



# LABORATORY UPDATE

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## Routine Testing

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

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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

Effective January 12, 2009, Test code 873: Testosterone, Total will be reported with the following always message: “In hypogonadal males, Testosterone, Total, LC/MS/MS (test code 15983; collect in red-top tube no gel) is the recommended assay (performed at Quest Diagnostics Nichols Institute).” **Please note that the specimen for the LC/MS/MS analysis must be submitted in a plain red top tube. Gel-barrier tubes will be rejected.**

<b>Cardiolipin Antibody (IgG)</b>	
Clinical Significance:	Cardiolipin Antibodies are seen in a subgroup of patients with autoimmune disorders, particularly Systemic Lupus Erythematosus (SLE), who are at risk for vascular thrombosis, thrombocytopenia, cerebral infarct and/or recurrent spontaneous abortion. Elevations of Cardiolipin Antibodies associated with increased risk have also been seen in idiopathic thrombocytopenic purpura, rheumatoid and psoriatic arthritis, and primary Sjögren's syndrome.
<b>Effective Date:</b>	<b>January 12, 2009</b>
<i>Former Test Name:</i>	<i>Cardiolipin IgG Antibody</i>
Test Code:	4662
CPT Code:	86147
Specimen Requirements:	1 mL citrated plasma (light blue-top) tube ( <b>minimum 0.5 mL</b> )
Reference Ranges:	<b>&lt; 10 GPL U/mL</b> <b>Negative</b>
	<b>10 – 15 GPL U/mL</b> <b>Equivocal</b>
	<b>16 – 40 GPL U/mL</b> <b>Positive - Uncertain risk factor; may be reactive</b>
	<b>&gt; 40 GPL U/mL</b> <b>Positive - Risk factor for thrombosis and pregnancy loss</b>
Additional Information:	Update minimum volumes, reference range and test name.

<b>Cardiolipin Antibody (IgM)</b>	
<b>Effective Date:</b>	<b>January 12, 2009</b>
<i>Former Test Name:</i>	<i>Cardiolipin IgM Antibody</i>
Test Code:	4663
CPT Code:	86147
Specimen Requirements:	1 mL citrated plasma (light blue-top) tube ( <b>minimum 0.5 mL</b> )
Units of Measure	GPL U/mL
Reference Ranges:	<b>&lt; 10 MPL U/mL</b> <b>Negative</b>
	<b>10 – 15 MPL U/mL</b> <b>Equivocal</b>
	<b>16 – 40 MPL U/mL</b> <b>Positive - Uncertain risk factor; may be reactive</b>
	<b>&gt; 40 MPL U/mL</b> <b>Positive - Risk factor for thrombosis and pregnancy loss</b>
Additional Information:	Update minimum volumes, reference range and test name.

<b>Cardiolipin Antibody (IgA)</b>							
<b>Effective Date:</b>	<b>January 12, 2009</b>						
<i>Former Test Name:</i>	<i>Cardiolipin IgA Antibody</i>						
Test Code:	4661						
CPT Code:	86147						
Specimen Requirements:	1 mL citrated plasma (light blue-top) tube ( <b>minimum 0.5 mL</b> )						
Reference Ranges:	<table border="1"> <tr> <td>&lt; 10 APL U/mL</td> <td>Negative</td> </tr> <tr> <td>10 – 15 APL U/mL</td> <td>Equivocal</td> </tr> <tr> <td>&gt;15 APL U/mL</td> <td>Positive</td> </tr> </table>	< 10 APL U/mL	Negative	10 – 15 APL U/mL	Equivocal	>15 APL U/mL	Positive
< 10 APL U/mL	Negative						
10 – 15 APL U/mL	Equivocal						
>15 APL U/mL	Positive						
Additional Information:	Update minimum volumes, reference range, and test name.						

