



March 2010 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.

TABLE OF CONTENTS

NEW TESTS			
Test Code	Test Name	Effective Date	Page #
40768	<i>Streptococcus pneumoniae</i> IgG Ab (13 Serotypes), MAID	03/29/2010	3
TEST CHANGES			
51430	Antimicrobial Level, Cycloserine HPLC	03/12/2010	5
51526	Antimicrobial Level, Sulfamethoxazole HPLC	03/12/2010	5
51959	Antimicrobial Level, Capreomycin, HPLC	03/12/2010	5
52050	Antimicrobial Level, Ethambutol, HPLC	03/12/2010	5
2210	Platelet Antibody Panel	03/15/2010	5
2213	Platelet Antibody Expanded Panel, FC	03/15/2010	5
20466	Platelet Circulation Antibody, FC	03/15/2010	5
20475	Platelet Circulating IgG, IgM, AND IgA Antibody Panel, FC	03/15/2010	5
60475	Epstein-Barr Virus Early Antigen (R+D) IgG, IFA (CSF)	05/10/2010	5
6044	Epstein-Barr Virus (EBV) Antibody Panel, Primary, IFA (CSF)	05/10/2010	5
60460	Epstein-Barr Viral Capsid Antigen (VCA) AB, IFA (CSF)	05/10/2010	5
60465	Epstein-Barr Viral Capsid Antigen IgG AB, IFA (CSF)	05/10/2010	5
60470	Epstein-Barr Viral Capsid Antigen IgM AB, IFA (CSF)	05/10/2010	5
60485	Epstein-Barr Nuclear Antigen (EBNA) AB, ACIF (CSF)	05/10/2010	5
52293	Antimicrobial Susc, <i>Nocardia</i> /Aerobic <i>Actinomyces</i> , MIC	05/10/2010	6
53035	Antimicrobial Susc, AFB Rapid Grower, MIC	05/10/2010	7
40577	Mitochondria M2 Antibody (IgG), EIA	05/17/2010	8
DISCONTINUED TESTS			
52715	<i>Nocardia</i> / <i>Streptomyces</i> Susceptibility MIC Panel	05/10/2010	9

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.



March 2010 **TEST UPDATES**

www.focusdx.com

Call (800) 445-4032 or email ClientServices@focusdx.com.

All third party marks — ®' and ™' — are the property of their respective owners.



NEW TESTS

<i>Streptococcus pneumoniae</i> IgG Ab (13 serotypes), MAID		
Effective Date:	March 29, 2010	
Unit Code:	40768	
CPT Code:	86317 (x13)	
List Price:	\$309.00	
Specimen Requirements:	0.5 mL (0.25 mL min.) serum	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 60 days Frozen: 1 year	
Reference Range:	Not applicable	
Methodology:	MAID	
Set-up Day(s):	Monday – Friday	
Results Available:	1-4 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
	<p>New Test</p> <p>Always message will be:</p> <p>Note: Serotype designations are American nomenclature, with Danish nomenclature in parentheses.</p> <p>Infants and young children receiving 4 doses of pneumococcal conjugate vaccine exhibit reduced frequencies of invasive disease and otitis media caused by <i>S. pneumoniae</i>. Although the minimum serum antibody concentration necessary for protection has not been rigorously established for any pneumococcal serotype, a value in the range of 0.15-0.50 mcg/mL has been suggested.</p> <p>Comparison of pre-vaccination and post-vaccination antibody levels, rather than assessing post-vaccination antibody levels only, provides a more complete evaluation of the pneumococcal conjugate vaccine response. A 4-fold increase in type-specific antibodies is expected after 4 doses of vaccine.</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)	Test Code Title
	40768	Serotype 1 (1)
	40769	Serotype 3 (3)
Focus Diagnostics	Page 3 of 9	March 2010



NEW TESTS

	40770	Serotype 4 (4)
	40771	Serotype 5 (5)
	40772	Serotype 6 (6A)
	40773	Serotype 14 (14)
	40774	Serotype 19 (19F)
	40775	Serotype 23 (23F)
	40776	Serotype 26 (6B)
	40777	Serotype 51 (7F)
	40779	Serotype 56 (18C)
	40780	Serotype 57 (19A)
	40781	Serotype 68 (9V)



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.

51430 - Antimicrobial Level, Cycloserine HPLC 51526 - Antimicrobial Level, Sulfamethoxazole HPLC 51959 - Antimicrobial Level, Capreomycin, HPLC 52050 - Antimicrobial Level, Ethambutol, HPLC	
Effective Date:	March 12, 2010
Specimen Requirements:	2 mL serum Serum separator tubes are unacceptable
Additional Information:	Update specimen requirements. Remove “wrap in aluminum foil to protect from light during transport”.

2210 – Platelet Antibody Panel 2213 – Platelet Antibody Expanded Panel, FC 20466 – Platelet Circulation Antibody, FC 20475 – Platelet Circulating IgG, IgM, AND IgA Antibody Panel, FC	
Effective Date:	March 15, 2010
Additional Information:	Add the following statement to the always message. This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.

Epstein-Barr Virus Early Antigen (R+D) IgG, IFA (CSF)	
Effective Date:	May 10, 2010
Unit Code:	60475
Reference Range:	<1:4
Assay Category:	FDA
Additional Information:	Update reference range, result flagging and assay category. If results are $\geq 1:4$ they are flagged “H” for high.

