



November 2009

TEST UPDATES

Revised

www.focusdx.com

Dear Client,

The document below has been revised.

The table for Focus code 20358 Interferon-Beta IgG, MAID (Reflex to Neutralization) has been updated.

We apologize for any confusion this may have caused.

Please do not respond to this e-mail address. For questions, please contact the Focus Diagnostics Client Services Department at 800-445-4032 or clientservices@focusdx.com.



November 2009

TEST UPDATES

Revised

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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TEST UPDATES

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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, Rifabutin, HPLC		
Effective Date:	Available Now	
Unit Code:	51949	
CPT Code:	82492	
List Price:	\$183.00	
Specimen Requirements:	2 mL (1mL 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 Friday	
Results Available:	3 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>Rifabutin peak levels occur approximately 2-4 hours after oral dosing with or without food. Desacetyl Rifabutin is an active metabolite of Rifabutin and typically appears at about 10% of the Rifabutin concentration. Peak levels may vary considerably from the mean during concurrent administration of other medications.</p> <p style="text-align: center;">Mean Rifabutin peak level: 0.375 mcg/mL</p> <p>Rifampin therapy may interfere with the Desacetyl Rifabutin metabolite level, but does not interfere with the actual Rifabutin level.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	1849	Rifabutin Level, HPLC
	1949	Desacetyl Rifabutin Level, HPLC

Dengue Virus IgG Avidity	
Effective Date:	January 18, 2010
Unit Code:	42605
CPT Code:	86790 (x2)
List Price:	\$148.00



NEW TESTS

Specimen Requirements:	0.5 mL (0.25 mL min.) serum	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Ranges:	>0.35	
Methodology:	ELISA	
Set-up Day(s):	Tuesday, Friday	
Results Available:	1 to 5 days	
FDA clearance type:	Laboratory Developed Test ASR I	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New Test</p> <p>Always message will be:</p> <p>REFERENCE RANGE: >0.35</p> <p>INTERPRETIVE CRITERIA: < OR = 0.35 Low IgG avidity >0.35 High IgG avidity</p> <p>Low dengue virus (DV) IgG avidity indicates acute primary DV infection. High DV IgG avidity for a specimen collected within 30 days of disease onset indicates acute secondary DV infection, and an increased risk for dengue hemorrhagic fever. For specimens with an unknown collection time relative to disease onset, a high IgG avidity index can not discriminate acute secondary infection from past infection.</p> <p>This assay 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. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	42605	DV IgG Avidity Index



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.

Antiretroviral Level, Amprenavir, HPLC	
Effective Date:	October 26, 2009
Unit Code:	51971
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

Antiretroviral Level, Delavirdine, HPLC	
Effective Date:	October 26, 2009
Unit Code:	51999
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

Antiretroviral Level, Kaletra™, HPLC	
Effective Date:	October 26, 2009
Unit Code:	51987
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

Antiretroviral Level, Nelfinavir, HPLC	
Effective Date:	October 26, 2009
Unit Code:	51973
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

<i>Clostr. difficile</i> Cytotoxin Antibody, Neutralization	
Effective Date:	October 26, 2009
Unit Code:	81055
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.



TEST CHANGES

<i>Borrelia hermsii</i> Antibody Panel, IFA	
Effective Date:	October 26, 2009
Unit Code:	40810
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

<i>Borrelia hermsii</i> IgG Antibody, IFA	
Effective Date:	October 26, 2009
Unit Code:	40815
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

<i>Borrelia hermsii</i> IgM Antibody, IFA	
Effective Date:	October 26, 2009
Unit Code:	40820
NYSDOH Approved:	Yes
Additional Information:	This test is now available for NY patient testing.

