



February 2011

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.



February 2011 **TEST UPDATES**

<http://www.focusdx.com>

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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New Tests

BK Virus DNA, Qualitative Real-Time PCR, CSF		
Effective Date:	April 4, 2011	
Unit Code:	18889	
CPT Code:	87798	
List Price:	\$298.00	
Specimen Requirements:	0.7 mL (0.3 mL min.) CSF (sterile, leak-proof container)	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	
Reference Ranges:	Not Detected	
Methodology:	Real-Time PCR	
Set-up Day(s):	Monday – Sunday	
Results Available:	1 day	
Assay Category:	LDT/ASR Class I	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <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>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	188890	BK Virus DNA QL, PCR, CSF

BK Virus DNA, Quantitative Real-Time PCR, CSF		
Effective Date:	April 4, 2011	
Unit Code:	18901	
CPT Code:	87799	
List Price:	\$349.00	
Specimen Requirements:	0.7 mL (0.3 mL min.) CSF (sterile, leak-proof container)	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	



New Tests

Reference Ranges:	<500 copies/mL	
Methodology:	Real-Time PCR	
Set-up Day(s):	Monday – Sunday	
Results Available:	1 day	
Assay Category:	LDT/ASR Class I	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <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>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	189010	BK Virus DNA QN PCR, CSF

JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF

Effective Date:	April 4, 2011
Unit Code:	16441
CPT Code:	87798
List Price:	\$298.00
Specimen Requirements:	0.7 mL (0.3 mL min.) CSF (sterile, leak-proof container)
Transport Temperature:	Frozen
Specimen Stability:	<p>Room temperature: 48 hours</p> <p>Refrigerated: 7 days</p> <p>Frozen: 30 days</p>
Reference Ranges:	Not Detected
Methodology:	Real-Time PCR
Set-up Day(s):	Monday – Sunday
Results Available:	1 day
Assay Category:	LDT
NYSDOH Approved:	No
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	<p>New test.</p> <p>Always message will be:</p>



New Tests

	<p>REFERENCE RANGE: NOT DETECTED</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> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	164410	JC Polyoma Virus DNA, QL PCR, CSF

JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF

Effective Date:	April 4, 2011	
Unit Code:	16442	
CPT Code:	87799	
List Price:	\$349.00	
Specimen Requirements:	0.7 mL (0.3 mL min.) CSF (sterile, leak-proof container)	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	
Reference Ranges:	<500 copies/mL	
Methodology:	Real-Time PCR	
Set-up Day(s):	Monday – Sunday	
Results Available:	1 day	
Assay Category:	LDT	
NYSDOH Approved:	No	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: <500 copies/mL</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> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title



New Tests

	164411	JC Polyoma Virus DNA, QN
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JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine	
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Effective Date:	April 4, 2011	
Unit Code:	16447	
CPT Code:	87798	
List Price:	\$298.00	
Specimen Requirements:	0.7 mL (0.3 mL min.) urine (sterile, leak-proof container)	
Transport Temperature:	Frozen	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	
Reference Ranges:	Not Detected	
Methodology:	Real-Time PCR	
Set-up Day(s):	Monday – Sunday	
Results Available:	1 day	
Assay Category:	LDT	
NYSDOH Approved:	No	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</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> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	164470	JC Polyoma Virus DNA, QL

JC Polyoma Virus DNA, Quantitative Real-Time PCR, Urine	
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Effective Date:	April 4, 2011	
Unit Code:	16446	
CPT Code:	87799	
List Price:	\$349.00	
Specimen Requirements:	0.7 mL (0.3 mL min.) urine (sterile, leak-proof container)	
Transport Temperature:	Frozen	



New Tests

Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	
Reference Ranges:	<500 copies/mL	
Methodology:	Real-Time PCR	
Set-up Day(s):	Monday – Sunday	
Results Available:	1 day	
Assay Category:	LDT	
NYSDOH Approved:	No	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: <500 copies/mL</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> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	164460	JC Polyoma Virus DNA, QN



Recent New York Approved Tests

47277 - <i>Mycobacterium tuberculosis</i> Complex, PCR, Non-Respiratory 47298 - <i>Mycobacterium tuberculosis</i> Complex, PCR, Respiratory	
Effective Date:	January 18, 2011
NYSDOH Approved:	Yes
Additional Information:	Effective January 18, 2011 these tests have been approved by the State of New York Department of Health.

<i>Kingella kingae</i> DNA, Qualitative Real-Time PCR	
Effective Date:	February 1, 2011
Unit Code:	45610
NYSDOH Approved:	Yes
Additional Information:	Effective February 1, 2011 this test has been approved by the State of New York Department of Health.



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.

HIV 1 RNA, Quantitative Real-Time PCR

Effective Date:	March 7, 2011
Unit Code:	40085
Specimen Stability:	Room temperature: 24 hours Refrigerated: 6 days Frozen: 42 days
Reference Range:	<20 copies/mL <1.30 Log copies/mL
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update stability and reference range.

