



February 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.

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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

Antimicrobial Level, Linezolid, HPLC		
Effective Date:	February 15, 2010	
Unit Code:	51550	
CPT Code:	80299	
List Price:	\$183.00	
Specimen Requirements:	2 mL (1 mL min.) serum (serum separator tubes are unacceptable)	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days	
Reference Range:	<0.01 mcg/mL	
Methodology:	HPLC	
Set-up Day(s):	Tuesday and Thursday	
Results Available:	3 to 5 days	
Assay Category:	Laboratory Developed Test	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New Test</p> <p>Always message will be:</p> <p>Linezolid peak levels occur approximately 1 – 2 hours after dosing with or without food:</p> <p>Mean adult single-dose level (600 mg tablet): 12.70 mcg/mL</p> <p>Mean adult single-dose level (600 mg I.V.): 12.90 mcg/mL</p> <p>Mean adult single-dose level (600 mg oral suspension): 11.00 mcg/mL</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	51550	Linezolid Level, HPLC

HTLV-I/II Antibody, w/Reflex to Western Blot	
Effective Date:	April 19, 2010
Unit Code:	36175
CPT Code:	86790
List Price:	\$103.00
Specimen Requirements:	1 mL (0.7 mL min.) serum
Transport Temperature:	Refrigerated



NEW TESTS

Specimen Stability:	Room temperature: 8 hours Refrigerated: 7 days Frozen: 30 days	
Reference Range:	Nonreactive	
Methodology:	Chemiluminescence	
Set-up Day(s):	Monday-Friday	
Results Available:	1-4 days	
Assay Category:	FDA	
NYSDOH Approved:	Yes	
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly, VA	
Additional Information:	New Test If the HTLV-I/II Antibody is reactive, then 8511 HTLV-I/II, Western Blot, will be performed at an additional charge of \$130.25 (add CPT code 86689).	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	6760 6761	HTLV I/II Antibody HTLV I/II, Western blot

HTLV-I/II Antibody, Western Blot	
Effective Date:	April 19, 2010
Unit Code:	8511
CPT Code:	86689
List Price:	\$130.25
Specimen Requirements:	1 mL (0.6 mL min.) serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 8 hours Refrigerated: 7 days Frozen: 30 days
Reference Range:	Negative
Methodology:	Western Blot
Set-up Day(s):	Tuesday-Friday
Results Available:	2-4 days
Assay Category:	Research Use Only
NYSDOH Approved:	Yes
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly, VA
Additional Information:	New Test Always message will be: This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics



NEW TESTS

	<p>of this test have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. This test should not be used for diagnosis without confirmation by other medically established means.</p> <p>HTLV Western Blot should be interpreted in conjunction with the HTLV Screening Immunoassay.</p> <p>This test is performed by: Quest Diagnostics Nichols Institute 14225 Newbrook Drive Chantilly, VA 20151</p> <p>Dr. Kenneth Sisco, M.D., PhD, Director</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	7420	Western blot
	7421	GD21
	7422	p19
	7423	p24
	7424	p26
	7425	p28
	7426	p32
	7430	p36
	7431	gp46
	7432	p53
	7433	rgp46-I
	7434	rgp46-II




Recent New York Approved Tests

20171 Hepatitis E Antibody (IgG)
20172 Hepatitis E Antibody (IgM)
20173 Hepatitis E Antibody (IgG, IgM)
45000 Cytomegalovirus DNA, Qualitative Real-Time PCR
43200 Herpes Simplex Virus, Type 1 & 2 DNA, Real-Time PCR

Effective Date:	February 8, 2010
NYSDOH Approved:	Yes
Additional Information:	Effective February, 2010 these test have been approved by the State of New York Department of Health.

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.

Fungitell® (1-3)-B-D-Glucan Assay	
Effective Date:	Immediate
Unit Code:	55310
Specimen Requirements:	<p>1 mL serum poured off into a cryogenic vial (i.e., DNase, RNase, pyrogen free). Glass tubes are unacceptable. Draw blood in plain red-top tube or SST, then pour off into a cryogenic vial.</p> 
Additional Information:	Clarify/update specimen requirements.