Lymphocyte Subset Panel 1																																	
Effective Date:	December 7, 2009																																
Unit Code:	20378																																
Units of Measure:	<table border="0"> <tr> <td>Lymphocytes, Absolute</td> <td>cells/uL</td> </tr> <tr> <td>Total B Cells</td> <td>(none)</td> </tr> <tr> <td>CD19, Absolute</td> <td>cells/uL</td> </tr> <tr> <td>CD19 Percentage</td> <td>%</td> </tr> <tr> <td>Total T Cells</td> <td>(none)</td> </tr> <tr> <td>CD3, Absolute</td> <td>cells/uL</td> </tr> <tr> <td>CD3 Percentage</td> <td>%</td> </tr> <tr> <td>T-Lymphocyte Subsets</td> <td>(none)</td> </tr> <tr> <td>CD4, Absolute</td> <td>cells/uL</td> </tr> <tr> <td>CD4 Percentage</td> <td>%</td> </tr> <tr> <td>CD8 Absolute</td> <td>cells/uL</td> </tr> <tr> <td>CD8 Percentage</td> <td>%</td> </tr> <tr> <td>Natural Killer Cells</td> <td>(none)</td> </tr> <tr> <td>CD3-CD16+CD56+ (Abs)</td> <td>cells/uL</td> </tr> <tr> <td>CD3-/CD16+CD56+ (%)</td> <td>%</td> </tr> <tr> <td>CD4/CD8 Ratio</td> <td>(none)</td> </tr> </table>	Lymphocytes, Absolute	cells/uL	Total B Cells	(none)	CD19, Absolute	cells/uL	CD19 Percentage	%	Total T Cells	(none)	CD3, Absolute	cells/uL	CD3 Percentage	%	T-Lymphocyte Subsets	(none)	CD4, Absolute	cells/uL	CD4 Percentage	%	CD8 Absolute	cells/uL	CD8 Percentage	%	Natural Killer Cells	(none)	CD3-CD16+CD56+ (Abs)	cells/uL	CD3-/CD16+CD56+ (%)	%	CD4/CD8 Ratio	(none)
Lymphocytes, Absolute	cells/uL																																
Total B Cells	(none)																																
CD19, Absolute	cells/uL																																
CD19 Percentage	%																																
Total T Cells	(none)																																
CD3, Absolute	cells/uL																																
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CD3-CD16+CD56+ (Abs)	cells/uL																																
CD3-/CD16+CD56+ (%)	%																																
CD4/CD8 Ratio	(none)																																
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																																
Additional Information:	Update units of measure for Absolute values. Portions of above information also apply to: 20384 Lymphocyte Subset Panel 2; 20376 Lymphocyte Subset Panel 3; 2590 Natural Killer Cells; 20372 T and B Cells, Total; 2340 Chronic Fatigue Syndrome Panel III																																



TEST CHANGES

<i>Histoplasma capsulatum</i> Identification, DNA Probe	
Effective Date:	December 23, 2009
Unit Code:	58500
CPT Code:	87149
Additional Information:	Update CPT code.

<i>Rickettsia</i> Antibody Panel with Reflex to Titers				
Effective Date:	January 11, 2010			
Unit Code:	40840			
Former Test Name:	<i>Rickettsia</i> Antibody Panel, IFA (Serum)			
Specimen Requirements:	1 mL serum (0.2 mL min.)			
Transport Temperature:	Room temperature			
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days			
Reference Range:	Not Detected			
Additional Information:	<p>If the <i>Rickettsia</i> Antibody screens are “Detected”, titers will be performed at an additional charge (add CPT code(s) 86757 per titer performed). “Detected” results will be flagged “A” for abnormal. Update reporting title, test codes, test code titles, transport temperature, specimen stability, flagging, and always message. Add reflex.</p> <p>This test is used in the following profile: 4080 – <i>Rickettsia</i> and <i>Coxiella burnetti</i> Antibody Panel</p> <p>Always message will be:</p> <p>Reference Range: Not Detected</p>			
CPU Interface Mapping:	Test Code (analyte)		Test Code Title	
	4098		RMSF IgG	
	4099		RMSF IgM	
	4100		<i>R. typhi</i> IgG	
	4101		<i>R. typhi</i> IgM	

<i>Rickettsia</i> (RMSF) Antibodies (IgG, IgM) with Reflex to Titers	
Effective Date:	January 11, 2010
Unit Code:	40855



TEST CHANGES

Former Test Name:	<i>Rickettsia</i> (Spotted Fever Group) Ab Panel, IFA (Serum)	
Specimen Requirements:	1 mL serum (0.2 mL min.)	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Range:	Not Detected	
Additional Information:	<p>If the Rocky Mountain Spotted Fever (RMSF) screens are “Detected”, titers will be performed at an additional charge (add CPT code(s) 86757 per titer performed).</p> <p>“Detected” results will be flagged “A” for abnormal.</p> <p>Update reporting title, test codes, test code titles, transport temperature, specimen stability, flagging, and always message. Add reflex.</p> <p>Always message will be:</p> <p>Reference Range: Not Detected</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4098 4099	RMSF IgG RMSF IgM

