



# LABORATORY UPDATE

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## Routine Testing

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## Quest Diagnostics Nichols Institute (San Juan Capistrano and Chantilly), Focus Diagnostics, Inc. and Specialty Laboratories

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The CPT Codes provided in this document 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 coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

**Test Changes**

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*DLO is pleased to inform you of the following new and updated laboratory testing information:*

### **Microbiology Transport Container Update**

#### **Use of Red Top Tubes to Submit Microbiology Specimens (Effective October 5, 2009)**

We can no longer accept specimens for Microbiology testing submitted in Red Top Tubes. Usually these were used to transport a sterile body fluid or tissue. The newer plastic tubes, are not “plain” red top tubes. The tube has silica particles added to it as a clot activator. Because these particles will affect the recovery of microorganisms and interfere with the preparation and interpretation of smears from samples submitted in them, we cannot accept these tubes as transport for specimens for Microbiology testing.

How to submit tissue and body fluid specimens:

- 1. Tissue:** Submit in a sterile container, preferably with a wide mouth. Add a small amount of non-bacteriostatic saline to prevent drying during transport. Small tissue samples can be submitted in the Port-A-Cul™ vial. Carefully remove the septum retaining seal and be sure to secure the stopper before transport.
- 2. Body Fluids and Aspirates:**  
Submit up to 5 mL body fluids in the sterile Port-A-Cul™ transport gel vial system provided by DLO. Specimens may also be submitted in a sterile leak-proof vial, but anaerobic bacteria recovery will be compromised.  
Store and transport at room temperature.

ALTERNATIVELY, submit fluids >10 mL such as peritoneal, pleural and other fluids in **BacT/ALERT SA** (blue label with blue top) and, if volume sufficient, **BacT ALERT SN** (pink label with red top) bottles.

#### **Hair, Nails and Skin Scrapings for Fungal Culture:**

Place all hair, skin, and nail specimens in a sterile dry container for transport to the laboratory at room temperature. A dry swab in a sterile container or a swab in a red cap, Amies liquid bacterial transport device are also acceptable.

**Contact your local DLO Client Service Department, or your Sales Representative, for details on how to order these supplies.**

## Test Changes

<b>Culture, Fungus, Blood</b>	
<b>Effective Date:</b>	<b>September 14, 2009</b>
Test Code:	4606
Specimen Requirements	<b>5 ml blood or bone marrow drawn into a Bactec® Myco/F Lytic aerobic blood bottle.</b>
Container Type	Bactec® Myco/F Lytic aerobic blood bottle
Other Acceptable Specimen Requirements	10ml blood or bone marrow drawn into an FDA Cleared (Non Bactec) Blood Culture Bottle
Specimen Stability	Room temperature: 48 hours Refrigerated and Frozen: Unacceptable
Rejection Criteria	<b>Received frozen</b> <b>Specimens in EDTA (lavender top tube)</b> <b>Specimens in Heparin (green top tube)</b> <b>Specimens in citrate, ACD or SPS (yellow-top tubes)</b> <b>Bactec® plus aerobic/f (silver label with gray-top) bottles</b> <b>Bactec® lytic/10 anaerobic/f (purple label and cap) bottles</b> <b>Bactec® peds bottle</b>
Additional Information	Update sample requirements.
<b>Mycobacterium, Blood Culture</b>	
<b>Effective Date:</b>	<b>September 14, 2009</b>
Test Code:	10526
Specimen Requirements	<b>5 ml blood or bone marrow drawn into a Bactec® Myco/F Lytic aerobic blood bottle.</b>
Container Type	Bactec® Myco/F Lytic aerobic blood bottle
Other Acceptable Specimen Requirements	FDA Cleared (Non Bactec) Blood Culture Bottle
Rejection Criteria	<b>Received frozen</b> <b>Specimens in EDTA (lavender top tube)</b> <b>Specimens in Heparin (green top tube)</b> <b>Specimens in citrate, ACD or SPS (yellow-top tubes)</b> <b>Bactec® plus aerobic/f (silver label with gray-top) bottles</b> <b>Bactec® lytic/10 anaerobic/f (purple label and cap) bottles</b> <b>Bactec® peds bottle</b>
Additional Information	Update sample requirements.
<b><i>Haemophilus influenzae</i> Type B Antigen</b>	
Clinical Significance:	Useful for rapid diagnosis of <i>Haemophilus influenzae</i> (Type B) as a cause of bacterial meningitis.
<b>Effective Date:</b>	<b>October 12, 2009</b>
Test Code:	<b>4505</b>
Specimen Requirements:	<b>1 mL serum (minimum: 0.3 mL);</b> <b>Serum collected in SST is acceptable. 1 mL CSF in sterile screw cap container is acceptable. Urine is not an acceptable specimen type.</b>
Specimen Stability:	<b>Room temperature: Unacceptable</b> <b>Refrigerated: 48 hours</b> <b>Frozen: 7 days</b>
Additional Information:	Update specimen requirements, test name and stability.

