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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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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 payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

Summary of Test Changes

Page Number	Test Name	Test Code(s)	Performing Site	Test Code	Test Name	Specimen Requirements	Transport Temperature	Specimen Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Reject Criteria	Other (see listing)
5	Lymphocytic Choriomeningitis Virus AB, IFA (Serum)	40625												x
5	West Nile Virus Antibody Panel, ELISA	40428												x
6	West Nile Virus Antibody Panel, ELISA (CSF)	60428												x
6	Epstein Barr Virus DNA, Qualitative Real-Time PCR	47510												x
6	Epstein Barr Virus DNA, Quantitative Real-Time PCR	48453												x
7	<i>Babesia microti</i> Antibodies (IgG, IgM)	41330								x				x
8	Tick-Borne Disease Antibody Panel	4090												x
9	<i>Helicobacter pylori</i> Antibody (IgA), Immunoblot	40551			x						x			x
10	<i>Helicobacter pylori</i> Antibody (IgG), Immunoblot	40550			x						x			x
11	<i>Helicobacter pylori</i> Antibodies (IgG, IgA), Immunoblot	40552			x						x			x
11	Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR	42690										x		x
12	Susceptibility, Anaerobic Bacteria, 1 Drug, MIC	51480			x	x	x	x			x	x	x	
12	Susceptibility, Anaerobic Bacteria, 2 Drug, MIC	51490			x	x	x	x			x	x	x	
12	Susceptibility, Anaerobic Bacteria, 3 Drug, MIC	51500			x	x	x	x			x	x	x	
13	Susceptibility Panel, Anaerobic Bacteria, MIC (Gradient)	51477			x	x	x	x			x	x	x	

Announcements

Memorial Day Holiday Notification

The Memorial Day holiday will be observed by Focus Diagnostics, Inc. on Monday, May 30, 2011. Client Services will be staffed from 8:00 am to 2:00 pm PDT. Regular laboratory services will resume on Tuesday, May 31, 2011.

The laboratory will be staffed on Monday, May 30, 2011, 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 Friday, May 27, 2011.

On Monday, May 30, 2011, 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.

New Test Offerings

The following tests will be available through Focus Diagnostics on the dates indicated below.

Susceptibility, <i>Mycobacterium tuberculosis</i>, Second-tier Drugs, Broth Method			
Clinical Significance:	Multidrug-resistant TB (MDR-TB) is caused by bacteria that are resistant to the most effective primary anti-TB drugs, isoniazid and rifampicin. Extensively drug-resistant TB (XDR-TB) is a form of TB caused by bacteria that are resistant to isoniazid and rifampicin (MDR-TB) as well as any fluoroquinolone and any of the second-line anti-TB injectable drugs (amikacin, kanamycin or capreomycin). Second line drugs for treatment of drug resistant <i>M. tuberculosis</i> are not as potent as the first line drugs.		
Effective Date:	June 6, 2011		
Test Code:	90342		
CPT Code(s):	87190 (x5)		
Specimen Requirements:	<p>Pure isolate on LJ slant, 7H10/7H11 medium or equivalent, safely contained in a double walled container. Isolate may be on agar or in a broth detection system.</p> <p>Mixed isolates or contaminated isolates will be sub-cultured to obtain a pure <i>M. tuberculosis</i> isolate (additional charges may be added).</p>		
Rejection Criteria:	Isolate that is not viable or is not <i>M. tuberculosis</i>		
Transport Temperature:	Room temperature		
Specimen Stability:	<p>Room temperature: Determined by viability</p> <p>Refrigerated: Determined by viability</p> <p>Frozen: Unacceptable</p>		
Set up/Analytic Time:	Set up: Mon-Fri; Report available: 4-14 days		
Reference Ranges:	Not applicable		
Methodology:	Broth Method		
Always Message:	<p>S = Susceptible R = Resistant</p> <p>Drug concentrations tested are based on 2008 World Health Organization recommendations. A correlation between results of second-line drug testing and clinical response has not been completely established.</p>		
CPU Interface Mapping:	Result Code:	Type:	Result Name:
	903421	Prompt	Organism
	903422		Amikacin 1.0
	903423		Capreomycin 2.5
	903424		Ciprofloxacin 1.0
	903425		Ethionamide 5.0
	903426		p-Aminosalicylic Acid 4.0

