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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](mailto: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	Specimen Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Reject Criteria	Other (see listing)
Adenovirus DNA, Qualitative Real-Time PCR	46990				X								X
Adenovirus DNA, Quantitative Real-Time PCR	46995				X								X
Adenovirus DNA, Qual to Quant Real-Time PCR Reflex	46999				X								X
Respiratory Virus PCR Panel with 2009 H1N1	4990				X								X
JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF	16441												X
JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF	16442												X
JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine	16447												X
JC Polyoma Virus DNA, Quantitative Real-Time PCR, Urine	16446												X
JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma	41336												X
JC Polyoma Virus DNA, Quantitative Real-Time PCR, Plasma	41446												X
BK and JC Virus DNA, Qualitative Real-Time PCR	47336												X

## New Test Offerings

<b>RPR (Diagnosis) with Reflex to Titer and Confirmatory Testing</b>	
Clinical Significance:	This is a nontreponemal screening test for syphilis. False positive results may occur due to systemic lupus erythematosus, leprosy, brucellosis, atypical pneumonia, typhus, yaws, pinta, or pregnancy. Monitoring of RPR is helpful in assessing effectiveness of therapy.
Effective Date:	Available now
Test Code:	36126
CPT Code(s):	86592
Specimen Requirements:	1 mL (0.2 mL min.) serum
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days
Set up/Analytic Time:	Set up: Tuesday and Friday; Report available: 1-5 day(s)
Reference Ranges:	Nonreactive
Methodology:	Flocculation
CPT Interface Mapping:	Result Code: Result Name:
	361260 RPR Screen 361261 RPR Titer
Always Message:	Reference range: Nonreactive  The RPR is a non-treponemal-specific test; therefore, a treponemal-specific confirmatory test should be performed unless prior syphilis infection has been documented for this patient.
Additional Information:	If result code 361260 RPR Screen is “reactive” result code 361261 RPR Titer will be performed at an additional charge (add CPT code 86593). If result code 361260 RPR Screen is “reactive” it will reflex to 20486 Treponema Pallidum Antibody, IFA (Serum) at an additional charge (add CPT code 86780).

<b>RPR (Monitor) with Reflex to Titer</b>							
Clinical Significance:	This is a nontreponemal screening test for syphilis. False positive results may occur due to systemic lupus erythematosus, leprosy, brucellosis, atypical pneumonia, typhus, yaws, pinta, or pregnancy. Monitoring of RPR is helpful in assessing effectiveness of therapy.						
<b>Effective Date:</b>	<b>Available now</b>						
Test Code:	<b>799</b>						
CPT Code(s):	<b>86592</b>						
Specimen Requirements:	<b>1 mL (0.2 mL min.) serum</b>						
Transport Temperature:	<b>Refrigerated</b>						
Specimen Stability:	<b>Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days</b>						
Set up/Analytic Time:	<b>Set up: Tuesday and Friday; Report available: 1-5 day(s)</b>						
Reference Ranges:	<b>Nonreactive</b>						
Methodology:	<b>Flocculation</b>						
CPT Interface Mapping:	<table border="1"> <thead> <tr> <th>Result Code:</th> <th>Result Name:</th> </tr> </thead> <tbody> <tr> <td><b>7990</b></td> <td><b>RPR Screen</b></td> </tr> <tr> <td><b>7991</b></td> <td><b>RPR Titer</b></td> </tr> </tbody> </table>	Result Code:	Result Name:	<b>7990</b>	<b>RPR Screen</b>	<b>7991</b>	<b>RPR Titer</b>
Result Code:	Result Name:						
<b>7990</b>	<b>RPR Screen</b>						
<b>7991</b>	<b>RPR Titer</b>						
Always Message:	<p><b>Reference range: Nonreactive</b></p> <p><b>The RPR is a non-treponemal-specific test; therefore, a treponemal-specific confirmatory test should be performed unless prior syphilis infection has been documented for this patient.</b></p>						
Additional Information:	<b>If result code 7990 RPR Screen is “reactive” result code 7991 RPR Titer will be performed at an additional charge (add CPT code 86593).</b>						