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & Chantilly),  
Focus Diagnostics, Inc. and Specialty Laboratories**

**New Tests**

The following tests will be available through Quest Diagnostics Nichols Institute on the dates indicated below.

<b>Aldosterone/Plasma Renin Activity Ratio, LC/MS/MS</b>				
Clinical Significance:	The aldosterone-renin ratio is used to screen for primary aldosteronism.			
Effective Date:	Now available			
Test Code:	16845			
CPT Code(s):	84244, 82088			
Specimen Requirements:	1.8 mL EDTA (lavender-top) plasma			
Transport Temperature:	Frozen			
Specimen Stability:	Room temperature: 24 hours Refrigerated: Unacceptable Frozen: 28 days			
Reference Ranges:	<b>PRA,LC/MS/MS:</b>	<b>0.25-5.82</b>	<b>ng/mL/h</b>	
	<b>ALDO/PRA Ratio:</b>	<b>0.9-28.9</b>	<b>Ratio</b>	
	<b>Aldosterone:</b>	<b>Upright 8:00-10:00 am</b>	<b>&lt; or = 28</b>	<b>ng/dL</b>
	<b>Adults:</b>	<b>Upright 4:00-6:00 pm</b>	<b>&lt; or = 21</b>	<b>ng/dL</b>
		<b>Supine 8:00-10:00 am</b>	<b>3-16</b>	<b>ng/dL</b>
	<b>Pediatric</b>	<b>1-12 months**:</b>	<b>2-70</b>	<b>ng/dL</b>
		<b>1-4 years**:</b>	<b>2-37</b>	<b>ng/dL</b>
	<b>5-9 years:</b>	<b>&lt; or = 9</b>	<b>ng/dL</b>	
	<b>10-13 years:</b>	<b>&lt; or = 21</b>	<b>ng/dL</b>	
	<b>14-17 years:</b>	<b>&lt; or = 35</b>	<b>ng/dL</b>	
	<b>Premature infants (31-35 weeks)**:</b>	<b>&lt; or = 144</b>	<b>ng/dL</b>	
	<b>Term infants**:</b>	<b>&lt; or = 217</b>	<b>ng/dL</b>	
<b>Tanner Stages**</b>	<b>II-III Males:</b>	<b>1-13</b>	<b>ng/dL</b>	
	<b>II-III Females:</b>	<b>2-20</b>	<b>ng/dL</b>	
	<b>IV-V Males:</b>	<b>3-14</b>	<b>ng/dL</b>	
	<b>IV-V Females:</b>	<b>4-32</b>	<b>ng/dL</b>	
<b>**Pediatric data from J Clin Endocrinol Metab. 1992;75:1491 and J Clin Endocrinol Metab. 1989; 69:1133-1136.</b>				
Methodology:	Liquid Chromatography Tandem Mass Spectrometry			
Assay Category:	Laboratory Developed Test			
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano			

