



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.

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

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

New Tests

Lipid Panel with non-HDL Cholesterol	
Clinical Significance:	Non-HDL Cholesterol is a predictor of initial coronary heart disease (CHD), independent of levels of low-density lipoprotein (LDL)-cholesterol. Non-HDL Cholesterol has also been associated with recurrent episodes of angina pectoris and nonfatal myocardial infarction in patients with multivessel CHD.
Effective Date:	July 14, 2008
Test Code:	70083
CPT Code(s):	80061
Specimen Requirements:	3 mL serum Patient should fast 9-12 hours prior to collection.
Transport Temperature:	Room temperature
Reference Ranges:	Triglycerides See individual test
	Cholesterol, Total See individual test
	HDL-Cholesterol See individual test
	LDL-Cholesterol (calculated) See individual test
	Cholesterol/HDL Ratio (calculated) See individual test
	Non-HDL Cholesterol (calculated) See below
	To determine the appropriate reference interval for non-HDL cholesterol, the National Cholesterol Education Program (NCEP) recommends adding 30 mg/dL to the LDL cholesterol target goal for each designated level of risk. For example, if the LDL cholesterol target goal is less than 100 mg/dL in patients with stable CHD or in subjects with a CHD equivalent such as diabetes mellitus, the corresponding non-HDL cholesterol target goal would be less than 130 mg/dL.
Methodology:	See individual tests for methodologies
FDA Status:	FDA Approved/Cleared

Thyroid Cascading Reflex		
Clinical Significance:	The Thyroid Cascading Reflex order code that will act as an aid to physicians in the diagnosis of common adult thyroid disorders. The initial results of a TSH, 3 rd generation will determine further reflex orders of T-4, free, TPO Antibodies and T-3, free orders and provide an interpretation based upon the results of the reflexed tests.	
Effective Date:	July 14, 2008	
Test Code:	15102	
CPT Code:	84443 (see below)	
Specimen Requirements:	Preferred: 4 mL serum (minimum: 2 mL)	
Transport Temperature	Room Temperature	
Specimen Stability	Room Temperature	4 Days
	Refrigerated	7 Days
	Frozen	28 Days
Reference Range:	TSH, 3rd Generation	0.40-4.50 mIU/L
	T-4, Free	0.8-1.8 ng/dL
	Thyroid Peroxidase Antibodies	<35 IU/mL
	T-3, Free	230-420 pg/dL
Methodology:	Immunoassay	
FDA Status:	FDA Approved/Cleared	
Additional Information:	The Thyroid Cascading Reflex begins with a TSH. If the TSH result is abnormal, T-4, Free (CPT code(s): 84439) will be performed at an additional charge. If the TSH is elevated and the T-4, free is either normal or low, TPO antibodies (CPT code(s): 86376) will be performed at an additional charge. If the TSH is low and the T-4, free is either normal or low, T-3, Free (CPT code(s): 84481) will be performed at an additional charge. Note: The Thyroid Cascading Reflex will only be performed on patients aged 20 years or older. Orders on patients younger than 20 will have a TSH only performed.	

HIV Test Name Changes

Effective July 14, 2008, the HIV test names will be standardized to the names indicated in the table below.

Test Code:	Updated Test Name:
5233	HIV Antibody, HIV-1, Western Blot <i>This test should be ordered <u>ONLY</u> as a confirmation for a previously positive HIV screening test.</i>
19728	HIV Antibodies, HIV-1/2, EIA, with Reflexes
37694	HIV Antibodies, HIV-1/HIV-2, EIA with Reflex to HIV-1 Western Blot
10110	HIV Antibodies, HIV-1/HIV-2, Western Blot/Immunoblot
37708	HIV Antibody, HIV-1, Western Blot w/rfl to HIV-2, EIA w/rfl to Immunoblot

Test Changes

HDL Cholesterol	
Clinical Significance:	HDL Cholesterol is inversely related to the risk for cardiovascular disease. It increases following regular exercise, moderate alcohol consumption and with oral estrogen therapy. Decreased levels are associated with obesity, stress, cigarette smoking and diabetes mellitus.
Effective Date:	July 14, 2008
Test Code:	608
Reference Range:	Male
	Female
	<5 years: Reference Range Not Established
	5-14 years: 38-76 mg/dL
	15-19 years: 31-65 mg/dL
	> or = 20 years: > or = 46 mg/dL
Additional Information:	Update adult female reference range. This change also affect the following tests: 7600 Lipid Panel 14852 Lipid Panel with Reflex to Direct LDL 70083 Lipid Panel with non-HDL Cholesterol

