



# **December 2009** **REVISED TEST** **UPDATES**

Dear Client,

The document below has been revised.

Revisions include:

**This revision requires immediate action.**

All Changes for Focus test **47885 Hepatitis C Viral RNA, Quantitative Real-Time PCR** will be effective January 13, 2010, due to unavailability of reagents. (This table is on page 12.)

-----

Reference range and units of measure have been revised for **Focus test 47985 Hepatitis B Virus DNA, Quantitative Real-Time PCR, test code (analyte) 97985**. (This table is on page 11.)

We apologize for any confusion this may cause.

Please do not respond to this e-mail address. For questions, please contact the Focus Diagnostics Client Services Department at 800-445-4032 or [clientservices@focusdx.com](mailto:clientservices@focusdx.com).



# December 2009

## REVISED TEST UPDATES

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](http://www.focusdx.com).

### TABLE OF CONTENTS

NEW TESTS			
Test Code	Test Name	Effective Date	Page #
55310	Fungitell® (1-3) –B-D-Glucan Assay	12/14/2009	4
4990	Respiratory Virus PCR Panel with 2009 H1N1	12/14/2009	4
42690	Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR	12/14/2009	5
40835	Streptozyne® Screen with Reflex to Titer	02/22/2010	6
TEST CHANGES			
46585	Influenza A H1N1 (2009) Real-Time RT-PCR <i>Also announced in an immediate update sent on 12/07/09</i>	12/14/2009	8
81070	Cytomegalovirus (CMV) Direct Detection, DFA	12/15/2009	8
81035	Chlamydia Direct Antigen Detection, DFA	12/15/2009	9
20486	Treponema Pallidum Antibody, IFA (Serum)	01/01/2010	9
63486	Treponema Pallidum Antibody, IFA (CSF)	01/01/2010	9
20493	Treponema Pallidum IgG and IgM Antibody Panel, IFA	01/01/2010	9
23015	Hepatitis B Virus DNA, Qualitative Real-Time PCR	02/08/2010	9
23099	HBV DNA Qual Reflex to HBV DNA Quant, PCR	02/08/2010	10
47985	Hepatitis B Virus DNA, Quantitative Real-Time PCR <b>***REVISED</b>	02/08/2010	11
47885	Hepatitis C Viral RNA, Quantitative Real-Time PCR <b>***REVISED</b>	01/13/2010	12
81161	Respiratory Syncytial Virus (RSV) Antigen	02/15/2010	12
51523	Antifungal Serum Level, Itraconazole, HPLC	02/15/2010	13
51987	Antiretroviral Level, Kaletra™, HPLC	02/15/2010	13
DISCONTINUED TESTS			
21035	Streptozyne, HA	02/22/2010	14
Holiday Notification			
N/A	Christmas/New Year Holiday Letter	12/25/2009 01/01/2010	15



# **December 2009** **REVISED TEST** **UPDATES**

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](mailto:ClientServices@focusdx.com).**

**All third party marks — ®' and ™' — are the property of their respective owners.**



## NEW TESTS

Fungitell® (1-3)-B-D-Glucan Assay		
Effective Date:	December 14, 2009	
Unit Code:	55310	
CPT Code:	84311	
List Price:	\$275.00	
Specimen Requirements:	1 mL (0.5 mL min.) serum (poured off) in glucan free tube. Tubes DNase, RNase, pyrogen free acceptable. Glass tubes are unacceptable.	
Transport Temperature:	Refrigerated	
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 5 days Frozen: 14 days	
Reference Range:	<60 pg/mL	
Methodology:	Protease zymogen-based colorimetric	
Set-up Day(s):	Monday and Thursday	
Results Available:	3 to 5 days	
FDA clearance type:	FDA	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New Test</p> <p>Always message will be:</p> <p>This assay is for the presumptive diagnosis of fungal infections and should be used in conjunction with other diagnostic procedures. (1-&gt;3)-beta-D-glucan values of &lt;60 pg/mL are considered negative and indicate the presumptive absence of fungal infection. Glucan values of &gt;=60 but &lt;79 pg/mL are considered indeterminate, and glucan values of &gt;=80 pg/mL are considered positive and indicate the presumptive presence of a fungal infection. This assay may not detect certain fungal species that do not produce or produce low levels of (1-&gt;3)-beta-D-glucan including: <i>Cryptococcus</i>, <i>Absidia</i>, <i>Mucor</i>, <i>Rhizopus</i>, and the yeast phase of <i>Blastomyces dermatitidis</i>.</p>	
CPU Interface Mapping:	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	5316	(1-3)-B-D-Glucan
	5317	Interpretation

Respiratory Virus PCR Panel with 2009 H1N1	
Effective Date:	December 14, 2009
Unit Code:	4990
CPT Code:	87798 (x7)
List Price:	\$1,192.00