<b>Plasma Renin Activity, LC/MS/MS</b>	
Clinical Significance:	Measurement of the Plasma Renin activities is useful in evaluating hypertension.
<b>Effective Date:</b>	<b>Now available</b>
Test Code:	<b>16846</b>
CPT Code(s):	<b>84244</b>
Specimen Requirements:	<b>0.8 mL EDTA (lavender-top) plasma</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature: 24 hours</b> <b>Refrigerated: Unacceptable</b> <b>Frozen: 28 days</b>
Reference Ranges:	<b>0.25-5.82 ng/mL/h</b>
Methodology:	<b>Liquid Chromatography Tandem Mass Spectrometry</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<b>PDGFRA Mutation Analysis</b>	
Clinical Significance:	Mutations in the PDGFRA gene are found in 5-8% of gastrointestinal stromal tumors (GISTs), especially in the 40-50% of KIT wild type GISTs. PDGFRA mutations also have been described in synovial sarcomas (SSs) and malignant peripheral nerve sheath tumors (MPNST). KIT and PDGFRA mutations in GISTs cause a ligand-independent auto-activation of the receptor; therefore, mutation-positive GISTs are good candidates for tyrosine kinase inhibitor treatment. GISTs with PDGFRA mutations (except D842V) are likely to respond to imatinib therapy.
<b>Effective Date:</b>	<b>September 14, 2009</b>
Test Code:	<b>16859</b>
CPT Code(s):	<b>83891, 83902, 83898, 83904 (x2), 83912</b>
Specimen Requirements:	<b>Formalin fixed paraffin embedded tissue</b>
Transport Temperature:	<b>Room Temperature</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Indefinite</b> <b>Frozen: Do Not Freeze</b>
Reference Ranges:	<b>Negative</b>
Methodology:	<b>Polymerase Chain Reaction, Sequencing</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<b>Smith-Lemli-Opitz Syndrome and Steroid Sulfatase Deficiency Screen</b>		
Clinical Significance:	This test is used to screen for fetal SLOS and STSD. It is a follow-up test designed to evaluate pregnancies with a low maternal serum unconjugated estriol (uE3) level detected during prenatal screening for Down syndrome and neural tube defects. The maternal serum uE3 level is <0.3 MoM (multiples of the median) in about 60% of SLOS cases and less than or equal to 0.1 MoM in STSD cases.	
Effective Date:	<b>September 14, 2009</b>	
Test Code:	<b>16764</b>	
CPT Code(s):	<b>82542, 84138, 82677, 84135</b>	
Specimen Requirements:	<b>5 mL random urine, no preservative in standard Urine Transport Container</b>	
Transport Temperature:	<b>Frozen</b>	
Specimen Stability:	<b>Room temperature: 24 hours Refrigerated: 4 days Frozen: 14 days</b>	
Reference Ranges:	<b>Interpretation: See report</b>	
	<b>8-Estriol/Estriol:</b>	<b>Normal: &lt; OR = 0.017 Affected: &gt; OR = 0.050</b>
	<b>(7PT+8PT)/PT:</b>	<b>Normal: &lt; OR = 0.050 Affected: &gt; OR = 0.080</b>
	<b>16alpha-OH-DHEA/Estriol:</b>	<b>Normal: &lt; OR = 2.60 Affected: &gt; OR = 5.80</b>
	<b>8-Estriol: 7-PT: 8-PT: Pregnanetriol (PT): 16alpha-OH-DHEA: Estriol: Pregnanediol:</b>	<b>&lt;2 mcg/L &lt;5 mcg/L &lt;5 mcg/L &gt;200 mcg/L &gt;100 mcg/L &gt;400 mcg/L &gt;1000 mcg/L</b>
Methodology:	<b>Gas Chromatography Mass Spectrometry</b>	
Assay Category:	<b>Laboratory Developed Test</b>	
Performing Site:	<b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>	

<b>Rett Syndrome Rearrangement (Deletion or Duplication)</b>	
Clinical Significance:	MECP2 deletions and duplications are associated with a broad spectrum of clinical phenotypes that range from mild learning disabilities and autism to mental retardation with spasticity in females. Duplications of the MECP2 region have been found in some males with severe mental retardation.
<b>Effective Date:</b>	<b>September 14, 2009</b>
Test Code:	<b>16662</b>
CPT Code(s):	<b>83891, 83900, 83901 (x9), 83909, 83912</b>
Specimen Requirements:	<b>5 mL EDTA (lavender-top) whole blood</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room Temperature and Refrigerated: 8 days Frozen: Unacceptable</b>
Reference Ranges:	<b>With report</b>
Methodology:	<b>Semi-Quantitative Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<b>Antimicrobial Level, Ethambutol, HPLC</b>	
Clinical Significance:	Ethambutol inhibits cell-wall synthesis in <i>M. tuberculosis</i> and other slow-growing mycobacteria, including <i>M. avium</i> , by inhibiting arabinosyltransferase, an enzyme employed during the synthesis of arabinoglycans found in mycobacterial cell-walls. Ethambutol blood levels should be monitored to ensure that adequate amount of the drug is administered, absorbed and subsequently excreted from the body to prevent drug build-up that might lead to toxic side effects.
<b>Effective Date:</b>	<b>October 5, 2009</b>
Test Code:	<b>16844</b>
CPT Code:	<b>80299</b>
Specimen Requirements:	<b>2 mL serum</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Unacceptable Frozen: 14 days</b>
Reference Ranges:	<b>&lt;0.1 ug/mL</b>
Methodology:	<b>High Performance Liquid Chromatography</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Focus Diagnostics, Inc.