Urine Electrophoresis Update

Effective July 15, 2008, the following Urine Electrophoresis tests will have the specimen requirement volumes standardized. The revised information is indicated in the table below:

Test Code	Test Name	Specimen Volume
750	Protein, Total And Protein Electrophoresis, Urine	Preferred Specimen Volume: 25mL Urine (No preservatives)
8525	Protein, Total And Protein Electrophoresis, Random Urine	
10263	Protein, Total And Protein Electrophoresis, Urine W/Refl	
2971	Protein, Total And Protein Electro, Rand Ur W/Scan	
1169	Protein, Total And Protein Electro, Urine W/Scan	
38944	Electrophoresis, Protein 24-Hour Urine And Immunofixation Studies	Minimum Specimen Volume: 10 mL

Redirects

Black Olive (Rf342) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP- Olive Black*</i>
Test Code:	38482
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.
Cranberry (Rf341) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP- Cranberry*</i>
Test Code:	38254
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.
Crayfish (Rf320) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP-Crayfish*</i>
Test Code:	38751
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.
Macadamia Nut (Rf345) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP- Macadamia Nut*</i>
Test Code:	38475
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

Papaya (Rf293) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP-Papaya*</i>
Test Code:	2720
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.
Peppertree (Rt217) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP- Peppertree (Schinus Molle)*</i>
Test Code:	30765
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.
Raspberry (Rf343) IgE	
Effective Date:	July 14, 2008
<i>Former Test Name:</i>	<i>Allergen (IgE), ImmunoCAP- Raspberry*</i>
Test Code:	26281
Specimen Requirements:	0.3 mL serum (minimum 0.15 mL)
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	See report
Methodology:	Immunoassay
Performing Site:	This test previously performed at IBT Reference Laboratory, will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

**Quest Diagnostics Nichols Institute, San Juan Capistrano & Chantilly
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

Herpes Simplex Virus, Type 1 & 2 DNA, Quantitative Real-Time PCR	
Clinical Significance:	The detection of HSV-1 and HSV-2 DNA is based upon the real-time amplification, detection and differentiation of specific HSV-1 and HSV-2 genomic DNA sequences by PCR from total DNA extracted from the specimen. The quantitative range of this assay is 100-100,000,000 copies/mL.
Effective Date:	July 21, 2008
Test Code:	19502
CPT Code(s):	87530 (x2)
Specimen Requirements:	1 mL CSF, pericardial fluid, vitreous fluid, pleural fluid, or amniotic fluid in sterile screw cap container, no additive (red-top) or SST (red-top/plastic) serum, or EDTA (lavender-top), PPT, or ACD plasma or swab in M4.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	<p>Source: HSV-1 DNA, Qn PCR: <100 HSV-1 copies/mL HSV-2 DNA, Qn PCR: <100 HSV-2 copies/mL</p> <p>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.</p>
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	This test is performed Focus Diagnostics, Inc.

JC Polyoma Virus DNA, Quantitative Real-Time PCR	
Clinical Significance:	JC Virus is the cause of progressive multifocal leukoencephalopathy (PML), a severe demyelinating disease of the central nervous system. PML is a particular concern for individuals infected with the human immunodeficiency virus. Quantification of JC virus DNA is based upon the real-time PCR amplification and detection of JCV genomic DNA. The quantitative range of this assay is 500 – 35,000,000 copies/mL.
Effective Date:	July 21, 2008
Test Code:	19503
CPT Code(s):	87799
Specimen Requirements:	0.7 mL CSF or urine in sterile screw cap container, ACD or EDTA (lavender-top) plasma, or no additive (red-top) or SST (red-top/plastic) serum
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	<500 copies/mL 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.
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	This test is performed Focus Diagnostics, Inc.

