



# LABORATORY UPDATE

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## Routine Testing

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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.

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

### Test Changes

<b>Amylase</b>	
Clinical Significance:	The most common cause of elevation of serum amylase is inflammation of the pancreas (pancreatitis). This elevation may be blunted by Citrates, IV Dextrose, Oxalates and Saquinavir.
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	243
Specimen Stability:	<b>Room temperature: 7 days</b> <b>Refrigerated: 7 days</b> <b>Frozen: 30 days</b>
Additional Information:	Update stability.
<b>Childhood Allergy (Food and Environmental) Profile</b>	
Effective Date:	<b>June 2, 2008</b>
Order Code:	10659
CPT Code(s):	<b>86003 x 15 Specific IgE</b> , 82785 Total IgE
Includes:	<b>d1 D. pteronyssinus</b> d2 D. farinae e1 Cat dander e5 Dog dander f1 Egg white f2 Milk f3 Codfish f4 Wheat f13 Peanuts f14 Soybean <b>f24 Shrimp</b> <b>f256 Walnut</b> i6 Cockroach <b>m2 Cladosporium herbarum</b> m6 <i>Alternaria alternata</i> Total IgE
Specimen Requirements:	5 mL serum
Additional Information	<b>Updated profile components.</b> The Childhood Allergy (Food and Environmental) Profile and the Food Profile have been updated to better reflect the prevalent allergens most likely to cause an allergic response in potentially affected individuals. Please note: Any profile component may be ordered separately.

<b>Food Allergy Profile</b>	
Effective Date:	<b>June 2, 2008</b>
Order Code:	10715
CPT Codes:	<b>86003 x 12 Specific IgE</b>
Includes:	f1 Egg white f2 Milk f3 Codfish f4 Wheat f8 Corn <b>f10 Sesame Seed</b> f13 Peanuts f14 Soybean f24 Shrimp f207 Clam f256 Walnut f338 Scallop
Specimen Requirements:	5 mL serum
Additional Information:	<b>Updated profile components.</b> The Childhood Allergy (Food and Environmental) Profile and the Food Profile have been updated to better reflect the prevalent allergens most likely to cause an allergic response in potentially affected individuals. Please note: Any profile component may be ordered separately.

<b>HIV-1 RNA, Quantitative bDNA (v3.0)</b>	
Clinical Significance:	Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA, quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy.
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	29273
Reference Range:	Copies/mL (Version 3.0): <75 copies/mL <b>LogCopies/mL (Version 3.0): &lt;1.88</b> Log copies/mL
Additional Information:	Update reference range. Please note: This test is included in the following group codes: 10596-HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype

<b>Lipase</b>	
Clinical Significance:	Confirmatory evidence for diagnosis of pancreatitis
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	606
Specimen Stability:	<b>Room temperature: 4 days</b> <b>Refrigerated: 7 days</b> <b>Frozen: 21 days</b>
Additional Information:	Update stability.

## Redirects

<b>Adenosine Deaminase, Blood</b>	
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	38409
Assay Category:	<b>Research Use Only</b>
Additional Information:	<a href="#">This test previously performed at Mayo Medical Laboratories, will now be performed at Quest Diagnostics Nichols Institute, Chantilly.</a>

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, San Juan Capistrano & Chantilly**

**New Tests**

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

<b>Lipoprotein Fractionation Panel 2, Ion Mobility</b>			
Clinical Significance:	There is a correlation between increased risk of premature heart disease with decreasing size of LDL particles. Ion Mobility offers the only direct measurement of lipoprotein particle size and concentration for each lipoprotein from HDL3 to large VLDL.		
Effective Date:	Available now		
Test Code:	19979		
CPT Code(s):	83704		
Specimen Requirements:	1 mL serum, fasting preferred		
Transport Temperature:	Refrigerated		
Specimen Stability:	Room temperature: 24 hours Refrigerated: 7 days Frozen: 30 days		
Reference Ranges:	LDL Particles, Total:	Males: 508-1279 Females: 272-1181	nmol/L nmol/L
	LDL Particle Size:	Males: 215.4-230.9 Females: 215.4-232.9	Angstrom Angstrom
	LDL Phenotype:	A	Pattern
	LDL I large:	Males: 48-164 Females: 51-186	nmol/L nmol/L
	LDL II large:	Males: 200-596 Females: 91-574	nmol/L nmol/L
	LDL III small:	Males: 136-627 Females: 82-442	nmol/L nmol/L
	LDL IV small:	Males: 38-164 Females: 33-129	nmol/L nmol/L
	HDL 2b large:	Males: 169-1153 Females: 384-1616	nmol/L nmol/L
	HDL 2a intermediate:	Males: 1174-3744 Females: 903-3779	nmol/L nmol/L
	HDL 3 small:	Males: 613-3344 Females: 475-4244	nmol/L nmol/L
	IDL 1 large:	Males: 11-41 Females: 10-38	nmol/L nmol/L
	IDL 2 small:	Males: 12-59 Females: 11-48	nmol/L nmol/L
	VLDL large:	Males: 0.2-2.5 Females: 0.2-1.8	nmol/L nmol/L
	VLDL intermediate:	Males: 1.1-7.3 Females: 1.0-5.7	nmol/L nmol/L
	VLDL small:	Males: 5.0-23.0 Females: 5.8-26.6	nmol/L nmol/L

