



# LABORATORY UPDATE

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## Advanced Beneficiary Notice of Noncoverage

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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**

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

**Advanced Beneficiary Notice of Noncoverage**  
**Change mandated by CMS, Effective March 1, 2009**

DLO will begin using the revised Advance Beneficiary Notice (ABN) of Noncoverage form which has been developed by the Centers for Medicare & Medicaid Services (CMS). The revised ABN is a separate form that must be reviewed, checked, signed and dated by the Medicare patient and must accompany any laboratory requisition with an order for a limited coverage test(s) for which Medicare is expected to deny payment. According to CMS, the revised form provides a standard and more effective communication to beneficiaries regarding services they may have to pay for and prices for the limited coverage test (s), which will result in beneficiaries taking a more active roll in their own health care management.

During the month of February, you will have received a package containing revised ABN forms with instructions for use. Please begin using form CMS-R-131 beginning March 1, 2009. Form ABN-G or ABN-L is invalid effective March 1, 2009 and can be discarded or returned to your Route Service Representative.

**Routine Testing**

**Test Changes**

<b>Creatinine Clearance w/eGFR</b>	
Clinical Significance:	Creatinine clearance is used to evaluate the glomerular filtration rate (GFR). Clearance is defined as that volume of plasma from which a measured amount of substance could be completely eliminated into the urine per unit of time. Daily creatinine production is fairly constant except when there is massive injury to muscle.
<b>Effective Date:</b>	<b>April 6, 2009</b>
Test Code:	<b>7943</b>
Specimen Requirements:	10 ml urine aliquot from a well-mixed, 24 hr collection; no preservative. Record total volume and collection time on specimen container and requisition. Indicate the patient's height and weight on the test requisition. <b>Minimum Specimen Volume: 0.5 mL</b> <b>A serum creatinine level must be collected within 24 hours of the beginning or ending of the urine collection.</b>
Specimen Stability:	Room Temperature: 7 days <b>Refrigerated: 7 days</b> <b>Frozen: 28 days</b>
Methodology:	<b>Spectrophotometry</b>
Additional Information:	Update specimen requirements, specimen stability and methodology.

<b>Cyclic Citrullinated Peptide (CCP) Antibody (IgG)</b>									
Clinical Significance:	This test is useful in discriminating Rheumatoid Arthritis patients from other patients.								
<b>Effective Date:</b>	<b>April 6, 2009</b>								
Test Code:	11173								
CPT Code:	86200								
Specimen Requirements:	1 mL serum (0.5 minimum)								
Transport Temperature:	Room Temperature								
Specimen Stability:	<b>Room temperature: 4 days</b> <b>Refrigerated: 7 days</b> <b>Frozen: 30 days</b>								
Units of Measure:	<b>Units</b>								
Reference Ranges:	<table border="1"> <tbody> <tr> <td>&lt; 20</td> <td><b>Negative</b></td> </tr> <tr> <td>20 – 39</td> <td><b>Weak Positive</b></td> </tr> <tr> <td>40 – 59</td> <td><b>Moderate Positive</b></td> </tr> <tr> <td>&gt; 59</td> <td><b>Strong Positive</b></td> </tr> </tbody> </table>	< 20	<b>Negative</b>	20 – 39	<b>Weak Positive</b>	40 – 59	<b>Moderate Positive</b>	> 59	<b>Strong Positive</b>
< 20	<b>Negative</b>								
20 – 39	<b>Weak Positive</b>								
40 – 59	<b>Moderate Positive</b>								
> 59	<b>Strong Positive</b>								
Methodology:	Immunoassay								
Assay Category:	FDA approved								
Additional Information:	Update specimen stability. Also included in 19867 (ANAchoice™ Rheumatoid Arthritis Panel).								

<b>Microalbumin, 24-Hour Urine (without Creatinine)</b>	
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 patients.
<b>Effective Date:</b>	<b>April 6, 2009</b>
Test Code:	<b>4555</b>
Specimen Requirements:	<b>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.</b>
Additional Information:	Update specimen requirements

<b>Microalbumin, Random Urine (with Creatinine)</b>	
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 patients.
<b>Effective Date:</b>	<b>April 6, 2009</b>
Test Code:	<b>6517</b>
Specimen Requirements:	<b>5 mL (2 mL minimum) random urine submitted in a plastic, leak-proof container. Do not use preservatives. Mix well if aliquoting.</b>
Additional Information:	Update specimen requirements

<b>Microalbumin, Random Urine (without Creatinine)</b>	
<b>Effective Date:</b>	<b>April 6, 2009</b>
Test Code:	<b>17674</b>
Specimen Requirements:	<b>5 mL (2 mL minimum) random urine submitted in a plastic, leak-proof container. Do not use preservatives. Mix well if aliquoting.</b>
Additional Information:	Update specimen requirements.

