



Dear Client,

The document below has been revised.

The following tests will not have an always message update.

We apologize for any confusion this may have caused.

40215 - California Encephalitis Virus Antibody, IFA (Serum)

40417 - Eastern Equine Encephalitis Virus Antibody, IFA (Serum)

40895 - St. Louis Encephalitis Virus Antibody, IFA (Serum)

41045 - Western Equine Encephalitis Virus Antibody, IFA (Serum)

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.



August 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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<p>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.</p>



Test Changes

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.

The following section contains updates to existing tests indicated in bold face type. For complete test information, contact Client Services at 800-445-4032 or visit our website at www.focusdx.com.

Bacterial Antigen Detection Panel, LA		
Effective Date:	October 12, 2009	
Unit Code:	2245	
Specimen Requirements:	2 mL (1 mL min.) serum or CSF Urine is not an acceptable specimen type.	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Ranges:	Not Detected	
Additional Information:	<p>Update specimen requirements, transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte).</p> <p>Message code (always message): REFERENCE RANGE: NOT DETECTED</p> <p>This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (this is an ask at order entry (prompt) code) 4543 4544 4545 4546 4547 4548	Source <i>Streptococcus</i> , GP B, Ag, Detection <i>H. influenzae</i> Type b Ag, Detection <i>S. pneumoniae</i> Ag Detection <i>N. meningitidis</i> Group C/W135 <i>N. meningitidis</i> Group A/Y Group B/ <i>E. coli</i> K1 Ag Detection
Haemophilus influenzae Type b Antigen		
Effective Date:	October 12,2009	
Unit Code:	40165	
Former Test Name:	<i>Haemophilus influenzae</i> , Type b, Antigen Detection, LA	
Specimen Requirements:	1 mL (0.3 mL min.) serum or CSF Urine is not an acceptable specimen type.	



Test Changes

Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Range	Not Detected	
Additional Information:	<p>Update specimen requirements, transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte).</p> <p>Message code (always message): REFERENCE RANGE: NOT DETECTED</p> <p>This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (this is an ask at order entry (prompt) code)	Source
	4021	<i>H. influenzae</i> Type b Ag

<i>N. meningitidis</i> Ag Detection (Groups A/Y & C/W135), LA		
Effective Date:	October 12, 2009	
Unit Code:	40175	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Range	Not Detected	
Additional Information:	<p>Update transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte).</p> <p>Message code (always message): REFERENCE RANGE: NOT DETECTED</p> <p>This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (this is an ask at order entry (prompt) code)	Source
	4222 4223	<i>N. meningitidis</i> Group C/W135 <i>N. meningitidis</i> Group A/Y



Test Changes

<i>N. meningitidis</i> Ag Detection (Group B & <i>E. coli</i> K1), LA		
Effective Date:	October 12, 2009	
Unit Code:	40177	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Range	Not Detected	
Additional Information:	Update transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte). Message code (always message): REFERENCE RANGE: NOT DETECTED This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (this is an ask at order entry (prompt) code)	Source
	4224	Group B/ <i>E. coli</i> K1 Ag Detection
<i>Streptococcus</i>, GP B, Ag, Detection, LA		
Effective Date:	October 12, 2009	
Unit Code:	40160	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Range	Not Detected	
Additional Information:	Update transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte). Message code (always message): REFERENCE RANGE: NOT DETECTED This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title



Test Changes

	100 (this is an ask at order entry (prompt) code) 4020	Source <i>Streptococcus</i> , GP B, Ag, Detection, LA
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***S. pneumoniae* Ag Detection, LA**

Effective Date:	October 12, 2009	
Unit Code:	40170	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 7 days	
Reference Range	Not Detected	
Additional Information:	Update transport temperature, specimen stability, reference range, message code (always message) and add test code (analyte). Message code (always message): REFERENCE RANGE: NOT DETECTED This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	100 (this is an ask at order entry (prompt) code) 4022	Source <i>S. pneumoniae</i> Ag Detection, LA

***Borrelia burgdorferi* IgG and IgM AB Panel, WB (Fluid)**

Effective Date:	October 19, 2009	
Unit Code:	70340	
Additional Information:	Update test code (analyte) titles and message code (always message). Add the following statement to the message code (always message): 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. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	7038	<i>B. burgdorferi</i> IgG WB
	7033	IgG Bands Present
	7039	<i>B. burgdorferi</i> IgM WB
	7135	IgM Bands Present