## NEW TESTS

<b>Specimen Requirements:</b>	Nasopharyngeal, throat swab or nasal swab in 3 mL M4 media or V-C-M medium (green-cap) tube or equivalent (UTM)
<b>Transport Temperature:</b>	Refrigerated
<b>Specimen Stability:</b>	Room temperature: 2 days Refrigerated: 7 days Frozen: 30 days
<b>Reference Range:</b>	Not Detected
<b>Methodology:</b>	See individual assays
<b>Set-up Day(s):</b>	Monday – Sunday
<b>Results Available:</b>	1 to 3 days
<b>FDA clearance type:</b>	LDT / FDA/EUA (Emergency Use Authorization)
<b>NYSDOH Approved:</b>	No
<b>Performing Site:</b>	Focus Diagnostics, Inc.
<b>Additional Information:</b>	New Test  This profile consists of the following tests: 46990 Adenovirus DNA, Qualitative Real-Time PCR 46585 Influenza A H1N1 (2009) Real-Time RT-PCR 44330 Parainfluenza Virus (Types 1,2, and 3) RNA, Qualitative Real-Time PCR 44320 RSV (Respiratory Syncytial Virus) RNA, Qualitative Real-Time PCR

### Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR

<b>Effective Date:</b>	December 14, 2009
<b>Unit Code:</b>	42690
<b>CPT Code:</b>	87798 (x2)
<b>List Price:</b>	\$298.00
<b>Specimen Requirements:</b>	Nasal, nasopharyngeal or throat swab in 3 mL (.35 mL min.) viral transport media (e.g. UTM, VCM, MR, M5, M6)
<b>Transport Temperature:</b>	Refrigerated
<b>Specimen Stability:</b>	Room temperature: 2 days Refrigerated: 7 days Frozen: 30 days
<b>Reference Range:</b>	Not detected
<b>Methodology:</b>	Real-Time RT-PCR
<b>Set-up Day(s):</b>	Monday – Sunday
<b>Results Available:</b>	1-3 days
<b>FDA clearance type:</b>	LDT
<b>NYSDOH Approved:</b>	No



## NEW TESTS

<b>Performing Site:</b>	Focus Diagnostics, Inc.	
<b>Additional Information:</b>	<p>New Test</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: NOT DETECTED</b></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. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p>	
<b>CPU Interface Mapping:</b>	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	100 (ask at order entry (prompt) code 12690 12691	Source Influenza A H1 Influenza A H3

Streptozyne® Screen with Reflex to Titer	
<b>Effective Date:</b>	February 22, 2010
<b>Unit Code:</b>	40835
<b>CPT Code:</b>	86403
<b>List Price:</b>	\$50.00
<b>Specimen Requirements:</b>	1 mL (0.2 mL min.) serum or plasma
<b>Transport Temperature:</b>	Refrigerated
<b>Specimen Stability:</b>	Room temperature: 8 hours Refrigerated: 7 days Frozen: 30 days
<b>Reference Ranges:</b>	Negative
<b>Methodology:</b>	HA
<b>Set-up Day(s):</b>	Monday – Friday
<b>Results Available:</b>	1-4 days
<b>FDA clearance type:</b>	FDA
<b>NYSDOH Approved:</b>	Yes
<b>Performing Site:</b>	Focus Diagnostics, Inc.
<b>Additional Information:</b>	<p>New Test</p> <p>If the Streptozyne screen is “Positive” a titer will be performed at an additional charge of \$65.00 (add CPT code 86406).</p> <p><b>Result flagging:</b> Screen results that are “Positive” will be flagged “A” for abnormal.</p>



## NEW TESTS

CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	40835	Streptozyme Screen



## 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](http://www.focusdx.com).

<b>Influenza A H1N1 (2009) Real-Time RT-PCR</b>		
<b>***Also announced in an immediate update sent on 12/07/09</b>		
<b>Effective Date:</b>	<b>December 14, 2009</b>	
<b>Unit Code:</b>	<b>46585</b>	
<b>Additional Information:</b>	<p>Update test code 6586 reporting title and always message.</p> <p><b>***This code is used as a reflex code for Focus unit code 42699 Influenza Type A/B RT-PCR Reflex to Influenza A H1N1 (2009) RT-PCR.</b></p> <p><b>Note:</b>            This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization. This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1). The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: NOT DETECTED</b></p> <p><b>The FDA authorized this test under an Emergency Use Authorization. Please refer to the Healthcare Provider and Patient Fact Sheets (<a href="http://www.focusdx.com/2009H1N1">http://www.focusdx.com/2009H1N1</a>).</b></p>	
<b>CPU Interface Mapping:</b>	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	100 (ask at order entry (prompt) code) 6585 <b>6586</b>	Source Influenza A RNA <b>2009 H1N1 Influenza RNA</b>

<b>Cytomegalovirus (CMV) Direct Detection, DFA</b>	
<b>Effective Date:</b>	<b>December 15, 2009</b>
<b>Unit Code:</b>	81070
<b>CPT Code:</b>	<b>87271</b>
<b>Additional Information:</b>	Update CPT code.