ANA IFA Screen with Reflex to Titer and Pattern, IFA	
Effective Date:	April 12, 2010
Unit Code:	20180
Former Test Name:	<i>Anti-Nuclear Antibody (ANA) (HEp-2 Substrate), IFA</i>
Reference Range:	<p>Screen: Negative Titer: <1:40</p>
Specimen Requirements:	1 mL (0.5 mL min.) serum
Transport Temperature:	Room temperature
Specimen Stability:	<p>Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days</p>
Additional Information:	<p>Update reporting title, reference range, specimen requirements, transport temperature, specimen stability, test codes, test code titles and remove always message.</p> <p>If a screen is positive a titer and pattern will be performed at an additional charge of \$60.00 (add CPT code 86039). Titer and pattern are not performed or reported if the screen is negative.</p> <p>If the screen is “Positive” it will be flagged “A” for abnormal. If the titer is \geq1:40 it will be flagged “H” for high.</p> <p>This test is used in the following profiles: (Please contact Focus Diagnostics for profile mapping)</p>



Test Changes

	2180 Lupus/ANA Panel 22200 Lupus Comprehensive Panel 22250 Lupus Panel 22260 Lupus Panel without Rheumatoid Factor 22202 Lupus Expanded Panel (C4) 22203 Lupus Expanded Panel (C3) 22206 Lupus Expanded Panel	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	1180	ANA screen
	1181	ANA titer
	1182	ANA pattern

Q Fever (<i>Coxiella burnetii</i>) Antibodies (IgG, IgM) with Reflex to Titers	
Effective Date:	April 19, 2010
Unit Code:	40795
Former Test Name:	<i>Coxiella burnetii</i> Antibody Panel, IFA
Reference Range:	Screen: Negative Titer: <1:16
Specimen Requirements:	1 mL (0.2 mL min.) serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update reporting title, reference range, specimen requirements, transport temperature, specimen stability, test codes, test code titles and always message.</p> <p><i>Coxiella burnetii</i> IgA will no longer be performed if the IgG or IgM are positive.</p> <p>If a screen is positive the appropriate titer will be performed at an additional charge of \$93.00 (add CPT code 86638 per titer performed). Titers are not performed or reported if screens are negative.</p> <p>If the screens are “POSITIVE” they will be flagged “A” for abnormal. If titers are performed and they are $\geq 1:16$ they will be flagged “H” for high.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: SCREEN: NEGATIVE TITER (IF PERFORMED): <1:16</p> <p>Q Fever Antibody testing includes differentiation of antibodies to Phase I and Phase II antigenic variants. <i>Coxiella burnetii</i>, which causes Q Fever, undergoes transitions between Phase I and Phase II states. These phases are serologically distinguishable and useful in the serodiagnosis of acute</p>

Test Changes

	<p>and chronic disease.</p> <p>In some cases, the ratio of titer of Phase II to Phase I may indicate the stage of the disease. A ratio of greater than 1 may indicate the acute stage; greater than or equal to 1, granulomatous hepatitis; and less than 1, the chronic stage or endocarditis.</p> <p>As with other infectious diseases, IgM antibodies are the first to appear. Usually they are detectable for a few weeks or, at the most, for a few months. IgG antibodies appear somewhat later but can persist for years, even for life.</p> <p>Although single Phase II IgG titers of 1:256 or greater are considered evidence of acute <i>C. burnetii</i> disease, the best criterion for a dependable diagnosis is still the demonstration of a fourfold or higher increase in antibody titer between the acute and convalescent serum samples.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	3570	Q Fever IgG Phase I Screen
	3571	Q Fever IgM Phase I Screen
	3572	Q Fever IgG Phase II Screen
	3573	Q Fever IgM Phase II Screen
	3574	Q Fever IgG Phase I Titer
	3575	Q Fever IgM Phase I Titer
	3576	Q Fever IgG Phase II Titer
	3577	Q Fever IgM Phase II Titer

Q Fever (<i>Coxiella burnetii</i>) IgG with Reflex to Titers	
Effective Date:	April 19, 2010
Unit Code:	40800
Former Test Name:	<i>Coxiella burnetii</i> IgG Antibody, IFA
Reference Range:	Screen: Negative Titer: <1:16
Specimen Requirements:	0.5 mL (0.2 mL min.) serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update reporting title, reference range, specimen requirements, transport temperature, specimen stability, test codes, test code titles and always message.</p> <p>If a screen is positive the appropriate titer will be performed at an additional charge of \$93.00 (add CPT code 86638 per titer performed). Titers are not performed or reported if screens are negative.</p> <p>If a screen is "POSITIVE" it will be flagged "A" for abnormal. If titers are performed and they are \geq1:16 they will be flagged "H" for high.</p>



