

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

ANNOUNCEMENTS		
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	Page #
	Reactivated Testing	2

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>17082</u>	Black Pepper (f280) IgG	11/4/2013	2
<u>14788</u>	Food Specific IgG Allergy (Adult) Panel	11/4/2013	3
<u>14791</u>	Food Specific IgG Allergy (Pediatric) Panel	11/4/2013	4
<u>29496</u>	Food Specific IgG Allergy Panel 1	11/4/2013	5
<u>37334</u>	Food Specific IgG Allergy Panel 2	11/4/2013	5
<u>91115</u>	Dabigatran with Reflex to Thrombin Time	11/11/2013	6
<u>91772</u>	KIT D816, Mutation Analysis (Mastocytosis)	11/11/2013	7
<u>91771</u>	MYD88, Mutation Analysis	11/11/2013	8

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>10239</u>	9941	<i>Aspergillus</i> IgG, IgM & IgA Antibodies	11/4/2013	9
<u>11011</u>	RF333	Flaxseed (f333) IgE	11/4/2013	10
<u>38140</u>	F8G	Maize/Corn (f8) IgG	11/4/2013	10
<u>38115</u>	RF212G	Mushroom (f212) IgG	11/4/2013	11
<u>11195</u>	RF325	Sheep Milk (f325) IgE	11/4/2013	11
<u>8766</u>		Varicella Zoster Virus Antibody (IgM)	11/4/2013	12
<u>39545</u>		Yeast (Bakers/Brewers) (f45g) IgG	11/4/2013	12
<u>19958</u>	3244	Testosterone, Total (Males), Immunoassay	11/11/2013	12
<u>9189</u>		Cryptococcal Antigen, Latex Screen with Reflex to Titer	11/25/2013	13
<u>30429</u>	S50100	Cryptococcus Antibody	11/25/2013	13

REDIRECTS				
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>14693</u>	3878	Pancreatic Elastase 1	11/11/2013	14

DISCONTINUED TESTS				
Please Note: Not all test codes assigned to each assay are listed in the table of contents.				

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

Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
15972	Dabigatran	11/11/2013	14
S52234	Lipoprotein Fractionation Panel 1, Ion Mobility	11/11/2013	15
A52249	Lipoprotein Fractionation Panel 2, Ion Mobility	11/11/2013	15
A51275	Cryptococcus Antigen Detection, LA (CSF)	11/25/2013	15
S51341	Epstein-Barr Virus (EBV) Panel, IFA (CSF)	11/25/2013	15

SEND OUTS				
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 #
S50072		Prednisolone	10/28/2013	15
S46155		Prednisone, Serum	10/28/2013	15
S51504		Interleukin 12	11/1/2013	16
S49629		Interleukin 4	11/1/2013	16
S49671		Interleukin 8	11/1/2013	16
S50543		Interleukin-10 Serum	11/1/2013	16
S49727		Interleukin-5	11/1/2013	16
S42145		Chlorpheniramine, Serum/Plasma	11/4/2013	16
10931	S40425	Hydroxyzine and Metabolite, SP	11/4/2013	17
S50733		N,N-Dimethylformamide (DMF) Exposure (N-Monomethylformamide), Urine	11/4/2013	17
S52172		Rufinamide, Serum/Plasma	11/4/2013	18

Announcement

Reactivated Testing							
Message	These assays are being re-activated.						
Effective Date	9/23/2013						
Performing Site	Focus Diagnostics, Inc.						
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>S50103</td> <td>Cysticercus IgG Antibody, Western Blot (Serum)</td> </tr> <tr> <td>S49928</td> <td>Cysticercus IgG Antibody, Western Blot (CSF)</td> </tr> </tbody> </table>	Test Codes:	Name:	S50103	Cysticercus IgG Antibody, Western Blot (Serum)	S49928	Cysticercus IgG Antibody, Western Blot (CSF)
Test Codes:	Name:						
S50103	Cysticercus IgG Antibody, Western Blot (Serum)						
S49928	Cysticercus IgG Antibody, Western Blot (CSF)						

New Test Offerings

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

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

Black Pepper (f280) IgG					
Message	***This test is not available for New York patient testing***				
Effective Date	11/4/2013				
Test Code	17082				
CPT Codes	86001				
Specimen Requirements	0.3 mL (0.15 mL minimum) serum				
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days				
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days				
Reference Range	<2.0 mcg/mL				
Units Of Measure	mcg/mL				
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.				
Methodology	Immunoassay				
Assay Category	Investigational Use Only				
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>86010104</td> <td>Black Pepper f280 IgG</td> </tr> </tbody> </table>	Result Code	Result Name	86010104	Black Pepper f280 IgG
Result Code	Result Name				
86010104	Black Pepper f280 IgG				

