

Focus Diagnostics

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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)	Re-redirect(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)
7	Angiotensin Converting Enzyme (CSF)	64005									x			x
8	<i>Mycoplasma pneumoniae</i> Culture	51045				x	x	x		x			x	x
8	Varicella-Zoster Virus AB (Immunity Screen), ACIF (Serum)	41015												x
9	HTLV I/II DNA, Qualitative Real-Time PCR	4220												x
9	Norovirus RNA, RT-PCR	44340												x
9	<i>Parechovirus</i> RNA, RT-PCR	48990												x
9	<i>Cytomegalovirus</i> DNA, Qualitative Real-Time PCR	45000												x
9	<i>Cytomegalovirus</i> DNA, Quantitative Real-Time PCR	45050												x
9	<i>Cytomegalovirus</i> DNA, Qual to Quant Real-Time PCR Reflex	45099												x
10	BK Virus DNA, Quantitative Real-Time PCR, Plasma/Serum	47902												x
10	Epstein Barr Virus DNA, Qual to Quant Real-Time PCR Reflex	47599												x
10	Influenza A H1N1 (2009) Real-Time RT-PCR	46585				x								
11	Influenza Type A/B RT-PCR Reflex to Influenza A H1N1 (2009) RT-PCR	42699				x								
11	<i>Clostridium difficile</i> Cytotoxin Antibody, Neutralization	81055				x	x	x		x	x		x	
11	Herpes Simplex Virus Type 1 & 2 DNA, Real-Time PCR	43200				x								

Summary of Test Changes Cont.

Page Number	Test Name	Test Code(s)	Re-direct(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)
11	Herpes Simplex Virus Type 1 & 2 DNA, Quantitative Real-Time PCR	43220				x								x

New Test Offerings

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

Lyme Disease (<i>Borrelia</i> spp) DNA Qualitative Real-Time PCR, Blood <i>** This test is not available for New York patient testing**</i> <i>** The recommended alternative for New York patient testing is 42300 – Lyme Disease (<i>Borrelia burgdorferi</i>) DNA Qualitative Real-Time PCR, Blood</i>	
Clinical Significance:	The diagnosis of Lyme disease is most often made by clinical examination combined with evidence of tick bite or exposure in endemic areas. Amplification of <i>Borrelia</i> genomic DNA from blood, fluids or tissues can support the diagnosis.
Effective Date:	May 2, 2011
Test Code:	15777
CPT Code(s):	87801
Specimen Requirements:	1 mL whole blood (EDTA or ACD)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: Unacceptable
Set up/Analytic Time:	Set up: Mon-Sun; Report available: 1-3 day(s)
Reference Ranges:	Not Detected
Methodology:	Real-Time Polymerase Chain Reaction

Lyme Disease (<i>Borrelia</i> spp) DNA Qualitative Real-Time PCR, Synovial Fluid/CSF <i>** This test is not available for New York patient testing**</i> <i>** The recommended alternative for New York patient testing is 42400 – Lyme Disease (<i>Borrelia burgdorferi</i>) DNA Qualitative Real-Time PCR, CSF or Synovial Fluid</i>	
Clinical Significance:	The diagnosis of Lyme disease is most often made by clinical examination combined with evidence of tick bite or exposure in endemic areas. Amplification of <i>Borrelia</i> genomic DNA from blood, fluids or tissues can support the diagnosis.
Effective Date:	May 2, 2011
Test Code:	15564
CPT Code(s):	87801
Specimen Requirements:	1 mL synovial fluid or CSF
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Set up/Analytic Time:	Set up: Mon-Sun; Report available: 1-3 day(s)
Reference Ranges:	Not Detected
Methodology	Real-Time Polymerase Chain Reaction

Lyme Disease (<i>Borrelia</i> spp) DNA Qualitative Real-Time PCR, Tick	
Clinical Significance:	The diagnosis of Lyme disease is most often made by clinical examination combined with evidence of tick bite or exposure in endemic areas. Amplification of <i>Borrelia</i> genomic DNA from blood, fluids, or tissues can support the diagnosis.
Effective Date:	May 2, 2011
Test Code:	15510
CPT Code(s):	87801
Specimen Requirements:	1 deer tick in 70% ethanol or in wet tissue in a sterile screw cap container
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 14 days
Set up/Analytic Time:	Set up: Mon-Sun; Report available: 1-3 day(s)
Reference Ranges:	Not Detected
Methodology:	Real-Time Polymerase Chain Reaction