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the information that is changing appears in this update. *Former test codes and test names have been italicized.*

Lymphocytic Choriomeningitis Virus AB, IFA (Serum)	
Effective Date:	July 11, 2011
Test Code:	40625
Always Message:	<p>REFERENCE RANGES: IgG <1:16 IgM <1:20</p> <p>Antibody to LCM is often detectable within a few days of clinical symptoms. An elevated IgM titer is indicative of recent or current infection. A four-fold rise in IgG titer between acute and convalescent specimens also indicates recent infection.</p> <p>This assay was developed and its performance characteristics 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>

West Nile Virus Antibody Panel, ELISA																			
Effective Date:	July 11, 2011																		
Test Code:	40428																		
Always Message:	<p>REFERENCE RANGE: IgG <1.30 IgM <0.90</p> <p>INTERPRETIVE CRITERIA</p> <table> <tbody> <tr> <td>IgG:</td> <td><1.30</td> <td>Antibody not detected</td> </tr> <tr> <td></td> <td>1.30 - 1.49</td> <td>Equivocal</td> </tr> <tr> <td></td> <td>>=1.50</td> <td>Antibody detected</td> </tr> <tr> <td>IgM:</td> <td><0.90</td> <td>Antibody not detected</td> </tr> <tr> <td></td> <td>0.90 - 1.10</td> <td>Equivocal</td> </tr> <tr> <td></td> <td>>1.10</td> <td>Antibody detected</td> </tr> </tbody> </table> <p>West Nile Virus (WNV) IgM is usually detectable by the time symptoms appear, but IgG may not be detectable until day 4 or day 5 of illness.</p> <p>Although WNV IgM persists for more than a year in some patients with WNV encephalitis, detection of WNV IgM remains a reliable indicator of recent infection for most patients.</p> <p>Antibodies induced by other flavivirus infections (e.g., Dengue, St. Louis Encephalitis) may show crossreactivity with WNV; thus, antibody detection using this panel is not diagnostically conclusive for WNV infection. Final diagnosis should be based on clinical assessment and confirmatory assays, such as the plaque reduction neutralization test.</p>	IgG:	<1.30	Antibody not detected		1.30 - 1.49	Equivocal		>=1.50	Antibody detected	IgM:	<0.90	Antibody not detected		0.90 - 1.10	Equivocal		>1.10	Antibody detected
IgG:	<1.30	Antibody not detected																	
	1.30 - 1.49	Equivocal																	
	>=1.50	Antibody detected																	
IgM:	<0.90	Antibody not detected																	
	0.90 - 1.10	Equivocal																	
	>1.10	Antibody detected																	

West Nile Virus Antibody Panel, ELISA (CSF)	
Effective Date:	July 11, 2011
Test Code:	60428
Always Message:	<p>REFERENCE RANGE: IgG <1.30 IgM <0.90</p> <p>INTERPRETIVE CRITERIA</p> <p>IgG: <1.30 Antibody not detected 1.30 - 1.49 Equivocal >=1.50 Antibody detected</p> <p>IgM: <0.90 Antibody not detected 0.90 - 1.10 Equivocal >1.10 Antibody detected</p> <p>In the very early stages of acute West Nile Virus (WNV) infection, IgM may be detectable in CSF before it becomes detectable in serum. Antibodies induced by other flavivirus infections (e.g., Dengue, St. Louis Encephalitis) may show crossreactivity with WNV; thus, antibody detection using this panel is not diagnostically conclusive for WNV infection. Final diagnosis should be based on clinical assessment and confirmatory assays, such as the plaque reduction neutralization test.</p> <p>WNV antibody results for CSF should be interpreted with caution. Complicating factors include low antibody levels found in CSF, passive transfer of antibody from blood, and contamination via bloody taps.</p>

Epstein Barr Virus DNA, Qualitative Real-Time PCR	
Effective Date:	July 11, 2011
Test Code:	47510
Always Message:	<p>REFERENCE RANGE: NOT DETECTED</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>