Food Specific IgG Allergy (Adult) Panel	
Message	**This test is not available for New York patient testing***
Effective Date	11/4/2013
Test Code	14788
CPT Codes	86001 (x11)
Specimen Requirements	3.5 mL (1.7 mL minimum) serum
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days
Reference Range	<2.0 mcg/mL
Units Of Measure	mcg/mL
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic

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

	interventions.																									
Methodology	Immunoassay																									
Assay Category	Investigational Use Only																									
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>85995765</td> <td>Casein f78 IgG</td> </tr> <tr> <td>86007160</td> <td>Cacao (Chocolate) f93 IgG</td> </tr> <tr> <td>86007372</td> <td>Codfish f3 IgG</td> </tr> <tr> <td>86007373</td> <td>Coffee f221 IgG</td> </tr> <tr> <td>85995768</td> <td>Maize/Corn f8 IgG</td> </tr> <tr> <td>85995766</td> <td>Egg White f1 IgG</td> </tr> <tr> <td>86007356</td> <td>Peanut f13 IgG</td> </tr> <tr> <td>85995769</td> <td>Soybean f14 IgG</td> </tr> <tr> <td>86008233</td> <td>Tomato f25 IgG</td> </tr> <tr> <td>85995770</td> <td>Wheat f4 IgG</td> </tr> <tr> <td>86008235</td> <td>Yeast IgG f45</td> </tr> </tbody> </table>		Result Code	Result Name	85995765	Casein f78 IgG	86007160	Cacao (Chocolate) f93 IgG	86007372	Codfish f3 IgG	86007373	Coffee f221 IgG	85995768	Maize/Corn f8 IgG	85995766	Egg White f1 IgG	86007356	Peanut f13 IgG	85995769	Soybean f14 IgG	86008233	Tomato f25 IgG	85995770	Wheat f4 IgG	86008235	Yeast IgG f45
Result Code	Result Name																									
85995765	Casein f78 IgG																									
86007160	Cacao (Chocolate) f93 IgG																									
86007372	Codfish f3 IgG																									
86007373	Coffee f221 IgG																									
85995768	Maize/Corn f8 IgG																									
85995766	Egg White f1 IgG																									
86007356	Peanut f13 IgG																									
85995769	Soybean f14 IgG																									
86008233	Tomato f25 IgG																									
85995770	Wheat f4 IgG																									
86008235	Yeast IgG f45																									

Food Specific IgG Allergy (Pediatric) Panel	
Message	**This test is not available for New York patient testing**
Effective Date	11/4/2013
Test Code	14791
CPT Codes	86001 (x10)
Specimen Requirements	3 mL (1.5 mL minimum) serum
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days
Reference Range	<2.0 mcg/mL
Units Of Measure	mcg/mL
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.
Methodology	Immunoassay
Assay Category	Investigational Use Only
Performing Site	Quest Diagnostics Nichols Institute, Valencia

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

CPU Mappings	Result Code	Result Name
	86007348	Beef f27 IgG
	85995765	Casein f78 IgG
	86007372	Codfish f3 IgG
	85995768	Maize/Corn f8 IgG
	85995766	Egg White f1 IgG
	86007355	Orange f33 IgG
	86007356	Peanut f13 IgG
	86007357	Pork f26 IgG
	85995769	Soybean f14 IgG
	85995770	Wheat f4 IgG

Food Specific IgG Allergy Panel 1													
Message	**This test is not available for New York patient testing**												
Effective Date	11/4/2013												
Test Code	29496												
Specimen Requirements	2 mL (1 mL minimum) serum												
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days												
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days												
Reference Range	<2.0 mcg/mL												
Units Of Measure	mcg/mL												
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.												
Methodology	Immunoassay												
Assay Category	Investigational Use Only												
Performing Site	Quest Diagnostics Nichols Institute, Valencia												
CPU Mappings	<table border="1"> <tr> <th>Result Code</th> <th>Result Name</th> </tr> <tr> <td>85995765</td> <td>Casein f78 IgG</td> </tr> <tr> <td>86007160</td> <td>Cacao (Chocolate) f93 IgG</td> </tr> <tr> <td>85995768</td> <td>Maize/Corn f8 IgG</td> </tr> <tr> <td>85995766</td> <td>Egg White f1 IgG</td> </tr> <tr> <td>85995770</td> <td>Wheat f4 IgG</td> </tr> </table>	Result Code	Result Name	85995765	Casein f78 IgG	86007160	Cacao (Chocolate) f93 IgG	85995768	Maize/Corn f8 IgG	85995766	Egg White f1 IgG	85995770	Wheat f4 IgG
	Result Code	Result Name											
	85995765	Casein f78 IgG											
	86007160	Cacao (Chocolate) f93 IgG											
	85995768	Maize/Corn f8 IgG											
	85995766	Egg White f1 IgG											
85995770	Wheat f4 IgG												