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & Chantilly),  
Focus Diagnostics, Inc., Specialty Laboratories**

**New Tests**

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

<b>Antimicrobial Level, Pyrazinamide, HPLC</b>	
Clinical Significance:	Pyrazinamide is used in the treatment of tuberculosis and serum levels should be monitored to ensure proper dosing levels and to prevent build up of toxic levels.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16726</b>
CPT Code:	<b>80299</b>
Specimen Requirements:	<b>2 mL no additive (red-top) serum</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Unacceptable Frozen: 14 days</b>
Reference Ranges:	<b>&lt; or = 0.5 mcg/mL</b>
Methodology:	<b>High Performance Liquid Chromatography</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Focus Diagnostics, Inc.

<b><i>Clostridium difficile</i> DNA and Toxin B Gene, Qualitative Real-Time PCR</b>	
Clinical Significance:	<i>Clostridium difficile</i> strains producing toxin A and/or toxin B are associated with diarrheal disease, whereas strains that produce neither toxin are not. Most <i>C. difficile</i> strains associated with diarrheal disease produce both toxin A and B. Thus, this qualitative real-time PCR assay is useful for the diagnosis of toxigenic <i>C. difficile</i> associated with diarrheal disease.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16739</b>
CPT Code:	<b>83891; 83896; 83898; 83912; 87798</b>
Specimen Requirements:	<b>1 gram stool</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Unacceptable Frozen: 30 days</b>
Reference Ranges:	<b>Not Detected</b>
Methodology:	<b>Real-Time Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Focus Diagnostics, Inc.

<b>Epstein-Barr Virus, ISH with Interpretation</b>	
Clinical Significance:	EBV is associated with Hodgkin's lymphoma, and EBV-LMP1, or small RNA's of EBV known as EBERS, can be detected in about 50% of cases of classic Hodgkin's lymphoma.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16688</b>
CPT Code(s):	<b>88365</b>
Specimen Requirements:	<b>Formalin fixed paraffin embedded tissue</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze</b>
Reference Ranges:	<b>With report</b>
Methodology:	<b>In-Situ Hybridization</b>
Assay Category:	<b>ASR Class 1</b>
Performing Site:	Quest Diagnostics Nichols Institute

<b>Herpes Simplex Virus Type 1 and 2, IHC with Interpretation</b>	
Clinical Significance:	For the detection of HSV infected tissue. Two serotypes of the herpes simplex virus, HSV-1 (also known as type one or oral) and HSV-2 (type 2 or genital), can establish lifelong latent infections with sensory ganglia. Periodically, the virus reactivates and can cause recurrent cold sores, encephalitis and eye and genital infections. HSV-1 usually establishes latency in the trigeminal ganglion, a collection of nerve cells near the ear. From there, it tends to recur on the lower lip or face. HSV-2 usually resides in the sacral ganglion at the base of the spine. From there, it can reactivate and can cause recurrent lesions in the genital area.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16720</b>
CPT Code(s):	<b>88342</b>
Specimen Requirements:	<b>Formalin fixed paraffin embedded tissue in IHC specimen transport kit Pathology report is required.</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze</b>
Reference Ranges:	<b>See report</b>
Methodology:	<b>Immunohistochemical Stain</b>
Assay Category:	<b>ASR Class 1</b>
Performing Site:	Quest Diagnostics Nichols Institute

<b>HEXA Mutation Analysis, Gene Sequencing</b>	
Clinical Significance:	This assay is for identification of small rare mutations in the HEXA gene. It can be used to confirm or clarify Tay-Sachs carrier status of individuals with positive or ambiguous hexoaminidase test results. It can also be used in prenatal diagnosis.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16612</b>
CPT Code(s):	<b>83891, 83892 (x14), 83894, 83898 (x14), 83904 (x14), 83912</b>
Specimen Requirements:	<b>5 mL EDTA (lavender-top) whole blood</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze</b>
Reference Ranges:	<b>See report</b>
Methodology:	<b>Polymerase Chain Reaction</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<b>HIV-1 RNA, Quantitative Real-Time PCR, CSF</b>	
Clinical Significance:	This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	<b>16186</b>
CPT Code(s):	<b>87536</b>
Specimen Requirements:	<b>3 mL CSF in sterile leak-proof container Collect at least 3 mL in a sterile screw-capped container (1.1 mL min). Do not use heparin tube for collection as heparin inhibits PCR. Ship CSF frozen.</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days</b>
Reference Ranges:	<b>Copies/mL: &lt;48                      Copies/mL Log copies/mL: &lt;1.68              Log copies/mL</b>
Methodology:	<b>Polymerase Chain Reaction</b>
Assay Category:	<b>FDA Approved/Cleared/Modified</b>
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.

<b>19619-FISH, Multiple Myeloma, 5,9,15 19722-FISH, Myeloma, 13q,14q, 17p w/reflex to 5,9,15</b>	
Clinical Significance:	Prognostic investigation in patients with multiple myeloma.
<b>Effective Date:</b>	<b>April 13, 2009</b>
Specimen Requirements:	3 mL bone marrow <b>in transport media</b> <b>Whole blood is unacceptable.</b> <b>Bone marrow, 1-3 mL in transport media (preferred) or bone marrow in sodium heparin tube (Green, dark/royal blue or tan top) accepted for this test.</b> Ship at room temperature. Do not freeze. Specimen viability decreases during transit. Send specimen to testing lab for viability determination. Do not reject.
Specimen Stability:	<b>Room temperature and Refrigerated: See Instructions</b> <b>Frozen: Unacceptable</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements and stability.