# TEST CHANGES

Chlamydia Direct Antigen Detection, DFA	
Effective Date:	December 15, 2009
Unit Code:	81035
CPT Code:	<b>87299</b>
Additional Information:	Update CPT code.

Treponema Pallidum Antibody, IFA (Serum)	
Effective Date:	January 1, 2010
Unit Code:	20486
CPT Code:	<b>86780</b>
Additional Information:	Update CPT code.

Treponema Pallidum Antibody, IFA (CSF)	
Effective Date:	January 1, 2010
Unit Code:	63486
CPT Code:	<b>86780</b>
Additional Information:	Update CPT code.

Treponema Pallidum IgG and IgM Antibody Panel, IFA	
Effective Date:	January 1, 2010
Unit Code:	20493
CPT Code:	<b>86780 (x2)</b>
Additional Information:	Update CPT codes.

Hepatitis B Virus DNA, Qualitative Real-Time PCR	
Effective Date:	February 8, 2010
Unit Code:	23015
Former Test Name:	<i>Hepatitis B Virus (HBV) DNA, Qualitative, PCR</i>
Specimen Requirements:	<b>3 mL (1.3 mL min.) EDTA plasma preferred; 3 mL (1.3 mL min.) serum acceptable</b>
Transport Temperature:	<b>Frozen</b>
Specimen Stability:	<b>Room temperature: unacceptable</b> <b>Refrigerated: 3 days</b> <b>Frozen: 6 weeks</b>
Clearance Type:	<b>FDA Approved/Modified</b>
NYSDOH Approved:	No
Additional Information:	Update reporting title, test code title, specimen requirements,



## TEST CHANGES

	<p>transport temperature, specimen stability, clearance type and always message.</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: NOT DETECTED</b></p> <p>The method used in this test is Real-Time PCR of the precore/core region of the HBV genome.</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>	
<b>CPU Interface Mapping:</b>	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	100 (ask at order entry (prompt) code) 2315	Source <b>HBV DNA Qualitative, PCR</b>

HBV DNA Qual Reflex to HBV DNA Quant, PCR	
<b>Effective Date:</b>	<b>February 8, 2010</b>
<b>Unit Code:</b>	23099
<b>Specimen Requirements:</b>	<b>3 mL (1.3 mL min.) EDTA plasma preferred; 3 mL (1.3 mL min.) serum acceptable</b>
<b>Transport Temperature:</b>	<b>Frozen</b>
<b>Specimen Stability:</b>	<b>Room temperature: unacceptable</b> <b>Refrigerated: 3 days</b> <b>Frozen: 6 weeks</b>
<b>Clearance Type:</b>	<b>FDA Approved/Modified</b>
<b>NYSDOH Approved:</b>	No
<b>Additional Information:</b>	<p>Update reporting title, test code title, specimen requirements, transport temperature, specimen stability, clearance type and always message.</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: NOT DETECTED</b></p> <p>The method used in this test is Real-Time PCR of the precore/core region of the HBV genome.</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><b>Reflex criteria:</b></p>



## TEST CHANGES

	If test code 12315 is “Detected” it will reflex to Focus code 47985 Hepatitis B Viral DNA, Quantitative Real-Time PCR at an additional charge.	
CPU Interface Mapping:	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	100 (ask at order entry (prompt) code) 12315	Source <b>HBV DNA Qualitative, PCR</b>

### Hepatitis B Virus DNA, Quantitative, Real-Time PCR \*\*\*REVISED

<b>Effective Date:</b>	<b>February 8, 2010</b>		
<b>Unit Code:</b>	47985		
<b>Former Test Name:</b>	<i>Hepatitis B Virus DNA, Quantitative, PCR</i>		
<b>Specimen Requirements:</b>	<b>3 mL (1.3 mL min.) EDTA plasma preferred; 3 mL (1.3 mL min.) serum acceptable</b>		
<b>Transport Temperature:</b>	<b>Frozen</b>		
<b>Specimen Stability:</b>	<b>Room temperature: unacceptable Refrigerated: 3 days Frozen: 6 weeks</b>		
<b>Reference Range:</b>	<b>&lt;29 IU/mL &lt;169 copies/mL (Reference range and units of measure have been revised)</b>		
<b>Clearance Type:</b>	<b>FDA Approved/Modified</b>		
<b>NYSDOH Approved:</b>	No		
<b>Additional Information:</b>	<p>Update reporting title, test code title, specimen requirements, transport temperature, specimen stability, reference range, clearance type and always message.</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: &lt;29 IU/mL &lt;169 copies/mL</b></p> <p>The method used in this test is Real-Time PCR of the precore/core region of the HBV genome.</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>		
CPU Interface Mapping:	<b>Test Code (analyte)</b>	<b>Test Code Title</b>	<b>Units of Measure</b>
	100 (ask at order entry (prompt) code) <b>87985</b> <b>97985</b>	Source <b>Hepatitis B Virus DNA</b> <b>Hepatitis B Virus DNA</b>	<b>IU/mL</b> <b>copies/mL</b>