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

	86008235 Yeast IgG f45
--	-----------------------------

Food Specific IgG Allergy Panel 2																													
Message	**This test is not available for New York patient testing**																												
Effective Date	11/4/2013																												
Test Code	37334																												
CPT Codes	86001 (x13)																												
Specimen Requirements	4 mL (2 mL minimum) serum																												
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days																												
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days																												
Reference Range	<2.0 mcg/mL																												
Units Of Measure	mcg/mL																												
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.																												
Methodology	Immunoassay																												
Assay Category	Investigational Use Only																												
Performing Site	Quest Diagnostics Nichols Institute, Valencia																												
CPU Mappings	<table border="1" style="width: 100%;"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr><td>86007364</td><td>Apple f49 IgG</td></tr> <tr><td>86007346</td><td>Banana f92 IgG</td></tr> <tr><td>86007348</td><td>Beef f27 IgG</td></tr> <tr><td>85995765</td><td>Casein f78 IgG</td></tr> <tr><td>86007350</td><td>Chicken f83 IgG</td></tr> <tr><td>86007160</td><td>Cacao (Chocolate) f93 IgG</td></tr> <tr><td>85995768</td><td>Maize/Corn f8 IgG</td></tr> <tr><td>85995766</td><td>Egg White f1 IgG</td></tr> <tr><td>86007355</td><td>Orange f33 IgG</td></tr> <tr><td>86007358</td><td>Potato White f35 IgG</td></tr> <tr><td>85995769</td><td>Soybean f14 IgG</td></tr> <tr><td>86008233</td><td>Tomato f25 IgG</td></tr> <tr><td>85995770</td><td>Wheat f4 IgG</td></tr> </tbody> </table>	Result Code	Result Name	86007364	Apple f49 IgG	86007346	Banana f92 IgG	86007348	Beef f27 IgG	85995765	Casein f78 IgG	86007350	Chicken f83 IgG	86007160	Cacao (Chocolate) f93 IgG	85995768	Maize/Corn f8 IgG	85995766	Egg White f1 IgG	86007355	Orange f33 IgG	86007358	Potato White f35 IgG	85995769	Soybean f14 IgG	86008233	Tomato f25 IgG	85995770	Wheat f4 IgG
Result Code	Result Name																												
86007364	Apple f49 IgG																												
86007346	Banana f92 IgG																												
86007348	Beef f27 IgG																												
85995765	Casein f78 IgG																												
86007350	Chicken f83 IgG																												
86007160	Cacao (Chocolate) f93 IgG																												
85995768	Maize/Corn f8 IgG																												
85995766	Egg White f1 IgG																												
86007355	Orange f33 IgG																												
86007358	Potato White f35 IgG																												
85995769	Soybean f14 IgG																												
86008233	Tomato f25 IgG																												
85995770	Wheat f4 IgG																												

