



July 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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DISCONTINUED TESTS

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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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NEW TESTS

Respiratory Virus PCR Panel IV	
Effective Date:	August 23, 2010
Unit Code:	4660
CPT Code:	87798 (X9)
List Price:	\$1839.00
Specimen Requirements:	Throat or nasopharyngeal swab in 3 mL (1 mL min.) M4 media, V-C-M media (green-cap) or equivalent (UTM)
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature - 48 hours Refrigerated - 7 days Frozen - 30 days
Reference Ranges:	Not Detected
Methodology:	See individual assays
Set-up Day(s):	Monday-Sunday
Results Available:	1-3 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	No
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	<p>New test.</p> <p>This panel consists of:</p> <p>47660 Rhinovirus RNA, RT-PCR;</p> <p>44320 RSV (Respiratory Syncytial Virus) RNA, Qualitative Real-Time PCR</p> <p>42684 Influenza Type A and B RNA, Qualitative Real-Time RT-PCR</p> <p>44330 Parainfluenza Virus (Types 1, 2 and 3) RNA, Qualitative Real-Time PCR</p> <p>46990 Adenovirus DNA, Qualitative Real-Time PCR</p> <p>49200 Human Metapneumovirus RNA, Qualitative Real-Time PCR</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p>



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.

Fungal Culture and Fungal Smear, India Ink Preparation, LM (CSF)	
Effective Date:	July 26, 2010
Unit Code:	5167
Specimen Requirements:	2 mL (1 mL min.) CSF
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	Culture: None Isolated Smear: No Encapsulated Yeast seen
Additional Information:	<p>Update specimen requirements, transport temperature, reference ranges and always message.</p> <p>Unit code 51605 Fungal Culture will be removed from this profile. Unit code 51609 Fungal Culture, CSF will be added to this profile.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p> <p>For the smear portion of this test, always message will be:</p> <p>The India ink prep is a non-specific method for the detection of encapsulated yeast cells of <i>Cryptococcus</i> species. The cryptococcal antigen assay may be a more sensitive method for diagnosis of cryptococcal infection of the CNS.</p>

Immunofixation Electrophoresis	
Effective Date:	August 9, 2010
Unit Code:	20285
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: Unacceptable Refrigerated: 7 days Frozen: 30 days
Additional Information:	Update transport temperature and specimen stability.



TEST CHANGES

	<p>This test is used in the following profiles:</p> <p>2195 Immunoglobulin Evaluation, Neph & IFE</p> <p>2260 Motor and Sensory Neuropathy Evaluation with GQ1b Antibody and IFE</p> <p>2585 Motor Neuropathy Panel with GQ1b Antibody and IFE</p>
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TSI (Thyroid Stimulating Immunoglobulin)

Effective Date:	August 9, 2010
Unit Code:	30551
Specimen Stability:	<p>Room Temperature: Unacceptable</p> <p>Refrigerated: 21 days</p> <p>Frozen: 60 days</p>
Rejection Criteria:	Gross hemolysis, gross lipemia, gross icteric specimens.
Reference Ranges:	Negative
Methodology:	Immunoassay
Assay Category:	FDA Cleared
Performing Site:	<p>Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92690-6130</p>
NYSDOH Approved:	Yes
Additional Information:	<p>Update specimen stability, rejection criteria, reference range, methodology, assay category, and always message.</p> <p>Always message will be:</p> <p>A positive result is one in which the Specimen to Reference Ratio (%) (SSR%) is >140% of the Reference control.</p> <p>Thyroid stimulating immunoglobulins (TSI) can engage the TSH receptors resulting in hyperthyroidism in Graves' disease patients. TSI levels can be useful in monitoring the clinical outcome of Graves' disease as well as assessing the potential for hyperthyroidism from maternal-fetal transfer.</p> <p>NOTE: A serum TSH level greater than 350 micro-International Units/mL can interfere with the TSI bioassay and potentially give false positive results.</p>



TEST CHANGES

Hypersensitivity Pneumonitis Antibody Panel, ID	
Effective Date:	August 9, 2010
Unit Code:	40580
Specimen Requirements:	0.50 mL (0.30 mL min) serum or CSF
Specimen Stability:	Serum: Room Temperature: 7 days Refrigerated: 14 days Frozen: 30 days CSF: Room Temperature: Unacceptable Refrigerated: 14 days Frozen: 30 days
Additional Information:	Update specimen requirements and specimen stability.