	<p><b>Comments:</b>  <b>LDL particles are measured in four fractions: LDL I and II, larger, more buoyant particles, and LDL III and IV, smaller, more dense particles. LDL Pattern A and Pattern B are characterized by LDL peak particle diameter greater or less than 215.4 A, respectively.</b>  <b>HDL particles are measured in three fractions: HDL 2b, large buoyant particles that are most strongly correlated with HDL cholesterol level, and HDL 2a and 3, small denser HDL particles.</b>  <b>IDL and VLDL fractions: Triglyceride-rich lipoprotein particles are measured in 5 fractions of increasing size (IDL1 and 2, and small, intermediate and large VLDL). Higher triglyceride levels are associated with increased numbers of larger particles. The smaller fractions are enriched in remnant particles.</b></p>		
Methodology:	<b>Calculated, Ion Mobility</b>		
Assay Category:	<b>Laboratory Developed Test</b>		
<b>Factor VIII Activity, Clotting with Reflex to Chromogenic Method</b>			
<i>*Includes: Factor VIII Activity, Clotting * Factor VIII Activity, Chromogenic</i>			
Clinical Significance:	In the presence of a suspected lupus anticoagulant, the one-stage APTT based assay may yield false low FVIII values consistent with "hemophilia" whereas the chromogenic assay avoids lupus anticoagulant interference and yields accurate FVIII results.		
<b>Effective Date:</b>	<b>May 5, 2008</b>		
Test Code:	<b>70050</b>		
CPT Code(s):	<b>85240</b>		
Specimen Requirements:	<b>3 mL 3.2% sodium citrate (lt. blue-top) plasma</b>		
Transport Temperature:	<b>Frozen *Do not thaw</b>		
Specimen Stability:	<b>Room temperature and Refrigerated: Unacceptable Frozen: 14 days -70 Degrees: 1 year</b>		
Reference Ranges:	<b>Coag Factor VIII Activity:</b>	<b>50-180</b>	<b>% normal</b>
	<b>Factor VIII, Chromogenic:</b>	<b>65-179</b>	<b>% activity</b>
Methodology:	<b>Photometric Clot Detection, Chromogenic Assay</b>		
Assay Category:	<b>FDA Approved/Cleared</b>		
Additional Information:	If the Factor VIII Activity, Clotting result is <or=20, Factor VIII Activity, Chromogenic (CPT Code(s): 85240) will be performed at an additional charge.		

<b>Heparin Induced Platelet Antibody with Reflex to SRA</b>							
Clinical Significance:	Diagnosis of Heparin-Induced Thrombocytopenia is based on clinical criteria but serologic confirmation is often necessary. The ELISA assay measures the heparin-pf-4 antibody complex to IgG, IgM and IgA. When the ELISA test is positive, testing by the Serotonin Release Assay (a platelet activation assay) is more predictive of thrombocytopenia and thrombosis and tests only IgG Heparin-PF4 antibodies. It is usually positive when the ELISA O.D. reading is > 1.0						
<b>Effective Date:</b>	<b>May 5, 2008</b>						
Test Code:	<b>15334</b>						
CPT Code(s):	<b>86022</b>						
Specimen Requirements:	<b>1 mL serum no additive (red-top) Separate from cells as soon as possible after clotting.</b>						
Transport Temperature:	<b>Frozen</b>						
Specimen Stability:	<b>Room temperature: 24 hours Refrigerated: 48 hours Frozen: 30 days</b>						
Reference Ranges:	<table border="0"> <tr> <td><b>Heparin-Induced PLT AB:</b></td> <td><b>Negative</b></td> </tr> <tr> <td><b>Patient O.D.:</b></td> <td><b>Not applicable</b></td> </tr> <tr> <td><b>Serotonin Release Assay:</b></td> <td><b>Less Than 20 % release</b></td> </tr> </table> <p>A sample is considered negative if there is: &lt;20% release. This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.</p>	<b>Heparin-Induced PLT AB:</b>	<b>Negative</b>	<b>Patient O.D.:</b>	<b>Not applicable</b>	<b>Serotonin Release Assay:</b>	<b>Less Than 20 % release</b>
<b>Heparin-Induced PLT AB:</b>	<b>Negative</b>						
<b>Patient O.D.:</b>	<b>Not applicable</b>						
<b>Serotonin Release Assay:</b>	<b>Less Than 20 % release</b>						
Methodology:	<b>Immunoassay, Radiobinding 14C Serotonin Radiolabel</b>						
Assay Category:	<b>Heparin-Induced Platelet Antibody: FDA Approved/Cleared Serotonin Release Assay (SRA): ASR Class 1</b>						
Additional Information:	If the Heparin-Induced PLT AB result is positive, the Serotonin Release Assay (CPT Code(s): 86022) will be performed at an additional charge.						