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

Dabigatran with Reflex to Thrombin Time																			
Message	**This test is not available for New York patient testing.**																		
Clinical Significance	Dabigatran is a new oral direct anti-thrombin drug and an alternative to Warfarin. The drug received FDA clearance in 2010 for the indication of stroke prevention in patients with atrial fibrillation. Routinely, the drug does not need to be monitored, however, there are instances where monitoring is needed: (1) Determination of failure of therapy vs. poor compliance (2) Potential dose adjustment required for renal or hepatic dysfunction (3) Titration.																		
Effective Date	11/11/2013																		
Test Code	91115																		
CPT Codes	80299																		
Specimen Requirements	1 mL (0.5 mL minimum) plasma collected in a 3.2% sodium citrate (light blue-top) tube																		
Reject Criteria	Gross hemolysis; visible fibrin clot; received room temperature or refrigerated																		
Instructions	Whole blood collected in 3.2% sodium citrate (light blue-top tube). Collect 90 to 120 minutes after the last dose (preferably after at least 3 doses). Centrifuge (light blue-top) tube 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.																		
Transport Temperature	Frozen																		
Specimen Stability	Room temperature and Refrigerated: Unacceptable Frozen: 30 days																		
Set-up/Analytic Time	Set up: Tues, Thurs, Sat; Report available: Next day																		
Reference Range	64 - 443 ng/mL																		
Always Message	The target peak therapeutic range is 64-443 ng/mL collected 90-120 minutes post dose. This range reflects steady state values for the 150 mg bid dosing regimen as reported in the PETRO trial for atrial fibrillation with a median creatinine clearance of 75 mL/min. Thromb Haemost 2012; 103(6): 1-12. Chest 2012; 141; e44S-e88S. 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.																		
Methodology	Clotting Assay																		
Assay Category	Laboratory Developed Test																		
Performing Site	Quest Diagnostics Nichols Institute, Chantilly																		
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>86007182</td> <td>Interpretation</td> <td></td> </tr> <tr> <td>86007181</td> <td>Dabigatran</td> <td>ng/mL</td> </tr> <tr> <td colspan="3">This is a true reflex. Please build the unit code below separately. Non-Orderable Reflex 91115-2 Thrombin Clotting Time</td> </tr> <tr> <th>Result Code</th> <th>Result Name</th> <th></th> </tr> <tr> <td>85992031</td> <td>Thrombin Clotting Time</td> <td>seconds</td> </tr> </tbody> </table>	Result Code	Result Name	Unit of Measure	86007182	Interpretation		86007181	Dabigatran	ng/mL	This is a true reflex. Please build the unit code below separately. Non-Orderable Reflex 91115-2 Thrombin Clotting Time			Result Code	Result Name		85992031	Thrombin Clotting Time	seconds
Result Code	Result Name	Unit of Measure																	
86007182	Interpretation																		
86007181	Dabigatran	ng/mL																	
This is a true reflex. Please build the unit code below separately. Non-Orderable Reflex 91115-2 Thrombin Clotting Time																			
Result Code	Result Name																		
85992031	Thrombin Clotting Time	seconds																	
Additional Information	If the Dabigatran result is <45 ng/mL, then Thrombin Time will be performed at an additional charge (CPT code: 85670).																		

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

KIT D816, Mutation Analysis (Mastocytosis)																				
Clinical Significance	<p>Point mutation of the KIT oncogene at codon 816 (D816V) is seen in >90% of systemic mastocytosis (SM) cases. The presence of KIT D816V mutation is one of the minor criteria for diagnosis of SM and mutation testing can assist in diagnosis, particularly in limited specimens. KIT D816 mutations, including D816V, D816H and D816Y, are also the most common KIT mutations seen in the core-binding factor acute myeloid leukemia (AML). In both t(8;21) and inv(16)/t(16;16) AML, cases with KIT D816 mutation are associated with worse outcomes than unmutated cases. This PCR-based DNA pyrosequencing assay sensitively detects the KIT D816V mutation down to 2%. If KIT mutation testing of gastrointestinal stromal tumor (GIST) or melanoma is needed, test code 19961 should be used instead, which tests for exons 8, 9, 11, 13 and 17 of the KIT gene by Sanger sequencing.</p>																			
Effective Date	11/11/2013																			
Test Code	91772																			
CPT Codes	81402																			
Specimen Requirements	<p>Preferred: 5 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p> <p>Acceptable: Whole blood collected in a sodium heparin (green-top) or ACD-B (yellow-top) tube 2 mL (0.5 mL minimum) bone marrow aspirate collected in an EDTA (lavender-top) tube Formalin-fixed, paraffin-embedded tissue block 10 slides (6 slide minimum) tissue submitted in a slide holder</p>																			
Reject Criteria	Received frozen																			
Transport Temperature	Room temperature																			
Specimen Stability	<p>Room temperature and Refrigerated: 7 days Frozen: Unacceptable</p>																			
Set-up/Analytic Time	Set up: Mon; Report available: 7 days																			
Reference Range	Not Detected																			
Methodology	DNA Sequencing																			
Assay Category	Laboratory Developed Test																			
Performing Site	Quest Diagnostics Nichols Institute, Chantilly																			
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86007404</td> <td>Prompt-Result</td> <td>Specimen Source:</td> </tr> <tr> <td>86007839</td> <td>Prompt-Result</td> <td>Block/Specimen ID:</td> </tr> <tr> <td>86006921</td> <td>Prompt-Result</td> <td>Clinical Indication:</td> </tr> <tr> <td>86010002</td> <td></td> <td>KIT D816 Mutation</td> </tr> <tr> <td>86010003</td> <td></td> <td>Interpretation</td> </tr> </tbody> </table>		Result Code	Type	Result Name	86007404	Prompt-Result	Specimen Source:	86007839	Prompt-Result	Block/Specimen ID:	86006921	Prompt-Result	Clinical Indication:	86010002		KIT D816 Mutation	86010003		Interpretation
Result Code	Type	Result Name																		
86007404	Prompt-Result	Specimen Source:																		
86007839	Prompt-Result	Block/Specimen ID:																		
86006921	Prompt-Result	Clinical Indication:																		
86010002		KIT D816 Mutation																		
86010003		Interpretation																		

