alt Specimen	Dry Kidney Stone: Ambient 12 months, Refrigerated 12 months, Frozen 12 months Filtered Material: Ambient 12 months, Refrigerated 12 months, Frozen 12 months
	<b>Note: Stones from all sources are now accepted.</b>
Collection Instructions	Dry stone in sterile screw cap container. Stones originating from sources not related to the kidney should be air-dried, then placed in a plastic tube or a urine collection cup. Do not use tape. Minute specimens may be placed in a gelatin capsule. Ship ambient.

# Test Changes: (cont'd)

<b>4155</b>	<b>Stone Analysis, Kidney</b>
Effective	March 7
Name	Stone Analysis without Image
Specimen/Stability	Stone: Ambient 12 months, Refrigerated 12 months, Frozen 12 months
Alt Specimen	Dry Kidney Stone: Ambient 12 months, Refrigerated 12 months, Frozen 12 months Filtered Material: Ambient 12 months, Refrigerated 12 months, Frozen 12 months
	<b>Note: Stones from all sources are now accepted.</b>
Collection Instructions	Dry stone in sterile screw cap container. Stones originating from sources not related to the kidney should be air-dried, then placed in a plastic tube or a urine collection cup. Do not use tape. Minute specimens may be placed in a gelatin capsule. Ship ambient.

---

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.

- S52049 HEPTIMAX® HCV RNA [10565X]**  
Test performed by Quest Diagnostics, Chantilly
- S52099 Iodine Serum/Plasma [16599]**  
Test performed by Quest Diagnostics, Chantilly
- S52050 Respiratory Virus PCR Panel with 2009 H1N1 [4990]**  
Test performed by Focus Diagnostics
- S52051 Interferon Beta 1a (IFNB-1a) Antibody [20555]**  
Test performed by Focus Diagnostics
- S52052 Interferon Beta 1b (IFNB-1b) Antibody [20777]**  
Test performed by Focus Diagnostics
- S52053 Hepatitis C Virus RNA, Qualitative PCR [34024X]**  
Test performed by Quest Diagnostics, San Juan Capistrano
- S52096 Histone Antibodies [37056X]**  
Test performed by Quest Diagnostics, San Juan Capistrano
- S52055 Angiotensin Converting Enzyme CSF [34692X]**  
Test performed by Quest Diagnostics, San Juan Capistrano
- S52098 FISH, B-Cell Chronic Lymphocytic Leukemia Panel [16864]**  
Test performed by Quest Diagnostics, San Juan Capistrano
- S52104 ColoVantage™ (Methylated Septin 9) [16983]**  
Test performed by Quest Diagnostics, Chantilly

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:

- S51705 FISH, B-Cell Chronic Lymphocytic Leukemia (B-CLL)[15787X]**  
Replaced by S52098 FISH, B-Cell Chronic Lymphocytic Leukemia Panel [16864]  
Performed by Quest Diagnostics, San Juan Capistrano
- S48676 Iodine [81574]**  
Replaced by S52099 Iodine Serum/Plasma [16599]  
Performed by Quest Diagnostics, Chantilly
- S46835 Porphyrins Fractionation Erythrocyte [8735]**  
Replaced by S52056-Porphyrins Evaluation, Erythrocytes [88886]  
Performed by Mayo Medical Laboratories
- S42950 Cytochemistry Stain for TdT**  
No replacement
- S48529 Colorado Tick Fever Virus [41375]**  
No replacement
- S48588 Erythrocyte Hypoxanthine Guanine Phosphoribosyl Transfer.**  
No replacement

## Effective March 4:

- S51786 HE4, Ovarian Cancer Monitoring [16500X]**  
Recommended replacement 2040-HE4, Ovarian CA Monitoring  
Performed by Specialty Laboratories

## Effective March 7:

- 4160 Kidney Stone Analysis with Stone Image**  
Replaced by 4161 - Stone Analysis  
Performed by Specialty Laboratories