**Adenovirus DNA, Quantitative Real-Time PCR**

Clinical Significance:	This test is used to determine the presence of Adenovirus in a patient's specimen. Organisms may be detected by PCR prior to diagnosis by immunological methods. PCR provides more rapid results than other methods, including culture.
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	<b>19726</b>
CPT Code(s):	<b>87799</b>
Specimen Requirements:	<b>0.85 mL EDTA (lavender-top) or ACD whole blood, serum, EDTA (lavender-top) or ACD plasma, CSF, BAL, sputum, urine, respiratory specimen in M4 media</b>
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days (Do not freeze whole blood)</b>
Reference Ranges:	<b>Adenovirus DNA, QN PCR &lt;500 copies/mL</b> <b>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</b>
Methodology:	<b>Real-Time Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	This test is performed at Focus Diagnostics.

**Herpesvirus 6 DNA, Quantitative Real-Time PCR**

Clinical Significance:	This test is used to determine the presence of HHV-6 DNA in patients' specimens. Organisms may be detected by PCR prior to detection by immunological methods. PCR provides more rapid results than other methods, including culture.
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	<b>19723</b>
CPT Code(s):	<b>87533</b>
Specimen Requirements:	<b>1 mL EDTA (lavender-top) or ACD whole blood, serum, EDTA (lavender-top) or ACD plasma, or CSF</b>
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days (Do not freeze whole blood)</b>
Reference Ranges:	<b>Herpes Virus 6 DNA, QN PCR: &lt;500 copies/mL</b> <b>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</b>
Methodology:	<b>Real-Time Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	This test is performed at Focus Diagnostics.

<b>Fentanyl and Norfentanyl, Serum</b>	
Clinical Significance:	Fentanyles are extensively used for anesthesia and analgesia. There are fentanyl transdermal patches available that are used in chronic pain management.
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	<b>40065</b>
CPT Code(s):	<b>83925</b>
Specimen Requirements:	<b>2 mL serum (red top no additive)</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature, Refrigerated and Frozen:14 days</b>
Reference Ranges:	<b>Fentanyl: 1.0-3.0 ng/mL</b> <b>Norfentanyl: by report</b>
Methodology:	<b>Tandem Mass Spectroscopy</b>
Assay Category:	<b>Laboratory Developed Test</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>5704-C4 and C3 Complement Group</b>	
Clinical Significance:	Decreased concentrations of both C3 and C4 suggest activation of the classical pathway whereas decreased concentration of just C3 suggests activation of the alternative pathway. Both complement factors may be used to monitor activity of patients with systemic lupus erythematosus (SLE) and immune complex-induced vasculitis
<b>Effective Date:</b>	<b>June 9, 2008</b>
Specimen Stability:	1 mL serum <b>Please note: plasma is not an acceptable specimen type.</b>
Additional Information:	Update acceptable specimen types. Please note these codes are included in the following group codes: 6431-Complement Profile; 37859- C3, C4, and Total (CH50); 37491-Lupus (SLE) Panel; 10716-Lupus (12) Panel; 11267-Circulating Immune Complex; 17725-Lupus Activity Panel 2; 7159-Complement Activation Panel; 37541-Angioedema Panel; 35071-C4 Activation Panel; 17706-Angioedema Panel, Hereditary, Comprehensive.