MYD88, Mutation Analysis	
Clinical Significance	<p>L265P mutation in the MYD88 gene is found in approximately 90% of Waldenström macroglobulinemia and IgM-expressing lymphoplasmacytic lymphoma (LPL). There is a low incidence of L265P MYD88 mutation in other systemic CD5-negative B-cell lymphoproliferative disorders including atypical chronic lymphocytic leukemia, nodal marginal zone lymphoma (MZL), splenic MZL and mucosa-associated lymphoid tissue (MALT)-type MZL. This PCR-based DNA pyrosequencing assay sensitively detects the L265P MYD88 mutation and can be used to help diagnose Waldenström macroglobulinemia or IgM-expressing lymphoplasmacytic lymphoma and to help in stratifying or subclassifying patients with IgM monoclonal gammopathy.</p>

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

Effective Date	11/11/2013																				
Test Code	91771																				
CPT Codes	81479																				
Specimen Requirements	<p>Preferred: 5 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p> <p>Acceptable: Whole blood collected in a sodium heparin (green-top) or ACD-B (yellow-top) tube 2 mL (0.5 mL minimum) bone marrow aspirate collected in an EDTA (lavender-top) tube Formalin-fixed, paraffin-embedded tissue block 10 slides (6 slide minimum) tissue submitted in a slide holder</p>																				
Reject Criteria	Received frozen																				
Transport Temperature	Room temperature																				
Specimen Stability	Room temperature and Refrigerated: 7 days Frozen: Unacceptable																				
Set-up/Analytic Time	Set up: Mon; Report available: 7 days																				
Reference Range	Not Detected																				
Methodology	DNA Sequencing																				
Assay Category	Laboratory Developed Test																				
Performing Site	Quest Diagnostics Nichols Institute, Chantilly																				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86007404</td> <td>Prompt-Result</td> <td>Specimen Source:</td> </tr> <tr> <td>86007839</td> <td>Prompt-Result</td> <td>Block/Specimen ID:</td> </tr> <tr> <td>86006921</td> <td>Prompt-Result</td> <td>Clinical Indication:</td> </tr> <tr> <td>86010004</td> <td></td> <td>MYD88 L265P Mutation</td> </tr> <tr> <td>86010005</td> <td></td> <td>Interpretation</td> </tr> </tbody> </table>			Result Code	Type	Result Name	86007404	Prompt-Result	Specimen Source:	86007839	Prompt-Result	Block/Specimen ID:	86006921	Prompt-Result	Clinical Indication:	86010004		MYD88 L265P Mutation	86010005		Interpretation
Result Code	Type	Result Name																			
86007404	Prompt-Result	Specimen Source:																			
86007839	Prompt-Result	Block/Specimen ID:																			
86006921	Prompt-Result	Clinical Indication:																			
86010004		MYD88 L265P Mutation																			
86010005		Interpretation																			

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 names and test codes have been italicized.

Aspergillus IgG, IgM & IgA Antibodies	
Effective Date	11/4/2013
Former Test Code	9941
Test Code	10239
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Range	<50 Units
Units Of Measure	Units

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

Always Message	Aspergillus Antibodies:	
	<50 Units	Negative
	50-70 Units	Indeterminate
	>70 Units	Positive
Assay Category	FDA Exempt	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
CPU Mappings	Result Code	Result Name
	86005760	Aspergillus IgG Abs
	86005761	Aspergillus IgM Abs
	86005762	Aspergillus IgA Abs
Tests Affected	Test Codes:	Name:
	9961	Aspergillus IgG Antibodies
	9946	Aspergillus IgM Antibodies

Flaxseed (f333) IgE		
Effective Date	11/4/2013	
Former Test Name	Allergen- Linseed (Flaxseed) IgE	
Former Test Code	RF333	
Test Code	11011	
Specimen Requirements	0.3 mL (0.15 mL minimum) serum	
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	
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	Result Code	Result Name
	55084740	Flaxseed (f333) IgE
	55084745	Class

