



June 2010

TEST UPDATES

<http://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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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.

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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.

MTB Complex PCR with AFB Culture & Smear, Broth Method																
Effective Date:	June 14, 2010															
Unit Code:	8220															
Transport Temperature:	Refrigerated															
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 5 days Frozen: Unacceptable															
Set-Up/Analytic Time:	For the culture and smear portion of the test: Smear - 2 hours Culture - 60-70 days															
Methodology:	For the culture and smear portion of the test: Broth and Agar Culture, AFB Smear															
Results Available:	For the culture and smear portion of the test: 60-70 days															
Additional Information:	<p>Update transport temperature, specimen stability, set-up/analytic time, methodology, results available time, and always message.</p> <p>The PCR portion of this test, unit code 51183 AFB, <i>Mycobacterium tuberculosis</i> Complex DNA, PCR will be replaced with unit code 47298 <i>Mycobacterium tuberculosis</i> Complex, PCR, Respiratory. Please contact Focus Diagnostics for CPU/Interface mapping information.</p> <p>For the culture and smear portion of this test, update transport temperature, specimen stability, methodology, set-up/analytic time, results available time, and always message.</p> <p>Always message will be:</p> <table border="0"> <tr> <td colspan="3">Number of AFB Observed, Fluorochrome stain</td> </tr> <tr> <td>200X</td> <td>400X</td> <td>Report Interpretation</td> </tr> <tr> <td colspan="3">-----</td> </tr> <tr> <td>0</td> <td>0</td> <td>No Acid-Fast Bacilli seen</td> </tr> <tr> <td>1-2/30F</td> <td>1-2/70F</td> <td>Doubtful, Repeat specimen</td> </tr> </table>	Number of AFB Observed, Fluorochrome stain			200X	400X	Report Interpretation	-----			0	0	No Acid-Fast Bacilli seen	1-2/30F	1-2/70F	Doubtful, Repeat specimen
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1-2/30F	1-2/70F	Doubtful, Repeat specimen														



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	1-9/10F 2-18/50F Rare (1+) Acid-Fast Bacilli seen 1-9F 4-36/10F Few (2+) Acid-Fast Bacilli seen 0-90/F 4-36/F Moderate (3+) Acid-Fast Bacilli seen >90/F >36/F Many (4+) Acid-Fast Bacilli seen
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Herpes Simplex Virus (HSV) Direct Detection, DFA

Effective Date:	July 19, 2010
Unit Code:	81105
Specimen Requirements:	<p>Air dried smears of vesicular scrapings on 2 separate slides, or scrapings/aspirate collected on a swab and transported in VCM or other virus transport medium.</p> <p>Note: If only 1 slide with one smear is submitted, typing will not be possible. The only result that can be reported is the presence or absence of HSV. You will be notified if this situation arises.</p>
Specimen Stability:	<p>Swab/Aspirate:</p> <p style="padding-left: 20px;">Room temperature: Unacceptable</p> <p style="padding-left: 20px;">Refrigerated: 72 Hours</p> <p style="padding-left: 20px;">Frozen: 7 Days (< or = -70 C)</p> <p>Slides:</p> <p style="padding-left: 20px;">Room temperature: 7 Days</p> <p style="padding-left: 20px;">Refrigerated: 7 Days</p> <p style="padding-left: 20px;">Frozen: Unacceptable</p>
Additional Information:	Update specimen requirements, specimen stability, remove always message.

Hepatitis E Antibody (IgG)

Effective Date:	August 16, 2010
Unit Code:	20171
Reference Ranges:	Not Detected
Additional Information:	<p>Update reference range and always message.</p> <p>Always message will be:</p> <p style="padding-left: 20px;">REFERENCE RANGE: NOT DETECTED</p> <p>Hepatitis E Virus (HEV) is a major cause of enteric non-A hepatitis worldwide. HEV IgG is typically detected within one month after infection, and persists for months to years after recovery.</p>



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	<p>Approximately 20% of the US population is positive for HEV IgG, indicating that HEV exposure is more common than previously thought.</p> <p>This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Focus Diagnostics. This test should not be used for diagnosis without confirmation by other medically established means.</p>
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Hepatitis E Antibody (IgM)

Effective Date:	August 16, 2010
Unit Code:	20172
Reference Ranges:	Not Detected
Additional Information:	<p>Update reference range and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>Hepatitis E Virus (HEV) is a major cause of enteric non-A hepatitis worldwide. HEV IgM is typically detected within 2-4 weeks after infection, and then declines rapidly during convalescence.</p> <p>This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Focus Diagnostics. This test should not be used for diagnosis without confirmation by other medically established means.</p>

Hepatitis E Antibody (IgG, IgM)

Effective Date:	August 16, 2010
Unit Code:	20173
Reference Ranges:	Not Detected
Additional Information:	<p>Update reference range and always message.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</p> <p>Hepatitis E Virus (HEV) is a major cause of enteric non-A hepatitis</p>



