



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.

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

Test Changes

ABO Group and Rh Type, Antibody Screen, RBC with Reflex to Identification and Antigen Typing	
Clinical Significance:	ABO Group and Rh Type are needed to identify candidates for the Rh immune globulin and to assess the risk of hemolytic disease of the newborn. Antibody identification is needed to assess the risk of hemolytic disease of the newborn and to identify sensitized persons at risk in the setting of future transfusions.
Effective Date:	December 7, 2009
Test Code:	785, 7788, 792, 11291, 36668, 8626, 794, 5149, 361, 795
Preferred Specimen:	5 ml of whole blood in a Yellow Top (ACD-A or ACD-B) Tube
Additional Information:	Change in preferred sample

LH		
Clinical Significance:	This test is useful in the differential diagnosis of pituitary and gonadal insufficiency.	
Effective Date:	December 7, 2009	
Test Code:	615	
Reference Ranges:	Male and Female <18 yrs	LH reference ranges established on post-pubertal patient population. Reference range not established for pre-pubertal patients using this assay. For pre-pubertal patients, the Quest Diagnostics Nichols Institute LH, Pediatrics assay is recommended (order code 36086).
	Male: 18-69 yrs	1.5 – 9.3 mIU/mL
	> or = 70 yrs	3.1 – 34.6 mIU/mL
	Female: Follicular Phase	1.9 – 12.5 mIU/mL
	Mid-Cycle Peak	8.7 – 76.3 mIU/mL
	Luteal Phase	0.5 – 16.9 mIU/mL
	Postmenopausal	15.9 – 54.0 mIU/mL
Additional Information:	Update reference ranges. Please note this change applies to the following tests: 30953 – LH, 2 specimens, 30954 – LH, 3 specimens, 30955 – LH, 4 specimens, 4571 – LH, 5 specimens, 34434 – LH, 6 specimens, 34435 – LH, 7 specimens, 34436 – LH, 8 specimens, 34437 – LH, 9 specimens.	

Lymphocyte Subset Panel 1		
Clinical Significance:	Immunophenotypic analysis may assist in evaluating cellular immunocompetency in suspected cases of primary and secondary immunodeficiency states.	
Effective Date:	December 7, 2009	
Test Code:	7197	
Units of Measure	% CD3 (Mature T Cells)	%
	Absolute CD3+ Cells	cells/uL
	% CD4 (Helper Cells)	%
	Absolute CD4+ Cells	cells/uL
	% CD8 (Suppressor T Cells)	%
	Absolute CD8+ Cells	cells/uL
	Helper/Suppressor Ratio	(none)
	% CD16+CD56 (Natural Killer Cells)	%
	Absolute NK Cells (CD16+CD56+ Cells)	cells/uL
	% CD19 (B Cells)	%
	Absolute CD19+ Cells	cells/uL
	Absolute Lymphocyte	cells/uL
Additional Information:	Update units of measure. Portions of the above information also apply to the following codes: Lymphocyte Subset Panel 2 – 36420, Lymphocyte Subset Panel 3 – 7195, Lymphocyte Subset Panel 4 – 7924, Lymphocyte Subset Panel 5 – 8360	

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.

Antimicrobial Level, Sulfamethoxazole, HPLC	
Clinical Significance:	Sulfamethoxazole peak levels occur approximately 1 – 4 hours after oral dosing with or without food. Minimal steady-state level (3 days): 57.4 – 68.0 µg/mL
Effective Date:	November 2, 2009
Test Code:	16990
CPT Code(s):	80299
Specimen Requirements:	2 mL serum
Transport Temperature:	Frozen
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 14 days
Reference Ranges:	<5.0 mcg/mL
Methodology:	High Performance Liquid Chromatography
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.

Brucella Antibody, Agglutination	
Clinical Significance:	Brucella is transmitted to humans from animals. Detection of agglutinating antibodies at titers of 1:80 or greater indicates Brucella infection. Recent Brucella infection is best demonstrated by a 4-fold increase in agglutinating antibody titer when testing acute and convalescent sera in parallel.
Effective Date:	November 2, 2009
Test Code:	982
CPT Code(s):	86622
Specimen Requirements:	0.5 mL serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	<1:80
Methodology:	Direct Agglutination
Assay Category:	FDA Approved/Cleared
Performing Site:	Focus Diagnostics, Inc.

BCR-ABL1 Kinase Domain Mutation, 35-Nucleotide Insertion	
Clinical Significance:	Chronic myelogenous leukemia (CML) is a hematopoietic stem cell disorder characterized by the philadelphia chromosome, the result of a (9;22) translocation that fuses the BCR gene with the ABL1 gene and produces the constitutively active BCR-ABL1 tyrosine kinase. Imatinib mesylate (STI571;Gleevec), a BCR-ABL tyrosine kinase inhibitor, is highly effective in treating the early stages of CML. Of patients treated in chronic phase, 95% achieved a complete hematologic remission and 60% achieve a major cytogenetic response. However, most patients in blast crisis either fail to respond or quickly relapse following an initial response to imatinib. Alternatively spliced BCR-ABL1 mRNA with 35-Nucleotide (NT) insertion is found in CML patients who show resistance to imatinib. The level of resistance may correlate with levels of expression the 35-NT transcript.
Effective Date:	November 2, 2009
Test Code:	16876
CPT Code(s):	83891, 83902, 83898 (x4), 83909, 83912
Specimen Requirements:	6 mL EDTA (lavender-top) whole blood Preferred sample type is whole blood. Bone marrow is acceptable. INSTRUCTION: Collect 6 mL of whole blood or 3 mL bone marrow in lavender-top (EDTA) tube. Whole blood or bone marrow is shipped refrigerated. Do not freeze whole blood or bone marrow. After collection of the sample, draw date and time, as well as sample type, must be written on the tube and included as requested information. Ship sample immediately due to short stability of 72 hours. If the stability of the sample cannot be determined, delay in result or cancellation of test may occur.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature and Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	Accompanies report
Methodology:	Polymerase Chain Reaction, Fragment Analysis
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Clopidogrel CYP2C19 Genotype (*1,*2,*3,*4,*5)	
Clinical Significance:	Clopidogrel (Plavix ®) is metabolized by CYP2C19 to its active form. This assay detects loss-of-function variants in the CYP2C19 gene leading to reduced therapeutic response to Clopidogrel treatment.
Effective Date:	November 2, 2009
Test Code:	16924
CPT Code(s):	83891, 83892 (x2), 83900, 83909, 83914 (x2) 83912
Specimen Requirements:	4 mL EDTA (lavender-top) whole blood (preferred) or 1 mL saliva in Oragene DNA self-collection kit is acceptable Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze. Saliva collection kits require patient to rinse mouth prior to spitting into Oragene collection kit. See Oragene product insert for further details.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: Unacceptable
Reference Ranges:	Accompanies report
Methodology:	Polymerase Chain Reaction/ Single Nucleotide Primer Extension
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