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

Maize/Corn (f8) IgG					
Message	***This test is not available for New York patient testing***				
Effective Date	11/4/2013				
Former Test Name	<i>Allergen- Corn IgG</i>				
Former Test Code	<i>F8G</i>				
Test Code	38140				
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days				
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days				
Reference Range	<2.0 mcg/mL				
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>85995768</td> <td>Maize/Corn f8 IgG</td> </tr> </tbody> </table>	Result Code	Result Name	85995768	Maize/Corn f8 IgG
Result Code	Result Name				
85995768	Maize/Corn f8 IgG				

Mushroom (f212) IgG	
Message	***This test is not available for New York patient testing***
Effective Date	11/4/2013
Former Test Name	<i>Allergen- Mushroom (Champignon) IgG</i>
Former Test Code	<i>RF212G</i>
Test Code	38115
Specimen Requirements	0.3 mL (0.15 mL minimum) serum
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Set-up/Analytic Time	Set up: Sun, Wed, Fri; Report available: 1-3 days
Reference Range	<2.0 mcg/mL
Units Of Measure	mcg/mL
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.
Methodology	Immunoassay
Assay Category	Investigational Use Only
Performing Site	Quest Diagnostics Nichols Institute, Valencia

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

CPU Mappings	Result Code	Result Name
	86007380	Mushroom f212 IgG

Sheep Milk (f325) IgE		
Effective Date	11/4/2013	
<i>Former Test Name</i>	Allergen- Sheep Milk IgE	
<i>Former Test Code</i>	RF325	
Test Code	11195	
Specimen Requirements	0.3 mL (0.15 mL minimum) serum	
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	
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	Result Code	Result Name
	86010055	Sheep Milk f325 IgE
	86010056	Class

Varicella Zoster Virus Antibody (IgM)		
Effective Date	11/4/2013	
Test Code	8766	
Units Of Measure	Remove index	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
Tests Affected	Test Codes:	Name:
	8756	Varicella Zoster Virus Antibodies (IgG,IgM)

Yeast (Bakers/Brewers) (f45g) IgG	
Effective Date	11/4/2013
<i>Former Test Name</i>	Allergen Yeast (Bakers/Brewers) IgG
Test Code	39545

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

Performing Site	Quest Diagnostics Nichols Institute, Valencia	
CPU Mappings	Result Code	Result Name
	86008235	Yeast IgG f45

Testosterone, Total (Males), Immunoassay		
Clinical Significance	Testosterone circulates almost entirely bound to transport proteins: normally less than 1-2% is free. The principal transport protein for testosterone is known as sex hormone binding globulin (SHBG) or testosterone-estradiol binding globulin (TeBG). Testosterone measurements are used to assess erectile dysfunction, infertility, gynecomastia, and osteoporosis and to assess hormone replacement therapy.	
Effective Date	11/11/2013	
<i>Former Test Name</i>	<i>Testosterone, Total (Males), ICMA</i>	
<i>Former Test Code</i>	<i>3244</i>	
Test Code	19958	
Transport Temperature	Room temperature	
Always Message	<p>In hypogonadal males, Testosterone, Total, LC/MS/MS is the recommended assay. This test code (15983) must be collected in a red-top tube with no gel. The Endocrine Society recommends obtaining at least two morning (8-10am) samples on different days when screening for hypogonadism.</p> <p>Males: Men with clinically significant hypogonadal symptoms and testosterone values repeatedly in the range of 200-300 ng/dL or less may benefit from testosterone treatment after adequate risk and benefits counseling.</p>	
Methodology	Competitive Chemiluminescent Immunoassay	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
CPU Mappings	Result Code	Result Name
	85986670	Testosterone, Male, Immuno
		Unit of Measure
		ng/dL

Cryptococcal Antigen, Latex Screen with Reflex to Titer		
Effective Date	11/25/2013	
Test Code	9189	
Specimen Stability	Room temperature: Unacceptable Refrigerated: 7 days Frozen: 60 days	
Performing Site	Quest Diagnostics Nichols Institute, Valencia	
CPU Mappings	9189- Cryptococcal Antigen, Latex Screen	
	Result Code	Type
	211326	Prompt-Result
	27011	Cryptococcal Ag Screen
	<p>This test is a true reflex. Please build the unit code below separately. Non-orderable Reflex RNK- Cryptococcal Antigen, Latex Titer</p>	