<b>Cardiolipin Antibodies (IgG, IgM)</b>			
<b>Effective Date:</b>	<b>January 12, 2009</b>		
Test Code:	36333		
CPT Code:	86147 (x2)		
Specimen Requirements:	1 mL citrated plasma (light blue-top) tube ( <b>minimum 0.5 mL</b> )		
Reference Ranges:	<b>Cardiolipin IgG (GPL U/mL)</b>	< 10	Negative
		10 – 15	Equivocal
		16 – 40	Positive - Uncertain risk factor; may be reactive
		> 40	Positive - Risk factor for thrombosis and pregnancy loss
	<b>Cardiolipin IgM (MPL U/mL)</b>	< 10	Negative
		10 – 15	Equivocal
		16 – 40	Positive - Uncertain risk factor; may be reactive
		> 40	Positive - Risk factor for thrombosis and pregnancy loss
Additional Information:	Update reference range.		

<b>Mitochondrial Antibody with Reflex to Titer</b>					
Clinical Significance:	A high Anti-Mitochondrial Antibody (AMA) titer supports the diagnosis of primary biliary cirrhosis (PBC). Low titers of AMA may be detected in other liver disorders, which include chronic active hepatitis and cryptogenic cirrhosis. Mitochondrial M2 Antibody has an even higher specificity for PBC.				
<b>Effective Date:</b>	<b>January 12, 2009</b>				
Test Code:	259				
CPT Code	86255				
Specimen Requirements:	<b>0.5 mL serum (minimum: 0.1 mL)</b>				
Specimen Stability:	<b>Room temperature: 7 days</b> <b>Refrigerated: 14 days</b> <b>Frozen: 30 days</b>				
Reference Ranges:	<table border="1"> <tr> <td><b>AMA Screen</b></td> <td><b>Negative</b></td> </tr> <tr> <td><b>AMA Titer</b></td> <td><b>&lt; 1:20</b></td> </tr> </table>	<b>AMA Screen</b>	<b>Negative</b>	<b>AMA Titer</b>	<b>&lt; 1:20</b>
<b>AMA Screen</b>	<b>Negative</b>				
<b>AMA Titer</b>	<b>&lt; 1:20</b>				
Methodology:	<b>Immunoassay</b>				
Additional Information:	Update specimen requirements and specimen stability. If the AMA screen is positive, the AMA Titer (CPT codes(s): 86256) will be added at an additional charge. Please note this change will also affect 19880-Sjögren's Syndrome Diagnostic Panel, Comprehensive.				

**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.

<b><i>Coxiella burnetii</i> DNA, Qualitative Real-Time PCR</b>	
Clinical Significance:	Real-time PCR detection of <i>Coxiella burnetii</i> can be used as a tool in the diagnosis of both acute and chronic Q fever. Real-time PCR assays offer superior sensitivity, rapid test result turn-around-time and the ability to detect <i>C. burnetii</i> DNA in multiple specimen types.
<b>Effective Date:</b>	<b>December 1, 2008</b>
Test Code:	<b>16596</b>
CPT Code(s):	<b>87798</b>
Specimen Requirements:	<b>0.7 mL serum, CSF, BAL or 1 respiratory swab in 3 mL, V-C-M medium (green-cap) tube or equivalent (UTM)</b>
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room temperature: 48 hours Refrigerated: 7 days 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><i>Treponema pallidum</i> DNA, Qualitative Real-Time PCR</b>	
Clinical Significance:	Detection of <i>Treponema pallidum</i> DNA by real-time PCR is a useful tool for the rapid diagnosis of primary, secondary and tertiary syphilis.
<b>Effective Date:</b>	<b>December 1, 2008</b>
Test Code:	<b>16595</b>
CPT Code(s):	<b>87798</b>
Specimen Requirements:	<b>0.7 mL CSF, serum, whole blood (EDTA or ACD) or 1 genital swab in 3 mL, V-C-M medium (green-cap) tube or equivalent (UTM)</b>
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room temperature: 48 hours Refrigerated: 7 days 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.



