



September 2009

TEST UPDATES

www.focusdx.com

This summary of test updates includes details and effective dates for new tests, changes to existing tests, and discontinued tests. For questions or additional information, please contact the Focus Diagnostics Client Services Department at (800) 445-4032. Visit our web site at www.focusdx.com.

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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 payer being billed.

Focus Diagnostics requires a current email address to continue to provide updates to our reference laboratory menu. Please inform our Client Services Department if there is a change in staffing or email address. Call (800) 445-4032 or email ClientServices@focusdx.com.



NEW TESTS

<i>Streptococcus pneumoniae</i> IgG Ab (23 serotypes), MAID		
Effective Date:	October 5, 2009	
Unit Code:	40962	
CPT Code:	86317 (x23)	
List Price:	\$554.00	
Specimen Requirements:	0.5 mL serum	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 60 days Frozen: 1 year	
Methodology:	MAID	
Set-up Day(s):	Monday – Friday	
Results Available:	1 to 4 days	
FDA clearance type:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test</p> <p>Always message will be:</p> <p>Note: Serotype designations are American nomenclature, with Danish nomenclature in parentheses.</p> <p>Studies from the 1980's using radioimmunoassay suggested that vaccine-induced <i>S. pneumoniae</i> type-specific antibody levels of approximately 2.0 mcg/mL were protective against invasive pneumococcal disease. Newer methods (ELISA and multiplexed immunoassay) incorporating an absorption step to remove cross-reactive antibodies yield results that are comparable to each other, but are lower than those obtained with the original radioimmunoassay. Rigorous studies of protective antibody levels as determined by the newer methods have not been performed. In addition to antibody quantity, protection also depends on antibody avidity and opsonophagocytic activity.</p> <p>Evaluation of the response to pneumococcal vaccination is best accomplished by comparing pre-vaccination and post-vaccination antibody levels. A 2- to 4-fold increase in type-specific antibodies measured 4-6 weeks after vaccination is expected in immunocompetent adults. The number of serotypes for which a 2- to 4-fold increase is observed varies greatly among individuals; a consensus panel has suggested that individuals older than 5 years should respond to at least approximately 70% of pneumococcal serotypes. Adults >65 years old may exhibit a smaller (<2-fold) increase in type-specific antibody levels.</p>	
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NEW TESTS

	This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4682	Serotype 1 (1)
	14002	Serotype 2 (2)
	4683	Serotype 3 (3)
	4684	Serotype 4 (4)
	4685	Serotype 5 (5)
	4686	Serotype 8 (8)
	4687	Serotype 9 (9N)
	4688	Serotype 12 (12F)
	4689	Serotype 14 (14)
	14017	Serotype 17 (17F)
	4691	Serotype 19 (19F)
	14020	Serotype 20 (20)
	14022	Serotype 22 (22F)
	4692	Serotype 23 (23F)
	4693	Serotype 26 (6B)
	14034	Serotype 34 (10A)
	14043	Serotype 43 (11A)
	4694	Serotype 51 (7F)
	14054	Serotype 54 (15B)
4696	Serotype 56 (18C)	
14057	Serotype 57 (19A)	
4697	Serotype 68 (9V)	
14070	Serotype 70 (33F)	

Angiotensin Converting Enzyme (ACE)	
Effective Date:	November 2, 2009
Unit Code:	10683
CPT Code:	82164
List Price:	\$69.00
Specimen Requirements:	1 mL serum (reject EDTA plasma)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 5 days Refrigerated: 7 days Frozen: 60 days
Reference Ranges:	6 months – 17 years: 13-100 U/L Adult range: 9-67 U/L
Methodology:	Kinetic
Set-up Day(s):	Tuesday – Saturday



NEW TESTS

Results Available:	2 to 5 days	
FDA clearance type:	Laboratory Developed Test	
NYSDOH Approved:	No	
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano	
Additional Information:	This test will replace 24005 Angiotensin Converting Enzyme (ACE).	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	10683	ACE, serum



TEST CHANGES

The following section contains updates to existing tests. For complete test information, contact Client Services at 800-445-4032 or visit our website at www.focusdx.com.