<b>Cortisone, Serum</b>	
Clinical Significance:	Measurement of both Free Cortisol and Cortisone are useful in diagnosing patients with low-renin hypertension caused by apparent mineralocorticoid excess. This may be due to either an inherited defect in 11HSD2 enzyme or an acquired inhibitor of the enzyme by such compounds as glycyrrhizic acid, a component of natural licorice.
<b>Effective Date:</b>	<b>June 9, 2008</b>
Test Code:	37098
Specimen Requirements:	1 mL no additive (red-top) serum <b>Please note PPT Potassium EDTA (white top) plasma is acceptable, SST red-top tubes are not acceptable</b>
Additional Information:	Update acceptable specimen types.

<b>37077-Cortisol, Free and Total, LC/MS/MS</b>		
<b>36423-Cortisol, Free, LC/MS/MS</b>		
Clinical Significance:	Free Cortisol is useful in the detection of patients with Cushing's syndrome for whom Free Cortisol concentrations are elevated.	
<b>Effective Date:</b>	<b>June 9, 2008</b>	
Specimen Requirements:	2 mL no additive (red-top) serum <b>Please note sodium heparin (green-top) plasma, SST (red-top) and no additive (royal blue-top) serum are not acceptable.</b>	
Additional Information:	Update acceptable specimen types.	
<b>Cortisol Response to ACTH Stimulation, Serum</b>		
Clinical Significance:	The cortisol response to infusion of synthetic ACTH is useful in diagnosing patients with adrenal insufficiency (Addison's disease).	
<b>Effective Date:</b>	<b>June 9, 2008</b>	
<i>Former Test Name:</i>	<i>Cortisol Stimulation by Adrenocorticotropin Hormone (ACTH), Serum</i>	
Test Code:	38149	
Specimen Requirements:	1 mL [x4] no additive (red-top) serum <b>Please note EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (green-top), sodium fluoride (gray-top), 3.2% sodium citrate (lt. blue-top), ACD solution B (yellow-top), potassium oxalate (gray-top) plasma and SST (red-top) serum are not acceptable.</b>	
Additional Information:	Update test name and acceptable specimen types.	
<b>Cystic Fibrosis D1152H Mutation Analysis</b>		
Clinical Significance:	This test detects a mutation primarily present in Ashkenazi-Jewish individuals. It can be detected in asymptomatic carriers as well as symptomatic (mild) CF patients.	
<b>Effective Date:</b>	<b>June 9, 2008</b>	
Test Code:	15335	
CPT Code(s):	83891, 83898, <b>83892 (x2), 83909, 83914</b> , 83912	
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood Whole blood in the following containers is also acceptable: ACD solution A (yellow-top), <b>ACD solution B (yellow-top), Lithium heparin (green-top), Sodium heparin (green-top)</b>	
Methodology:	Polymerase Chain Reaction, <b>Single Nucleotide Primer Extension</b>	
Assay Category:	<b>Laboratory Developed Test</b>	
Additional Information:	Update methodology, CPT coding, acceptable specimen type, assay category, and always message.	
<b>Dihydropyrimidine Dehydrogenase (DPD)</b>		
Clinical Significance:	This test identifies individuals who are at risk to experience severe adverse effects when treated with pyrimidine-based chemotherapeutic agents, such as 5-fluorouracil (5-FU). It also confirms clinical diagnosis of DPD deficiency.	
<b>Effective Date:</b>	<b>June 9, 2008</b>	
Test Code:	15538	
CPT Code(s):	83891, 83898, <b>83892 (x2), 83909, 83914</b> , 83912	
Specimen Requirements:	5 mL EDTA (lavender-top) or ACD solution B (yellow-top) whole blood. <b>Please note EDTA (royal blue-top) whole blood is not acceptable. ACD solution A (yellow-top) whole blood is acceptable.</b>	
Methodology:	Polymerase Chain Reaction, <b>Single Nucleotide Primer Extension</b>	
Assay Category:	<b>Laboratory Developed Test</b>	
Additional Information:	Update methodology, CPT coding, acceptable specimen type, assay category, and always message.	
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<b>37097-Epidermal Antibodies with Reflex to Titers 266-Striated Muscle Antibody w/Refl to Titer</b>	
<b>Effective Date:</b>	<b>June 9, 2008</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature: 4 days Refrigerated: 14 days Frozen: 30 days; -70 degrees: Indefinite</b>
Additional Information:	Update transport temperature and stability. Please note this change also affects the following group codes. Please note these tests are included in the following group codes: 7550-Myasthenia Gravis Panel 1; 10211-Myasthenia Gravis Panel 3; 37491-Lupus (SLE) Panel; 11306-Lambert-Eaton Syndrome Antibody Panel; 19873-Autoimmune Hepatitis Diagnostic Panel; 19876-Primary Biliary Cirrhosis Diagnostic Panel, Comprehensive.