Parvovirus B19 DNA, Quantitative Real-Time PCR	
Clinical Significance:	Parvovirus B19 infection has a wide variety of disease manifestations, including Fifth disease, transient aplastic crisis, persistent anemia and congenital hydrops fetalis. Quantification of parvovirus B19 genomic DNA is based upon real-time PCR amplification and detection. The quantitative range of this assay is 100 – 100,000,000 copies/mL.
Effective Date:	July 21, 2008
Test Code:	19724
CPT Code(s):	87799
Specimen Requirements:	1 mL amniotic fluid in plastic leak-proof container Heparinized specimens are unacceptable. Use of Vacutainer brand PPT collection tube is preferred. Centrifuge specimen within 6 hours of collection; then, freeze for immediate transport. No aliquoting is required. For serum, remove serum within 6 hours of collection, transfer to a sterile, polypropylene tube, and freeze. Amniotic fluid is collected aseptically per established clinical procedure, placed in a sterile, polypropylene tube, and frozen. In all cases, do not allow freeze-thaw cycle to occur. If submitting bone marrow or whole blood, ship room temperature or refrigerated. Do not freeze.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	< 100 copies/mL 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.
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	This test is performed Focus Diagnostics, Inc.

<i>Toxoplasma gondii</i> DNA, Quantitative Real-Time PCR	
Clinical Significance:	<i>Toxoplasma gondii</i> , an obligate intracellular parasite, is an important opportunistic pathogen of immunosuppressed patients and pregnant women. Real-time PCR methods are useful in quantifying <i>T. gondii</i> in clinical specimens of immunosuppressed patients or in the amniotic fluid of mothers thought to be recently infected. The quantitative range of this assay is 100 – 1,000,000 copies/mL.
Effective Date:	July 21, 2008
Test Code:	19725
CPT Code(s):	87799
Specimen Requirements:	1 mL CSF in plastic leak-proof container Collect using standard procedures. Store samples refrigerated following collection. Ship refrigerated (cold packs). Do not freeze whole blood.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	< 100 copies/ mL 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.
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	This test is performed Focus Diagnostics, Inc.

Varicella Zoster Virus (VZV) DNA, Quantitative Real-Time PCR	
Clinical Significance:	Varicella-Zoster virus (VZV) is a member of the Herpesviridae family that causes chickenpox as a primary infection and can reactivate later in life as herpes zoster or shingles. VZV infection in immunocompromised individuals often leads to a progressive disease state involving multiple organs. The detection of Varicella-Zoster Virus (VZV) DNA is based upon the real-time amplification and detection of specific ZVZ genomic DNA sequences by PCR from total DNA extracted from the specimen. The quantitative range of this assay is 500 – 2,000,000 copies/mL.
Effective Date:	July 21, 2008
Test Code:	19493
CPT Code(s):	87799
Specimen Requirements:	0.7 mL CSF in sterile screw cap container, or bronchial lavage/wash in M5 Multi-use Media, or swab in M4, or EDTA (lavender-top) whole blood
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days; Whole blood is unacceptable frozen
Reference Ranges:	<500 copies/mL 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.
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	This test is performed Focus Diagnostics, Inc.

Assay Category Update

Effective July 14 2008, the following codes (performed at Focus Diagnostics, Inc) will have an assay category updates.

Test Code:	Test Name	Assay Category
16046	Adenovirus DNA, Qualitative Real-Time PCR	Laboratory Developed Test
17610	Atypical Pneumonia DNA Panel, Qualitative Real-Time PCR	Laboratory Developed Test
16003	Chlamydomphila pneumoniae DNA, Qualitative Real-Time PCR	Laboratory Developed Test
16001	Herpes Virus 6 DNA, Qualitative Real-Time PCR	Laboratory Developed Test
15062	Legionella DNA, Qualitative Real-Time PCR	Laboratory Developed Test
15498	Mycoplasma pneumoniae DNA, Qualitative Real-Time PCR	Laboratory Developed Test
16047	RSV (Respiratory Syncytial Virus)RNA, Qualitative Real-Time PCR	Laboratory Developed Test

AFB Susceptibility Update

Effective July 28, 2008, the following code (performed at Focus Diagnostics) will have a prompted analyte added for organism. Please provide the organism with each order.

Test Code:	Test Name
19585	AFB Susceptibility, Custom Drug Panel (1)

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.

