

July 2013 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
<u>2630</u>	Blackberry (f211) IgE	8/5/2013	2
<u>3308</u>	Corn Smut, <i>Tilletia tritici</i> (m201), IgE**	8/5/2013	2
<u>35352</u>	Gelatin (c74) IgE	8/5/2013	3
<u>23864</u>	Sunflower Seed (k84) IgE	8/5/2013	3
<u>16185</u>	HIV-1 RNA, Qualitative TMA	8/13/2013	4

TEST CHANGES				
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	Former Test Code	Test Name	Effective Date	Page #
<u>16983</u>		Colovantage(R) (Methylated Septin 9)	7/29/2013	4
<u>16984</u>		Colovantage(R) (Methylated Septin 9) NY	7/29/2013	5
<u>3547</u>		PSA (Free and Total)	8/5/2013	5
<u>799</u>		RPR (Monitor) with Reflex to Titer	8/5/2013	5
<u>8766</u>		Varicella Zoster Virus Antibody (IgM)	8/5/2013	6
<u>S51293</u>		Beta-Globin Complete	8/12/2013	6
<u>90961</u>		Chromosomal Microarray, Hematologic Malignancy, ClariSure (R) Oligo-SNP	8/12/2013	6

DISCONTINUED TESTS			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
<u>RF211</u>	Allergen - Blackberry IgE	8/5/2013	7
<u>C74</u>	Allergen - Gelatin IgE	8/5/2013	7
<u>K84</u>	Allergen - Sunflower Seed IgE	8/5/2013	7
<u>S50483</u>	Allergen Specific IgE Smut Corn*	8/5/2013	7
<u>RC207</u>	Allergen - Protamine IgE	8/6/2013	7
<u>1230</u>	Immune Complex Assay, Raji Cell	8/6/2013	7
<u>S51706</u>	FISH, ALK, 2p23 Rearrangement	8/12/2013	7
<u>7721B</u>	<i>Borrelia burgdorferi</i> IgG & IgM Abs IB + Bands [ALT Criteria]	8/13/2013	8
<u>8938</u>	<i>Borrelia burgdorferi</i> IgG & IgM Abs w/Reflex IB [Alternate]	8/13/2013	8
<u>7721CB</u>	<i>Borrelia burgdorferi</i> IgG & IgM Abs IB + Bands CSF [ALT]	8/13/2013	8
<u>6906</u>	<i>Borrelia burgdorferi</i> Panel	8/13/2013	8
<u>9885</u>	HIV-1 DNA DetectR	8/13/2013	8

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Medical Director Change

Effective 5/31/2013 Quest Diagnostics, Valencia new Medical Director is Basel Kashlan, M.D., FCAP., Laboratory Director

Effective 6/15/2013 Focus Diagnostics, Inc. new Medical Director is Rick L. Pesano, MD., Laboratory Director, CLIA 05D0644251

New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

Blackberry (f211) IgE							
Effective Date	8/5/2013						
Test Code	2630						
CPT Codes	86003						
Specimen Requirements	0.3 mL (0.15 mL minimum) serum						
Transport Temperature	Room temperature						
Specimen Stability	Room temperature and Refrigerated: 14 days Frozen: 30 days						
Set-up/Analytic Time	Set up: daily; Report available: 1-14 days						
Reference Range	<0.35 kU/L						
Units Of Measure	kU/L						
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute. 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.						
Methodology	Immunoassay						
Performing Site	Quest Diagnostics Nichols Institute, Valencia						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>55169005</td> <td>Blackberry (f211) IgE</td> </tr> <tr> <td>55169010</td> <td>Class</td> </tr> </tbody> </table>	Result Code	Result Name	55169005	Blackberry (f211) IgE	55169010	Class
Result Code	Result Name						
55169005	Blackberry (f211) IgE						
55169010	Class						