20400-BETA-2 Microglobulin, RID (Serum) 30400-BETA-2 Microglobulin, RID (Urine) 60400-BETA-2 Microglobulin, RID (CSF)	
Effective Date:	August 9, 2010
Specimen Requirements:	0.1 mL (0.050 mL min)
Additional Information:	Update specimen requirements.

Influenza Type A and B RNA, Qualitative Real-Time PCR									
Effective Date:	August 23, 2010								
Unit Code:	42684								
Additional Information:	Remove test code (analyte) 100 Source. Add test code (analyte) 426840 Source. This code is used in the following profiles: 3018 – Respiratory Virus PCR Panel II 4660 – Respiratory Virus PCR Panel IV (available August 23, 2010)								
CPU Interface Mapping:	<table border="1"> <thead> <tr> <th>Test Code (analyte)</th> <th>Test Code Title</th> </tr> </thead> <tbody> <tr> <td>426840 (ask at order entry (prompt) code)</td> <td>Source</td> </tr> <tr> <td>42684</td> <td>Influenza A RNA, PCR</td> </tr> <tr> <td>42685</td> <td>Influenza B RNA, PCR</td> </tr> </tbody> </table>	Test Code (analyte)	Test Code Title	426840 (ask at order entry (prompt) code)	Source	42684	Influenza A RNA, PCR	42685	Influenza B RNA, PCR
	Test Code (analyte)	Test Code Title							
426840 (ask at order entry (prompt) code)	Source								
42684	Influenza A RNA, PCR								
42685	Influenza B RNA, PCR								



TEST CHANGES

RSV (Respiratory Syncytial Virus) RNA, Qualitative Real-Time PCR		
Effective Date:	August 23, 2010	
Unit Code:	44320	
Additional Information:	Remove test code (analyte) 100 Source. Add test code (analyte) 443200 Source. This code is used in the following profiles: 3018 – Respiratory Virus PCR Panel II 4660 – Respiratory Virus PCR Panel IV (available August 23, 2010)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	443200 (ask at order entry (prompt) code) 44320	Source RSV RNA, Qualitative PCR
Parainfluenza Virus (Types 1, 2 and 3) RNA, Qualitative Real-Time PCR		
Effective Date:	August 23, 2010	
Unit Code:	44330	
Additional Information:	Remove test code (analyte) 100 Source. Add test code (analyte) 443300 Source. This code is used in the following profile: 4660 – Respiratory Virus PCR Panel IV (available August 23, 2010)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	443300 (ask at order entry (prompt) code) 44330 44331 44332	Source Parainfluenza 1 RNA Parainfluenza 2 RNA Parainfluenza 3 RNA
Adenovirus DNA, Qualitative Real-Time PCR		
Effective Date:	August 23, 2010	
Unit Code:	46990	
Additional Information:	Remove test code (analyte) 100 Source. Add test code (analyte) 469900 Source. This code is used in the following profile: 4660 – Respiratory Virus PCR Panel IV (available August 23, 2010)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	469900 (ask at order entry (prompt) code) 46990	Source Adenovirus DNA, QL PCR



TEST CHANGES

Human Metapneumovirus RNA, Qualitative Real-Time PCR		
Effective Date:	August 23, 2010	
Unit Code:	49200	
Additional Information:	Remove test code (analyte) 100 Source. Add test code (analyte) 492000 Source This code is used in the following profiles: 3018 – Respiratory Virus PCR Panel II 4660 – Respiratory Virus PCR Panel IV (available August 23, 2010)	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	492000 (ask at order entry (prompt) code) 49200	Source hMPV RNA, QL PCR