TEST CHANGES

	<p>worldwide. Both HEV IgM and IgG are typically detected within one month after infection; IgM levels decline rapidly during convalescence, whereas IgG levels persist for months to years after recovery. Approximately 20% of the US population is positive for HEV IgG, indicating that HEV exposure is more common than previously thought.</p> <p>These tests were performed using kits that have not been cleared or approved by the FDA. The analytical performance characteristics of these tests have been determined by Focus Diagnostics. These tests should not be used for diagnosis without confirmation by other medically established means.</p>
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AFB, Culture and Smear, Conventional Method and Broth Method

Effective Date:	August 16, 2010																					
Unit Code:	51163																					
Specimen Stability:	Room Temperature: Unacceptable (Blood/Bone marrow 48 Hours) Refrigerated: 5 Days (Blood/Bone marrow: Unacceptable) Frozen: Unacceptable																					
Set-Up/Analytic Time:	Smear - 2 hours Culture - 60-70 days																					
Methodology:	Broth and Agar Culture, AFB Smear																					
Additional Information:	<p>Update specimen stability, set-up/analytic time, methodology, and always message.</p> <p>Always message will be:</p> <p style="text-align: center;">Number of AFB Observed, Fluorochrome stain</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">200X</th> <th style="text-align: center;">400X</th> <th style="text-align: center;">Report Interpretation</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td>No Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">1-2/30F</td> <td style="text-align: center;">1-2/70F</td> <td>Doubtful, Repeat specimen</td> </tr> <tr> <td style="text-align: center;">1-9/10F</td> <td style="text-align: center;">2-18/50F</td> <td>Rare (1+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">1-9F</td> <td style="text-align: center;">4-36/10F</td> <td>Few (2+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">10-90/F</td> <td style="text-align: center;">4-36/F</td> <td>Moderate (3+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">>90/F</td> <td style="text-align: center;">>36/F</td> <td>Many (4+) Acid-Fast Bacilli seen</td> </tr> </tbody> </table>	200X	400X	Report Interpretation	0	0	No Acid-Fast Bacilli seen	1-2/30F	1-2/70F	Doubtful, Repeat specimen	1-9/10F	2-18/50F	Rare (1+) Acid-Fast Bacilli seen	1-9F	4-36/10F	Few (2+) Acid-Fast Bacilli seen	10-90/F	4-36/F	Moderate (3+) Acid-Fast Bacilli seen	>90/F	>36/F	Many (4+) Acid-Fast Bacilli seen
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TEST CHANGES

AFB Smear																												
Effective Date:	August 16, 2010																											
Unit Code:	51185																											
Former Test Name:	AFB, Smear, FM and LM																											
CPT Code:	87015, 87206																											
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 5 Days Frozen: Unacceptable																											
Results Available:	24 hours																											
Methodology:	Fluorescent Microscopy																											
Additional Information:	<p>Update reporting title, CPT code, specimen stability, methodology, max lab time and always message.</p> <p>Always message will be:</p> <table style="margin-left: 40px;"> <thead> <tr> <th colspan="3" style="text-align: center;">Number of AFB Observed, Fluorochrome stain</th> </tr> <tr> <th style="text-align: center;">200X</th> <th style="text-align: center;">400X</th> <th style="text-align: center;">Report Interpretation</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;">-----</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td>No Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">1-2/30F</td> <td style="text-align: center;">1-2/70F</td> <td>Doubtful, Repeat specimen</td> </tr> <tr> <td style="text-align: center;">1-9/10F</td> <td style="text-align: center;">2-18/50F</td> <td>Rare (1+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">1-9F</td> <td style="text-align: center;">4-36/10F</td> <td>Few (2+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">10-90/F</td> <td style="text-align: center;">4-36/F</td> <td>Moderate (3+) Acid-Fast Bacilli seen</td> </tr> <tr> <td style="text-align: center;">>90/F</td> <td style="text-align: center;">>36/F</td> <td>Many (4+) Acid-Fast Bacilli seen</td> </tr> </tbody> </table> <p>The smear result should be used as an adjunct in evaluating a patient's tuberculosis status. Cultural examination is recommended for laboratory diagnosis.</p>	Number of AFB Observed, Fluorochrome stain			200X	400X	Report Interpretation	-----			0	0	No Acid-Fast Bacilli seen	1-2/30F	1-2/70F	Doubtful, Repeat specimen	1-9/10F	2-18/50F	Rare (1+) Acid-Fast Bacilli seen	1-9F	4-36/10F	Few (2+) Acid-Fast Bacilli seen	10-90/F	4-36/F	Moderate (3+) Acid-Fast Bacilli seen	>90/F	>36/F	Many (4+) Acid-Fast Bacilli seen
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HIV-2 Antibody, IBL (New York)	
Effective Date:	August 16, 2010
Unit Code:	71090
Additional Information:	<p>Specimens with a result of Negative or Indeterminate will reflex to HIV-2 Antibody, EIA (New York)</p> <p>This test is for New York patients only.</p>