Corn Smut, <i>Tilletia tritici</i> (m201), IgE**	
Effective Date	8/5/2013
Test Code	3308
CPT Codes	86003
Specimen Requirements	0.3 mL (0.15 mL minimum) serum
Transport Temperature	Room temperature
Specimen Stability	Room temperature and Refrigerated: 14 days Frozen: 30 days
Set-up/Analytic Time	Set up: daily; Report available: 1-14 days

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Reference Range	<0.35 kU/L							
Units Of Measure	kU/L							
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute. 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.							
Methodology	Immunoassay							
Performing Site	Quest Diagnostics Nichols Institute, Valencia							
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>55156105</td> <td>Tilletia tritici (m201) IgE</td> </tr> <tr> <td>55156110</td> <td>Class</td> </tr> </tbody> </table>		Result Code	Result Name	55156105	Tilletia tritici (m201) IgE	55156110	Class
Result Code	Result Name							
55156105	Tilletia tritici (m201) IgE							
55156110	Class							

Gelatin (c74) IgE							
Effective Date	8/5/2013						
Test Code	35352						
CPT Codes	86003						
Specimen Requirements	0.3 mL (0.15 mL minimum) serum						
Transport Temperature	Room temperature						
Specimen Stability	Room temperature and Refrigerated: 14 days Frozen: 30 days						
Set-up/Analytic Time	Set up: daily; Report available: 1-14 days						
Reference Range	<0.35 kU/L						
Units Of Measure	kU/L						
Methodology	Immunoassay						
Performing Site	Quest Diagnostics Nichols Institute, Valencia						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>55084905</td> <td>Gelatin (c74) IgE</td> </tr> <tr> <td>55084910</td> <td>Class</td> </tr> </tbody> </table>	Result Code	Result Name	55084905	Gelatin (c74) IgE	55084910	Class
Result Code	Result Name						
55084905	Gelatin (c74) IgE						
55084910	Class						

Sunflower Seed (k84) IgE	
Effective Date	8/5/2013
Test Code	23864
CPT Codes	86003
Specimen Requirements	0.3 mL (0.15 mL minimum) serum
Transport Temperature	Room temperature
Specimen Stability	Room temperature and Refrigerated: 14 days

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	Frozen: 30 days	
Set-up/Analytic Time	Set up: daily; Report available: 1-3 days	
Reference Range	<0.35 kU/L	
Units Of Measure	kU/L	
Methodology	Immunoassay	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
CPU Mappings	Result Code	Result Name
	55182205	Sunflower Seed (k84) IgE
	55182210	Class

HIV-1 RNA, Qualitative TMA		
Clinical Significance	The Aptima(R) HIV-1 TNA Qualitative assay may be used: 1. As an aid in the diagnosis of acute and primary HIV-1 infection. 2. To confirm HIV-1 infection in persons who repeatedly test positive for HIV-1 infection. 3. To resolve indeterminate or inconclusive HIV-1 Western blot results.	
Effective Date	8/13/2013	
Test Code	16185	
CPT Codes	87535	
Specimen Requirements	1.6 mL (0.6 mL minimum) plasma collected in EDTA K2 (lavender-top) plastic tube. Alternates: Serum; Plasma collected in ACD solution A (yellow-top) tube or 3.2% sodium citrate (light blue-top) tube or PPT potassium EDTA (white-top) tube	
Reject Criteria	Whole blood; Unspun PPT; Frozen plasma received in PPT in situ	
Instructions	Collect plasma in EDTA (lavender-top) or a (white-top) PPT Vacutainer(TM) plasma preparation tube. Separate plasma or serum from the cells by centrifugation within 6 hours after collection. Transfer the plasma or serum to a plastic screw-cap vial and ship frozen.	
Transport Temperature	Frozen	
Specimen Stability	Room temperature: 72 hours Refrigerated: 5 days Frozen: 35 days	
Set-up/Analytic Time	Set up: Tue, Fri; Report available 2-6 days	
Reference Range	Not detected	
Methodology	Transcription-Mediated Amplification (TMA)	
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano	
CPU Mappings	Result Code	Result Name
	86003824	HIV-1 RNA,QL TMA

Test Changes

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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 names and test codes have been italicized.