### 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>Beta 2-Glycoprotein I Antibodies (IgG, IgA, IgM)</b>			
Clinical Significance:	Beta-2-Glycoprotein 1, apolipoprotein H, is a cofactor in antiphospholipid antibody binding and is the critical antigen in the antiphospholipid antibody syndrome. Beta-2-Glycoprotein 1 Antibody is the anchor binding protein for cardiolipin and gives a truer expression of the phospholipid antibodies that are pathophysiologically present.		
Effective Date:	<b>January 12, 2009</b>		
Test Code:	30340		
Reference Ranges:	<b>IgG</b>	<20 U/mL	<b>Negative</b>
		<b>20-30 U/mL</b>	<b>Equivocal - Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;30 U/mL</b>	<b>Positive - Risk factor for thrombosis and pregnancy loss</b>
	<b>IgA</b>	<10 U/mL	<b>Negative</b>
		<b>10-20 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;20 U/mL</b>	<b>Positive – Risk factor for thrombosis</b>
	<b>IgM</b>	<10 U/mL	<b>Negative</b>
		<b>10-20 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;20 U/mL</b>	<b>Positive – Risk factor for thrombosis and pregnancy loss</b>
Performing Site:	Quest Diagnostics Nichols Institute		
Additional Information:	Update reference range. Please note this test is included in the following group code: 14890-Antiphospholipid Antibody Panel.		

<b>Beta2-Glycoprotein I Antibody (IgG)</b>		
Effective Date:	<b>January 12, 2009</b>	
Test Code:	36554	
Reference Ranges:	<20 U/mL	<b>Negative</b>
	<b>20-30 U/mL</b>	<b>Equivocal - Found in small percentage of the healthy population; may be reactive</b>
	<b>&gt;30 U/mL</b>	<b>Positive - Risk factor for thrombosis and pregnancy loss</b>
Performing Site:	Quest Diagnostics Nichols Institute	
Additional Information:	Update reference range. Please note this test is included in the following group code: 19872 - Antiphospholipid Syndrome Diagnostic Panel.	

<b>Beta2-Glycoprotein I Antibody (IgM)</b>		
<b>Effective Date:</b>	<b>January 12, 2009</b>	
Test Code:	36553	
Reference Ranges:	<10 U/mL	<b>Negative</b>
	<b>10-20 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
	<b>&gt;20 U/mL</b>	<b>Positive – Risk factor for thrombosis and pregnancy loss</b>
Performing Site:	Quest Diagnostics Nichols Institute	
Additional Information:	Update reference range. Please note this test is included in the following group code: 19872 - Antiphospholipid Syndrome Diagnostic Panel.	

<b>Beta2-Glycoprotein I Antibody (IgA)</b>		
<b>Effective Date:</b>	<b>January 12, 2009</b>	
Test Code:	36552	
Reference Ranges:	<10 U/mL	<b>Negative</b>
	<b>10-20 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
	<b>&gt;20 U/mL</b>	<b>Positive – Risk factor for thrombosis</b>
Performing Site:	Quest Diagnostics Nichols Institute	
Additional Information:	Update reference range. Please note this test is included in the following group code: 19872 - Antiphospholipid Syndrome Diagnostic Panel.	

<b>Phosphatidylserine Antibodies (IgA, IgG, IgM)</b>			
Clinical Significance:	Phosphatidylserine Antibodies are used to assist in the diagnosis, management, and possible prevention of thrombotic complications as part of the Antiphospholipid syndrome.		
<b>Effective Date:</b>	<b>January 12, 2009</b>		
Test Code:	10062		
Reference Ranges:	<b>IgA</b>	<20 U/mL	Negative
		<b>20-30 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;30 U/mL</b>	<b>Positive – Risk factor for thrombosis</b>
	<b>IgG</b>	<10 U/mL	Negative
		<b>10-20 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;20 U/mL</b>	<b>Positive – Risk factor for thrombosis and pregnancy loss</b>
	<b>IgM</b>	<25 U/mL	Negative
		<b>25-35 U/mL</b>	<b>Equivocal – Found in small percentage of the healthy population; may be reactive</b>
		<b>&gt;35 U/mL</b>	<b>Positive – Risk factor for thrombosis and pregnancy loss</b>
Performing Site:	Quest Diagnostics Nichols Institute		
Additional Information:	Update reference range. Please note this test is included in the following group code: 14890 - Antiphospholipid Antibody Panel.		