6044 – Epstein-Barr Virus (EBV) Antibody Panel, Primary, IFA (CSF) 60460 – Epstein-Barr Viral Capsid Antigen (VCA) AB, IFA (CSF) 60465 - Epstein-Barr Viral Capsid Antigen IgG AB, IFA (CSF) 60470 - Epstein-Barr Viral Capsid Antigen IgM AB, IFA (CSF) 60485 - Epstein-Barr Nuclear Antigen (EBNA) AB, ACIF (CSF)	
Effective Date:	May 10, 2010
Assay Category:	FDA
Additional Information:	Update assay category.



Test Changes

Antimicrobial Susc, <i>Nocardia</i> /Aerobic Actinomycetes, MIC		
Effective Date:	May 10, 2010	
Unit Code:	52293	
Specimen Requirements:	Pure culture safely contained. Identification of the isolate is required.	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 90 days (determined by viability) Refrigerated: 90 days (determined by viability) Frozen: Unacceptable	
Methodology:	Broth Microdilution	
Additional Information:	<p>Update specimen requirements, transport temperature, specimen stability, methodology, and always message. Add test codes 9179 Cefepime, 9120 Doxycycline, 9246 Moxifloxacin and 9307 Tigecycline. Remove test code 9127 Gatifloxacin.</p> <p>Always message will be:</p> <p>Drug concentrations are expressed in mcg/mL.</p> <p>S = SUSCEPTIBLE I = INTERMEDIATE R = RESISTANT</p> <p>Moxifloxacin and Tigecycline MIC's are reported without interpretations (no CLSI interpretations).</p> <p>This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Focus Diagnostics. This test should not be used for diagnosis without confirmation by other medically established means.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	150 (ask at order entry (prompt)) 9103 9360 9179 9178 9196 9119 9120 9228 9227 9243 9246 9307	Organism Amikacin Amoxicillin/Clavulanate Cefepime Ceftriaxone Ciprofloxacin Clarithromycin Doxycycline Imipenem Linezolid Minocycline Moxifloxacin Tigecycline



Test Changes

	9313 9306	Tobramycin Trimethoprim/Sulfamethoxazole
--	--------------	---

Antimicrobial Susc, AFB Rapid Grower, MIC

Effective Date:	May 10, 2010	
Unit Code:	53035	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 90 days (determined by viability) Refrigerated: 90 days (determined by viability) Frozen: Unacceptable	
Additional Information:	<p>Update transport temperature, specimen stability, and always message. Add test codes 9120 Doxycycline, 9246 Moxifloxacin and 9307 Tigecycline. Remove test code 9243 Minocycline.</p> <p>Always message will be:</p> <p>Drug concentrations are expressed in mcg/mL.</p> <p>S = SUSCEPTIBLE I = INTERMEDIATE R = RESISTANT</p> <p>Moxifloxacin, Tigecycline, and Trimethoprim/sulfamethoxazole MICs are reported without interpretation (no CLSI interpretations).</p> <p>Tobramycin is considered to be superior to Amikacin for <i>M. chelonae</i> and is reported only for <i>M. chelonae</i>.</p> <p>Imipenem MICs are reported without interpretation for <i>M. chelonae</i> and <i>M. abscessus</i> due to CLSI recommendations regarding variability (CLSI).</p> <p>This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Focus Diagnostics. This test should not be used for diagnosis without confirmation by other medically established means.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	5575 (ask at order entry (prompt)) 810 815 812 9119 9120 9228 9227	Organism Amikacin Cefoxitin Ciprofloxacin Clarithromycin Doxycycline Imipenem Linezolid



Test Changes

	9246 9307 9313 818	Moxifloxacin Tigecycline Toberamycin Trimethoprim/Sulfamethoxazole
--	---	---

Mitochondria M2 Antibody (IgG), EIA

Effective Date:	May 17, 2010	
Unit Code:	40577	
Former Test Name:	<i>Mitochondrial M2 Antibody, MAID</i>	
CPT Code:	83520	
Reference Range:	< or = 20.0 Units	
Specimen Requirements:	1 mL (0.3 mL min.) serum	
Transport Temperature:	Refrigerated	
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Assay Category:	FDA	
NYSDOH Approved:	Yes	
Additional Information:	<p>Update reporting title, CPT code, reference range, specimen requirements, transport temperature, specimen stability, assay category, test code, test code title and always message.</p> <p>If the result is >20.0 it will be flagged “H” for high.</p> <p>This test is used in the following profiles: (Please contact Focus Diagnostics for profile mapping. Profile mapping may be different.) 2202 Lupus Comprehensive Panel 22200 Lupus Comprehensive Panel 22202 Lupus Expanded Panel (C4)</p> <p>Always message will be:</p> <p>REFERENCE RANGE: < or =20.0 Units</p> <p>INTERPRETIVE CRITERIA: < or = 20 Units Negative 20.1 - 24.9 Units Equivocal > or = 25.0 Units Positive</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	40577	Mitochondria M2 Ab (IgG)



DISCONTINUED TESTS

<i>Nocardia/Streptomyces</i> Susceptibility MIC Panel	
Effective Date:	May 10, 2010
Unit Code:	52715
Additional Information:	This test will be discontinued. Recommended alternative is: 52293 Antimicrobial Susc, <i>Nocardia</i>/Aerobic <i>Actinomyces</i>, MIC

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.