<b>Epidermal Growth Factor Receptor (EGFR), ELISA</b>	
Clinical Significance:	Patients with high expression of EGFR are most likely to respond to newly developed antineoplastic drugs that target this receptor. These drugs slow or inhibit the ability of metastases and tumors to grow and spread.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	10920
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days <b>Frozen: 21 days</b>
Additional Information:	Update frozen stability.

<b>Factor XI Jewish Mutation</b>	
Clinical Significance:	This test identifies Ashkenazi-Jewish individuals who are at risk of having prolonged bleeding incidents (especially during surgery) due to mutations in the Factor XI gene.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	16023
CPT Code(s):	83891, <b>83898</b> , 83892 (x2), 83909, <b>83914</b> , 83912
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood ACD solution B (yellow-top), Sodium heparin (green-top), or <b>ACD solution A (yellow-top) whole blood, bone marrow or tissue biopsy and amniotic fluid, are also acceptable specimen types.</b> <b>Please note: EDTA (royal blue-top) whole blood is not acceptable.</b>
Methodology:	Polymerase Chain Reaction, <b>Single Nucleotide Primer Extension</b>
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update acceptable specimen types, CPT coding, methodology, assay category and always message.

<b>1777-Protein C Activity 8754-Protein C Activity with Reflex to Protein C Antigen</b>	
Clinical Significance:	The Protein C Activity done by a RVV type matrix coagulation assay is more sensitive to subclinical vitamin K deficiency, hepatic failure, coumadin and DIC. Some genetic mutations of protein C will be missed by the chromogenic assay which will be satisfactorily detected with the protein C clottable assay system. Alternatively, chromogenic assay may be more reliable to measure half-life and recovery of protein C concentrates.
Effective Date:	<b>June 16, 2008</b>
Specimen Stability:	<b>Room temperature and refrigerated: Unacceptable Frozen: Frozen Only; -70 Degrees: 1 year</b>
Additional Information:	Update specimen stability. Please note these tests are included in the following group codes: 39457-Protein C & Protein S, Functional; 11051-Thrombosis Panel; 11327-Thrombophilia Screen, Inherited; 8757-Protein C Activity and Antigen; 7942-Protein C and S Activity with Reflex to Protein C and/or S Antigen.

### Focus Diagnostics Redirects

<b>Lyme Disease DNA, Real-Time PCR, Blood</b>	
Clinical Significance:	Lyme disease is caused by a bacterium <i>Borrelia burgdorferi</i> and is transmitted by ticks. PCR is highly specific for identification of the organism.
Effective Date:	<b>June 16, 2008</b>
Test Code:	34287
Specimen Requirements:	<b>1 mL</b> EDTA (lavender-top), ACD solution A (yellow-top), or ACD solution B (yellow-top) whole blood ( <b>minimum 0.5 mL</b> )
Transport Temperature:	Refrigerated
Specimen Stability:	<b>Room temperature: 2 days</b> Refrigerated: 7 days Frozen: Unacceptable
Reference Ranges:	Lyme Disease DNA, Blood: Not detected <b>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</b> <b>This test is performed pursuant to a license with Roche Molecular Systems, Inc.</b>
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update sample volume, stability, always message, and assay category. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

<b>Lyme Disease DNA, Real-Time PCR, CSF or Synovial Fluid</b>	
Clinical Significance:	Lyme disease is caused by a bacterium <i>Borrelia burgdorferi</i> and is transmitted by ticks. PCR is highly specific for identification of the organism.
Effective Date:	<b>June 16, 2008</b>
Test Code:	30297
Specimen Requirements:	1 mL CSF or synovial fluid ( <b>minimum 0.5 mL</b> )
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours <b>Refrigerated: 7 days</b> <b>Frozen: 30 days</b>
Reference Ranges:	<b>Source:</b> Lyme Disease DNA,CSF/SF: Not detected <b>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</b> <b>This test is performed pursuant to a license with Roche Molecular Systems, Inc.</b>
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update stability, always message, assay category and add source analyte. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