Test Changes

	<p>Always message will be:</p> <p>REFERENCE RANGE: SCREEN: NEGATIVE TITER (IF PERFORMED): <1:16</p> <p>Active Q fever infections are characterized by a four fold increase in Phase II IgG between acute and convalescent samples. In chronic Q fever, Phase I IgG and/or IgM titers are usually greater than Phase II titers. Past infection is usually associated with roughly equivalent Phase I and Phase II IgG titers. Diagnosis of acute Q fever based on a single IgG titer is difficult. Phase II IgG titer between 1:16 and 1:256 in the absence of Phase I IgG titers are not considered significant and may be seen in the healthy, asymptomatic population.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	3579	Q Fever IgG Phase I Screen
	3580	Q Fever IgG Phase II Screen
	3581	Q Fever IgG Phase I Titer
	3582	Q Fever IgG Phase II Titer

Q Fever (<i>Coxiella burnetii</i>) IgM with Reflex to Titers	
Effective Date:	April 19, 2010
Unit Code:	40805
Former Test Name:	<i>Coxiella burnetii</i> IgM Antibody, IFA
Reference Range:	Screen: Negative Titer: <1:16
Specimen Requirements:	0.5 mL (0.2 mL min.) serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Additional Information:	<p>Update reporting title, reference range, specimen requirements, transport temperature, specimen stability, test codes, test code titles and always message.</p> <p>If a screen is positive the appropriate titer will be performed at an additional charge of \$93.00 (add CPT code 86638 per titer performed). Titers are not performed or reported if screens are negative.</p> <p>If a screen is "POSITIVE" it will be flagged "A" for abnormal. If titers are performed and they are $\geq 1:16$ they will be flagged "H" for high.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: SCREEN: NEGATIVE</p>

Test Changes

	TITER (IF PERFORMED): <1:16	
	Active Q fever infections are characterized by the presence of Phase II IgM. In chronic Q fever, Phase I IgG and/or IgM titers are usually greater than Phase II titers.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	3583	Q Fever IgM Phase I Screen
	3584	Q Fever IgM Phase II Screen
	3585	Q Fever IgM Phase I Titer
	3586	Q Fever IgM Phase II Titer

<i>Chlamydia pneumoniae</i> Culture		
Effective Date:	April 19, 2010	
Unit Code:	81030	
Former Test Name:	<i>Chlamydia pneumoniae</i> Culture	
Reference Range:	Not Isolated	
Specimen Requirements:	Bronchoalveolar lavage, throat swab, nasopharyngeal aspirate or wash, tracheal aspirate, lung tissue, or other respiratory secretions. Use viral-chlamydial or chlamydial transport media. Whole blood acceptable.	
Rejection Criteria:	Reject specimen received in non-chlamydia approved viral transport media (VTM), or Gen-Probe tubes.	
Transport Temperature:	All specimen types except whole blood: Frozen Whole blood: Room temperature up to 48 hours	
Specimen Stability:	Room temperature: Whole blood only 48 hours (all other specimen types unacceptable) Refrigerated: 48 hours Frozen at <- 60 degrees centigrade: 14 days (do not freeze whole blood)	
Additional Information:	Update reporting title, reference range, specimen requirements, rejection criteria, transport temperature, specimen stability, test code title, and remove always message.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	6690	<i>C. pneumoniae</i> Culture

<i>Trichomonas</i> Direct Detection, DFA	
Effective Date:	April 19, 2010
Unit Code:	52095
Transport Temperature:	Room Temperature
Specimen Stability;	Room temperature: 7 days slides – 48 hours raw specimen Refrigerated: Unacceptable Frozen: Unacceptable
Additional Information:	Update transport temperature and specimen stability.



Test Changes

Hepatitis D Virus Antibody Panel, EIA	
Effective Date:	April 19, 2010
Unit Code:	2401
Specimen Requirements:	1.5 mL (0.75 mL min.) serum (plasma is not acceptable)
Additional Information:	Update specimen requirements.