Microsporidia Detection, LM		
Effective Date:	September 20, 2010	
Unit Code:	51016	
Specimen Requirements:	1g or 3 mL fresh stool in 10% formalin ****RAW STOOL IS NOT ACCEPTABLE****	
Transport Temperature:	Room Temperature	
Specimen Stability:	Room Temperature: 30 days (specimen or slide) Refrigerated: 30 days (slides Unacceptable) Frozen: Unacceptable	
Additional Information:	Update specimen requirements, transport temperature, specimen stability, test code reporting title, and remove always message. This code is used in the following profile: 5885 <i>Coccidia</i> Evaluation Panel	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	138	<i>Microsporidia Spores</i>

Cycloserine, HPLC	
Effective Date:	September 20, 2010
Unit Code:	51430
Former Test Name:	Antimicrobial Level, Cycloserine HPLC
Additional Information:	Update reporting title, test code reporting title and always message. Always message will be: REFERENCE RANGE: <0.5 mcg/mL



TEST CHANGES

	<p>Cycloserine peak levels occur 4 to 8 hours after oral dosing of 250 mg twice daily. Food may delay or reduce gastrointestinal absorption.</p> <p>Steady State Peak Levels (250 mg): 25 - 30 mcg/mL</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	5143	Cycloserine, HPLC

Adenovirus Direct Detection, DFA

Effective Date:	September 20, 2010
Unit Code:	81165
Specimen Requirements:	<p>3 mL (1 mL min.) nasal, nasopharyngeal or bronchial wash or aspirate, or 1 throat swab, in sterile container or VTM or equivalent.</p> <p>Acceptable specimen: Tracheal aspirate or other non-listed respiratory source specimen submitted, air dried, on microscope slide.</p>
Transport Temperature:	Specimens other than slides: Refrigerated Slides, Room Temperature preferred
Specimen Stability:	<p>Room Temperature: Specimens, Unacceptable Slides, 7 days</p> <p>Refrigerated: Specimens, 72 hours Slides, 7 days</p> <p>Frozen: -20 Deg C: Slides and Specimens, Unacceptable < or = -70 Deg C: Specimens 7 days Slides Unacceptable</p>
Additional Information:	Update specimen requirements, transport temperature, and specimen stability.

RNP AB (IgG), MAID, with Reflex to IHA Titer

Effective Date:	September 27, 2010
Unit Code:	20221
Former Test Name:	RNP Antibody IgG, MAID



TEST CHANGES

Additional Information:	<p>Update reporting title and reflex criteria, add test code 202210 RNP/Sm Ab IHA Titer.</p> <p>If result is Equivocal or Positive, RNP/Sm Ab IHA TITER will be performed for an additional charge of \$99.00.</p> <p>This test is used in the following profile: 2280 Lupus Panel II</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	3240	RNP Antibody IgG, MAID
	202210	RNP/Sm Ab IHA Titer

Sm Ab (IgG), MAID, with Reflex to IHA Titer

Effective Date:	September 27, 2010	
Unit Code:	20226	
Former Test Name:	Sm IgG Antibody, MAID	
Additional Information:	<p>Update reporting title and reflex criteria, add test code 202260 Sm AB IHA Titer.</p> <p>If result is Equivocal or Positive, Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>This test is used in the following profile: 2280 Lupus Panel II</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	3241	Sm IgG Antibody, MAID
	202260	Sm AB IHA Titer

RNP and Sm Ab (IgG), MAID, w/Reflex to IHA Titer

Effective Date:	September 27, 2010	
Unit Code:	20231	
Former Test Name:	RNP and Sm Antibodies IgG, MAID	
Additional Information:	<p>Update reporting title and reflex criteria; remove test codes 4266 RNP/Sm Ab IHA Titer and 4267 Sm Ab IHA Titer, add test codes 202310 RNP/Sm Ab IHA Titer and 202311 Sm Ab IHA Titer.</p> <p>If result is Equivocal or Positive, RNP/Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>This test is used in the following profiles: 2180 Lupus/ANA Panel 2750 Extractable Nuclear Antigen (ENA) Antibody Panel, MAID</p>	



