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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

Test Name	Test Code(s)	Performing Site	Test Code	Test Name	Specimen Requirements	Transport Temperature	Shipping Temperature	Specimen Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Reject Criteria	Other (see listing)
DNase-B Antibody -This change requires immediate action	40126					X	X			X				
Neopterin	20256									X				
<i>Yersinia enterocolitica</i> Antibodies (IgG, IgA)	41065													X
<i>Trichinella</i> IgG Antibody, ELISA	40990							X						
<i>Toxocara</i> Antibody, ELISA (Serum)	40945							X						
Interferon-Beta IgG, MAID (Reflex to Neutralization)	20358							X						
Tick ID with Reflex to Lyme Disease DNA, Real-Time PCR, Tick	57100													X
<i>Bordetella pertussis</i> IgG and IgA Antibodies, MAID	42255						X	X	X	X				X
<i>Bordetella pertussis</i> IgG Antibodies, MAID	42250						X	X	X	X				X
Filaria IgG4 Antibody, ELISA	40495					X	X	X		X				X

Announcement

Labor Day Holiday Notification

The Labor Day holiday will be observed by Focus Diagnostics, Inc. on Monday, September 5, 2011. Client Services will be staffed from 8:00 AM to 2:00 PM PDT. Regular laboratory services will resume on Tuesday, September 6, 2011.

The laboratory will be staffed on Monday, September 5, 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, September 2, 2011.

On Monday, September 5, 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.

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.

DNase-B Antibody - This change requires immediate action		
Effective Date:	August 22, 2011	
Test Code:	40126	
Transport Temperature:	Refrigerated	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 8 days Frozen: 90 days	
Reference Range:	< 5 yrs: 5-17 yrs: Adults (> or = 18 yrs):	< or = 250 U/mL < or = 375 U/mL < or = 300 U/mL
Performing Site:	Quest Diagnostics Nichols Institute, Valencia	
Additional Information:	The validation of a new kit was necessitated due to a back order issue with current vendor.	

Neopterin	
Effective Date:	September 19, 2011
Test Code:	20256
Reference Ranges:	<15 nmol/L
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<i>Yersinia enterocolitica</i> Antibodies (IgG, IgA)	
Effective Date:	September 19, 2011
Test Code:	41065
Always message:	<p>REFERENCE RANGE: <0.90</p> <p>INTERPRETIVE CRITERIA: <0.90 Antibody not detected 0.90 - 1.10 Equivocal >1.10 Antibody detected</p> <p><i>Yersinia enterocolitica</i> is associated with a wide spectrum of clinical and immunological manifestations, including enteritis, colitis, reactive arthritis, and erythema nodosum. <i>Y. enterocolitica</i>-specific IgA and IgG are both typically detected following acute infection; IgA usually disappears after 2-3 months, whereas IgG persists for at least a year. IgA persistence is observed in some patients with chronic reactive arthritis.</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>

40990 <i>Trichinella</i> IgG Antibody, ELISA	
40945 <i>Toxocara</i> Antibody, ELISA (Serum)	
20358 Interferon-Beta IgG, MAID (Reflex to Neutralization)	
Effective Date:	September 19, 2011
Specimen Stability:	Room temperature: 7 days

Tick ID with Reflex to Lyme Disease DNA, Real-Time PCR, Tick	
Effective Date:	October 17, 2011
Test Code:	57100
Reflex Criteria:	<p>The following results will reflex to 15510 Lyme Disease (<i>Borrelia spp</i>) DNA Qualitative Real-Time PCR, Tick for an additional charge. (Add CPT code(s): 87801).</p> <p><i>Ixodes scapularis</i> (Deer Tick) <i>Ixodes pacificus</i> (Western Black-legged Tick) <i>Ixodes angustus</i> <i>Ixodes</i> species (probably <i>Ixodes pacificus</i>). Head and mouthparts missing. <i>Ixodes</i> species (probably <i>Ixodes scapularis</i>). Head and mouthparts missing. <i>Ixodes spinipalpis</i></p>