Colovantage(R) (Methylated Septin 9)	
Clinical Significance	Methylated Septin 9 is a DNA marker associated with colorectal cancer.
Effective Date	7/29/2013
Test Code	16983
Reject Criteria	Received room temperature; Received refrigerated; Less than 5 mL of specimen
Instructions	This test requires 10 mL of plasma (minimum volume 5 mL). Specimens with less than 5 mL of plasma will be rejected. To obtain this volume of plasma, collect blood in two (2) 10 mL EDTA (lavender-top) tubes or five (5) standard EDTA (lavender-top) tubes. Centrifuge the blood samples, separate plasma and combine them. Send plasma in a single 10 mL pour-off tube. If a 10 mL pour-off tube is not available, two (2) 5 mL pour-off tubes can be used.
Set-up/Analytic Time	Set-up: Mon-Fri; Report available 3 days
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. Performance characteristics refer to the analytical performance of the test.
Performing Site	This test previously performed at Quest Diagnostics Nichols Institute, Valencia will now be performed at Quest Diagnostics Nichols Institute, Chantilly.

Colovantage(R) (Methylated Septin 9) NY	
Clinical Significance	Methylated Septin 9 is a DNA marker associated with colorectal cancer.
Effective Date	7/29/2013
Test Code	16984
Reject Criteria	Received room temperature; Received refrigerated; Less than 5 mL of specimen
Instructions	This test requires 10 mL of plasma (minimum volume 5 mL). Specimens with less than 5 mL of plasma will be rejected. To obtain this volume of plasma, collect blood in two (2) 10 mL EDTA (lavender-top) tubes or five (5) standard EDTA (lavender-top) tubes. Centrifuge the blood samples, separate plasma and combine them. Send plasma in a single 10 mL pour-off tube. If a 10 mL pour-off tube is not available, two (2) 5 mL pour-off tubes can be used.
Set-up/Analytic Time	Set-up: Mon-Fri; Report available 3 days
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. Performance characteristics refer to the analytical performance of the test.
Performing Site	This test previously performed at Quest Diagnostics Nichols Institute, Valencia will now be performed at Quest Diagnostics Nichols Institute, Chantilly.

PSA (Free and Total)	
Effective Date	8/5/2013
Test Code	3547
Specimen Stability	Room temperature and Refrigerated: 72 hours Frozen: 5 months
Performing Site	Quest Diagnostics Nichols Institute, Valencia

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Tests Affected	Test Codes:	Name:
	3545	PSA, Total with Reflex to PSA, Free

RPR (Monitor) with Reflex to Titer	
Effective Date	8/5/2013
Test Code	799
Always Message	The message below only applies to reactive results: 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.
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Varicella Zoster Virus Antibody (IgM)		
Effective Date	8/5/2013	
Test Code	8766	
Units Of Measure	Index	
Always Message	Results from any one IgM assay should not be used as a sole determinant of a current or recent infection. Because an IgM test can yield false positive results and low levels of IgM antibody may persist for more than 12 months post infection, reliance on a single test result could be misleading. If an acute infection is suspected, consider obtaining a new specimen and submit for both IgG and IgM testing in two or more weeks.	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
Tests Affected	Test Codes:	Name:
	8756	Varicella Zoster Virus Antibodies (IgG,IgM)

Beta-Globin Complete	
Effective Date	8/12/2013
Test Code	S51293
Specimen Requirements	Cultured chorionic villi samples are no longer acceptable
Instructions	Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze. For prenatal diagnosis with a fetal specimen: 1) parents must be documented carriers of one of the mutations tested; 2) maternal blood must be available; 3) contact the laboratory genetic counselor before submission. Remove CVS instruction
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Chromosomal Microarray, Hematologic Malignancy, ClariSure(R) Oligo-SNP	
Effective Date	8/12/2013
Former Test Name	Chromosomal Microarray, Oncology, ClariSure® Oligo-SNP
Test Code	90961