TEST CHANGES

CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	8251	RNP Ab IgG, MAID
	8250	Sm Ab IgG, MAID
	202310	RNP/Sm Ab IHA Titer
	202311	Sm Ab IHA Titer

2202 Lupus Comprehensive Panel
22200 Lupus Comprehensive Panel

Effective Date:	September 27, 2010
Additional Information:	<p>Update profile components and always message.</p> <p>The following tests will be removed from these profiles: RNP/Sm Ab IHA Titer Sm Ab IHA Titer</p> <p>For the RNP AB IgG, MAID portion of these profiles:</p> <p>Reporting title will be updated to: RNP Ab (IgG), MAID w/Reflex to IHA Titer.</p> <p>If result is Equivocal or Positive, RNP/Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>For the Sm AB IgG, MAID portion of these profiles:</p> <p>Reporting title will be updated to: Sm Ab (IgG), MAID, w/Reflex to IHA Titer.</p> <p>If result is Equivocal or Positive, Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p> <p>Always message will be:</p> <p>The TPO, myocardial, parietal, striational muscle, and Ribosomal P antibody tests were developed and their performance characteristics have been determined by Focus Diagnostics. They have not been cleared or approved by the U.S. Food and Drug</p>



TEST CHANGES

	<p>Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the tests.</p>
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22202 Lupus Expanded Panel (C4)

Effective Date:	September 27, 2010
Additional Information:	<p>Update profile components and always message.</p> <p>The following tests will be removed from these profiles: RNP/Sm Ab IHA Titer Sm Ab IHA Titer</p> <p>For the RNP AB IgG, MAID portion of these profiles:</p> <p style="padding-left: 40px;">Reporting title will be updated to: RNP Ab (IgG), MAID w/Reflex to IHA Titer.</p> <p style="padding-left: 40px;">If result is Equivocal or Positive, RNP/Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>For the Sm AB IgG, MAID portion of these profiles:</p> <p style="padding-left: 40px;">Reporting title will be updated to: Sm Ab (IgG), MAID, w/Reflex to IHA Titer.</p> <p style="padding-left: 40px;">If result is Equivocal or Positive, Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p> <p>Add the following to existing always message:</p> <p>The TPO, myocardial, parietal, striational muscle, and Ribosomal P antibody tests were developed and their performance characteristics have been determined by Focus Diagnostics. They have 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 tests.</p>



TEST CHANGES

22250 Lupus Panel
22260 Lupus Panel Without Rheumatoid Factor

Effective Date:	September 27, 2010
Additional Information:	<p>Update profile components and always message.</p> <p>The following tests will be removed from these profiles: RNP/Sm Ab IHA Titer Sm Ab IHA Titer</p> <p>For the RNP AB IgG, MAID portion of these profiles:</p> <p>Reporting title will be updated to: RNP Ab (IgG), MAID w/Reflex to IHA Titer.</p> <p>If result is Equivocal or Positive, RNP/Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>For the Sm AB IgG, MAID portion of these profiles:</p> <p>Reporting title will be updated to: Sm Ab (IgG), MAID, w/Reflex to IHA Titer.</p> <p>If result is Equivocal or Positive, Sm Ab IHA Titer will be performed for an additional charge of \$99.00.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p> <p>Always message will be:</p> <p>The TPO and Ribosomal P antibody tests were developed and their performance characteristics have been determined by Focus Diagnostics. They have 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 tests.</p>



DISCONTINUED TESTS

Herpes Simplex Virus (HSV) 1/2 Antibody, ACIF (Serum)	
Effective Date:	September 20, 2010
Unit Code:	40524
Additional Information	This test will be discontinued. The recommended alternative test code is 40520 HSV 1/2 IgM and Type-Specific IgG (HerpeSelect), ELISA.

West Nile Virus Antibody Neutralization Test (PRNT)	
Effective Date:	September 20, 2010
Unit Code:	88315
Additional Information:	This test will be discontinued. No recommended alternative is available.

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.