<i>Bordetella pertussis</i> IgG and IgA Antibodies, MAID	
Effective Date:	October 24, 2011
Test Code:	42255
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days
Reference Ranges:	PT IgG <45 IU/mL PT IgA <10 IU/mL FHA IgG <90 IU/mL FHA IgA <50 IU/mL
Always Message:	<p>REFERENCE RANGES:</p> <p>PT IgG <45 IU/mL PT IgA <10 IU/mL FHA IgG <90 IU/mL FHA IgA <50 IU/mL</p> <p>Levels of antibodies recognizing pertussis toxin (PT) and filamentous hemagglutinin (FHA) are typically increased following vaccination or natural exposure to <i>Bordetella pertussis</i>. This assay is not appropriate for assessing immunity to pertussis because the specific antibodies and antibody levels that correlate with protection have not been well defined. Detection of IgG antibodies is more sensitive than detection of IgA antibodies, since not all vaccinated or exposed individuals mount a detectable IgA response. The indicated reference range values reflect the 95th percentile of antibody levels from blood donors; thus, antibody levels above the reference range are highly suggestive of recent infection or vaccination. Increased levels of FHA antibodies alone may represent cross-reactive antibodies induced by infection with other <i>Bordetella</i> species, <i>Mycoplasma pneumoniae</i>, <i>Chlamydophila pneumoniae</i> or nonencapsulated <i>Haemophilus influenzae</i>.</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>

<i>Bordetella pertussis</i> IgG Antibodies, MAID	
Effective Date:	October 24, 2011
Test Code:	42250
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	PT IgG <45 IU/mL FHA IgG <90 IU/mL
Always Message:	<p>REFERENCE RANGES:</p> <p>PT IgG <45 IU/mL FHA IgG <90 IU/mL</p> <p>Levels of antibodies recognizing pertussis toxin (PT) and filamentous hemagglutinin (FHA) are typically increased following vaccination or natural exposure to <i>Bordetella pertussis</i>. This assay is not appropriate for assessing immunity to pertussis because the specific antibodies and antibody levels that correlate with protection have not been well defined. The indicated reference range values reflect the 95th percentile of antibody levels from blood donors; thus, antibody levels above the reference range are highly suggestive of recent infection or vaccination. Increased levels of FHA antibodies alone may represent cross-reactive antibodies induced by infection with other <i>Bordetella</i> species, <i>Mycoplasma pneumoniae</i>, <i>Chlamydophila pneumoniae</i>, or nonencapsulated <i>Haemophilus influenzae</i>.</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>
Additional Information:	<p>Please note this test is included in the following group code:</p> <ul style="list-style-type: none"> • 2505 - Immune Status Panel, DPT

Filaria IgG4 Antibody, ELISA

Effective Date:	October 24, 2011
Test Code:	40495
Specimen Requirements:	0.2 mL serum (minimum 0.1 mL)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	Negative
Always Message:	REFERENCE RANGE: NEGATIVE This assay detects filarial IgG4 associated with infections caused by the major filarial parasites, including <i>Dirofilaria immitis</i> , <i>Wuchereria bancrofti</i> , <i>Brugia malayi</i> , and <i>Onchocerca volvulus</i> . Detection of IgG4 subclass antibody offers enhanced specificity without sacrifice of sensitivity. Chronic filarial infections manifesting as elephantiasis may not show a significant IgG4 response, and cannot be ruled out by this assay.

Discontinued Tests

Lyme Disease (<i>Borrelia burgdorferi</i>) DNA Qualitative Real-Time PCR, Tick	
Effective Date:	October 17, 2011
Test Code:	42200
Additional Information:	The recommended alternative is: 15510 - Lyme Disease (<i>Borrelia</i> spp) DNA, Qualitative Real-Time PCR, Tick

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.