<b>Lyme Disease DNA, Real-Time PCR, Tick</b>	
Clinical Significance:	Certain species of ticks have been identified as vectors of <i>Borrelia burgdorferi</i> , the causative agent for Lyme disease. This information may be useful in determining risk of exposure.
Effective Date:	<b>June 16, 2008</b>
Test Code:	30280
Specimen Requirements:	Deer tick in 70% ethanol or in wet tissue submitted in sterile screw cap container Specimens submitted in formalin will not be accepted.
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	Room temperature, Refrigerated or Frozen: 14 days
Reference Ranges:	Lyme Disease DNA, Tick: Not detected <b>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</b> <b>This test is performed pursuant to a license with Roche Molecular Systems, Inc.</b>
Methodology:	<b>Real-Time Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update transport temperature, always message, methodology, and assay category. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

<b>Lyme Disease DNA, Real-Time PCR, Urine</b>	
Clinical Significance:	The assay is used to detect the presence of <i>Borrelia burgdorferi</i> DNA in a urine sample. Diagnosis of Lyme disease should not rely solely upon the result of a PCR assay. Patients with a positive PCR result should be evaluated with other tests to establish the diagnosis of the disease.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	36181
Specimen Requirements:	<b>4 mL</b> random urine in sterile screw cap container ( <b>minimum 2 mL</b> )
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room temperature: 2 days</b> <b>Refrigerated: 7 days</b> Frozen: 30 days
Reference Ranges:	Lyme Disease DNA, Urine: Not detected <b>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</b> <b>This test is performed pursuant to a license with Roche Molecular Systems, Inc.</b>
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update sample volume, acceptable sample types, transport temperature, stability, always message and assay category. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

<b>Tick (and Other Arthropods) Identification</b>	
Clinical Significance:	Arthropods/insects may be vectors of disease and may cause infestations of skin, hair, and mucous membranes. Diagnosis of a disease or infestation may be achieved by recovery and identification of the intact arthropod/ insect.
<b>Effective Date:</b>	<b>June 16, 2008</b>
<i>Former Test Code:</i>	37399
Test Code:	<b>3946</b>
Specimen Requirements:	<b>Alcohol Preserved Tick, Insect, Larva, Etc.</b> in sterile screw cap container <b>Place specimen in 70% alcohol as soon as possible. Submit in a screw-capped container, ensuring that the cap is as tight as possible to avoid leakage in transit.</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>For preserved samples:</b> Room temperature: Indefinite Refrigerated: Indefinite <b>Frozen: Unacceptable</b>
Reference Ranges:	Not applicable
Methodology:	<b>Microscopic and Macroscopic Examination and Conventional Identification Techniques</b>
Assay Category:	Laboratory Developed Test
Additional Information:	Update test code, specimen requirements, transport temperature, stability, and methodology <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

<b>Tick ID w/Reflex to Lyme Disease DNA</b>	
Clinical Significance:	Lyme disease borreliae ( <i>Borrelia burgdorferi</i> ) are transmitted to humans most commonly by Ixodes ticks. During a blood meal, <i>B. burgdorferi</i> migrate to the salivary glands where transmission to humans occurs, generally after at least 36 hours of attachment. Ticks with the potential of carrying <i>B. burgdorferi</i> may be tested by molecular methods to assess the risk of transmission.
<b>Effective Date:</b>	<b>June 16, 2008</b>
<i>Former Test Name:</i>	<i>Tick/Arthropods ID w/Reflex to Lyme Disease DNA, Tick</i>
Test Code:	10710
CPT Code(s):	87168
Specimen Requirements:	<b>Tick in 70% ethanol</b> submitted in sterile screw cap container <b>Do NOT send live ticks. Do not submit in formalin. Frozen ticks will be rejected.</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: Unacceptable
Reference Ranges:	<b>Tick ID: No range</b> Lyme Disease DNA, Tick: Not detected <b>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</b> <b>This test is performed pursuant to a license with Roche Molecular Systems, Inc.</b>
Methodology:	<b>Microscopy with reflex to Polymerase Chain reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Additional Information:	Update test and result name, specimen requirements, transport temperature, reference range, always message and assay category. If <i>Ixodes scapularis</i> , <i>Ixodes pacificus</i> <i>Ixodes angustus</i> <i>Ixodes spinipalis</i> <i>Dermacentor variabilis</i> , <i>Dermacentor albipictus</i> , or <i>Amblyomma americanum</i> is identified then Lyme Disease DNA (CPT code(s): 87476) will be performed at an additional charge. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