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Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano		
CPU Mappings	Result Code	Type	Result Name
	86008400		ClariSureOligo,Hemat Malig
	85997860	Prompt-Result	Specimen Type/Source/Vol:
	86007537	Prompt-Result	Clinical Indication:
	86001207	Prompt-Result	Prior Therapy/Transplant:
	86007538	Prompt-Result	Referring Physician:
	85997863	Prompt-Result	Referring Physician Phone:
	85997864	Prompt-Result	Client/Phone #:
	86007469	Prompt-Result	Client Accession #:
	86007539	Prompt-Result	Patient ID:

Discontinued

Allergen - Blackberry IgE	
Effective Date	8/5/2013
Test Code	RF211
Additional Information	The recommended alternative is 2630 Blackberry (f211) IgE in the New Test Offering section

Allergen - Gelatin IgE	
Effective Date	8/5/2013
Test Code	C74
Additional Information	The recommended alternative is 35352 Gelatin (c74) IgE in the New Test Offering section

Allergen - Sunflower Seed IgE	
Effective Date	8/5/2013
Test Code	K84
Additional Information	The recommended alternative is 23864 Sunflower Seed (k84) IgE in the New Test Offering section

Allergen Specific IgE Smut Corn*	
Effective Date	8/5/2013
Test Code	S50483
Additional Information	The recommended alternative is 3308 Corn Smut, <i>Tilletia tritici</i> (m201), IgE in the New Test Offering section
Tests Affected	Test Codes:
	RM201
	Name:
	Allergen - Ustilago Nuda/Tritici IgG

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Allergen - Protamine IgE	
Effective Date	8/6/2013
Test Code	RC207
Additional Information	There is no recommended alternative

Immune Complex Assay, Raji Cell	
Effective Date	8/6/2013
Test Code	1230
Additional Information	The recommended alternative is S51808 C3d Circulating Immune Complexes performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

FISH, ALK, 2p23 Rearrangement	
Effective Date	8/12/2013
Test Code	S51706
Additional Information	The recommended alternative is 91028 Lung Cancer (NSCLC), ALK 2p23 Rearrangement, FISH

<i>Borrelia burgdorferi</i> IgG & IgM Abs IB + Bands [ALT Criteria]	
Effective Date	8/13/2013
Test Code	7721B
Additional Information	The recommended alternative is 7711B <i>Borrelia burgdorferi</i> IgG & IgM Abs + Bands [CDC CRITERIA]

<i>Borrelia burgdorferi</i> IgG & IgM Abs w/Reflex IB [Alternate]	
Effective Date	8/13/2013
Test Code	8938
Additional Information	The recommended alternative is 8942 <i>Borrelia burgdorferi</i> IgG & IgM Abs w/Reflex IB + Bands [CDC]

<i>Borrelia burgdorferi</i> IgG & IgM Abs IB + Bands CSF [ALT]	
Effective Date	8/13/2013
Test Code	7721CB
Additional Information	The recommended alternative is 7711CB <i>Borrelia burgdorferi</i> IgG & IgM Abs IB + Bands CSF [CDC]

<i>Borrelia burgdorferi</i> Panel	
Effective Date	8/13/2013
Test Code	6906
Additional Information	The recommended alternative is: 8944 Lyme Disease C6 Antibodies, Total ELISA and 7716B- <i>Borrelia burgdorferi</i> IgG & IgM Abs EIA & Immunoblot + Bands

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HIV-1 DNA DetectR	
Effective Date	8/13/2013
Test Code	9885
Additional Information	The recommended alternative is 16185 HIV-1 RNA, Qualitative, TMA listed in the New Test Offering section