## Specialty Redirects

<b>Selenium, Random Urine</b>				
Clinical Significance:	Selenium is considered an essential trace element. It enters the food chain through plants. Selenium plays an important role in the control of thyroid hormone metabolism. Selenium deficiency may cause reduced growth rates, owing to a feedback response, which lowers tri-iodothyronine-mediated synthesis of growth hormone in the pituitary, while a combined deficiency of selenium and iodine exacerbates hypothyroidism. Selenium is important for proper reproductive performance.			
Effective Date:	<b>October 12, 2009</b>			
Test Code :	<b>16867</b>			
CPT Code(s) :	<b>84255, 82570</b>			
Specimen Requirements:	<b>7 mL random urine Avoid worksite collection.</b>			
Transport Temperature:	<b>Room temperature</b>			
Specimen Stability:	<b>Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days</b>			
Reference Ranges:	<b>Selenium Urine</b>	<b>&lt;160 ug/L</b>		
	<b>Creatinine Urine</b>	<b>0-6 months</b>	<b>2.0-32.0</b>	<b>mg/dL</b>
		<b>7-11 months</b>	<b>2.0-36.0</b>	<b>mg/dL</b>
<b>1-2 years</b>		<b>2.0-128.0</b>	<b>mg/dL</b>	
<b>3-8 years</b>		<b>2.0-149.0</b>	<b>mg/dL</b>	
<b>9-12 years</b>		<b>2.0-183.0</b>	<b>mg/dL</b>	
<b>&gt;12 years: Male:</b>		<b>20.0-370.0</b>	<b>mg/dL</b>	
<b>Female:</b>	<b>20.0-320.0</b>	<b>mg/dL</b>		
<b>Selenium/Creatinine Ratio</b>	<b>&lt;140.0 ug/g creat</b>			
Methodology:	<b>Inductively Coupled Plasma/Mass Spectrometry ICP/MS</b>			
Assay Category:	<b>Laboratory Developed Test</b>			
Performing Site:	<b>Specialty Laboratories</b>			

<b>Selenium, 24 hour Urine</b>	
Effective Date:	<b>October 12, 2009</b>
Test Code :	<b>16866</b>
CPT Code(s) :	<b>84255</b>
Specimen Requirements:	<b>2 mL (minimum 1 mL) aliquot of a 24-hour urine Collect urine in an acid washed plastic container. Acidify with hydrochloric or nitric acid (1 mL of concentrated acid for each 100 mL urine). Avoid worksite collection.</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature 5 days Refrigerated: 14 days Frozen: 30 days</b>
Reference Ranges:	<b>&lt;240 ug/24hr</b>
Methodology:	<b>Inductively Coupled Plasma Mass Spectrophotometry ICP/MS</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	<b>Specialty Laboratories</b>

## Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

<b>Cystic Fibrosis Screen</b>	
Clinical Significance:	General screen for carrier status and assessment of CF risk. This test will identify approximately 90% of Cystic Fibrosis (CF) mutations in the Caucasian population, and 97% in the Ashkenazi Jewish population.
<b>Effective Date:</b>	<b>October 12, 2009</b>
Test Code:	<b>10458</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test code and CPU interface mapping.