## Focus Diagnostics

### Test Changes

<b><i>E. coli</i>, Pathogenicity Study For Diarrhea, CC</b>	
Clinical Significance:	This 4 test panel includes tests for enteroinvasive, enteropathogenic/enteroadherent, enterohemorrhagic, and enterotoxigenic <i>E. coli</i> . See individual assays for each test description.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	<b>17372</b>
Specimen Requirements:	Pure culture of <i>E. coli</i> safely contained in a double walled container <b>Stool is not an acceptable specimen type.</b>
Additional Information	Update acceptable specimen type.
<b><i>E. coli</i>, Enteroinvasive (EIEC), CC</b>	
Clinical Significance:	The term enteroinvasive <i>E. coli</i> (EIEC) is used to differentiate a small number of <i>E. coli</i> bioserotypes that can invade the intestinal mucosa and cause a dysentery-like syndrome similar to shigellosis. EIEC have a predilection for colonic mucosa causing an illness marked by fever, severe abdominal cramps, malaise, toxemia, and occasional early watery diarrhea followed by gross dysentery consisting of scanty stools of blood and mucus.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	<b>19586</b>
Specimen Requirements:	Pure culture of <i>E. coli</i> safely contained in a double walled container <b>Stool is not an acceptable specimen type.</b>
Additional Information	Update acceptable specimen type.
<b>Legionella DNA, QL Real Time PCR</b>	
Clinical Significance:	<i>Legionellae</i> are ubiquitous in environmental water sources and may cause sporadic as well as epidemic cases of atypical pneumonia after inhalation of contaminated water droplets. This assay detects and differentiates <i>Legionella pneumophila</i> and non- <i>pneumophila</i> <i>Legionella</i> species in patient respiratory specimens.
<b>Effective Date:</b>	<b>June 16, 2008</b>
Test Code:	<b>15062</b>
Specimen Requirements:	1 mL bronchial lavage/wash <b>or sputum</b> in sterile leak-proof container <b>OR Throat swab or Nasopharyngeal swab in Multi Microbe Media (M4) or V-C-M medium (green-cap) tube or equivalent (UTM)</b> <b>Please note: cultured organisms are not acceptable.</b> <b>Respiratory Samples in M4 Media: Use sterile vials containing 3 mL of sterile M4 media. If using swabs, use only sterile Dacron or rayon swabs or rayon swabs. Do NOT use calcium alginate swabs, as they may contain substances that inhibit PCR testing. Break applicator sticks off near the tip to permit tightening of the cap.</b> <b>Sputum: Collect in a sputum collection kit or a sterile, plastic container with a leak-proof cap.</b> <b>Bronchial Lavage: Collect in a sterile container with a leak-proof cap.</b>
Additional Information:	Update specimen requirements. <a href="#">This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Focus Diagnostics, Inc.</a>

## Specialty Laboratories

### Redirects

<b>Benzodiazepines, Serum</b>																													
Effective Date:	June 2, 2008																												
Former Test Code:	<a href="#">23096</a>																												
Test Code:	70071																												
Specimen Requirements:	2 mL (red top no additive) serum																												
Transport Temperature:	Refrigerated																												
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 5 days Frozen: 14 days																												
Reference Ranges:	<table> <tr> <td>Alprazolam:</td> <td>5-25 ng/mL</td> </tr> <tr> <td>Alpha-Hydroxyalprazolam:</td> <td>5-25 ng/mL</td> </tr> <tr> <td>Alpha-Hydroxytriazolam:</td> <td>5-20 ng/mL</td> </tr> <tr> <td>Chlordiazepoxide:</td> <td>100-3000 ng/mL</td> </tr> <tr> <td>Clonazepam:</td> <td>20-60 ng/mL</td> </tr> <tr> <td>Desalkylflurazepam:</td> <td>30-150 ng/mL</td> </tr> <tr> <td>Diazepam:</td> <td>100-1500 ng/mL</td> </tr> <tr> <td>Lorazepam:</td> <td>50-240 ng/mL</td> </tr> <tr> <td>Midazolam:</td> <td>50-600 ng/mL</td> </tr> <tr> <td>Norchlordiazepoxide:</td> <td>100-3000 ng/mL</td> </tr> <tr> <td>Nordiazepam:</td> <td>100-1500 ng/mL</td> </tr> <tr> <td>Oxazepam:</td> <td>200-500 ng/mL</td> </tr> <tr> <td>Temazepam:</td> <td>50-1000 ng/mL</td> </tr> <tr> <td>Triazolam:</td> <td>5-20 ng/mL</td> </tr> </table>	Alprazolam:	5-25 ng/mL	Alpha-Hydroxyalprazolam:	5-25 ng/mL	Alpha-Hydroxytriazolam:	5-20 ng/mL	Chlordiazepoxide:	100-3000 ng/mL	Clonazepam:	20-60 ng/mL	Desalkylflurazepam:	30-150 ng/mL	Diazepam:	100-1500 ng/mL	Lorazepam:	50-240 ng/mL	Midazolam:	50-600 ng/mL	Norchlordiazepoxide:	100-3000 ng/mL	Nordiazepam:	100-1500 ng/mL	Oxazepam:	200-500 ng/mL	Temazepam:	50-1000 ng/mL	Triazolam:	5-20 ng/mL
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Temazepam:	50-1000 ng/mL																												
Triazolam:	5-20 ng/mL																												
Methodology:	Tandem Mass Spectroscopy																												
Assay Category:	Laboratory Developed Test																												
Additional Information:	<a href="#">This test, previously performed at NMS Labs, will now be performed at Specialty Laboratories.</a>																												