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

	Result Code	Result Name
	211333	Cryptococcal Ag Titer

Cryptococcus Antibody					
Effective Date	11/25/2013				
<i>Former Test Code</i>	S50100				
Test Code	30429				
CPT Codes	86403				
Specimen Requirements	1 mL (0.5 mL minimum) serum				
Reject Criteria	Gross hemolysis				
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days				
Set-up/Analytic Time	Set up: Mon, Wed, Fri; Report available: 2-5 days				
Reference Range	< 1:2				
Methodology	Agglutination				
Performing Site	Focus Diagnostics, Inc.				
CPU Mappings	<table border="1" style="width: 100%;"> <tr> <td style="text-align: center;">Result Code</td> <td style="text-align: center;">Result Name</td> </tr> <tr> <td style="text-align: center;">85984250</td> <td style="text-align: center;">Cryptococcus Antibody</td> </tr> </table>	Result Code	Result Name	85984250	Cryptococcus Antibody
Result Code	Result Name				
85984250	Cryptococcus Antibody				

Redirect

Pancreatic Elastase 1							
Clinical Significance	The Elastase-1 is a quantitative enzyme linked immunosorbent assay for measuring concentrations of elastase-1 in feces as an aid in diagnosis of the exocrine pancreatic function.						
Effective Date	11/11/2013						
<i>Former Test Code</i>	3878						
Test Code	14693						
Specimen Requirements	1 gm (0.3 gm minimum) Stool						
Reject Criteria	Specimen stored at room temperature >5 days; Specimen collected in Formalin, MF, SAF, or PVA; Cary-Blair media						
Instructions	Collect undiluted feces in clean, dry, sterile leak proof container. Do not add fixative or preservative.						
Transport Temperature	Refrigerated						
Set-up/Analytic Time	Set up days: Tues, Thurs; Report available: 2 days						
Reference Range	<table style="width: 100%;"> <tr> <td>Normal:</td> <td style="text-align: right;">>200 mcg/g</td> </tr> <tr> <td>Moderate Pancreatic Insufficiency:</td> <td style="text-align: right;">100-200 mcg/g</td> </tr> <tr> <td>Severe Pancreatic</td> <td></td> </tr> </table>	Normal:	>200 mcg/g	Moderate Pancreatic Insufficiency:	100-200 mcg/g	Severe Pancreatic	
Normal:	>200 mcg/g						
Moderate Pancreatic Insufficiency:	100-200 mcg/g						
Severe Pancreatic							

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

	Insufficiency: <100 mcg/g					
Units Of Measure	mcg/g					
Always Message	Elastase-1 (E-1) assay results are expressed in mcg/g, which represent mcg E1/g feces. It is not necessary to interrupt enzyme substitution therapy.					
Methodology	Immunoassay					
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85997201</td> <td>Pancreatic Elastase-1</td> </tr> </tbody> </table>		Result Code	Result Name	85997201	Pancreatic Elastase-1
Result Code	Result Name					
85997201	Pancreatic Elastase-1					

Discontinued Tests

Dabigatran	
Effective Date	11/11/2013
Test Code	15972
Additional Information	The replacement code is 91115 - Dabigatran with Reflex to Thrombin Time in the New Test Offerings Section.

Lipoprotein Fractionation Panel 1, Ion Mobility	
Effective Date	11/11/2013
Test Code	S52234
Additional Information	<p>The recommended alternatives are:</p> <ul style="list-style-type: none"> ● 91604- Cardio IQ™ Lipoprotein Fractionation, Ion Mobility ● 91716- Cardio IQ™ Lipid Panel ● 91729- Cardio IQ™ Lipoprotein (a)

Lipoprotein Fractionation Panel 2, Ion Mobility	
Effective Date	11/11/2013
Test Code	A52249
Additional Information	The recommended alternative is test code 91604- Cardio IQ™ Lipoprotein Fractionation, Ion Mobility.

Cryptococcus Antigen Detection, LA (CSF)	
Effective Date	11/25/2013
Test Code	A51275
Additional Information	The recommended alternative is 11196- Cryptococcal Antigen, Latex Screen with Reflex to Titer.

Epstein-Barr Virus (EBV) Panel, IFA (CSF)	
Effective Date	11/25/2013

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

Test Code	S51341
Additional Information	The recommended alternative is 34179- Epstein Barr Virus DNA, Qualitative Real-Time PCR.

Test Send Outs (Referrals)

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION**.

Prednisolone	
Effective Date	10/28/2013
Test Code	S50072
Additional Information	This test will be discontinued, there is no recommended alternative.

Prednisone, Serum	
Effective Date	10/28/2013
Test Code	S46155
Additional Information	This test will be discontinued, there is no recommended alternative.