Norovirus, EIA (Stool)	
Effective Date:	August 26, 2009
Unit Code:	81106
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

Parvovirus B19 Antibodies (IgG, IgM)	
Effective Date:	November 2, 2009
Unit Code:	41380
Former Test Name:	Parvovirus Antibodies (IgG, IgM)
Specimen Requirements:	1 mL (0.2 mL min) serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	<0.9
Methodology:	EIA
Assay Category:	FDA
NYSDOH Approved:	Yes
Additional Information:	<p>Update test name, minimum specimen volume, transport temperature, specimen stability, reference range, methodology, assay category, always message and remove test code (analyte) 9990</p> <p>Interpretation.</p> <p>Always message will be:</p> <p>INTERPRETIVE CRITERIA:</p> <p style="padding-left: 40px;"><0.9 Negative</p> <p style="padding-left: 40px;">0.9 - 1.1 Equivocal</p> <p style="padding-left: 40px;">>1.1 Positive</p> <p>IgG persists for years and provides life-long immunity. Results from any one IgM assay should not be used as a sole determinant of a current or recent infection. Because IgM tests can yield false positive results and low levels of IgM antibody may persist for months post infection, reliance on a single test result could be misleading. If an acute infection is suspected, consider obtaining a new specimen and submit for both IgG and IgM testing in two or more weeks. To diagnose current infection, consider Parvovirus B19 DNA, PCR (Focus unit code 43010).</p>



TEST CHANGES

CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	11089	Parvovirus IgG Index
	11088	Parvovirus IgM Index

Parvovirus B19 Antibody (IgG)	
Effective Date:	November 2, 2009
Unit Code:	41381
Former Test Name:	Parvovirus Antibody (IgG)
Specimen Requirements:	1 mL (0.1 mL min) serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	<0.9
Methodology:	EIA
Assay Category:	FDA
NYSDOH Approved:	Yes
Additional Information:	<p>Update test name, minimum specimen volume, transport temperature, specimen stability, reference range, methodology, assay category, and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: <0.9</p> <p>INTERPRETIVE CRITERIA:</p> <p style="padding-left: 40px;"><0.9 Negative</p> <p style="padding-left: 40px;">0.9 - 1.1 Equivocal</p> <p style="padding-left: 40px;">>1.1 Positive</p> <p>IgG persists for years and provides life-long immunity. To diagnose current infection, consider Parvovirus B19 DNA, PCR (Focus unit code 43010).</p>

Parvovirus B19 Antibody (IgM)	
Effective Date:	November 2, 2009
Unit Code:	41383
Former Test Name:	Parvovirus Antibody (IgM)
Specimen Requirements:	1 mL (0.1 mL min) serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 4 days



TEST CHANGES

	Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	<0.9
Methodology:	EIA
Assay Category:	FDA
NYSDOH Approved:	Yes
Additional Information:	<p>Update test name, minimum specimen volume, transport temperature, specimen stability, reference range, methodology, assay category, and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: <0.9</p> <p>INTERPRETIVE CRITERIA: <0.9 Negative 0.9 - 1.1 Equivocal >1.1 Positive</p> <p>Results from any one IgM assay should not be used as a sole determinant of a current or recent infection. Because IgM tests can yield false positive results and low levels of IgM antibody may persist for months post infection, reliance on a single test result could be misleading. If an acute infection is suspected, consider obtaining a new specimen and submit for both IgG and IgM testing in two or more weeks. To diagnose current infection, consider Parvovirus B19 DNA, PCR (Focus unit code 43010).</p>

Candida albicans Antibodies (IgG, IgA, IgM)

Effective Date:	November 16, 2009
Unit Code:	20125
Reference Ranges:	<1.0
Additional Information:	Update reference range.

Candida albicans Antibody (IgG)

Effective Date:	November 16, 2009
Unit Code:	20095
Reference Ranges:	<1.0
Additional Information:	Update reference range.



DISCONTINUED TESTS

Angiotensin Converting Enzyme (Serum)	
Effective Date:	November 2, 2009
Unit Code:	24005
Additional Information:	This test will be discontinued. Please order 10683 Angiotensin Converting Enzyme (ACE)). See test information in the New Test section of this document.

<i>Streptococcus pneumoniae</i> IgG, Pre-and Post-Vaccination (6 serotypes)	
Effective Date:	November 16, 2009
Unit Code:	4416
Additional Information	This test will be discontinued. The recommended alternative is 40765 <i>Streptococcus pneumoniae</i> IgG AB (6 Serotypes), MAID.

<i>Streptococcus pneumoniae</i> IgG, Pre-and Post-Vaccination (12 serotypes)	
Effective Date:	November 16, 2009
Unit Code:	4417
Additional Information:	This test will be discontinued. The recommended alternative is 40762 <i>Streptococcus pneumoniae</i> IgG AB (12 Serotypes), MAID.

<i>Streptococcus pneumoniae</i> IgG, Pre-and Post-Vaccination (7 serotypes)	
Effective Date:	November 16, 2009
Unit Code:	4429
Additional Information	This test will be discontinued. The recommended alternative is 40752 <i>Streptococcus pneumoniae</i> IgG AB (7 Serotypes), MAID.

<i>Streptococcus pneumoniae</i> IgG, Pre-and Post-Vaccination (14 serotypes)	
Effective Date:	November 16, 2009
Unit Code:	4462
Additional Information	This test will be discontinued. The recommended alternative is 40682 <i>Streptococcus pneumoniae</i> IgG AB (14 Serotypes), MAID.

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