



November 2010

TEST UPDATES

<http://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.



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TEST UPDATES

<http://www.focusdx.com>

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.

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NEW TESTS

<i>Isospora</i> Detection, FM		
Effective Date:	December 6, 2010	
Unit Code:	54500	
CPT Code:	87015, 87210	
List Price:	\$113.00	
Specimen Requirements:	0.5 g or 1 mL stool in 10% formalin, SAF or equivalent	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room temperature: 1 year Refrigerated: 30 days Frozen: unacceptable	
Reference Ranges:	Not Detected	
Methodology:	FM and LM	
Set-up Day(s):	Monday-Friday	
Results Available:	2-3 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	New test.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	545000	<i>Isospora</i>

<i>Kingella kingae</i> DNA, Qualitative Real-Time PCR	
Effective Date:	December 6, 2010
Unit Code:	45610
CPT Code:	87798
List Price:	\$298.00
Specimen Requirements:	0.7 mL (0.3 mL min.) synovial fluid or whole blood (EDTA, ACD)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Real-Time PCR
Set-up Day(s):	Monday-Sunday
Results Available:	1-3 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	No
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	New test.



NEW TESTS

	<p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	456100	Ask at order entry (prompt) code	Source
	456101		<i>K kingae</i> DNA



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.

Chlamydia trachomatis/psittaci Culture

Effective Date:	January 10, 2011		
Unit Code:	81025		
Specimen Requirements:	Endocervix, urethra, conjunctiva, rectal mucosa without feces, fluid aspirate, tissue, nasopharynx, or throat swab in 3 mL universal transport media or equivalent.		
Transport Temperature:	Frozen @ <-70 degrees centigrade		
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: <-70 degrees centigrade (-20 degrees C unacceptable)		
Rejection Criteria:	Specimens submitted in viral transport media, wooden shaft and calcium alginate swabs, dry swabs, transwabs or swabs in bacterial gel-based transport media, DNA probe transport, tissues in formalin or other fixatives, transports for antigen detection by EIA.		
Reference Ranges:	Not isolated		
Additional Information:	Update specimen requirements, transport temperature, stability, rejection criteria, and reference range. Remove always message, add source test code.		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	810250	Ask at order entry (prompt) code	Source
	8125		<i>Chlamydia culture</i>

Herpes Simplex Virus (HSV) Rapid Culture

Effective Date:	January 10, 2011		
Unit Code:	81095		
Additional Information:	Add source test code.		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	810950	Ask at order entry (prompt) code	Source
	8119		HSV 48 Hour Culture



TEST CHANGES

<i>Mycoplasma</i> Culture, Genital			
Effective Date:	January 10, 2011		
Unit Code:	51001		
Additional Information:	Add source test code.		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	510010	Ask at order entry (prompt) code	Source
	6521		<i>Mycoplasma hominis</i>
	6520		<i>Ureaplasma urealyticum</i>

<i>Mycoplasma pneumoniae</i> Culture			
Effective Date:	January 10, 2011		
Unit Code:	51045		
Additional Information:	Add source test code.		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	510450	Ask at order entry (prompt) code	Source
	101		Status
	1045		Result

<i>Pneumocystis jirovecii</i> (<i>P. carinii</i>), DFA			
Effective Date:	January 10, 2011		
Unit Code:	51015		
Additional Information:	Add source test code.		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	510150	Ask at order entry (prompt) code	Source
	236		<i>Pneumocystis jirovecii</i> DFA

Epstein-Barr Virus (EBV) Antibody Panel, Primary, IFA (Serum)	
Effective Date:	January 10, 2011
Unit Code:	40440
Additional Information:	<p>Update always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGES: VCA IgG <1:10 VCA IgM <1:20 EBNA AB <1:10</p>

TEST CHANGES

	<p>EB VCA IgG and IgM are stimulated in virtually all primary EBV infections. VCA-IgM appears immediately after onset of symptoms and usually disappears within 2-3 months. VCA-IgG also appears immediately after onset of symptoms, but persists indefinitely, falling gradually with time unless restimulated as in reactivated infection and chronic disease. EBNA antibodies can be detected 2-6 months after acute illness, and usually persist for life.</p>
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Aspergillus DNA, Qualitative Real-Time PCR

Effective Date:	January 17, 2011		
Unit Code:	48003		
Former Test Name:	<i>Aspergillus</i> DNA, PCR		
CPT Code:	87798 (X3)		
Specimen Requirements:	3 mL (2 mL min.) bronchial lavage, sputum, whole blood (EDTA, ACD), or 3mm tissue		
Transport Temperature:	Refrigerated: Bronchial lavage, sputum and whole blood Frozen: Tissue		
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days		
Reference Ranges:	Not Detected		
Additional Information:	<p>Update reporting title, test codes, specimen requirements, transport temperature, stability, reference range, CPT code and always message. "Detected" results will be flagged "A" for abnormal. Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>		
CPU Interface Mapping:	Test Code (analyte)	Type	Test Code Title
	480030	Ask at order entry (prompt) code	Source
	480031		<i>Aspergillus spp</i>
	480032		<i>A fumigatus</i>
	480033		<i>A terreus</i>