## TEST CHANGES

<b>Hepatitis C Viral RNA, Quantitative, Real-Time PCR</b>			
Effective Date:	<b>January 13, 2010</b> ***Revised due to unavailability of reagents		
Unit Code:	47885		
Former Test Name:	<i>Hepatitis C Virus RNA, Quantitative, RT-PCR</i>		
Specimen Requirements:	<b>3 mL (1.3 mL min.) EDTA plasma preferred; 3 mL (1.3 mL min.) serum acceptable</b>		
Transport Temperature:	<b>Frozen</b>		
Specimen Stability:	<b>Room temperature: unacceptable Refrigerated: 3 days Frozen: 6 weeks</b>		
Methodology:	<b>Real-Time PCR</b>		
Reference Range:	<b>&lt;43 IU/mL &lt;1.63 Log IU/mL</b>		
Clearance Type:	<b>FDA Approved/Modified</b>		
NYSDOH Approved:	<b>No</b>		
Additional Information:	<p>Update reporting title, test codes, test code titles, specimen requirements, transport temperature, specimen stability, methodology, reference range, clearance type, NYSDOH approved status and always message.</p> <p>Always message will be:</p> <p><b>REFERENCE RANGE: &lt;43 IU/mL &lt;1.63 Log IU/mL</b></p> <p><b>This test was performed using the COBAS(R) AmpliPrep/COBAS(R) TaqMan(R) HCV Test Kit (Roche Molecular Systems, Inc.).</b></p>		
CPU Interface Mapping:	<b>Test Code (analyte)</b>	<b>Test Code Title</b>	<b>Units of Measure</b>
	100 (ask at order entry (prompt) code) <b>87885</b>	Source <b>HCV RNA, PCR, Quant</b>	<b>IU/mL</b>
	<b>97885</b>	<b>HCV RNA, PCR, Quant</b>	<b>Log IU/mL</b>

<b>Respiratory Syncytial Virus (RSV) Antigen</b>	
Effective Date:	<b>February 15, 2010</b>
Unit Code:	81161
Former Test Name:	<i>Respiratory Syncytial Virus (RSV) Antigen, EIA</i>
CPT Code:	<b>87807</b>
Reference Range:	<b>Not Detected</b>
Methodology:	<b>Immunochromatographic</b>



## TEST CHANGES

<b>Additional Information:</b>	Update reporting title, test code title, CPT code, reference range and methodology.	
<b>CPU Interface Mapping:</b>	<b>Test Code (analyte)</b>	<b>Test Code Title</b>
	8116	RSV Antigen

Antifungal Serum Level, Itraconazole, HPLC	
<b>Effective Date:</b>	February 15, 2010
<b>Unit Code:</b>	51523
<b>CPT Code:</b>	82492
<b>Additional Information:</b>	Update CPT code.

Antiretroviral Level, Kaletra™, HPLC	
<b>Effective Date:</b>	February 15, 2010
<b>Unit Code:</b>	51987
<b>CPT Code:</b>	80299 (x2)
<b>Additional Information:</b>	Update CPT code.



## DISCONTINUED TESTS

<b>Streptozyme, HA</b>	
<b>Effective Date:</b>	<b>February 22, 2010</b>
<b>Unit Code:</b>	21035
<b>Additional Information:</b>	<b>This test will be discontinued. Please order 40835 Streptozyme Screen with Reflex to Titer available February 22 (see new test section of this update), in its place.</b>



## HOLIDAY NOTIFICATION

### Christmas/New Year Holiday Notification

The Christmas and New Year holidays will be observed by Focus Diagnostics, Inc. on Friday, December 25, 2009 and Friday, January 1, 2010. Client Services will be staffed from 8:00 am to 2:00 pm PST. Regular laboratory services will resume on Saturday, December 26, 2009 and Saturday, January 2, 2010.

The laboratory will be staffed on Friday, December 25, 2009 and Friday, January 1, 2010, 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 Thursday, December 24, 2009 and Thursday December 31, 2009.

On Friday, December 25, 2009 and Friday, January 1, 2010, 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.

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.