<b>Clonazepam and 7-amino Clonazepam, Urine</b>					
Effective Date:	June 2, 2008				
Former Test Code:	<a href="#">3483</a>				
Test Code:	40064				
Specimen Requirements:	2 mL urine				
Specimen Stability:	Room temperature: 72 hours Refrigerated and Frozen :14 days				
Reference Ranges:	<table> <tr> <td colspan="2">By report</td> </tr> <tr> <td>Limit of quantitation:</td> <td>Clonazepam: &lt;5.0 ng/mL 7-amino Clonazepam: &lt;5.0 ng/mL</td> </tr> </table>	By report		Limit of quantitation:	Clonazepam: <5.0 ng/mL 7-amino Clonazepam: <5.0 ng/mL
By report					
Limit of quantitation:	Clonazepam: <5.0 ng/mL 7-amino Clonazepam: <5.0 ng/mL				
Methodology:	Tandem Mass Spectroscopy				
Assay Category:	Laboratory Developed Test				
Additional Information:	<a href="#">This test, previously performed at NMS Labs, will now be performed at Specialty Laboratories.</a>				

<b>Trazodone</b>	
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	4732
Specimen Requirements:	<b>1 mL serum (red top no additive)</b>
Specimen Stability:	<b>Room temperature: 7 days Frozen: 60 days</b>
Reference Ranges:	<b>800-1600 ng/mL</b>
Additional Information:	<a href="#">This test, previously performed at NMS Labs, will now be performed at Specialty Laboratories.</a>

<b>Isohemagglutinin Titer</b>							
<b>Effective Date:</b>	<b>May 5, 2008</b>						
Test Code:	29837						
CPT Code(s):	86886 (x3)						
Specimen Requirements:	<b>2 mL serum (red top no additive)</b>						
Transport Temperature:	<b>Refrigerated</b>						
Specimen Stability:	<b>Room temperature: Unacceptable Refrigerated: 7 days Frozen: 60 days</b>						
Reference Ranges:	<table border="0"> <tr> <td><b>Isohemagglutinin Titer (A1):</b></td> <td><b>&lt;1:2</b></td> </tr> <tr> <td><b>Isohemagglutinin Titer (A2):</b></td> <td><b>&lt;1:2</b></td> </tr> <tr> <td><b>Isohemagglutinin Titer (B):</b></td> <td><b>&lt;1:2</b></td> </tr> </table>	<b>Isohemagglutinin Titer (A1):</b>	<b>&lt;1:2</b>	<b>Isohemagglutinin Titer (A2):</b>	<b>&lt;1:2</b>	<b>Isohemagglutinin Titer (B):</b>	<b>&lt;1:2</b>
<b>Isohemagglutinin Titer (A1):</b>	<b>&lt;1:2</b>						
<b>Isohemagglutinin Titer (A2):</b>	<b>&lt;1:2</b>						
<b>Isohemagglutinin Titer (B):</b>	<b>&lt;1:2</b>						
Methodology:	<b>Hemagglutination</b>						
Assay Category:	<b>FDA Approved/Cleared</b>						
Additional Information:	This test is performed at Specialty Laboratories.						

### Discontinued Tests

<b>Isohemagglutinin Titer</b>	
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	14572
Additional Information :	This test will be discontinued. The recommended alternative is 29837 Isohemagglutinin Titer sent to Specialty Laboratories.

<b>Fentanyl and Norfentanyl Serum</b>	
<b>Effective Date:</b>	<b>June 2, 2008</b>
Test Code:	30324
Additional Information :	This test will be discontinued. The recommended alternative is 40065 Fentanyl and Norfentanyl, Serum sent to Specialty Laboratories.

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