



May 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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DISCONTINUED TESTS			
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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.

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NEW TESTS

<i>Mycobacterium tuberculosis</i> Complex, PCR, Non-Respiratory	
Effective Date:	June 14, 2010
Unit Code:	47277
CPT Code:	87556
List Price:	\$298.00
Specimen Requirements:	<p>Preferred: 3 mL CSF, first void clean catch urine or urine with no preservative.</p> <p>Acceptable: 3 mL (1 mL MIN) random urine, random clean catch urine, catheterized urine.</p> <p>10 mL (5 mL MIN) gastric fluid.</p> <p>150 mL (2 mL MIN) pericardial fluid, peritoneal fluid, pleural fluid, amniotic fluid, cyst fluid, synovial fluid or vitreous fluid.</p> <p>2 grams fresh (unfixed) tissue or tissue biopsy</p> <p>3 mL (1 mL min) whole blood</p>
Transport Temperature:	Refrigerated
Specimen Stability:	<p>Room Temperature: Unacceptable</p> <p>Refrigerated: 14 days</p> <p>Frozen: 90 days</p>
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
Additional Information:	<p>New Test</p> <p>“Detected” results will be flagged “A” for Abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>This test should not be used as a substitute for culture. It should be used as an adjunct to culture.</p> <p>The method used in this test is Real-Time PCR of the IS 6110 locus of the M. tuberculosis complex.</p>



NEW TESTS

	<p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. Performance characteristics refer to the analytical performance of the test. This test should not be used for diagnosis without confirmation by other medically established means.</p> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	472770 (This is an ask at order entry (prompt) code)	Non-Respiratory Source
	472771	MTB Complex, PCR

<i>Mycobacterium tuberculosis</i> Complex, PCR, Respiratory	
Effective Date:	June 14, 2010
Unit Code:	47298
CPT Code:	87556
List Price:	\$298.00
Specimen Requirements:	<p>Preferred: 7 mL (2 mL min.) bronchial lavage/wash, tracheal lavage/wash, or sputum.</p> <p>Acceptable: 7 mL nasopharyngeal lavage/wash</p>
Transport Temperature:	Refrigerated
Specimen Stability:	<p>Room Temperature: Unacceptable</p> <p>Refrigerated: 14 days</p> <p>Frozen: 90 days</p>
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
Additional Information:	<p>New Test</p> <p>“Detected” results will be flagged “A” for Abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>This test should not be used as a substitute for culture. It should</p>



NEW TESTS

	<p>be used as an adjunct to culture.</p> <p>The method used in this test is Real-Time PCR of the IS 6110 locus of the <i>M. tuberculosis</i> complex.</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. Performance characteristics refer to the analytical performance of the test. This test should not be used for diagnosis without confirmation by other medically established means.</p> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	472980 (This is an ask at order entry (prompt) code)	Respiratory Source
	472981	MTB Complex, PCR

Fungal Culture, CSF		
Effective Date:	July 19, 2010	
Unit Code:	51609	
CPT Code:	87102	
List Price:	\$82.00	
Specimen Requirements:	2 mL (0.5 mL min) CSF	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room Temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable	
Reference Ranges:	None Isolated	
Methodology:	Culture	
Set-up Day(s):	Monday-Sunday	
Results Available:	28-35 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics	
Additional Information:	New test	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	516090	Fungal Culture, CSF



NEW TESTS

Fungal Culture, Other than Skin, Hair or Nails		
Effective Date:	July 19, 2010	
Unit Code:	51603	
CPT Code:	87102	
List Price:	\$82.00	
Specimen Requirements:	Tissue biopsy, 2 mL (1 mL min.) sputum or other fluids. Blood or CSF are Unacceptable.	
Transport Temperature:	Refrigerated	
Specimen Stability:	Room Temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable	
Reference Ranges:	None Isolated	
Reject Criteria:	Whole blood and CSF are not acceptable specimen types.	
Methodology:	Microscopic	
Set-up Day(s):	Monday-Sunday	
Results Available:	28-35 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics	
Additional Information:	New test	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	516030	Status
	516031	Fungal Culture