<b>Phosphatidylserine Antibodies (IgG, IgM)</b>			
<b>Effective Date:</b>	<b>January 12, 2009</b>		
Test Code:	36595		
Reference Ranges:	<b>IgG</b>	<10 U/mL	Negative
		10-20 U/mL	Equivocal – Found in small percentage of the healthy population; may be reactive
		>20 U/mL	Positive – Risk factor for thrombosis and pregnancy loss
	<b>IgM</b>	<25 U/mL	Negative
		25-35 U/mL	Equivocal – Found in small percentage of the healthy population; may be reactive
		>35 U/mL	Positive – Risk factor for thrombosis and pregnancy loss
Performing Site:	Quest Diagnostics Nichols Institute		
Additional Information:	Update reference range.		

<b>Phosphatidylserine Antibody (IgA)</b>		
<b>Effective Date:</b>	<b>January 12, 2009</b>	
Test Code:	10163	
Reference Ranges:	<20 U/mL	Negative
	20-30 U/mL	Equivocal – Found in small percentage of the healthy population; may be reactive
	>30 U/mL	Positive – Risk factor for thrombosis
Performing Site:	Quest Diagnostics Nichols Institute	
Additional Information:	Update reference range.	

<b><i>Saccharomyces cerevisiae</i> (ASCA) IgA</b>	
Clinical Significance:	Antibodies to <i>Saccharomyces cerevisiae</i> are found in approximately 75% of patients with Crohn's disease, 15% of patients with ulcerative colitis, and 5% of the healthy population. High titers of antibody increase the likelihood of disease, and specifically Crohn's disease, and are associated with more aggressive disease.
<b>Effective Date:</b>	<b>January 19, 2009</b>
<i>Former Test Name:</i>	<i>Saccharomyces cerevisiae Antibodies (ASCA) (IgA)</i>
Test Code:	10295
Transport Temperature:	<b>Room temperature</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test and result name and transport temperature. Please note this test is included in the following group code: 16503-Inflammatory Bowel Disease Differentiation Panel.

<b><i>Saccharomyces cerevisiae</i> (ASCA) IgG</b>	
<b>Effective Date:</b>	<b>January 19, 2009</b>
<i>Former Test Name:</i>	<i>Saccharomyces cerevisiae Antibodies (ASCA) (IgG)</i>
Test Code:	10294
Transport Temperature:	<b>Room temperature</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test and result name and transport temperature. Please note this test is included in the following group code: 16503-Inflammatory Bowel Disease Differentiation Panel.

<b>HIV-2 Antibody, EIA with Reflex to Western Blot</b>	
<i>*Includes: HIV-2 Antibody, EIA * Anti-HIV-2 Western Blot</i>	
Clinical Significance:	HIV-2 is closely related to HIV-1 regarding nucleic acid sequence and clinical disease. HIV-2 is endemic to West Africa with nearly all cases in the United States identified in citizens or travelers from West Africa. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Western blot is useful to confirm repeatedly reactive EIA results.
<b>Effective Date:</b>	<b>January 26, 2009</b>
<i>Former Test Name:</i>	<i>HIV-2 Antibody, EIA with Positives Reflexed to Immunoblot</i>
Test Code:	<b>37363</b>
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Methodology:	Immunoassay ( <b>Reflex: Western Blot</b> )
Assay Category:	HIV-2 EIA: FDA Approved/ Cleared (HIV-2 WB: Research use only)
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test code and test name, and methodology. If HIV-2 EIA screen is repeatedly reactive, HIV-2 WB will be performed at an additional charge (CPT code(s):86689).

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