Lyme Disease (<i>Borrelia</i> spp) DNA Qualitative Real-Time PCR, Urine	
<i>** This test is not available for New York patient testing**</i>	
<i>** The recommended alternative for New York patient testing is 42500 – Lyme Disease (<i>Borrelia burgdorferi</i>) DNA Qualitative Real-Time PCR, Urine</i>	
Clinical Significance:	The diagnosis of Lyme disease is most often made by clinical examination combined with evidence of tick bite or exposure in endemic areas. Amplification of <i>Borrelia</i> genomic DNA from blood, fluids or tissues can support the diagnosis.
Effective Date:	May 2, 2011
Test Code:	15868
CPT Code(s):	87801
Specimen Requirements:	4 mL random urine
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Set up/Analytic Time:	Set up: Mon-Sun; Report available: 1-3 day(s)
Reference Ranges:	Not Detected
Methodology:	Real-Time Polymerase Chain Reaction

Modified Hodge Test	
Clinical Significance:	<i>Klebsiella pneumoniae</i> carbapenemase (KPC)-producing organisms can be a difficult therapeutic challenge, due to their broad spectrum of resistance to beta-lactams. The profile of KPC beta-lactam resistance is similar to that of extended-spectrum beta-lactamases (ESBLs) with the addition of resistance to the carbapenems (imipenem, meropenem, doripenem, and ertapenem). In addition, KPC producers may be cross-resistant to a wide range of antibiotic classes including the aminoglycosides, fluoroquinolones, and sulfa drugs.
Effective Date:	June 13, 2011
Test Code:	55655
CPT Code(s):	87184
Specimen Requirements:	1 pure <i>Enterobacteriaceae</i> slant (preferred), swab or plate Organism identification must be supplied
Rejection Criteria:	Mixed isolates, organisms other than <i>Enterobacteriaceae</i>, nonviable organisms, and frozen samples are all unacceptable for this test.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: Varies with species and transport system Refrigerated: Varies with species and transport system Frozen: Unacceptable
Set up/Analytic Time:	Set up: Mon-Sun; Report available: 2-3 day(s)
Reference Ranges:	Negative
Methodology:	Modified Disk Diffusion

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.*

Angiotensin Converting Enzyme (CSF)	
Effective Date:	June 13, 2011
Test Code:	64005
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Methodology:	Kinetic
Always Message:	REFERENCE RANGE: <4 ACE Units INTERPRETIVE CRITERIA: <4 ACE Units Normal Level > or = 4 ACE Units Increased Level CSF levels of angiotensin converting enzyme (ACE) are increased in approximately 50% of patients with neurosarcoidosis, but in less than 10% of systemic sarcoidosis patients without neurologic manifestations. This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.

<i>Mycoplasma pneumoniae</i> Culture			
Effective Date:	June 13, 2011		
Test Code:	51045		
Specimen Requirements:	<p>3 mL (1mL min.) sputum, bronchial washings, tracheal aspirate, bronchoalveolar lavage, nasopharyngeal aspirate, respiratory fluid, 1 throat swab or 1 nasopharyngeal swab. Submit specimens in UTM, M4, M5 or equivalent.</p> <p>Other acceptable specimen types are: Lung tissue, sterile body fluids (pleural fluid, pericardial fluid or others) Submit in a sterile container, do not add transport medium. Add minimal sterile saline to tissue to prevent drying.</p>		
Transport Temperature:	Refrigerated: tissue and sterile fluid Frozen < or = to -70 degrees centigrade: all other sample types		
Specimen Stability:	Room temperature: unacceptable Refrigerated: 48 hours Frozen < or = to -70 degrees centigrade: 30 days (do not freeze tissue or sterile body fluids)		
Reference Range:	Not Isolated		
CPU Interface Mapping:	Result Code:	Type:	Result Name:
	510450 101 1045	Prompt	Source Culture Status <i>M. pneumoniae</i> culture
Always Message:	Culture methods for <i>M. pneumoniae</i> are relatively insensitive and a negative result does not exclude mycoplasma infection. Molecular detection with PCR is more sensitive in the acute phase of illness.		