Fungal Smear, Other than Skin, Hair, or Nails, KOH Preparation, LM	
Effective Date:	July 19, 2010
Unit Code:	51677
CPT Code:	87210
List Price:	\$53.00
Specimen Requirements:	Tissue biopsy, 2 mL (1 mL min.) sputum or other fluids.
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	No yeast or fungi seen
Methodology:	Microscopic
Set-up Day(s):	Monday-Friday
Results Available:	1-3 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes



NEW TESTS

Performing Site:	Focus Diagnostics	
Additional Information:	New test	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	516770	Fungal smear, KOH preparation, LM

Fungal Culture and Fungal Smear, KOH, Other than Skin, Hair or Nails	
Effective Date:	July 19, 2010
Unit Code:	5164
CPT Code:	87102, 87210
List Price:	\$135.00
Specimen Requirements:	Tissue biopsy, 2 mL (1 mL min.) sputum or other fluids.
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	Culture: None Isolated Smear: No yeast or fungi seen
Methodology:	Microscopic
Set-up Day(s):	Culture: Monday-Sunday Smear: Monday-Friday
Results Available:	28-35 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics
Additional Information:	<p>New test.</p> <p>This test includes Unit Codes 51603 Fungal Culture, Other than Skin, Hair or Nails and 51677 Fungal Smear, Other than Skin, Hair, or Nails, KOH Preparation, LM.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p>



NEW TESTS

Fungal Culture, Skin, Hair or Nails		
Effective Date:	July 19, 2010	
Unit Code:	51600	
CPT Code:	87101	
List Price:	\$82.00	
Specimen Requirements:	3-5 pieces (2 pieces min.)(scrapings) skin, hair, or nails	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room Temperature: 7 days Refrigerated: 7 days Frozen: Unacceptable	
Reference Ranges:	None Isolated	
Methodology:	Microscopic	
Set-up Day(s):	Monday-Sunday	
Results Available:	28-35 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics	
Additional Information:	New test	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	516000	Status
	516001	Fungal Culture

Fungal Smear, Skin, Hair, or Nails, KOH Preparation, LM		
Effective Date:	July 19, 2010	
Unit Code:	51676	
CPT Code:	87220	
List Price:	\$53.00	
Specimen Requirements:	3-5 pieces (2 pieces min.)(scrapings) skin, hair, or nails	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room Temperature: 7 days Refrigerated: 7 days Frozen: Unacceptable	
Reference Ranges:	No yeast or fungi seen	
Methodology:	Microscopic	
Set-up Day(s):	Monday-Friday	
Results Available:	1-3 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics	



NEW TESTS

Additional Information:	New test	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	516760	KOH Preparation

Fungal Culture and Fungal Smear, KOH, Skin, Hair or Nails	
Effective Date:	July 19, 2010
Unit Code:	5163
CPT Code:	87101, 87220
List Price:	\$135.00
Specimen Requirements:	3-5 pieces (2 pieces min.)(scrapings) skin, hair, or nails
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 7 days Refrigerated: 7 days Frozen: Unacceptable
Reference Ranges:	Culture: None Isolated Smear: No yeast or fungi seen
Methodology:	Microscopic
Set-up Day(s):	Culture: Monday-Sunday Smear: Monday-Friday
Results Available:	28-35 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics
Additional Information:	<p>New test.</p> <p>This test includes Unit Codes 51600 Fungal Culture, Skin, Hair or Nails and 51676 Fungal Smear, Skin, Hair, or Nails, KOH Preparation, LM.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p>



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.

17743 Rheumatoid Factor (IgM)
 19705 Rheumatoid Factor (IgA, IgG, IgM)
 20432 C3d Circulating Immune Complexes
 20428 Immune Complex Detection by C1q Binding
 20556 Neutrophil Antibody, Flow Cytometry

Effective Date:	May 24, 2010
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Effective May 24, 2010, SST will be listed as reject criteria.

