



October 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

Antimicrobial Level, Sulfamethoxazole, HPLC		
Effective Date:	Available Now	
Unit Code:	51526	
CPT Code:	80299	
List Price:	\$183.00	
Specimen Requirements:	2 mL serum	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days	
Reference Range:	<5.0 mcg/mL	
Methodology:	HPLC	
Set-up Day(s):	Monday and Thursday	
Results Available:	2 to 5 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>Sulfamethoxazole peak levels occur approximately 1 - 4 hours after oral dosing with or without food.</p> <p>Minimal steady-state level (3 days): 57.4-68.0 mcg/mL</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	51526	Sulfamethoxazole Level, HPLC

<i>Brucella</i> Antibody, Agglutination	
Effective Date:	Available Now
Unit Code:	40020
CPT Code:	86622
List Price:	\$91.00
Specimen Requirements:	0.5 mL serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	<1:80
Methodology:	DA



NEW TESTS

Set-up Day(s):	Monday, Tuesday and Wednesday	
Results Available:	2 to 8 days	
FDA clearance type:	FDA	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New Test</p> <p>Always message will be:</p> <p>Reference Range: <1:80</p> <p>The most reliable serologic indicator of brucellosis is a four-fold increase in antibody titer when testing acute and convalescent sera in parallel. In the absence of paired sera, a single specimen titer of 1:80 or greater is consistent with brucellosis in a patient with a compatible clinical history.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	40020	<i>Brucella antibody titer</i>

Interferon Beta 1a (IFNB-1a) AB	
Effective Date:	Available Now
Unit Code:	20555
CPT Code:	86849
List Price:	\$464.00
Specimen Requirements:	1 mL serum
Transport Temperature:	Room Temperature
Specimen Stability:	Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days
Reference Range:	<1:20
Methodology:	Tissue Culture/Neutralization
Set-up Day(s):	Monday or Tuesday
Results Available:	5 to 14 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>



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	REFERENCE RANGE: <1:20 INTERPRETIVE CRITERIA: <1:20 Negative > or = 1:20 - <1:100 Elevated NABs > or = 1:100 Highly Elevated NABs Highly elevated NABs (>=1:100) have been reported to correlate with predictable loss of interferon-beta bioactivity. In patients with elevated NAB levels from >=1:20 to <1:100, interferon-beta bioactivity may still be present, but does not correlate to the exact NAB titer and continued patient monitoring may be warranted. There is no apparent loss of interferon-beta bioactivity in patients who test positive in the binding antibody assay, but negative for NABs; however, continued patient monitoring may also be warranted in this instance as well.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	20555 21555	IFNB 1a Neutralizing AB titer Interpretation

Interferon Beta 1b (IFNB-1b) AB	
Effective Date:	Available Now
Unit Code:	20777
CPT Code:	86849
List Price:	\$464.00
Specimen Requirements:	1 mL serum
Transport Temperature:	Room Temperature
Specimen Stability:	Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days
Reference Range:	<1:20
Methodology:	Tissue Culture/Neutralization
Set-up Day(s):	Monday or Tuesday
Results Available:	5 to 14 days
FDA clearance type:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	New Test Always message will be: REFERENCE RANGE: <1:20



NEW TESTS

	INTERPRETIVE CRITERIA: <1:20 Negative > or = 1:20 - <1:100 Elevated NAbs > or = 1:100 Highly Elevated NAbs Highly elevated NAbs (>=1:100) have been reported to correlate with predictable loss of interferon-beta bioactivity. In patients with elevated NAb levels from >=1:20 to <1:100, interferon-beta bioactivity may still be present, but does not correlate to the exact NAb titer and continued patient monitoring may be warranted. There is no apparent loss of interferon-beta bioactivity in patients who test positive in the binding antibody assay, but negative for NAbs; however, continued patient monitoring may also be warranted in this instance as well.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	20777	IFNB 1b Neutralizing AB titer Interpretation
	21777	

Respiratory Virus PCR Panel II	
Effective Date:	Available Now
Unit Code:	3018
CPT Code:	87798 (x7)
List Price:	\$1243.00
Specimen Requirements:	Throat or nasopharyngeal swab in 3 mL M4 Media or V-C-M Medium (green-cap) tube or equivalent (UTM) or 1 mL nasopharyngeal aspirate or bronchial lavage/wash in a sterile leak-proof container.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Range:	Not Detected
Methodology:	Real-Time RT-PCR
Set-up Day(s):	Monday-Sunday
Results Available:	1 to 3 days
FDA clearance type:	Laboratory Developed Test
NYSDOH Approved:	No
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	New Test This test was formerly available only as a custom test, 3018 Custom BAL Respiratory PCR Panel II. This test is now available as 3018 Respiratory Virus PCR Panel II and listed in our on-line test listing at