Thrombophilia Screen II, Inherited		
Clinical Significance:	Factor V Leiden (R506Q) is the most common genetic determinant for hereditary venous thrombosis. Another DNA variant, the HR2 allele, has been associated with a 3-4 fold increased risk to venous thrombosis when it occurs in the presence of the Factor V Leiden mutation.	
Effective Date:	July 21, 2008	
<i>Former Test Name:</i>	<i>Thrombophilia Screen, Inherited</i>	
Test Code:	11327	
Specimen Requirements:	1 mL x3 2% Sodium Citrate (lt. blue-top) plasma (minimum: 0.5 mL x3) AND 5 mL EDTA (lavender-top) whole blood	
Specimen Stability:	Plasma:	Whole blood:
	Room temperature: Unacceptable	Room temperature: 8 days
	Refrigerated: Unacceptable	Refrigerated: 8 days
	Frozen: 3 weeks	Frozen: 3 weeks
Transport Temperature:	Frozen	
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano	
Additional Information:	Update stability and sample volume. We continue to receive whole blood at room temperature. Please note: the transport temperature for this group code is frozen. This is not a change to this test code.	

<i>Bordetella pertussis/parapertussis Smear, DFA</i>	
Clinical Significance:	<i>Bordetella pertussis</i> is the cause of whooping cough that may occur in unimmunized individuals. <i>B. parapertussis</i> is a related organism that causes a similar but milder disease than <i>B. pertussis</i> .
Effective Date:	July 21, 2008
<i>Former Test Name:</i>	<i>Bordetella pertussis/parapertussis by DFA</i>
Test Code:	34966
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano.
Additional Information:	Update test name and assay category.

30298-<i>Mycobacterium tuberculosis</i> complex, PCR, Respiratory	
30277-<i>Mycobacterium tuberculosis</i> complex, PCR, Non-respiratory	
Clinical Significance:	This is an amplified method used to detect <i>Mycobacterium tuberculosis</i> complex nucleic acid in the raw specimen. It is used to aid the physician in the rapid diagnosis and treatment of a possible tuberculosis infection. A negative result does not rule out disease. Results should be supported by additional alternate testing.
Effective Date:	July 21, 2008
Assay Category:	ASR Class 3
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update assay category and always message. Please note this test is included in the following group codes: 14685-Mycobacteria PCR, Culture and Smear, Non-Respiratory; 14684-Mycobacteria PCR, Culture and Smear, Respiratory.

Pancreatic Elastase-1										
Clinical Significance:	The Elastase-1 is a quantitative enzyme linked immunsorbent assay for measuring concentrations of elastase-1 in feces as an aid in diagnosis of the exocrine pancreatic function.									
Effective Date:	July 21, 2008									
Test Code:	14693									
Reference Ranges:	<table border="1"> <thead> <tr> <th></th> <th>Normal:</th> <th></th> </tr> </thead> <tbody> <tr> <td>Moderate Pancreatic Insufficiency:</td> <td>100-200</td> <td>mcg/g</td> </tr> <tr> <td>Severe Pancreatic Insufficiency:</td> <td><100</td> <td>mcg/g</td> </tr> </tbody> </table> <p>Elastase-1 (E-1) assay results are expressed in mcg/g, which represent mcg E1/g feces. It is not necessary to interrupt enzyme substitution therapy.</p>		Normal:		Moderate Pancreatic Insufficiency:	100-200	mcg/g	Severe Pancreatic Insufficiency:	<100	mcg/g
	Normal:									
Moderate Pancreatic Insufficiency:	100-200	mcg/g								
Severe Pancreatic Insufficiency:	<100	mcg/g								
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano									
Additional Information:	Update reference range.									

Discontinued Tests

Lead, Serum or Plasma	
Effective Date:	July 21, 2008
Test Code:	3173
Additional Information:	This test, currently performed by National Medical Services, will be discontinued. The recommended alternative is 599(X) Lead, Blood. Blood lead is the preferred specimen for monitoring exposure to LEAD. Ninety-nine percent of the lead in blood is located within the erythrocytes, and the blood level correlates well with clinical manifestation. Various Federal and State government agencies (e.g. CDC, OSHA, State of New York Dept. of Health, State of California Dept. of Health, etc.) have established regulations on preventative and remedial actions based on blood lead level. Plasma lead does not correlate well with clinical symptoms and should not be used for monitoring lead exposure.

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