



LABORATORY UPDATE

www.dlolab.com

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

Redirects

- Meperidine and Normeperidine, Urine 2

New Tests

- Chlamydia/Chlamydomphila Antibody Panel 1 (IgG) 3
- Cyclosporine LC/MS/MS Whole Blood..... 3
- Gastic Parietal Cell Antibody, ELISA 4
- Hemoglobin A1C w/ Reflex to Glycomark® 4
- HIV-1 Coreceptor Tropism..... 5
- QNS HPV High Risk 5

Test Changes

- Cystic Fibrosis assays – Update assay category and CPT code (s)..... 6
- Hepatitis D Antigen – Update assay category. 6
- Hepatitis D Virus (HDV) IgM Antibody, EIA – Update assay category..... 7
- Hepatitis D Antibody, Total – Update assay category..... 7
- Interferon-Alpha, EIA – Update test name and reference range..... 7
- Rabies Antibody, ELISA – Update assay category. 7

Discontinued Tests

- Chlamydia IGG Antibody..... 8
- Cyclosporine A, HPLC (B) 8
- Parietal Cell Antibody w/ Reflex to Titer 8
- SensiTrop II™ (HIV-1 Co-Receptor Tropism)..... 8
- Antimicrobial Level, Pyrazinamide, SP..... 8
- HTLV-I/II Antibody, EIA..... 8

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:

Redirects

Meperidine and Normeperidine, Urine		
Effective Date:	June 8, 2009	
<i>Former Test Name:</i>	<i>Meperidine & Normeperidine urine</i>	
<i>Former Test Code:</i>	<i>21109</i>	
Test Code:	70074	
CPT Code(s):	83925	
Transport Temperature:	Room temperature	
Reference Ranges:	Limit of Quantitation:	
	Meperidine	12 ng/mL
	Normeperidine	8 ng/mL
Methodology:	Liquid Chromatography/Tandem Mass Spectrometry	
Assay Category:	Laboratory Developed Test	
Performing Site:	<i>This test, previously performed at NMS Labs, will now be performed at Specialty Laboratories.</i>	
Additional Information:	Update test name, test code, CPT code, transport temperature, reference range, methodology, assay category, 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.

Chlamydia/Chlamydophila Antibody Panel 1 (IgG)	
Clinical Significance:	Chlamydia/Chlamydophila species include C.Pneumoniae, C.Psittaci, and C.Trachomatis. Each may cause pneumonia and other overlapping medical conditions.
Effective Date:	Now Available
Test Code:	37125
CPT Code(s):	86631 x3
Specimen Requirements:	1 ml Serum
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 7 Days Refrigerated: 14 Days Frozen: 30 Days
Reference Ranges:	IgG < 1:64
Methodology:	IFA (Immunofluorescence Assay)
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics

Cyclosporine LC/MS/MS Whole Blood	
Clinical Significance:	Cyclosporine is a commonly used immunosuppressive drug in patients receiving transplants. LCMSMS methods have higher specificity for the parent compound than FPIA. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity
Effective Date:	Now Available
Test Code:	15220
CPT Code:	80158
Specimen Requirements:	5 ml Whole Blood collected in an EDTA Lavender Top. Optimum time to collect sample: 1 Hour before next dose
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: 24 Hours Refrigerated: 5 Days Frozen: Unacceptable
Reference Ranges:	100-300 ng/mL Toxic: >300
Methodology:	Liquid Chromatography Tandem Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute San Juan Capistrano

Gastric Parietal Cell Antibody, ELISA	
Clinical Significance:	Gastric Parietal Cell Antibodies (GPA) test results are used in the diagnosis of Pernicious Anemia.
Effective Date:	Now Available
Test Code:	15114
CPT Code:	83516
Specimen Requirements:	1 ml Serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: 8 Hours Refrigerated: 2 Weeks Frozen: 1 Month
Reference Ranges:	<=20.0 Negative 20.1 – 24.9 Equivocal >=25.0 Positive
Methodology:	Enzyme Linked Immunosorbent Immunoassay
Assay Category:	FDA Approved
Performing Site:	Quest Diagnostics Nichols Institute San Juan Capistrano