DISCONTINUED TESTS

Centromere Ab, IFA	
Effective Date:	April 12, 2010
Unit Code:	20183
Additional Information:	This test will be discontinued. Recommended alternative is: 20180 ANA IFA Screen with Reflex to Titer and Pattern, IFA
HTLV-I/II Antibody, ELISA (serum)	
Effective Date:	April 19, 2010
Unit Code:	41100
Additional Information:	This test will be discontinued. Recommended alternative is: 36175 HTLV-I/II Antibody, w/reflex to Western blot
HTLV-I/II Ab, ELISA	
Effective Date:	April 19, 2010
Unit Code:	61100
Additional Information:	This test will be discontinued. Recommended alternative is: 36175 HTLV-I/II Antibody, w/reflex to Western blot
HTLV 1/2 IBL	
Effective Date:	April 19, 2010
Unit Code:	49106
Additional Information:	This test will be discontinued. Recommended alternative is: 8511 HTLV-I/II Antibody, Western blot
HTLV-I/II Antibody Reflex Panel	
Effective Date:	April 19, 2010
Unit Code:	41102
Additional Information:	This test will be discontinued. Recommended alternative is: 36175 HTLV-I/II Antibody, w/reflex to Western blot
HTLV-I/II Antibody, WB (serum)	
Effective Date:	April 19, 2010
Unit Code:	41105
Additional Information:	This test will be discontinued. Recommended alternative is: 8511 HTLV-I/II Antibody, Western blot



DISCONTINUED TESTS

HTLV-I/II Differentiation, IBL	
Effective Date:	April 19, 2010
Unit Code:	41106
Additional Information:	This test will be discontinued. Recommended alternative is: 8511 HTLV-I/II Antibody, Western blot
HTLV-I/II Antibody, ELISA (CSF)	
Effective Date:	April 19, 2010
Unit Code:	61103
Additional Information:	This test will be discontinued. Recommended alternative is: 36175 HTLV-I/II Antibody, w/reflex to Western blot
HTLV-I/II Antibody, WB (CSF)	
Effective Date:	April 19, 2010
Unit Code:	61105
Additional Information:	This test will be discontinued. Recommended alternative is: 8511 HTLV-I/II Antibody, Western blot
Chlamydia Group Antibody Screen, CF (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60260
Additional Information:	This test will be discontinued. Recommended alternative is: 40260 Chlamydia Group Antibody Screen, CF (serum)
Chlamydia Group Antibody Screen, IFA (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60265
Additional Information:	This test will be discontinued. Recommended alternative is: 40265 Chlamydia Group Antibody Screen, IFA (serum)
Neisseria gonorrhoeae Antibody, CF (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60200
Additional Information:	This test will be discontinued. Recommended alternative is: 40200 <i>Neisseria gonorrhoeae</i> Antibody, CF (serum)



DISCONTINUED TESTS

Herpesvirus 6 IgG Antibody, IFA (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60530
Additional Information:	This test will be discontinued. Recommended alternative is performed by Specialty Laboratories. 7786C Herpesvirus-6, Human IgG Antibodies CSF Please send this test directly to Specialty Laboratories.
Herpesvirus 6 IgM Antibody, IFA (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60535
Additional Information:	This test will be discontinued. Recommended alternative is performed by Specialty Laboratories. 7796C Herpesvirus-6, Human IgM Antibodies CSF Please send this test directly to Specialty Laboratories.
Herpesvirus 6 IgG and IgM Antibody Panel, IFA (CSF)	
Effective Date:	April 26, 2010
Unit Code:	60540
Additional Information:	Recommended alternative is performed by Specialty Laboratories. 7776C Herpesvirus-6, Human IgG & IgM Antibodies CSF Please send this test directly to Specialty Laboratories.
Parainfluenza Virus (Types 1,2, and 3) Antibodies, CSF	
Effective Date:	April 26, 2010
Unit Code:	60755
Additional Information:	This test will be discontinued. Recommended alternative is: 40755 Parainfluenza Virus (Types 1,2, and 3) Antibodies, serum
Respiratory Syncytial Virus Antibody, CSF	
Effective Date:	April 26, 2010
Unit Code:	60830
Additional Information:	This test will be discontinued. Recommended alternative is: 40830 Respiratory Syncytial Virus Antibody, serum

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.