Varicella-Zoster Virus AB (Immunity Screen), ACIF (Serum)			
Effective Date:	June 13, 2011		
Test Code:	41015		
Always Message:	<p>REFERENCE RANGE: <1:4</p> <p>INTERPRETIVE CRITERIA:</p> <p style="padding-left: 40px;"><1:4 Antibody Not Detected - evidence for susceptibility to VZV infection.</p> <p style="padding-left: 40px;">> or = 1:4 Antibody Detected - evidence for immunity against VZV infection.</p> <p>A positive titer (greater than or equal to 1:4) indicates a history of VZV infection or vaccination. In infected individuals, this test is usually positive within 2 days after the onset of rash and is thereafter positive for life. The absence of detectable antibody may indicate susceptibility to VZV infection.</p> <p>This assay was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>		

4220 - HTLV III DNA, Qualitative Real-Time PCR	
44340 - Norovirus RNA, RT-PCR	
48990 - Parechovirus RNA, RT-PCR	
Effective Date:	June 13, 2011
Always Message:	REFERENCE RANGE: NOT DETECTED
	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.

Cytomegalovirus DNA, Qualitative Real-Time PCR	
Effective Date:	June 13, 2011
Test Code:	45000
Always Message:	REFERENCE RANGE: NOT DETECTED
	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.

Cytomegalovirus DNA, Quantitative Real-Time PCR	
Effective Date:	June 13, 2011
Test Code:	45050
Always Message:	REFERENCE RANGE: <200 copies/mL
	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.

Cytomegalovirus DNA, Qual to Quant Real-Time PCR Reflex	
Effective Date:	June 13, 2011
Test Code:	45099
Always Message:	REFERENCE RANGE: NOT DETECTED
	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. For samples with a Detected result, the Cytomegalovirus DNA Quantitative Real-Time PCR assay (unit code 45050) is performed for an additional fee.

BK Virus DNA, Quantitative Real-Time PCR, Plasma/Serum	
Effective Date:	June 13, 2011
Test Code:	47902
Always Message:	<p>REFERENCE RANGE: <500 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>

Epstein Barr Virus DNA, Qual to Quant Real-Time PCR Reflex	
Effective Date:	June 13, 2011
Test Code:	47599
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. For samples with a Detected result, the Epstein Barr Virus DNA Quantitative Real-Time PCR assay (unit code 48453) is performed for an additional fee.</p>

Influenza A H1N1 (2009) Real-Time RT-PCR	
Effective Date:	June 20, 2011
Test Code:	46585
Specimen Requirements:	<p>Nasal swab, Nasopharyngeal swab, Nasal aspirate or throat swab in Multi Microbe Media (M4) or V-C-M medium (green-cap) tube or equivalent (UTM).</p> <p>Swabs must be sterile Dacron, nylon, or rayon with plastic shafts. Place swab in sterile viral transport media containing protein stabilizer, antibiotics to inhibit bacterial fungal growth, and buffer solution (e.g. UTM, VCM, M4, M5, M6 and other media intended to transport chlamydia, mycoplasma or viruses).</p>
Additional Information:	<p>Throat swabs are not approved for New York patient testing.</p> <p>Please note this test is included in the following group code: 4990 – Respiratory Virus PCR Panel with 2009 H1N1</p>

Influenza Type A/B RT-PCR Reflex to Influenza A H1N1 (2009) RT-PCR	
Effective Date:	June 20, 2011
Test Code:	42699
Specimen Requirements:	Nasal swab, Nasopharyngeal swab, Nasal aspirate or throat swab in Multi Microbe Media (M4) or V-C-M medium (green-cap) tube or equivalent (UTM). Swabs must be sterile Dacron, nylon, or rayon with plastic shafts. Place swab in sterile viral transport media containing protein stabilizer, antibiotics to inhibit bacterial fungal growth, and buffer solution (e.g. UTM, VCM, M4, M5, M6 and other media intended to transport chlamydia, mycoplasma or viruses).

<i>Clostridium difficile</i> Cytotoxin Antibody, Neutralization	
Effective Date:	June 27, 2011
Test Code:	81055
Specimen Requirements:	2 mL serum
Rejection Criteria:	Stool, other sterile body fluids, specimens beyond stability or received in inappropriate container.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	< or = 1:2 titer
Methodology:	Antibody Neutralization

Herpes Simplex Virus Type 1 & 2 DNA, Real-Time PCR	
Effective Date:	June 27, 2011
Test Code:	43200
Specimen Requirements:	Add vaginal swab as an acceptable specimen type. Submit in Aptima Vaginal Swab Collection Kit.

Herpes Simplex Virus Type 1 & 2 DNA, Quantitative Real-Time PCR	
Effective Date:	June 27, 2011
Test Code:	43220
Specimen Requirements:	Add vaginal swab as an acceptable specimen type. Submit in Aptima Vaginal Swab Collection Kit.

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.