Hemoglobin A1C w/ Reflex to Glycomark®	
Clinical Significance:	Assesses long term diabetic control in Diabetes Mellitus.
Effective Date:	Now Available
Test Code:	16715
CPT Code(s):	83036 If reflex performed: 84378
Specimen Requirements:	Submit two separate specimens: 1) Whole Blood Full Lavender Top EDTA Tube 2) 1 ml Serum
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 7 Days Refrigerated: 7 Days Frozen: 6 Months
Reference Ranges:	Non-diabetic: <6.0% of total Hgb
Methodology:	Immunoturbidimetry
Reflex Criteria:	If Hemoglobin A1c is ≥6.5 and ≤8.0, Glycomark® will be performed at an additional charge

HIV-1 Coreceptor Tropism	
Clinical Significance:	The use of CCR5 antagonists in patients harboring CXCR4 (X4) or dual/mixed (D/M) viruses has proven to be ineffective and leads to the emergence of X4 viruses as the predominant species in D/M patients. In clinical trials, X4 virus was found in 55% of patients failing maraviroc therapy vs. only 9% of patients who experienced treatment failure in the placebo arm. The use of CCR5 antagonists, therefore, requires screening for viral tropism to exclude patients harboring X4 or D/M virus. Detection of X4 virus prior to the initiation of therapy has been associated with a reduced response to maraviroc (http://www.pfizer.com/files/products/uspi_maraviroc.pdf).
Effective Date:	April 13, 2009
Test Code:	16710
CPT Code(s):	87901
Specimen Requirements:	2 mL EDTA (lavender-top) plasma Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Separate plasma from the cells by centrifugation within 6 hours after collection, transfer the plasma to a separate plastic screw-cap vial, and ship frozen.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days
Reference Ranges:	CXCR4(X4): Not Detected
Methodology:	Sequencing and Heteroduplex Tracking Analysis
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

QNS HPV High Risk	
Clinical Significance:	The "Quantity not sufficient (QNS) HPV High Risk" assay is intended to be used to test for the presence of High Risk HPV in samples with less than 4mL of starting volume following the performance of the ThinPrep® Liquid based Pap test.
Effective Date:	June 1, 2009
Test Code:	16737 (automatic replacement code)
CPT Code:	87621
Specimen Requirements:	2mL PreservCyt® Solution in ThinPrep® vial
Transport Temperature:	Room Temperature
Specimen Stability:	Room temperature and Refrigerated: 90 days Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	Signal Amplification
Assay Category:	FDA approved/cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	This test is not available as a separate orderable code. If the specimen received is < 4 mL, the routine ThinPrep HR HPV test will automatically be replaced by the QNS HPV HR test. Note: this will affect ThinPrep Pap Test with Reflex to HR HPV (31530), ThinPrep Pap Test with Imaging with Reflex to HR HPV (58316), ThinPrep Pap + HR HPV (15003), and ThinPrep Pap with Imaging + HR HPV (58317).

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.

Effective June 8, 2009, the following test codes will have CPT code(s) and assay category updates.

Test Code:	Test Name:	Assay Category	CPT Code(s)
10458	Cystic Fibrosis Carrier Screen	FDA Approved/Cleared	83891; 83909; 83914 (x32) ; 83900; 83901 (x13); 83912
<i>Please note the test code above is included in group code: 17625 - Male Infertility Genetic Analysis</i>			
10910	Ashkenazi Jewish Panel	ASR Class 1	83891; 83909; 83914 (x32) ; 83901 (x13); 83912; 83901 (x3); 83914 (x4); 83912; 83901 (x2); 83914 (x8); 83912; 83901; 83914 (x2); 83912; 83901; 83914; 83912; 83901 (x4); 83914 (x7); 83912; 83901; 83914 (x2); 83912; 83901 (x2); 83914 (x4); 83912; 83891; 83909;
10226	Cystic Fibrosis, Fetus	FDA Approved/Modified	88235; 83891 (x2); 83909 (x2); 83914 (x64) ; 83900 (x2); 83901(x26); 83912 (x2)