Epstein Barr Virus DNA, Quantitative Real-Time PCR	
Effective Date:	July 11, 2011
Test Code:	48453
Always Message:	<p>REFERENCE RANGE: <200 copies/mL</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>

<i>Babesia microti</i> Antibodies (IgG, IgM)	
Effective Date:	July 18, 2011
Test Code:	41330
Reference Range:	IgG <1:64 IgM <1:20
Always Message:	<p>Reference Ranges: IgG <1:64 IgM <1:20</p> <p>Elevated antibody levels to <i>B. microti</i> indicate exposure to the organism. Human babesiosis infection is transmitted by the bite of an infected <i>Ixodes</i> tick or less frequently from transfusion with blood from an infected donor. Definitive diagnosis is made by identifying intraerythrocytic organisms in peripheral blood. In patients with low parasitemia, antibody detection by IFA is recommended. IgG levels greater than or equal to 1:1024 can be detected in acute phase patients with parasites in blood smears. The IFA assay can be used as a seroepidemiologic tool to study the frequency and distribution of <i>B. microti</i> in endemic areas especially in persons with mixed infections also involving <i>Borrelia burgdorferi</i>.</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>

Tick-Borne Disease Antibody Panel		
Effective Date:	July 18, 2011	
Test Code:	4090	
Always Message:	<p>This panel assesses the IgG and IgM responses to 4 of the major organisms responsible for tick-borne infections. The organisms responsible for Lyme disease, human granulocytic ehrlichiosis (HGE), and babesiosis are all transmitted by ticks in the genus <i>Ixodes</i> (deer tick, black-legged tick). Rare cases of concomitant transmission of Lyme disease, HGE, and babesiosis have been described. In contrast, human monocytic ehrlichiosis (HME), often referred to as rashless Rocky Mountain spotted fever and caused by <i>Ehrlichia chaffeensis</i>, is usually transmitted by <i>Amblyomma americanum</i> (Lone star tick). In all 4 diseases, detection of a four-fold rise in IgG titers between acute and convalescent sera or detection of IgM in any serum specimen suggests recent or current infection. Lyme disease IgM titers usually peak 4-6 weeks after infection and may persist in the presence of disease. Lyme disease IgG levels usually begin to rise 2-3 weeks after infection, and may stay elevated in cases of prolonged disease. Seronegative cases of Lyme disease have been reported. Crossreactivity with other <i>Borrelia</i> and <i>Treponema</i> species is observed. <i>Anaplasma phagocytophilum</i> is the agent causing HGE, a disease distinct and separate from HME. Serologic crossreactivity between <i>A. phagocytophilum</i> and <i>E. chaffeensis</i> is minimal (5-15%).</p> <p>Definitive diagnosis of babesiosis is made by identifying intraerythrocytic organisms in peripheral blood. In patients with low parasitemia, antibody detection is recommended for diagnosis. IgG levels greater than or equal to 1:1024 are usually detected in acute phase babesiosis patients with parasites in blood smears.</p> <p>These tests were developed and their performance characteristics have been determined by Focus Diagnostics. They have 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 tests.</p>	
CPU Interface Mapping:	Result Code:	Result Name:
	3040	<i>B. burgdorferi</i> IgG
	3041	<i>B. burgdorferi</i> IgM
	3042	Interpretation
	3045	<i>E. chaffeensis</i> IgG
	3046	<i>E. chaffeensis</i> IgM
	3047	Interpretation
	3050	<i>A. phagocytophilum</i> IgG
	3051	<i>A. phagocytophilum</i> IgM
	3052	Interpretation
	3055	<i>B. microti</i> IgG
	3056	<i>B. microti</i> IgM
3057	Interpretation	