4092 *Toxoplasma gondii* IgG and IgM, ELISA (Serum)
 4094 *Toxoplasma gondii* IgG, IgM, IgA, Antibody Panel, ELISA (Serum)

Effective Date:	June 21, 2010
Additional Information:	For the IgM portion of these tests, results ≥ 1.10 will be flagged "H" for High.

Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgA)

Effective Date:	July 19, 2010
Unit Code:	40480
Former Test Name:	Epstein-Barr Viral Capsid Antigen (VCA) IgA Ab, IFA
Reference Ranges:	<1:10
Additional Information:	<p>Update reporting title, reference range, result flagging and always message. Results $\geq 1:10$ will be flagged "H" for high.</p> <p>Always message will be: REFERENCE RANGE: <1:10 INTERPRETIVE CRITERIA: <1:10 Antibody not detected 1:10 - 1:40 Past Infection > or = 1:80 Chronic/Reactivated infection</p> <p>VCA IgA titers > or = 1:80 are suggestive of chronic or reactivated EBV infection, whereas a titer of 1:10, 1:20, or 1:40 typically indicates past infection.</p>

TEST CHANGES

Voriconazole Level, HPLC		
Effective Date:	July 19, 2010	
Unit Code:	51929	
Former Test Name:	Antifungal Serum or Plasma Level, Voriconazole, HPLC	
Reference Ranges:	<0.1 mcg/mL	
Additional Information:	<p>Update reporting title, reference range, test code title and always message.</p> <p>Always message will be:</p> <p>Results are expressed in mcg/mL</p> <p>Population Pharmacokinetic Parameters</p> <p>Day 1, 400 mg Oral Q12 2.3 mcg/mL</p> <p>Days 2-10, 200 mg Oral Q12 2.1 mcg/mL</p> <p>Day 1, 6 mg/kg IV Q12 4.7 mcg/mL</p> <p>Days 2-10, 3 mg/kg IV Q12 3.1 mcg/mL</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	1929	Voriconazole Level, HPLC

Blood and Tissue Parasite Detection		
Effective Date:	July 19, 2010	
Unit Code:	55335	
Specimen Requirements:	<p>Blood: 4 blood smears, 2 thick not fixed and 2 thin methanol fixed, obtained by fingerstick or venipuncture needle or 7 mL fresh whole blood in EDTA (purple top) received within 48 hours of collection.</p> <p>Tissue: 2 tissue touch preparation slides of appropriate clinical material, methanol fixed, or tissue biopsy in moist sterile gauze received within 48 hours of collection.</p>	
Specimen Stability:	<p>Blood/tissue:</p> <p>Room Temperature: 48 hours</p> <p>Refrigerated: 48 hours</p> <p>Frozen: Unacceptable</p> <p>Slides:</p> <p>Room Temperature: 30 days unstained; 90 days stained</p> <p>Refrigerated: 30 days unstained; 90 days stained</p> <p>Frozen: Unacceptable</p>	
Additional Information:	Update specimen requirements, stability and test code title.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	55335 55336	Blood/Tissue Parasite Detection % Parasitemia