Interleukin 12	
Effective Date	11/1/2013
Test Code	S51504
Reference Range	<3.0 pg/mL

Interleukin 4	
Effective Date	11/1/2013
Test Code	S49629
Reference Range	<1 pg/mL

Interleukin 8	
Effective Date	11/1/2013
Test Code	S49671
Reference Range	<7.8 pg/mL

Interleukin-10 Serum	
Effective Date	11/1/2013
Test Code	S50543
Reference Range	<1.5 pg/mL

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

Interleukin-5	
Effective Date	11/1/2013
Test Code	S49727
Reference Range	<7.8 pg/mL

Chlorpheniramine, Serum/Plasma					
Effective Date	11/4/2013				
Test Code	S42145				
CPT Codes	80299				
Specimen Requirements	<p>Preferred: 1 mL (0.4 mL minimum) serum collected in a red-top tube (no gel)</p> <p>Acceptable: Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube</p>				
Specimen Stability	<p>Room temperature and Refrigerated: 30 days</p> <p>Frozen: 6 months</p>				
Set-up/Analytic Time	Set up: Mon, Wed, Fri; Report available: 3 days (after set up)				
Reference Range	Peak concentrations of 10 ng/mL chlorpheniramine were obtained 3 hours following single oral administration of 8 mg. Toxic effects have been reported in adults at concentrations greater than 400 ng/mL in serum.				
Methodology	Liquid Chromatography/Tandem Mass Spectrometry				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85814900</td> <td>Chlorpheniramine, S/P</td> </tr> </tbody> </table>	Result Code	Result Name	85814900	Chlorpheniramine, S/P
Result Code	Result Name				
85814900	Chlorpheniramine, S/P				

Hydroxyzine and Metabolite, SP	
Effective Date	11/4/2013
Former Test Name	Hydroxyzine
Former Test Code	S40425
Test Code	10931
Specimen Requirements	<p>Preferred: 1 mL (0.4 mL minimum) serum collected in a red-top tube (no gel)</p> <p>Acceptable: Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube</p>
Instructions	Promptly centrifuge and separate serum or plasma into a plastic, screw-capped vial using appropriate guidelines
Specimen Stability	<p>Room temperature and Refrigerated: 30 days</p> <p>Frozen: 6 months</p>
Set-up/Analytic Time	Set up: Mon, Wed, Fri; Report available: 3 days (after set up)
Reference Range	<p>Hydroxyzine</p> <p>The following mean peak serum or plasma concentrations of hydroxyzine have been reported: 25 mg oral dose: 43 ng/mL at 3 hours</p>

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

	<p>50 mg oral dose: 70 ng/mL at 2 hours, 30 ng/mL at 6 hours, and 22 ng/mL at 12 hours 100 mg oral dose: 78 ng/mL at 4 hours and 35 ng/mL at 8 hours</p> <p>Cetirizine</p> <p>Cetirizine is an active metabolite of hydroxyzine. No reference data available.</p>						
Methodology	Liquid Chromatography/Tandem Mass Spectrometry						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85995695</td> <td>Hydroxyzine</td> </tr> <tr> <td>86010046</td> <td>Cetirizine</td> </tr> </tbody> </table>	Result Code	Result Name	85995695	Hydroxyzine	86010046	Cetirizine
Result Code	Result Name						
85995695	Hydroxyzine						
86010046	Cetirizine						

N,N-Dimethylformamide (DMF) Exposure (N-Monomethylformamide), Urine	
Effective Date	11/4/2013
Test Code	S50733
Specimen Requirements	5 mL (2.2 mL minimum) urine collected in a plastic urine container
Specimen Stability	Room temperature: Undetermined Refrigerated: 7 days Frozen: Undetermined
Reference Range	Biological Exposure Index (ACGIH): Following workplace exposure to N,N-Dimethylformamide: 15 mg/L measured in a urine specimen collected at end of shift.
Additional Information	Please note: Result code 107116 - Creatinine is being removed.

Rufinamide, Serum/Plasma	
Effective Date	11/4/2013
Test Code	S52172
CPT Codes	80299
Specimen Requirements	<p>Preferred: 1 mL serum collected in a red-top tube (no gel)</p> <p>Acceptable: Plasma collected in an EDTA (lavender-top), sodium heparin (green-top), lithium heparin (green-top) or EDTA (pink-top) tube</p>
Specimen Stability	Room temperature and Refrigerated: 30 days Frozen: 6 months
Set-up/Analytic Time	Set up: Mon, Wed, Fri: Report available: 3 days (after set up)
Reference Range	Maintenance therapy with 45 mg/kg (approximately 1600 mg) daily rufinamide resulted in plasma concentrations ranging from 5000 - 48000 ng/mL (n = 74).
Units Of Measure	ng/mL
Methodology	Liquid Chromatography/Tandem Mass Spectrometry