



LABORATORY UPDATE

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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

Stone Analysis	
Clinical Significance:	Stone Analysis is used in determining the etiology of stones. The results are often useful in determining the cause and treatment.
Effective Date:	March 8, 2010
<i>Former Test Name:</i>	<i>Stone Analysis, Non-Kidney Stones</i>
Test Code :	30260
Specimen Requirements:	Stone(s) --or-- Filtered Material --or-- Dry Kidney Stone Dry stone in sterile screw cap container. Stones originating from sources not related to the kidney should be air-dried, then placed in a plastic tube or a urine collection cup. Do not use tape. Minute specimens may be placed in a gelatin capsule. Ship ambient.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 12 Months Refrigerated: 12 Months Frozen: 12 Months
Methodology:	Nidus, Component 1, Component 2: IR (FTIR) Stone Weight: GRAVMET
Additional Information:	Update test name, specimen requirements, and stability.

Discontinued Tests

Kidney Stone Analysis with Stone Image	
Effective Date:	March 8, 2010
Test Code:	30261
Additional Information:	This test will be discontinued. Please refer to 30260 Stone Analysis, in the test change section.

Redirects

HE4, Ovarian Cancer Monitoring	
Clinical Significance:	The HE4 EIA assay is an enzyme immunoassay for the quantitative determination of human HE4 antigen in serum. HE4 is a biomarker for ovarian cancer.
Effective Date:	March 8, 2010
Test Code:	16500
Performing Site:	Previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano, that will now be sent to Quest Diagnostic Specialty Laboratories, Valencia.
Additional Information:	Update test code and performing site.

**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.

Fungitell (1-3) –B-D-Glucan Assay	
Clinical Significance:	Invasive fungal infections (IFI) are increasing, especially among immunocompromised patients. Most pathogenic fungi have (1->3)-beta-D-glucan in their cell walls and minute quantities are sloughed into the bloodstream and appear in the serum in cases of IFI. Monitoring serum (1->3)-beta-D-glucan for evidence of elevated and rising levels provides a convenient surrogate marker for IFI.
Effective Date:	February 8, 2010
Test Code:	16283
CPT Code(s):	84311
Specimen Requirements:	1 mL serum (poured off) in glucan free tube. Tubes DNase, RNase, pyrogen free acceptable. Glass tubes are unacceptable.
Transport Temperature:	Refrigerated (cold packs)
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 5 days Frozen: 14 days
Reference Ranges:	<60 pg/mL
Methodology:	Protease zymogen-based colorimetric
Assay Category:	FDA Approved/Cleared
Performing Site:	Focus Diagnostics, Inc.

Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR	
Clinical Significance:	Identification of H1 and H3 subtypes will aid physicians in making treatment choices for patients infected with seasonal influenza A virus.
Effective Date:	February 8, 2010
Test Code:	16251
CPT Code(s):	87798 (x2)
Specimen Requirements:	Nasal, nasopharyngeal or throat swab in 3 mL M4 media or V-C-M medium (green-cap) tube or equivalent (UTM)
Transport Temperature:	Refrigerated (cold packs)
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Real-Time RT-PCR
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.

APC Gene Deletion or Duplication	
Clinical Significance:	This test detects large deletion and duplication mutations in the APC gene which cause Familial Adenomatous Polyposis (FAP). It can be used to identify mutations in affected patients or their at-risk family members.
Effective Date:	February 8, 2010
Test Code:	16930
CPT Code(s):	83891, 83900, 83901 (x22), 83909, 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 freeze.
Rejection Criteria:	Specimens received frozen; Gross hemolysis
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze
Reference Ranges:	Accompanies report
Methodology:	Semi-quantitative fluorescent PCR
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

APC Gene Sequencing	
Clinical Significance:	This test detects small mutations in the APC gene which cause Familial Adenomatous Polyposis (FAP). It can be used to identify mutations in affected patients or their at-risk family members.
Effective Date:	February 8, 2010
Test Code:	16934
CPT Code(s):	83891, 83898 (x31), 83892 (x31), 83904 (x31), 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 freeze.
Rejection Criteria:	Specimens received frozen; Gross hemolysis
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze
Reference Ranges:	Accompanies report
Methodology:	DNA Sequencing
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Ashkenazi Jewish Panel (11 Tests)	
Clinical Significance:	This panel detects Jewish mutations in the following diseases: Bloom, Canavan, Cystic Fibrosis, Fanconi Anemia (C), Familial Dysautonomia, Gaucher, Glycogen Storage Disease I, Maple Syrup Urine Disease, Mucopolidosis IV, Niemann-Pick, and Tay-Sachs
Effective Date:	March 15, 2010
Test Code:	16936
CPT Code(s):	83891 (x3), 83900, 83901(x33), 83892 (x7), 83914 (x67), 83909 (x4), 83912 (x11)
Specimen Requirements:	5 mL in each of 3 EDTA (lavender-top) tubes Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.
Rejection Criteria:	Frozen specimens
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze
Reference Ranges:	Accompanies report
Methodology:	Polymerase Chain Reaction, Allele-Specific Hybridization, Allele specific primer extension, fluorescent detection using color coded microspheres
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Lupus Anticoagulant Comprehensive Evaluation with Reflexes