TEST CHANGES

Fungal Smear, India Ink Preparation, LM (CSF)		
Effective Date:	July 26, 2010	
Unit Code:	51075	
Specimen Requirements:	2 mL CSF	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room Temperature: 72 Hours Refrigerated: 72 Hours Frozen: Unacceptable	
Reference Ranges:	No Encapsulated Yeast Seen	
Additional Information:	<p>Update specimen requirements, transport temperature, specimen stability, reference range, always message.</p> <p>Always message will be:</p> <p>The India ink prep is a non-specific method for the detection of encapsulated yeast cells of <i>Cryptococcus neoformans</i>. The cryptococcal antigen assay may be a more sensitive method for diagnosis of cryptococcal infection of the CNS.</p>	
<i>Bordetella pertussis/parapertussis</i> Direct Detection, DFA		
Effective Date:	July 19, 2010	
Unit Code:	51000	
Former Test Name:	<i>Bordetella pertussis/parapertussis</i> Dir Detection, DFA	
Specimen Requirements:	Preferred specimen: 2 nasopharyngeal slides, air dried/fixd Acceptable specimen: nasopharyngeal swab in Bordetella transport medium or non-charcoal containing transport medium or nasopharyngeal aspirate (0.5 mL min) in sterile container.	
Transport Temperature:	Slides: Room Temperature Swab or aspirate: Refrigerated	
Specimen Stability:	Room Temperature: Slides: 7 days; Swab/aspirate: 48 hours Refrigerated: Slides: 7 days; Swab/aspirate: 72 hours Frozen: Unacceptable (all specimen types)	
Additional Information:	Update specimen requirements, transport temperature, specimen stability and test codes.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	510001	<i>Bordetella pertussis</i> ,DFA
	510002	<i>Bordetella parapertussis</i> ,DFA



DISCONTINUED TESTS

AFB, <i>Mycobacterium tuberculosis</i> Complex DNA, PCR	
Effective Date:	June 14, 2010
Unit Code:	51183
Additional Information:	This test will be discontinued. The recommended alternative test codes are 47277, Mycobacterium Tuberculosis Complex, PCR, Non-Respiratory, and 47298, Mycobacterium Tuberculosis Complex, PCR, Respiratory.

Antimicrobial Synergy Studies	
Effective Date:	July 19, 2010
Unit Code:	51740
Additional Information:	This test will be discontinued. The recommended alternative test code is 51780 Antimicrobial Combination Testing, Synergy, 2 Drug.

Antimicrobial Synergy Study with MBCs	
Effective Date:	July 19, 2010
Unit Code:	51745
Additional Information:	This test will be discontinued. The recommended alternative test code is 51780 Antimicrobial Combination Testing, Synergy, 2 Drug.

Fungal Culture	
Effective Date:	July 19, 2010
Unit Code:	51605
Additional Information:	This test will be discontinued. The recommended alternative test codes are 51609 Fungal Culture, CSF; 51600 Fungal Culture, Skin, Hair or Nails; and 51603 Fungal Culture, Other than Skin, Hair or Nails.

Fungal Smear, KOH Preparation, LM	
Effective Date:	July 19, 2010
Unit Code:	51675
Additional Information:	This test will be discontinued. The recommended alternative test codes are 51676 Fungal Smear, Skin, Hair, or Nails, KOH Preparation, LM, or 51677 Fungal Smear, Other than Skin, Hair, or Nails, KOH Preparation, LM.



DISCONTINUED TESTS

Fungal Culture and Fungal Smear, KOH Preparation, LM	
Effective Date:	July 19, 2010
Unit Code:	5160
Additional Information	This test will be discontinued. The recommended alternative test codes are 5163 Fungal Culture and Fungal Smear, KOH, Skin, Hair or Nails, or 5164 Fungal Culture and Fungal Smear, KOH, Not Skin, Hair or Nails.

Immune Cell Function	
Effective Date:	July 19, 2010
Unit Code:	23442
Additional Information	This test will be discontinued. The recommended alternative test code is 15435X Immune Cell Function. This test is performed at Quest Diagnostics Nichols Institute, San Juan Capistrano. Please send directly to Quest Diagnostics Nichols Institute, San Juan Capistrano.



HOLIDAY NOTIFICATION

Memorial Day Holiday Notification

The Memorial Day holiday will be observed by Focus Diagnostics, Inc. on Monday, May 31, 2010. Client Services will be staffed from 8:00 am to 2:00 pm PST. Regular laboratory services will resume on Tuesday, June 1, 2010.

The laboratory will be staffed on Monday, May 31, 2010, 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 Friday, May 28, 2010.

On Monday, May 31, 2010, 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.

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.