TEST CHANGES

<i>Borrelia burgdorferi</i> IgG and IgM Antibody Panel, WB (CSF)	
Effective Date:	January 24, 2011
Unit Code:	6034
Specimen Requirements:	2 mL (0.50 mL min) CSF only
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update specimen requirements, transport temperature, stability and always message. Always message will be:</p> <p>REFERENCE RANGE: ANTIBODY NOT DETECTED</p> <p>No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for CSF. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).</p>

<i>Borrelia burgdorferi</i> IgG and IgM Antibody Panel, WB (SF)	
Effective Date:	January 24, 2011
Unit Code:	70340
Former Test Name:	<i>Borrelia burgdorferi</i> IgG and IgM Antibody Panel, WB (Fluid)
Specimen Requirements:	1 mL (0.50 mL min) Synovial fluid only
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update reporting title, specimen requirements, transport temperature, stability and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: ANTIBODY NOT DETECTED</p> <p>No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for synovial fluid. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The</p>



TEST CHANGES

	Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).
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***Borrelia burgdorferi* IgG Antibody, WB (CSF)**

Unit Code:	60645
Effective Date:	January 24, 2011
Specimen Requirements:	1 mL (0.25 mL min) CSF only
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	Update specimen requirements, transport temperature, stability and always message. Always message will be: REFERENCE RANGE: ANTIBODY NOT DETECTED No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for CSF. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).

***Borrelia burgdorferi* IgG Antibody, WB (SF)**

Effective Date:	January 24, 2011
Unit Code:	70645
Former Test Name:	<i>Borrelia burgdorferi</i> IgG Antibody, WB (Fluid)
Specimen Requirements:	1 mL (0.25 mL min) Synovial fluid only
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days

TEST CHANGES

<p>Additional Information:</p>	<p>Update reporting title, specimen requirements, transport temperature, stability and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: ANTIBODY NOT DETECTED</p> <p>No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for synovial fluid. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).</p>
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***Borrelia burgdorferi* IgM Antibody, WB (CSF)**

<p>Unit Code:</p>	<p>60650</p>
<p>Effective Date:</p>	<p>January 24, 2011</p>
<p>Specimen Requirements:</p>	<p>1 mL (0.25 mL min) CSF only</p>
<p>Transport Temperature:</p>	<p>Refrigerated</p>
<p>Specimen Stability:</p>	<p>Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days</p>
<p>Additional Information:</p>	<p>Update specimen requirements, transport temperature, stability and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: ANTIBODY NOT DETECTED</p> <p>No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for CSF. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).</p> <p>This test is used in the following profiles: 6034 <i>Borrelia burgdorferi</i> IgG and IgM Antibody Panel, WB (CSF)</p>

TEST CHANGES

<i>Borrelia burgdorferi</i> IgM Antibody, WB (SF)	
Effective Date:	January 24, 2011
Unit Code:	70650
Former Test Name:	<i>Borrelia burgdorferi</i> IgM Antibody, WB (Fluid)
Specimen Requirements:	1 mL (0.25 mL min) Synovial fluid only
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update reporting title, specimen requirements, transport temperature, stability and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: ANTIBODY NOT DETECTED</p> <p>No interpretive criteria for <i>B. burgdorferi</i> Western blot have been established for synovial fluid. The presence of <i>Borrelia burgdorferi</i> reactive antibodies in fluids may represent either compartmental antibody production or transudation of plasma antibody. The Western blot test will confirm the presence of <i>Borrelia burgdorferi</i> specific antibodies detected by serologic screening methods (ELISA, IFA).</p>

<i>Toxocara</i> Antibody, ELISA (Fluid)	
Effective Date:	January 24, 2011
Unit Code:	60945
Specimen Requirements:	1 mL (0.25 mL min) eye fluid (aqueous humor or vitreous fluid). CSF is no longer acceptable.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	Update specimen requirements, transport temperature and stability.



DISCONTINUED TESTS

Cryptosporidium and *Isospora* Dir Detection, DFA and FM

Effective Date:	January 17, 2011
Unit Code:	51585
Additional Information:	This test will be discontinued. The recommended alternatives are 52500 <i>Cryptosporidium</i> Antigen, EIA and/or 54500 <i>Isospora</i> Detection, FM.



HOLIDAY NOTIFICATION

Thanksgiving Holiday Notification

The Thanksgiving holiday will be observed by Focus Diagnostics, Inc. on Thursday, November 25, 2010. Client Services will be staffed from 8:00 am to 2:00 pm. Regular laboratory services will resume on Friday, November 26, 2010.

The laboratory will be staffed on Thursday, November 25th for STAT testing only from 8:00 am to 11:00 am for the following test:

Pneumocystis Stain (Monoclonal DFA)

NOTE: STAT specimens must be received at Focus by 11:00 am.

All requests for Cellular Testing, Flow Cytometry and whole blood for PCR testing must be received by noon Wednesday, November 24, 2009.

On Thursday, November 25th, our local couriers will service the Southern California locations that are normally scheduled for a Sunday pick-up. If you are not on the Sunday route and require a pick-up, please call Client Services to arrange for courier service.

All times are Pacific Standard Time.

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 for a listing of new tests and test updates.