Test Changes

California Encephalitis Virus Antibody, IFA (Serum) ***Revised		
Effective Date:	October 19, 2009	
Unit Code:	40215	
Former Test Name:	California Encephalitis Virus AB Panel, IFA (Serum)	
Additional Information:	<p>Update test code (analyte) titles. <u>Always message will not be updated.</u></p> <p>These test codes (analytes) are also used in profiles: 2015 Meningoencephalitis (Encephalitis) Panel (Serum) 2030 Meningoencephalitis Comprehensive Panel (Serum) 2240 Arbovirus Antibody Panel, IFA (Serum) 4895 Arbovirus and West Nile Virus Antibody Panel (Serum)</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	994	CA Enceph. Virus IgG
	998	CA Enceph. Virus IgM
	9994	Interpretation
Chlamydia Group Antibody Screen, IFA (CSF)		
Effective Date:	October 19, 2009	
Unit Code:	60265	
Additional Information:	<p>Update test code (analyte) titles and message code (always message).</p> <p>Add the following statement to the message code (always message):</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. 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
	2697	Chlamydia IgG
	2698	Chlamydia IgM
	2699	Interpretation
Chlamydia Group Antibody Screen, IFA (Serum)		
Effective Date:	October 19, 2009	
Unit Code:	40265	
Additional Information:	<p>Update test code (analyte) and message code (always message).</p> <p>Add the following statement to the message code (always message):</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. The FDA has determined that such clearance or approval is not necessary. Performance</p>	



Test Changes

	characteristics refer to the analytical performance of the test.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	7401	<i>Chlamydia</i> IgG
	7402	<i>Chlamydia</i> IgM
	7403	Interpretation

Eastern Equine Encephalitis Virus Antibody, IFA (Serum) *Revised**

Effective Date:	October 19, 2009	
Unit Code:	40417	
Additional Information:	<p>Update test code (analyte) titles. <u>Always message will not be updated.</u></p> <p>These test codes (analytes) are also used in profiles: 2015 Meningoencephalitis (Encephalitis) Panel (Serum) 2030 Meningoencephalitis Comprehensive Panel (Serum) 2240 Arbovirus Antibody Panel, IFA (Serum) 4895 Arbovirus and West Nile Virus Antibody Panel (Serum)</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	993	E. Equine Enceph. Virus IgG
	997	E. Equine Enceph. Virus IgM
	9993	Interpretation

***Giardia lamblia* IgG, IgA, IgM Antibody Panel, IFA**

Effective Date:	October 19, 2009	
Unit Code:	46050	
Additional Information:	<p>Update test code (analyte) titles and message code (always message).</p> <p>Add the following statement to the message code (always message):</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. 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
	4650	<i>Giardia</i> IgG
	4651	<i>Giardia</i> IgA
	4652	<i>Giardia</i> IgM
	4654	Interpretation

Lymphocyte Antigen Stimulation Screen-*Candida*, CC

Effective Date:	October 19, 2009	
Unit Code:	23504	
Additional Information:	<p>Update test code (analyte) titles and message code (always message).</p> <p>Add the following statement to the message code (always message):</p>	



Test Changes

	<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. 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
	2915	<i>Candida Stimulation Index</i>
	2916	Interpretation

Lymphocyte Antigen Stimulation Screen-PPD, CC

Effective Date:	October 19, 2009	
Unit Code:	24504	
Former Test Name:	Lymphocyte Antigen Stimulation Screen, PPD, CC	
Additional Information:	<p>Update test code (analyte) titles message code (always message).</p> <p>Add the following statement to the message code (always message):</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. 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
	2917	PPD Stimulation Index
	2918	Interpretation

Lymphocyte Antigen Stimulation Screen-Tetanus Toxoid, CC

Effective Date:	October 19, 2009	
Unit Code:	22504	
Additional Information:	<p>Update test code (analyte) titles and message code (always message).</p> <p>Add the following statement to the message code (always message):</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. 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
	2912	Tetanus Stimulation Index
	2913	Interpretation



Test Changes

St. Louis Encephalitis Virus Antibody, IFA (Serum) ***Revised		
Effective Date:	October 19, 2009	
Unit Code:	40895	
Additional Information:	Update test code (analyte) titles. <u>Always message will not be updated.</u> These test codes (analytes) are also used in profile: 2030 Meningoencephalitis Comprehensive Panel (Serum)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	991	St. Louis Enceph. Virus IgG
	995	St. Louis Enceph. Virus IgM
	9995	Interpretation
Western Equine Encephalitis Virus Antibody, IFA (Serum) ***Revised		
Effective Date:	October 19, 2009	
Unit Code:	41045	
Former Test Name:	Western Equine Encephalitis IgG & IgM AB Pnl IFA (Serum)	
Additional Information:	Update test code (analyte) titles. <u>Always message will not be updated.</u> These test codes (analytes) are also used in profile: 2030 Meningoencephalitis Comprehensive Panel (Serum)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	992	W. Equine Enceph. Virus IgG
	996	W. Equine Enceph. Virus IgM
	9996	Interpretation



Test Changes

Labor Day Holiday Notification

The Labor Day holiday will be observed by Focus Diagnostics, Inc. on Monday, September 7, 2009. Client Services will be staffed from 8:00 am to 2:00 pm PST. Regular laboratory services will resume on Tuesday, September 8, 2009.

The laboratory will be staffed on Monday, September 7th 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 must be received by noon Friday, September 4, 2009.

On Monday, September 7th, 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.