FMR1 Gene Sequencing	
Clinical Significance:	This assay is for identification of small and rare mutations in the FMR1 gene. It can be used in Fragile X patients without CGG expansion or gene deletion/ duplication. It can also be used in prenatal diagnosis.
Effective Date:	November 2, 2009
Test Code:	16658
CPT Code(s):	83891, 83894, 83898 (x18), 83904 (x18), 83892 (x18), 83912
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not refrigerate or freeze.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze
Reference Ranges:	Accompanies report
Methodology:	Polymerase Chain Reaction, Gel Electrophoresis, Sequencing
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

MUM1, IHC with Interpretation

Clinical Significance:	Multiple myeloma oncogene-1 (MUM1) is a 50 kDa protein encoded by the MUM1 gene. IRF4/MUM1 is expressed in the nuclei and cytoplasm of plasma cells and a small percentage of germinal center (GC) B cells located in the "light zone". This antibody labels MUM1 protein in centrocytes and their progeny, plasma cells, activated T cells, and a wide spectrum of hematolymphoid neoplasms derived from these cells.
Effective Date:	November 2, 2009
Test Code:	16957
CPT Code(s):	88342
Specimen Requirements:	Formalin fixed paraffin embedded tissue in IHC specimen transport kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze
Reference Ranges:	Accompanies report
Methodology:	Immunohistochemical Stain
Assay Category:	FDA Approved/ Cleared
Performing Site:	Quest Diagnostics Nichols Institute

Formaldehyde/Formalin (k80) IgE**

Clinical Significance:	Formaldehyde and its derivatives are used in many chemical and industrial applications.
Effective Date:	December 7, 2009
Test Code:	17075
CPT Code:	86003
Specimen Requirements:	0.3 mL serum (0.15 mL minimum)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	Accompanies report
Methodology:	Immunoassay
Assay Category:	ASR Class I
Additional Information:	This test will be performed at Quest Diagnostics Nichols Institute, Chantilly, VA.

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.

Alpha-Globin Common Mutation Analysis	
Clinical Significance:	Alpha Thalassemia is a common hereditary trait and disease among individuals of Asian heritage. Disease ranges in severity from mild abnormalities of erythrocytic indices to severe anemia. Genetic counseling may be advised for some patients.
Effective Date:	December 14, 2009
Test Code:	11175
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood Extracted DNA is not an acceptable specimen type
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements.

Beta-Globin Complete	
Clinical Significance:	1. To identify disease-causing mutations in individuals affected with beta-thalassemia. 2. To identify carriers in high-risk ethnic group or people with positive family history. 3. Prenatal diagnosis of beta-thalassemia
Effective Date:	December 14, 2009
Test Code:	14974
Specimen Requirements:	5 mL whole blood in EDTA (lavender-top) or ACD solution B (yellow-top) tube Extracted DNA is not an acceptable specimen type Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze. For prenatal diagnosis with a fetal specimen: 1) parents must be documented carriers of one of the mutations tested; 2) maternal blood must be available; 3) contact the laboratory genetic counselor before submission. Chorionic villi (CVS): 2 sterile T25 flasks, filled with culture medium. Specimen stability is crucial. Store and ship ambient immediately. Do not refrigerate or freeze.
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements.

Homocysteine, Total, Urine	
Clinical Significance:	Urinary total homocysteine is useful in monitoring patients on therapy for classical homocystinuria, monitoring patients on treatment for deficiencies of vitamin B6, B12, or folic acid.
Effective Date:	December 14, 2009
Test Code:	26318
Specimen Requirements:	2.5 mL random urine submitted in each of 2 separate sterile screw cap containers. Ship specimen frozen on dry ice. From one thoroughly mixed sterile collection container, divide into two sterile collections: (1) minimum 2.5 mL in sterile screw cap container AND (2) minimum 0.5 mL in sterile 12x75 mm standard tube (to be used for Creatinine testing). Freeze immediately. Send both samples together. Fasting for 10 hours is recommended.
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 4 Days Frozen: 21 Days
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements, stability and test code.

Discontinued Tests

Antimicrobial Serum Level, Sulfamethoxazole, SP	
Effective Date:	December 14, 2009
Test Code:	8344
Additional Information:	This test will be discontinued. The recommended alternative is 16990-Antimicrobial Level, Sulfamethoxazole, HPLC.

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