



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.

Test Changes

- Metanephrines, Fractionated, LC/MS/MS, Random Urine – Update specimen requirements. ... 9
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DLO is pleased to inform you of the following new and updated laboratory testing information:

Test Changes

Microalbumin, 24-Hour Urine (with Creatinine)	
Clinical Significance:	Microalbumin is albumin excreted in the urine and is a sensitive marker of nephropathy. It is used to screen for early renal disease in diabetic patients.
Effective Date:	May 4, 2009
Test Code:	15281
CPT Code:	82043, 82570
Specimen Requirements:	5 mL (2 mL minimum) aliquot from a well-mixed 24-hour, submitted in a plastic, leak-proof container. Do not use preservatives. Record 24-hour urine volume on test request form and urine vial.
Additional Information:	Update for additional CPT code and specimen requirements.

Prostatic Acid Phosphatase (PAP)	
Clinical Significance:	PAP measurement has found clinical application in the management of Prostatic cancer patients. Serum PAP measurements have been useful in monitoring remission or relapse of a Prostatic malignancy and in assessing the effectiveness of various treatment regimes. Thus, normalization in serum PAP levels has been observed following successful therapeutic intervention, while recurrent or residual disease has been associated with elevated levels of PAP.
Effective Date:	May 4, 2009
Test Code:	208
Specimen Requirements:	1 mL serum Samples should be obtained before rectal examination, biopsy, prostatectomy or prostatic massage, since manipulating the prostate gland may lead to elevated PAP levels persisting up to 24-48 hours. Specimen must be frozen if received by the laboratory greater than 24 hours after collection.
Additional Information:	Update specimen requirements.

PSA, Free and Total	
Clinical Significance:	In men over 50 years with total PSA between 4.0 and 10.0 ng/mL, the percent (%) free PSA gives an estimate of the probability of cancer. In these circumstances the measurement of the % free PSA may aid in avoiding unnecessary biopsies.
Effective Date:	May 4, 2009
Test Code:	31348
Specimen Requirements:	2 mL frozen serum plastic screw-cap vial. Do not collect specimen after a transrectal biopsy, results may be falsely elevated.
Reject Criteria:	Gross hemolysis, gross lipemia, gross icterus
Methodology:	Immunoassay
Additional Information:	Update specimen requirements, reject criteria and methodology.

PSA, Total	
Clinical Significance:	Elevated serum PSA concentrations have been reported in men with prostate cancer, benign prostatic hypertrophy, and inflammatory conditions of the prostate.
Effective Date:	May 4, 2009
Test Code:	5363
Specimen Requirements:	1 mL serum; Do not collect specimen after a transrectal biopsy, results may be falsely elevated.
Reject Criteria:	Gross hemolysis, gross lipemia, gross icterus
Methodology:	Immunoassay
Additional Information:	Update specimen requirements, reject criteria and methodology.

PTH, Intact and Calcium	
Clinical Significance:	This assay is useful in making the diagnosis of primary hyperparathyroidism, secondary hyperparathyroidism, and a differential diagnosis of hypercalcemia. The assay helps in distinguishing hypercalcemia caused by either hyperparathyroidism or malignant disease.
Effective Date:	May 4, 2009
Test Code:	8837
Specimen Requirements:	2 mL serum Spin to separate serum and transfer to plastic transport tube. Freeze immediately and submit to laboratory frozen. Do not submit glass tubes. Sodium or lithium heparin plasma is no longer acceptable.
Reject Criteria:	Gross Hemolysis, Gross Lipemia, Gross Icterus
Methodology:	Immunoassay/Spectrophotometry
Additional Information:	Update method, reject criteria and specimen requirements.

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

Redirects

Iodine, 24-Hour Urine	
Effective Date:	May 18, 2009
<i>Former Test Code:</i>	38959
Test Code:	16602
CPT Code:	83789
Specimen Requirements:	10 mL aliquot of a 24-hour urine (sterile, leakproof container, no preservative)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature and Refrigerated: 10 days Frozen: Unacceptable
Reference Ranges:	75-500 mcg/24H
Methodology:	Inductively Coupled Plasma-Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	This test, previously performed at Mayo Medical Laboratories, will now be performed at Quest Diagnostics Nichols Institute, Chantilly.