<b>Corticotropin Releasing Hormone</b>																			
Clinical Significance:	CRH concentrations are increased in the last two trimesters of pregnancy due to placental production and in patients with Cushing's syndrome due to ectopic production of CRH.																		
<b>Effective Date:</b>	<b>October 19, 2009</b>																		
Test Code:	36589																		
Specimen Requirements:	<b>3 mL sodium heparin (green-top) plasma</b> <b>PTH-related protein (special collection tube) is not acceptable</b>																		
Reference Ranges:	<table border="1"> <tbody> <tr> <td><b>Adults:</b></td> <td></td> <td><b>&lt; or = 42</b></td> <td>pg/mL</td> </tr> <tr> <td rowspan="3">Pregnancy</td> <td>First Trimester</td> <td><b>&lt;or= 40</b></td> <td>pg/mL</td> </tr> <tr> <td>Second Trimester</td> <td><b>&lt;or= 153</b></td> <td>pg/mL</td> </tr> <tr> <td>Third Trimester</td> <td><b>&lt;or= 847</b></td> <td>pg/mL</td> </tr> <tr> <td>Pediatric:</td> <td>Cord Blood</td> <td><b>&lt;or= 338</b></td> <td>pg/mL</td> </tr> </tbody> </table> <p>Pregnancy and cord blood reference ranges from J.Clinical Endocrinology and Metabolism, 1986: Vol.63: pp.1199-1203.</p>	<b>Adults:</b>		<b>&lt; or = 42</b>	pg/mL	Pregnancy	First Trimester	<b>&lt;or= 40</b>	pg/mL	Second Trimester	<b>&lt;or= 153</b>	pg/mL	Third Trimester	<b>&lt;or= 847</b>	pg/mL	Pediatric:	Cord Blood	<b>&lt;or= 338</b>	pg/mL
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Pediatric:	Cord Blood	<b>&lt;or= 338</b>	pg/mL																
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano																		
Additional Information:	Update specimen requirements, test code and reference range.																		

<b>Growth Hormone Releasing Hormone</b>							
Clinical Significance:	In more than 99% of patients with acromegaly there is hypersecretion of Growth Hormone due to a primary pituitary tumor. The remaining cases result from GHRH hypersecretion due to hypothalamic or peripheral tumors or rarely, due to neuroendocrine tumors.						
<b>Effective Date:</b>	<b>October 19, 2009</b>						
Test Code:	<b>37557</b>						
Specimen Requirements:	<b>4 mL sodium heparin (green-top) plasma</b> <b>PTH-related protein (special collection tube) is not acceptable</b>						
Reference Ranges:	<table border="1"> <tbody> <tr> <td><b>Adult : Males and Females</b></td> <td><b>&lt;or = 41</b></td> <td>pg/mL</td> </tr> <tr> <td>Pediatric: 4-14 years</td> <td>6.8-19.0</td> <td>pg/mL</td> </tr> </tbody> </table> <p>Pediatric data from Horm Metabol Res (1987) 19:434-436.</p>	<b>Adult : Males and Females</b>	<b>&lt;or = 41</b>	pg/mL	Pediatric: 4-14 years	6.8-19.0	pg/mL
<b>Adult : Males and Females</b>	<b>&lt;or = 41</b>	pg/mL					
Pediatric: 4-14 years	6.8-19.0	pg/mL					
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano						
Additional Information:	Update specimen requirements, test code and Adult reference range.						

<b>Thyrotropin Releasing Hormone</b>	
Clinical Significance:	TRH is used in evaluating patients with dysfunction of the hypothalamic-pituitary-thyroid gland axis. TRH is especially useful in patients with hyperthyroidism and inappropriate secretion of TSH such as due to pituitary tumors.
<b>Effective Date:</b>	<b>October 19, 2009</b>
Test Code:	<b>36588</b>
Specimen Requirements:	2 mL <b>sodium heparin (green-top)</b> plasma <b>PTH-related protein (special collection tube) is not acceptable</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements.

### Discontinued Tests

<b>Selenium, Urine</b>	
<b>Effective Date:</b>	<b>October 12, 2009</b>
Test Code:	8829
Additional Information:	This test will be discontinued. The recommended alternative is 16866 Selenium, 24 hour Urine or 16867 Selenium, Random Urine performed at Specialty Laboratories.

AM=6am-12pm, PM=12pm-6pm, E=6pm-12am, Next Day=12am-6am Pacific Time