<b>Treponema Pallidum AB, Particle Agglutination</b>					
Clinical Significance:	The TP-PA test is designed to be used as an aid in the confirmation of antibodies to the treponemal organisms that cause syphilis. Other diseases such as yaws or pinta give positive results.				
<b>Effective Date:</b>	<b>Available now</b>				
Test Code:	<b>653</b>				
CPT Code(s):	<b>86780</b>				
Specimen Requirements:	<b>1 mL (0.5mL min.) serum</b>				
Transport Temperature:	<b>Room temperature</b>				
Specimen Stability:	<b>Room temperature: 7 days Refrigerated: 7 days Frozen: 30 days</b>				
Set up/Analytic Time:	<b>Set up: Tuesday and Friday; Report available: 1-5 day(s)</b>				
Reference Ranges:	<b>Nonreactive</b>				
Methodology:	<b>Particle Agglutination</b>				
CPT Interface Mapping:	<table border="1"> <thead> <tr> <th>Result Code:</th> <th>Result Name:</th> </tr> </thead> <tbody> <tr> <td><b>6530</b></td> <td><b>T. Pallidum AB (TP-PA)</b></td> </tr> </tbody> </table>	Result Code:	Result Name:	<b>6530</b>	<b>T. Pallidum AB (TP-PA)</b>
Result Code:	Result Name:				
<b>6530</b>	<b>T. Pallidum AB (TP-PA)</b>				

## 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.*

<b>Adenovirus DNA, Qualitative Real-Time PCR</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
Test Code:	46990
Specimen Requirements:	Add as acceptable specimen types: <b>Bone marrow ( ACD or EDTA), tissue or stool</b>
Assay Category:	<b>ASR Class I</b>
Always Message:	<b>REFERENCE RANGE: NOT DETECTED</b>  <b>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.</b>

<b>Adenovirus DNA, Quantitative Real-Time PCR</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
Test Code:	46995
Specimen Requirements:	Add as acceptable specimen type: <b>Bone marrow ( ACD or EDTA)</b>
Assay Category:	<b>ASR Class I</b>
Always Message:	<b>REFERENCE RANGE: &lt;500 copies/mL</b>  <b>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.</b>

<b>Adenovirus DNA, Qual to Quant Real-Time PCR Reflex</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
Test Code:	46999
Specimen Requirements:	Add as acceptable specimen type: <b>Bone marrow ( ACD or EDTA)</b>
Assay Category:	<b>ASR Class I</b>
Always Message:	<b>REFERENCE RANGE: NOT DETECTED</b>  <b>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 Detected results, the Adenovirus DNA Quantitative Real-Time PCR assay (unit code 46995) is performed for an additional fee.</b>

<b>Respiratory Virus PCR Panel with 2009 H1N1</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
Test Code:	4990
Specimen Requirements:	<b>3 mL throat or nasopharyngeal swabs in M4 media or V-C-M media (green-cap) tube or equivalent (UTM)</b>
Assay Category:	<b>ASR Class I</b>
Always Message:	<b>REFERENCE RANGE: NOT DETECTED</b>  <b>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.</b>
Additional Information:	Changes being made to the Adenovirus DNA, Qualitative Real-Time PCR part of profile only.

<b>16441 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF</b>	
<b>16442 - JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF</b>	
<b>16447 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine</b>	
<b>16446 - JC Polyoma Virus DNA, Quantitative Real-Time PCR, Urine</b>	
<b>41336 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma</b>	
<b>41446 - JC Polyoma Virus DNA, Quantitative Real-Time PCR, Plasma</b>	
<b>47336 - BK and JC Virus DNA, Qualitative Real-Time PCR</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
Assay Category:	<b>ASR Class I</b>
Always Message:	<b>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.</b>

## Discontinued Tests

<b>JC Virus DNA Qual Reflex to JC Virus DNA Quant</b>	
<b>Effective Date:</b>	<b>December 12, 2011</b>
<b>Test Code:</b>	43336
<b>Additional Information:</b>	The recommended alternative is: Please order the appropriate source specific test in its place. 16441 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF 16447 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine 41336 - JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma

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](http://www.focusdx.com) for a listing of new tests and test updates.