<b>GlycoMark®</b>				
<b>Effective Date:</b>	<b>April 13, 2009</b>			
Test Code:	<b>19599</b>			
Reference Ranges:	Adults:	Males:	10.7 – 32.0	mcg/mL
		Females:	6.8 – 29.3	mcg/mL
	Pediatric:	<b>0-1 years:</b>	<b>Not established</b>	<b>mcg/mL</b>
		<b>2-17 years:</b>	<b>Females: 11.2-35.7</b>	<b>mcg/mL</b>
			<b>Males: 15.0-38.0</b>	<b>mcg/mL</b>
Performing Site:	This test currently performed at Quest Diagnostics Nichols Institute, Chantilly.			
Additional Information:	Update performing site. Add pediatric reference range.			

<b>Vitamin B12 Binding Capacity, Unsat (Transcobalamin)</b>	
Clinical Significance:	Vitamin B12 Binding Capacity, Unsaturated (Transcobalamin), binds and transports Vitamin B12 in the circulation. Increased concentrations are associated with patients with myeloproliferative disorders. Decreased concentrations are associated with infants with megaloblastic anemia or Transcobalamin deficiency.
<b>Effective Date:</b>	<b>April 13, 2009</b>
<b>Test Code:</b>	<b>928</b>
Performing Site:	This test currently performed at Quest Diagnostics Nichols Institute, Chantilly and San Juan Capistrano, <b>will now be performed at Quest Diagnostics Nichols Institute, Chantilly.</b>
Additional Information:	Update performing site <a href="#">and test name.</a>

<b>von Willebrand Factor Collagen Binding Assay</b>			
Clinical Significance:	This test is a surrogate assay for the measurement of von Willebrand Factor-mediated platelet adhesion. The intensity of activity (collagen bound to A-3 domains of VWF protein) is directly related to the intensity of high weight multimers and therefore is a superior test in comparison to VWF:Rcof for distinguishing VWD Types IIA,IIB and IIM. It may be of value in acquired von Willebrand syndrome.		
Effective Date :	<b>April 13, 2009</b>		
Test Code :	10924		
Reference Range:	vWf:Collagen Binding:	45-198	% normal
	<b>Ratio (CBA/vW Ag):</b>	<b>&gt; or = 0.50</b>	ratio
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano		
Additional Information:	Update reference range and always message. Please note this test code is included in the following group codes: 15540-von Willebrand Comprehensive Panel.		

**Effective April 13, 2009, the following test codes will have a SOURCE prompt added.**

Test Code	Test Name
11365	<i>Bordetella pertussis/parapertussis</i>
10601	Cytomegalovirus DNA, QL RT PCR
10600	Cytomegalovirus DNA, QN RT PCR
34179	Epstein Barr Virus DNA, QL RT PCR
10186	Epstein Barr Virus DNA, QN RT PCR
16001	Herpes Virus 6 DNA, QL RT-PCR
34296	Parvovirus B19 DNA, QL Real Time PCR
34052	Varicella zoster Virus (VZV) DNA, QL RT PCR
19502	HSV, Type 1 and 2 DNA, QN Real Time PCR
30297	Lyme Disease DNA, QL, RT PCR, CSF/SF
19727	Herpes Virus 7 DNA, QN Real Time PCR
19493	Varicella zoster Virus (VZV) DNA, QN Real Time PCR
19724	Parvovirus B19 DNA, QN Real Time PCR
34181	Hepatitis B Virus DNA, Qualitative, PCR
34257	Herpes Simplex Virus 1 and 2, PCR
19723	HerpesVirus 6 DNA QN, Real Time PCR
15873	Herpes Virus 8 DNA QL Real Time PCR

<b>Collagen Cross-Linked N-Telopeptide (NTx), 24-Hour Urine</b>	
Effective Date:	<b>April 20, 2009</b>
Test Code:	<b>36421</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test code.

## Discontinued Tests

<b>Immunohistochemistry (IHC) Marker</b>	
<b>Effective Date :</b>	<b>April 13, 2009</b>
Test Code:	15684
Additional Information:	This test will be discontinued.

<b>IHC Marker, Stain Only</b>	
<b>Effective Date :</b>	<b>April 13, 2009</b>
Test Code:	16004
Additional Information:	This test will be discontinued.

<b>JAK2 Mutation (V617F) Analysis, QN, Cell based</b>	
<b>Effective Date:</b>	<b>April 13, 2009</b>
Test Code:	16172
Additional Information:	This test will be discontinued. Please use test code 16175-JAK2 Mutation (V617F) QN, Plasma, Leumeta™.

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