BK Virus DNA, Qualitative Real-Time PCR, Plasma

Effective Date:	April 4, 2011
Unit Code:	48900
Former Test Name:	<i>BK Virus DNA, Qualitative Real-Time PCR</i>
Specimen Requirements:	0.7 mL (0.3 mL min.) EDTA (lavender-top) plasma CSF and urine are unacceptable for this test code.
Assay Category:	LDT/ASR Class I
Additional Information:	<p>Update reporting title, specimen requirements, assay category and always message.</p> <p>For CSF – Please use 18889 BK Virus DNA, Qualitative Real-Time PCR, CSF For Urine – Please use 48901 BK Virus DNA, Qualitative Real-Time PCR, Urine</p> <p>Always message will be:</p> <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>



Test Changes

BK Virus DNA, Qualitative Real-Time PCR, Urine	
Effective Date:	April 4, 2011
Unit Code:	48901
Assay Category:	LDT/ASR Class I
Additional Information:	<p>Update assay category and always message.</p> <p>Always message will be:</p> <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>

BK Virus DNA, Quantitative Real-Time PCR, Plasma	
Effective Date:	April 4, 2011
Unit Code:	47900
Former Test Name:	<i>BK Virus DNA, Quantitative Real-Time PCR</i>
Specimen Requirements:	0.7 mL (0.3 mL min.) EDTA (lavender-top) plasma CSF and urine are unacceptable for this test code.
Assay Category:	LDT/ASR Class I
Additional Information:	<p>Update reporting title, specimen requirements, assay category and always message.</p> <p>This test is used in profile 4190 BK and JC Virus DNA, Quantitative Real-Time PCR.</p> <p>For CSF - Please use 18901 BK Virus DNA, Quantitative Real-Time PCR, CSF For Urine - Please use 47901 BK Virus DNA, Quantitative Real-Time PCR, Urine</p> <p>Always message will be:</p> <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.</p>



Test Changes

	Performance characteristics refer to the analytical performance of the test.
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BK Virus DNA, Quantative Real-Time PCR, Urine

Effective Date:	April 4, 2011
Unit Code:	47901
Assay Category:	LDT/ASR Class I
Additional Information:	<p>Update assay category and always message.</p> <p>Always message will be:</p> <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>

JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma

Effective Date:	April 4, 2011
Unit Code:	41336
Former Test Name:	JC Polyoma Virus DNA, Qualitative Real-Time PCR
Specimen Requirements:	0.7 mL (0.3 mL min.) EDTA (lavender-top) plasma CSF and urine are unacceptable for this test code.
Assay Category:	LDT
Additional Information:	<p>Update reporting title, specimen requirements, assay category and always message.</p> <p>For CSF - Please use 16441 JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF For Urine - Please use 16447 JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NOT DETECTED</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>



Test Changes

	This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.
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JC Polyoma Virus DNA, Quantitative Real-Time PCR, Plasma

Effective Date:	April 4, 2011
Unit Code:	41446
Former Test Name:	JC Polyoma Virus DNA, Quantitative Real-Time PCR
Specimen Requirements:	0.7 mL (0.3 mL min.) EDTA (lavender-top) plasma CSF and urine are unacceptable for this test code.
Assay Category:	LDT
Additional Information:	<p>Update reporting title, specimen requirements, assay category and always message.</p> <p>This test is used in profile 4190 BK and JC Virus DNA, Quantitative Real-Time PCR.</p> <p>For CSF - Please use 16442 JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF</p> <p>For Urine - Please use 16446 JC Polyoma Virus DNA, Quantitative Real-Time PCR, Urine</p> <p>Always message will be:</p> <p>REFERENCE RANGE: <500 copies/mL</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> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>

BK and JC Virus DNA, Quantitative Real-Time PCR, Plasma

Effective Date:	April 4, 2011
Unit Code:	4190
Former Test Name:	BK and JC Virus DNA, Quantitative Real-Time PCR
Specimen Requirements:	0.7 mL (0.3 mL min.) EDTA (lavender-top) plasma CSF and urine are unacceptable for this test code
Additional Information:	Update reporting title and specimen requirements.



DISCONTINUED TESTS

BK Virus DNA, Qual to Quant Real-Time PCR Reflex

Effective Date:	April 4, 2011
Unit Code:	48999
Additional Information:	<p>This test will be discontinued. The recommended alternative is dependent on the type of specimen being sent.</p> <p>For Plasma - Please use 47900 - BK Virus DNA, Quantitative Real-Time PCR, Plasma</p> <p>For CSF - Please use 18901 BK Virus DNA, Quantitative Real-Time PCR, CSF</p> <p>For Urine - Please use 47901 BK Virus DNA, Quantitative Real-Time PCR, Urine</p>

Toxoplasma gondii IgG, IgM, IgA Antibody Panel, ELISA (CSF)

Effective Date:	April 11, 2011
Unit Code:	6094
Additional Information:	<p>This test will be discontinued. The recommended alternative is 6092 <i>Toxoplasma gondii</i> IgG AND IgM, ELISA (CSF).</p>

Toxoplasma gondii Recent Infection Antibody Panel

Effective Date:	April 11, 2011
Unit Code:	4099
Additional Information:	<p>This test will be discontinued. The recommended alternative is 4094 <i>Toxoplasma gondii</i> IgG, IgM, IgA, Antibody Panel, ELISA (serum) with 40927 <i>Toxoplasma gondii</i> IgG Avidity (AviDx), ELISA.</p>

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.