<i>Helicobacter pylori</i> Antibody (IgA), Immunoblot		
Effective Date:	July 25, 2011	
Test Code:	40551	
Former Test Name:	<i>Helicobacter pylori</i> Antibody (IgA), Western Blot	
Always Message:	<p>INTERPRETIVE CRITERIA:</p> <p>REFERENCE RANGE: NEGATIVE NEGATIVE - No specific antibodies to <i>H. pylori</i> detected</p> <p>EQUIVOCAL - Antibodies to one specific <i>H. pylori</i> protein other than CagA and VacA detected</p> <p>POSITIVE: LOW PATHOGENIC STRAIN - Antibodies to at least two specific <i>H. pylori</i> proteins other than CagA and VacA detected</p> <p>POSITIVE: HIGHLY PATHOGENIC STRAIN - Specific antibodies to CagA and/or VacA detected</p> <p>Individuals infected with <i>H. pylori</i> strains expressing Cytotoxin-associated gene A (CagA) protein and/or Vacuolating-Cytotoxin A (VacA) protein are at increased risk for developing gastric or peptic ulcers and/or gastric carcinoma. Detection of antibodies to one or both of these proteins indicates infection with a highly pathogenic strain of <i>H. pylori</i>.</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>	
Methodology:	Immunoblot	
CPU Interface Mapping:	Result Code:	Result Name:
	40551	<i>H. pylori</i> Ab (IgA)

<i>Helicobacter pylori</i> Antibody (IgG), Immunoblot		
Effective Date:	July 25, 2011	
Test Code:	40550	
Former Test Name:	<i>Helicobacter pylori</i> Antibody (IgG), Western Blot	
Always Message:	<p>INTERPRETIVE CRITERIA: REFERENCE RANGE: NEGATIVE NEGATIVE - No specific antibodies to <i>H. pylori</i> detected EQUIVOCAL - Antibodies to one specific <i>H. pylori</i> protein other than CagA and VacA detected POSITIVE: LOW PATHOGENIC STRAIN - Antibodies to at least two specific <i>H. pylori</i> proteins other than CagA and VacA detected POSITIVE: HIGHLY PATHOGENIC STRAIN - Specific antibodies to CagA and/or VacA detected Individuals infected with <i>H. pylori</i> strains expressing Cytotoxin-associated gene A (CagA) protein and/or Vacuolating-Cytotoxin A (VacA) protein are at increased risk for developing gastric or peptic ulcers and/or gastric carcinoma. Detection of antibodies to one or both of these proteins indicates infection with a highly pathogenic strain of <i>H. pylori</i>.</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>	
Methodology:	Immunoblot	
CPU Interface Mapping:	Result Code:	Result Name:
	40550	<i>H. pylori</i> Ab (IgG)

Helicobacter pylori Antibodies (IgG, IgA), Immunoblot		
Effective Date:	July 25, 2011	
Test Code:	40552	
Former Test Name:	<i>Helicobacter pylori Antibody (IgG, IgA), Western Blot</i>	
Always Message:	<p>INTERPRETIVE CRITERIA: REFERENCE RANGE: NEGATIVE NEGATIVE - No specific antibodies to <i>H. pylori</i> detected EQUIVOCAL - Antibodies to one specific <i>H. pylori</i> protein other than CagA and VacA detected POSITIVE: LOW PATHOGENIC STRAIN - Antibodies to at least two specific <i>H. pylori</i> proteins other than CagA and VacA detected POSITIVE: HIGHLY PATHOGENIC STRAIN - Specific antibodies to CagA and/or VacA detected</p> <p>Individuals infected with <i>H. pylori</i> strains expressing Cytotoxin-associated gene A (CagA) protein and/or Vacuolating-Cytotoxin A (VacA) protein are at increased risk for developing gastric or peptic ulcers and/or gastric carcinoma. Detection of antibodies to one or both of these proteins indicates infection with a highly pathogenic strain of <i>H. pylori</i>.</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>	
Methodology:	Immunoblot	
CPU Interface Mapping:	Result Code:	Result Name:
	40550	<i>H. pylori</i> Ab (IgG)
	40551	<i>H. pylori</i> Ab (IgA)

Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR	
<i>*** This test is not available for New York patient testing. There is not a recommended alternative for NY patient testing available at this time. ***</i>	
Effective Date:	July 25, 2011
Test Code:	42690
CPT Code(s):	87502
Always Message:	<p>This assay detects and differentiates between seasonal influenza A H1 and influenza A H3 viruses. This assay does not detect the presence of 2009 H1N1 influenza A virus.</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. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>