Hepatitis D Antigen	
Clinical Significance:	Hepatitis D agent occurs only in patients infected with HBV. Patients with Hepatitis D are more likely to develop fulminant hepatitis and chronic hepatitis than patients infected only with HBV. Hepatitis Delta Antigen detection is transient and occurs before development of antibody.
Effective Date:	June 8, 2009
Test Code:	23880
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update assay category.

Hepatitis D Virus (HDV) IgM Antibody, EIA	
Clinical Significance:	Hepatitis D virus (HDV) infection occurs in association with HBV infection. A positive result for HDV IgM indicates recent HDV infection.
Effective Date:	June 8, 2009
Test Code:	35664
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update assay category.

Hepatitis D Antibody, Total	
Clinical Significance:	Hepatitis D Virus (HDV) infection occurs in association with HBV infection. A positive result for HDV total antibody may indicate either acute or chronic HDV infection.
Effective Date:	June 8, 2009
Test Code:	4990
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update assay category.

Interferon Alpha, EIA	
Clinical Significance:	Elevated interferon-alpha levels may be seen in viral disease, chronic fatigue-immune dysfunction syndrome, and some inflammatory diseases.
Effective Date:	June 8, 2009
<i>Former Test Name:</i>	<i>Interferon-Alpha, EIA (serum)</i>
Test Code:	34887
Reference Range:	<5 IU/mL
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update test name, reference range and always message.

Rabies Antibody, ELISA	
Clinical Significance:	This assay is designed to measure rabies antibodies induced by rabies vaccination only. Antibody levels of 0.50 IU/mL or greater are expected post-vaccination.
Effective Date:	June 8, 2009
Test Code:	37118
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update assay category .

Discontinued Tests

Chlamydia IGG Antibody	
Effective Date:	Immediately
Test Code:	987
Performing Site:	Quest Diagnostics West Hills
Additional Information:	This test will be discontinued. Please refer to the Directory of Services for a replacement.

Cyclosporine A, HPLC (B)	
Effective Date:	Immediately
Test Code:	4845
Performing Site:	Quest Diagnostics West Hills
Additional Information:	This test will be discontinued. The recommended alternative is 15220 – Cyclosporine LC/MS/MS Whole Blood performed at Quest Diagnostics Nichols Institute San Juan Capistrano

Parietal Cell Antibody w/ Reflex to Titer	
Effective Date:	Immediately
Test Code:	262
Performing Site:	Quest Diagnostics West Hills
Additional Information:	This test will be discontinued. Please refer to the Directory of Services for a replacement.

SensiTrop II™ (HIV-1 Co-Receptor Tropism)	
Effective Date:	June 1, 2009
Test Code:	70081
Performing Site:	Pathway Diagnostics Corporation
Additional Information:	This test will be discontinued. The recommended alternative is 16710 - HIV-1 Coreceptor Tropism performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

Antimicrobial Level, Pyrazinamide, SP	
Effective Date:	June 8, 2009
Test Code:	30308
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	This test will be discontinued. The recommended alternative is 16726 - Antimicrobial Level, Pyrazinamide, HPLC performed by Focus Diagnostics, Inc.

HTLV I/II Antibody, EIA	
Effective Date:	June 8, 2009
Test Code:	34311
Additional Information:	This test will be discontinued. The recommended alternative is 36175 - HTLV-I/II Antibody, EIA with Positives Reflexed to Western Blot performed at Quest Diagnostics Nichols Institute.

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

DLO	Page 8 of 8	May 2009
-----	-------------	----------