Specialty Redirects

Kidney Stone Analysis with Stone Image	
Effective Date:	May 18, 2009
Test Code:	30261
Specimen Requirements:	Dry stone in sterile screw cap container Specimens 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, refrigerated, and frozen: Indefinite
Reference Ranges:	With report
Performing Site:	This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Specialty Laboratories.
Additional Information:	Update test and result name and report format, collection instruction, transport temperature, stability, reference range, and performing site.

Stone Analysis, Non-Kidney Stones	
Effective Date:	May 18, 2009
Test Code:	30260
Specimen Requirements:	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.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, refrigerated, and frozen: Indefinite
Reference Ranges:	With report
Performing Site:	This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Specialty Laboratories.
Additional Information:	Update test and result names and format, collection instruction, transport temperature, stability, and reference range.

New Tests

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

HIV-1 RNA, Qualitative TMA	
Clinical Significance:	The APTIMA® HIV-1 RNA Qualitative assay may be used: 1. As an aid in the diagnosis of acute and primary HIV-1 infection. 2. To confirm HIV-1 infection in persons who repeatedly test positive for HIV-1 antibodies. 3. To resolve indeterminate or inconclusive HIV-1 Western blot results.
Effective Date:	February 3, 2009
Test Code:	16185
CPT Code(s):	87535
Specimen Requirements:	1.6 mL EDTA K2 (lavender-top) plastic plasma Collect plasma in EDTA (lavender-top) or a (white-top) PPT Vacutainer (TM) plasma preparation tube. Separate plasma from the cells by centrifugation within 6 hours after collection. Transfer the plasma to a plastic screw-cap vial and ship frozen.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 72 hours Refrigerated: 5 days Frozen: 35 days
Reference Ranges:	NOT DETECTED
Methodology:	Transcription-mediated Amplification
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Iodine, Random Urine	
Clinical Significance:	Iodine is an essential element that is required for thyroid hormone production. The measurement of urinary iodine serves as an index of adequate iodine intake.
Effective Date:	May 18, 2009
Test Code:	16601
CPT Code:	83789
Specimen Requirements:	10 mL random urine (sterile, leakproof container)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature and Refrigerated: 10 days Frozen: Unacceptable
Reference Ranges:	34-523 mcg/L
Methodology:	Inductively Coupled Plasma-Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

Iodine, Serum and Plasma	
Effective Date:	May 18, 2009
Test Code:	16599
CPT Code:	83789
Specimen Requirements:	1 mL No additive (dark blue-top tube, trace metal-free) serum --or-- 1 mL EDTA (dark blue-top tube, trace metal-free) plasma
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature and Refrigerated: 10 days Frozen: Not established
Reference Ranges:	52-109 mcg/L
Methodology:	Inductively Coupled Plasma-Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

Reticulin IgG Screen with Reflex to Titer	
Clinical Significance:	Anti-Reticulin IgG occurs most frequently in patients with gluten sensitive enteropathy, i.e. celiac disease and dermatitis herpetiformis.
Effective Date:	May 18, 2009
Test Code:	16530
CPT Code:	86255
Specimen Requirements:	0.5 mL serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 4 days; Refrigerated: 7 days; Frozen: 30 days
Reference Ranges:	Negative
Methodology:	Immunoassay
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	If the Reticulin IgG Screen is positive, the antibody titer will be added at an additional charge (CPT: 86256).

Rubella Virus RNA, Qualitative Real-Time PCR	
Clinical Significance:	Detection of rubella virus RNA by real-time RT-PCR is a useful tool for the rapid diagnosis of congenital rubella virus infection
Effective Date:	May 11, 2009
Test Code:	16730
CPT Code:	87798
Specimen Requirements:	0.7 mL Amniotic fluid, serum (SST or no additive red top), or respiratory swab in 3 mL M4 media, V-C-M medium (green-cap) tube, or equivalent (UTM)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours; Refrigerated: 7 days; Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Real-Time PCR
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.