Susceptibility, Anaerobic Bacteria, 1 Drug, MIC	
Effective Date:	July 25, 2011
Test Code:	51480
<i>Former Test Name:</i>	<i>Antimicrob Susc, Anaerobic, Custom MIC (1)</i>
CPT Code(s):	87181
Specimen Requirements:	Pure culture of anaerobic isolate on a slant, plate or swab. Swabs transport in an appropriate Amies agar gel transport medium (or equivalent). Organism identification must be supplied.
Rejection Criteria:	Isolate in Thioglycollate broth Aerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable))
Transport Temperature:	Refrigerated (preferred and may help improve isolate viability)
Specimen Stability:	Room temperature: Determined by viability Refrigerated: Determined by viability Frozen: Unacceptable
Methodology:	Etest Gradient

Susceptibility, Anaerobic Bacteria, 2 Drug, MIC	
Effective Date:	July 25, 2011
Test Code:	51490
<i>Former Test Name:</i>	<i>Antimicrob Susc, Anaerobic, Custom MIC (2)</i>
CPT Code(s):	87181
Specimen Requirements:	Pure culture of anaerobic isolate on a slant, plate or swab. Swabs transport in an appropriate Amies agar gel transport medium (or equivalent). Organism identification must be supplied.
Rejection Criteria:	Isolate in Thioglycollate broth Aerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable))
Transport Temperature:	Refrigerated (preferred and may help improve isolate viability)
Specimen Stability:	Room temperature: Determined by viability Refrigerated: Determined by viability Frozen: Unacceptable
Methodology:	Etest Gradient

Susceptibility, Anaerobic Bacteria, 3 Drug, MIC	
Effective Date:	July 25, 2011
Test Code:	51500
<i>Former Test Name:</i>	<i>Antimicrob Susc, Anaerobic, Custom MIC (3)</i>
CPT Code(s):	87181
Specimen Requirements:	Pure culture of anaerobic isolate on a slant, plate or swab. Swabs transport in an appropriate Amies agar gel transport medium (or equivalent). Organism identification must be supplied.
Rejection Criteria:	Isolate in Thioglycollate broth Aerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable))
Transport Temperature:	Refrigerated (preferred and may help improve isolate viability)
Specimen Stability:	Room temperature: Determined by viability Refrigerated: Determined by viability Frozen: Unacceptable
Methodology:	Etest Gradient

Susceptibility Panel, Anaerobic Bacteria, MIC (Gradient)	
Effective Date:	July 25, 2011
Test Code:	51477
<i>Former Test Name:</i>	<i>Anaerobic Bacteria, MIC Panel</i>
Specimen Requirements:	Pure culture of anaerobic isolate on a slant, plate or swab Swabs transport in an appropriate Amies agar gel transport medium (or equivalent)
Rejection Criteria:	Isolate in Thioglycollate broth Aerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable))
Transport Temperature:	Refrigerated (preferred and may help improve isolate viability)
Specimen Stability:	Room temperature: Determined by viability Refrigerated: Determined by viability Frozen: Unacceptable
Always Message:	Drug concentrations are expressed in mcg/mL. S = Susceptible I = Intermediate R = Resistant Although most antimicrobials are reported for all anaerobes, several antimicrobials have limited testing and reporting based on identification of the isolate: Cefoxitin and Cefotetan are reported only for <i>Clostridium</i> species (not <i>C. perfringens</i>); Meropenem is reported only for <i>Bacteroides fragilis</i> group and <i>Clostridium</i> species (not <i>C. perfringens</i>); Penicillin is not reported for <i>Bacteroides fragilis</i> group.

Discontinued Tests

AFB Susceptibility, <i>M. Tuberculosis</i> Complex, Secondary Panel, Broth Method	
Effective Date:	July 18, 2011
Test Code:	51912
Additional Information:	<ul style="list-style-type: none">• The recommended alternative is 90342 Susceptibility, <i>Mycobacterium tuberculosis</i>, Second-tier Drugs, Broth Method, available June 6, 2011 (see new test section of this update).

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.