***Rickettsia* (Typhus Fever) Antibodies (IgG, IgM) with Reflex to Titers**

Effective Date:	January 11, 2010
Unit Code:	41000
Former Test Name:	<i>Rickettsia</i> (Typhus Fever Group) Antibody Panel, IFA
Specimen Requirements:	1 mL serum (0.2 mL min.)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Range:	Not Detected
Additional Information:	<p>If the <i>Rickettsia</i> (Typhus Fever) screens are “Detected”, titers will be performed at an additional charge (add CPT code(s) 86757 per titer performed).</p> <p>“Detected” results will be flagged “A” for abnormal.</p> <p>Update reporting title, test codes, test code titles, transport temperature, specimen stability, flagging, and always message. Add reflex.</p> <p>Always message will be:</p> <p>Reference Range: Not Detected</p>



TEST CHANGES

CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4100	<i>R. typhi</i> IgG
4101	<i>R. typhi</i> IgM	

Interferon-Beta IgG, MAID (Reflex to Neutralization)***Revised	
Effective Date:	January 11, 2010
Unit Code:	20358
Additional Information:	<p>If the Interferon-Beta IgG is ≥ 4.0, Interferon Beta (IFNB) Antibody Neutralization Assay will be performed at an additional charge (add CPT code 86849). CPT code has been corrected.</p> <p>Update reflex criteria.</p>

<i>E. coli</i> O157:H7 Serotyping		
Effective Date:	January 18, 2010	
Unit Code:	52065	
Reference Range:	Negative for O157:H7	
Additional Information:	<p>Update reference range, test code title, and always message.</p> <p>Always message will be:</p> <p>A result of "Negative for O157:H7" indicates that sorbitol-negative <i>E. coli</i> was isolated, but serotyping did not detect the O157:H7 serotype antigens. A result of "Positive for O157:H7" indicates the presence of the disease associated O157:H7 serotype. Some isolates may lack the H7 antigen (non-motile strains) and will be reported as "Positive for O157" only. This serotyping assay does not detect other <i>E. coli</i> serotypes associated with the disease and it does not detect the disease associated shiga-toxin.</p>	
CPU Interface Mapping:	Test Code (Analyte)	Test Code Title
	307	<i>E. coli</i> Serotyping



DISCONTINUED TESTS

Interferon Beta (IFNB) Antibody Neutralization Assay	
Effective Date:	January 11, 2010
Unit Code:	20468
Additional Information:	This test will be discontinued. Please order 20555 Interferon Beta 1a (IFNB-1a) or 20777 Interferon Beta 1b (IFNB-1b) in its place.

<i>Rickettsia</i> (Spotted Fever Group) IgG AB, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	40860
Additional Information:	This test will be discontinued. Please order 40855 <i>Rickettsia</i> (Spotted Fever Group) Ab Panel, IFA (Serum) (see changes to 40855 in the test change section of this update) in its place.

<i>Rickettsia</i> (Spotted Fever Group) IgM AB, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	40865
Additional Information:	This test will be discontinued. Please order 40855 <i>Rickettsia</i> (Spotted Fever Group) Ab Panel, IFA (Serum) (see changes to 40855 in the test change section of this update) in its place.

<i>Rickettsia</i> IgG Antibody, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	40845
Additional Information:	This test will be discontinued. Please order 40840 <i>Rickettsia</i> Antibody Panel, IFA (Serum) (see changes to 40840 in the test change section of this update) in its place.

<i>Rickettsia</i> IgM Antibody, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	40850
Additional Information:	This test will be discontinued. Please order 40840 <i>Rickettsia</i> Antibody Panel, IFA (Serum) (see changes to 40840 in the test change section of this update) in its place.



DISCONTINUED TESTS

<i>Rickettsia</i> (Typhus Fever Group) IgG AB, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	41005
Additional Information:	This test will be discontinued. Please order 41000 <i>Rickettsia</i> (Typhus Fever Group) Antibody Panel, IFA (see changes to 41000 in the test change section of this update) in its place.

<i>Rickettsia</i> (Typhus Fever Group) IgM AB, IFA (Serum)	
Effective Date:	January 11, 2010
Unit Code:	41010
Additional Information:	This test will be discontinued. Please order 41000 <i>Rickettsia</i> (Typhus Fever Group) Antibody Panel, IFA (see changes to 41000 in the test change section of this update) in its place.

Rifabutin Level, BA	
Effective Date:	January 18, 2010
Unit Code:	51712
Additional Information:	This test will be discontinued. Please order 51949 Antimicrobial Level, Rifabutin, HPLC in its place.



HOLIDAY NOTIFICATION

Thanksgiving Holiday Notification

The Thanksgiving holiday will be observed by Focus Diagnostics, Inc. on Thursday, November 26, 2009. Client Services will be staffed from 8:00 am to 2:00 pm PST. Regular laboratory services will resume on Friday, November 27, 2009.

The laboratory will be staffed on Thursday, November 26th 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 25, 2009.

On Thursday, November 26th, 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.