***Includes: Lupus Anticoagulant * Hexagonal Phase Confirm * dRVVT Screen *dRVVT Confirm * dRVVT 1:1 Mix * dPT Screen * dPT Confirm*

Clinical Significance:	The Lupus Anticoagulant Comprehensive Profile incorporates 3 screening and reflexed confirmatory tests to increase the sensitivity for detecting Lupus Anticoagulant. The dPT Screen and Confirm, in combination with the PTT-LA/ Hexagonal Phase Confirm and dRVVT Screen/Confirm, analyze the extrinsic, intrinsic, and common pathways of coagulation - a Triple Pathway Analysis.
Effective Date:	March 15, 2010
Test Code:	16827
CPT Code(s):	85730, 85613, 85611
Specimen Requirements:	4 mL 3.2% Sodium Citrate (lt. blue-top) plasma Platelet Poor Plasma: Centrifuge light blue-top tube 15 minutes at approx. 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcl). Freeze immediately and ship on dry ice.
Rejection Criteria:	Grossly lipemic; Grossly icteric; Gross hemolysis
Transport Temperature:	Frozen Do not thaw
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 90 days
Reference Ranges:	See individual assays
Methodology:	Clot Detection
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	If the PTT-LA is >40 seconds the Hexagonal Phase Confirm will be performed at an additional charge (CPT code(s): 85597) If the dRVVT Screen is >42 seconds the dRVVT Confirm will be performed at an additional charge (CPT code(s): 85597) If the dPT Screen is >53 seconds the dPT Confirm will be performed at an additional charge (CPT code(s): 85613)

VEGF Mutation Analysis	
Clinical Significance:	This genotyping test provides information on the genetic background of patients who already have cancer. Different genotypes have been reported to correlate with response or side-effects to certain medications.
Effective Date:	March 15, 2010
Test Code:	16959
CPT Code(s):	83891, 83900, 83901 (x2), 83892 (x2), 83914 (x4), 83909, 83912
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood
Rejection Criteria:	Blood: Frozen, clotted, or grossly hemolyzed. FFPE: All baked slides.
Transport Temperature:	Room temperature: 8 days Refrigerated: 14 days Frozen: Unacceptable
Specimen Stability:	Room temperature
Reference Ranges:	VEGF-634: Not Detected VEGF-1154: Not Detected VEGF-1498: Not Detected VEGF-2578: Not Detected
Methodology:	SNaPshot
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

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.

Manganese, Serum/Plasma	
Clinical Significance:	Manganese is an essential trace metal. Toxicity that can result from excessive exposure can cause serious organ damage. Manganese can be measured in a variety of body fluids and tissues.
Effective Date:	March 22, 2010
Test Code:	951
Specimen Requirements:	2 mL no additive (royal blue-top) serum For serum sample, blood may be drawn into a royal blue top evacuated tube without additive, allowed to clot at 18-28 degrees C within 4 hours of collection. Serum separated is poured into a labeled acid-washed plastic vial for transportation. Do not use powdered gloves. (The royal blue top evacuated tubes should be free of the trace element desired). For plasma samples, follow the above instructions except that the sample does not go through the clotting process. Patient should refrain from taking mineral supplements at least 3 days prior to sample collection.
Rejection Criteria:	Samples received room temperature or collected in gel barrier tubes; hemolyzed or moderately lipemic; SST tubes are not acceptable/
Reference Range:	< OR = 1.1 mcg/L
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements, and reject criteria.

Discontinued Tests

36098-Pyridinium Collagen Cross-Links, 24-Hour Urine 36097- Pyridinium Collagen Cross-Links, 2-Hour Urine	
Effective Date:	March 8, 2010
Additional Information:	These tests will be discontinued. The recommended alternatives are 17406-C Telopeptide (CTx); 36167-Collagen Cross-Linked N-Telopeptide (NTx), Urine; 36421-Collagen Cross-Linked N-Telopeptide (NTx), 24-Hour U.