NEW TESTS

	<p>www.focusdx.com.</p> <p>This panel includes: Influenza Type A and B RNA, Qualitative Real-Time RT-PCR Parainfluenza Virus (Types 1, 2, & 3) RNA, Qualitative Real-Time PCR RSV (Respiratory Syncytial Virus) RNA, Qualitative Real-Time PCR Human Metapneumovirus RNA, Qualitative Real-Time PCR</p> <p>See individual assays for always messages.</p>
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Respiratory Virus PCR Panel III	
Effective Date:	Available Now
Unit Code:	49990
CPT Code:	87798 (x8)
List Price:	\$1659.00
Specimen Requirements:	Throat or nasopharyngeal swab in 3 mL M4 Media or V-C-M Medium (green-cap) tube or equivalent (UTM) or 1 mL nasopharyngeal aspirate or bronchial lavage/wash in a sterile leak-proof container.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Range:	Not Detected
Methodology:	Real-Time PCR/Real-Time RT-PCR
Set-up Day(s):	Monday-Sunday
Results Available:	1 to 3 days
FDA clearance type:	Laboratory Developed Test
NYSDOH Approved:	No
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	<p>New Test This test was formerly available only as a custom test, 49990 Custom Respiratory Virus Panel, Qualitative Real-Time PCR. This test is now available as 49990 Respiratory Virus PCR Panel III and listed in our on-line test listing at www.focusdx.com.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>This test was developed and its performance characteristics have been</p>



NEW TESTS

	<p>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. and ViroNovative BV.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (ask at order entry (prompt))	Source
	4420	RSV RNA, Qualitative PCR
	4421	Influenza A RNA, PCR
	4422	Influenza B RNA, PCR
	4423	Parainfluenza 1 RNA
	4424	Parainfluenza 2 RNA
	4425	Parainfluenza 3 RNA
	4426	Adenovirus DNA, QL PCR
99200	hMPV RNA, QL PCR	



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.

Respiratory Virus PCR Panel I	
Effective Date:	November 9, 2009
Unit Code:	44420
Former Test Name:	Respiratory Virus Panel, Qualitative Real-Time PCR
Additional Information:	Update reporting title.

Mycoplasma Comprehensive Culture	
Effective Date:	December 14, 2009
Unit Code:	51002
Former Test Name:	Mycoplasma Culture, Fastidious Pathogens
Transport Temperature:	Frozen (room temperature whole blood only)
Specimen Stability:	Room temperature: Unacceptable (24 hours whole blood only) Refrigerated: 48 hours (do not refrigerate whole blood) Frozen: 30 days (do not freeze whole blood)
Additional Information:	Update reporting title, transport temperature, specimen stability, and always message. Always message will be: <i>Mycoplasma species other than M. pneumoniae and M. hominis, and Ureaplasma urealyticum are reported but not speciated. The absence of isolation of a Mycoplasma or Ureaplasma does not rule out the potential presence in the specimen. Due to the fastidious nature of these organisms, negative cultures may be obtained. Sound clinical judgment is always recommended.</i>

M. avium Complex MIC Panel		
Effective Date:	December 23, 2009	
Unit Code:	50776	
Additional Information:	Update CPU interface mapping. Add 776 Ethionamide and 777 Isoniazid.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	150 (ask at order entry (prompt) code) 875 891 1898 775	Organism Amikacin Ciprofloxacin Clarithromycin Ethambutol



TEST CHANGES

	776 777 900 950 779 880 868	Ethionamide Isoniazid Linezolid Moxifloxacin Rifampin Rifabutin Streptomycin
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M. avium Complex MIC and Drug Combinations		
Effective Date:	December 23, 2009	
Unit Code:	50777	
Additional Information:	Update CPU interface mapping for the MAC MIC part of profile. Add 3776 Ethionamide and 3777 Isoniazid .	
CPU Interface Mapping:	Test Code (Analyte)	Test Code Title
	150 (ask at order entry (prompt) code) 1700 1710 1720 1730 3776 3777 1750 1770 1780 1790 1800	Organism Amikacin Ciprofloxacin Clarithromycin Ethambutol Ethionamide Isoniazid Linezolid Moxifloxacin Rifampin Rifabutin Streptomycin

Mycobacterium Slow Grower MIC		
Effective Date:	December 23, 2009	
Unit Code:	51887	
Additional Information:	Update CPU interface mapping for the MAC MIC part of profile. Add 511 Doxycycline , 512 Ethionamide and 513 Isoniazid . Remove 505 Minocycline .	
CPU Interface Mapping:	Test Code (Analyte)	Test Code Title
	150 (ask at order entry (prompt) code) 500 501 502 511 503 512 513	Organism Amikacin Ciprofloxacin Clarithromycin Doxycycline Ethambutol Ethionamide Isoniazid

TEST CHANGES

	504	Linezolid
	506	Moxifloxacin
	507	Rifampin
	508	Rifabutin
	509	Streptomycin
	510	Trimeth/Sulfa



DISCONTINUED TESTS

Antimicrobial Serum Level, Sulfamethoxazole, SP	
Effective Date:	December 14, 2009
Unit Code:	51699
Additional Information:	This test will be discontinued. Please order 51526 Antimicrobial Level, Sulfamethoxazole, HPLC. See test information in the New Test section of this document.

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.