FISH, Duplication 15q11q13	
Clinical Significance:	This assay detects duplications in the 15q11-q13 region associated with autism and mild mental retardation/developmental delay.
Effective Date:	April 6, 2009
Test Code:	19045
CPT Code(s):	88271, 88275, 88291
Specimen Requirements:	5 mL sodium heparin (green-top) whole blood Whole blood 2-5 mL. In sodium heparin tube (Green, Dark/royal blue or tan top). Ship at room temperature. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: See instructions Frozen: Unacceptable
Reference Ranges:	See report
Methodology:	Fluorescence in Situ Hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute

FISH, Duplication 22q11.2	
Clinical Significance:	Clinical phenotype of duplicaton 22q11.2 can be mild to severe with overlapping features with DG/VCFS (Yobb et al, 2005).
Effective Date:	April 6, 2009
Test Code:	16672
CPT Code(s):	88271, 88275, 88291
Specimen Requirements:	5 mL sodium heparin (green-top) whole blood Whole blood 3-5 mL (1 mL minimum). Green vacutainer (sodium heparin only). Ship at room temperature. Other vacutainer tubes containing sodium heparin are acceptable. See Genetics Specimen Collection Section for detailed specimen instructions. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: See Instructions Frozen: Unacceptable
Reference Ranges:	See report
Methodology:	Fluorescence in Situ Hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute

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.

Metanephrines, Fractionated, LC/MS/MS, Random Urine	
Clinical Significance:	Useful in the evaluation of pheochromocytoma.
Effective Date:	May 11, 2009
Test Code:	14961
Specimen Requirements:	5 mL random urine with 6N HCL in plastic screw cap container (preferred) Urine collected with boric acid is unacceptable.
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements.

Reticulin IgA Screen with Reflex to Titer	
Clinical Significance:	Anti-Reticulin IgA occurs most frequently in patients with gluten sensitive enteropathy, i.e. celiac disease and dermatitis herpetiformis.
Effective Date:	May 18, 2009
Test Code:	37520
Reject Criteria:	Gross Hemolysis, Hyperlipemia and post mortem specimens are unacceptable
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Methodology:	Immunoassay
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test code, test name, result name, result code, transport temperature, stabilities, assay category, methodology, reject criteria, remove always message. If the Reticulin IgA Screen is positive, then the Antibody Titer will be added at an additional charge (CPT: 86256).

Assay Category Update

Effective May 11, 2009, the following codes will have an assay category update.

Assay Category:	Laboratory Developed Test
Test Code:	Test Name
16045	Histone Deacetylase-1 and -2, IHC

Assay Category:	FDA Approved/Cleared
Test Code:	Test Name
39584	bcl-2, IHC
11230	CD117, IHC
37566	CD20
10024	CD3, IHC/Interpretation
39614	CD30 (KI-1)
10868	CD43
15798	CD45 (Leukocyte Common Antigen), IHC
12112	CD45RO
38995	CD5
39502	Cytokeratin (AE1/AE3), IHC with Interpretation
37079	E-Cadherin, IHC
36160	Estrogen Receptor (ER), IHC with Interpretation
10027	IgM, IHC
39615	Kappa Light Chain
29914	Ki 67, IHC with Interpretation
19100	MIB 1 (Ki67), IHC w/o Interp
12740	Micrometastasis Detection in Lymph Nodes
36162	p53 Oncoprotein
19253	p53 Oncoprotein, IHC w/o Interpretation
15465	CD15, IHC

Discontinued Tests

Entamoeba histolytica Antibody (IgG), ELISA	
Effective Date:	May 11, 2009
Test Code:	30262
Additional Information:	This test will be discontinued. The recommended alternative is 34278-Entamoeba Histolytica IgG ELISA

535-Hydroxyproline, Total 24-Hour Urine 685-Hydroxyproline, Free, 24-Hour Urine 10515-Hydroxyproline, Total, 2 Hour Urine 37407-Hydroxyproline, Total, Random Urine	
Effective Date:	May 11, 2009
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	These tests will be discontinued. The recommended alternative is 37558 - Hydroxyproline, LC/MS, Plasma.

Reticulin IgG Antibody	
Effective Date:	May 18, 2009
Test Code:	14781
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	This test will be discontinued. The recommended alternative is 16530 - Reticulin IgG Screen with Reflex to Titer.

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