

8/5/2014 - Immediate Action, 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>12786</u>	Celiac Disease Serology	8/11/2014	2
<u>92480</u>	Leishmania Antibody (IgG)	9/8/2014	2
<u>38007</u>	NAbFeron® (IFNB-1) Neutralizing Antibody Test	10/13/2014	3

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>30551</u>		TSI (Thyroid Stimulating Immunoglobulin)	8/18/2014	4
<u>S50437</u>		MuSK Quantitative Titers Antibody Test	9/22/2014	4
<u>S52438</u>		Neuromyelitis Optica (NMO)	9/22/2014	4
<u>S49551</u>		Sensory Neuropathy Profile-xp	9/22/2014	5
<u>S48689</u>		Sulfatide Autoantibody Test	9/22/2014	5
<u>S51553</u>		Interferon-beta IgG, MAID (Reflex to Neutralization)	10/13/2014	5

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>18115</u>	Celiac Disease Panel #2	8/11/2014	5
<u>S51543</u>	HLA Typing for Celiac Disease	8/11/2014	6
<u>S51609NY</u>	Thyroid Stimulating IG (NY)	8/18/2014	6
<u>S51554</u>	Leishmania Antibody, IFA	9/8/2014	6
	Focus Antifungal Susceptibility Test Deletions	9/22/2014	6
<u>S52051</u>	Interferon-beta 1a (IFNB-1a) AB	10/13/2014	6
<u>S52052</u>	Interferon-beta 1b (IFNB-1b) Ab	10/13/2014	6

NY UPDATE		
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 #
<u>1468</u>	Human Anti-mouse Antibody (HAMA)	7

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 #
<u>92028</u>		Progensa® PCA3	8/5/2014	7

8/5/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

92545		Celiac Genetics	8/11/2014	7
		Collection Instructions Update to BloodCenter of Wisconsin, Inc.	8/11/2014	8
92535		Mold Susceptibility, 5 Drug	9/22/2014	8

Due to the background information related to these changes, we are unable to use our normal method of communication. These changes listed in this document are effective in less than 30 days. Please note the individual effective dates below, as some of these changes require IMMEDIATE ACTION.

New Test Offerings

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

Celiac Disease Serology																																		
Message	Includes: Gliadin Antibody, IgA*Gliadin Antibody, IgG*Tissue Transglutaminase IgA Antibody (tTG) *Endomysial Antibody Screen (IgA), Reflex to Titer*Immunoglobulin A (IgA)																																	
Effective Date	8/11/2014																																	
Test Code	12786																																	
CPT Codes	82784, 83516 (x3), 86255																																	
Specimen Requirements	4 mL (1.7 mL minimum) serum collected in a red-top tube(no gel)																																	
Transport Temperature	Refrigerated																																	
Specimen Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 21 days																																	
Set-up/Analytic Time	Set up: Mon-Fri; Report available: Next day																																	
Reference Range	See individual tests																																	
Methodology	Enzyme Immunoassay, Indirect Immunofluorescence Assay, Immunoturbidimetric																																	
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>12786A</td> <td>Interpretive Comment:</td> <td></td> </tr> <tr> <td>45073600</td> <td>IgA</td> <td>mg/dL</td> </tr> <tr> <td>79732</td> <td>Gliadin(Deamidated) Ab,IgG</td> <td></td> </tr> <tr> <td>79742</td> <td>Gliadin(Deamidated) Ab,IgA</td> <td></td> </tr> <tr> <td>40000700</td> <td>tTG IgA Ab</td> <td>U/mL</td> </tr> <tr> <td>45060440</td> <td>Endomysial Ab (IgA) Screen</td> <td></td> </tr> <tr> <td>15064B</td> <td>Additional Testing</td> <td></td> </tr> <tr> <td colspan="3"><i>This test is a true reflex. Please build the unit code below separately. Non-orderable Reflex: 18008 Endomysial Ab Titer</i></td> </tr> <tr> <th>Result Code</th> <th>Result Name</th> <th></th> </tr> <tr> <td>45060445</td> <td>Endomysial Ab Titer</td> <td></td> </tr> </tbody> </table>	Result Code	Result Name	Unit of Measure	12786A	Interpretive Comment:		45073600	IgA	mg/dL	79732	Gliadin(Deamidated) Ab,IgG		79742	Gliadin(Deamidated) Ab,IgA		40000700	tTG IgA Ab	U/mL	45060440	Endomysial Ab (IgA) Screen		15064B	Additional Testing		<i>This test is a true reflex. Please build the unit code below separately. Non-orderable Reflex: 18008 Endomysial Ab Titer</i>			Result Code	Result Name		45060445	Endomysial Ab Titer	
Result Code	Result Name	Unit of Measure																																
12786A	Interpretive Comment:																																	
45073600	IgA	mg/dL																																
79732	Gliadin(Deamidated) Ab,IgG																																	
79742	Gliadin(Deamidated) Ab,IgA																																	
40000700	tTG IgA Ab	U/mL																																
45060440	Endomysial Ab (IgA) Screen																																	
15064B	Additional Testing																																	
<i>This test is a true reflex. Please build the unit code below separately. Non-orderable Reflex: 18008 Endomysial Ab Titer</i>																																		
Result Code	Result Name																																	
45060445	Endomysial Ab Titer																																	

Additional Information	If the Endomysial Antibody (IgA) Screen (CPT: 86255) is positive, an Endomysial Antibody Titer will be performed at an additional charge (CPT: 86256).
------------------------	--

Leishmania Antibody (IgG)					
Clinical Significance	Detection of Leishmania IgG provides strong support for the diagnosis of visceral leishmaniasis. Some (but not all) patients with cutaneous leishmaniasis also have detectable serum levels of Leishmania IgG. Sera from patients with <i>Trypanosoma cruzi</i> infection (Chagas' disease) show significant cross-reactivity in the Leishmania IgG assay.				
Effective Date	9/8/2014				
Test Code	92480				
CPT Codes	86717				
Specimen Requirements	0.2 mL (0.1 mL minimum) serum				
Reject Criteria	Gross hemolysis; grossly lipemic				
Transport Temperature	Room temperature				
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days				
Set-up/Analytic Time	Set up: Wed; Report available: 1-8 days				
Reference Range	< 1.00 Interpretive Criteria: < 1.00 Negative > or = 1.00 Positive				
Always Message	This assay is intended to aid in the diagnosis of visceral leishmaniasis. Its use in diagnosing cutaneous leishmaniasis is limited, since a detectable antibody response is often absent in this form of the disease. Sera from patients with Chagas' disease (<i>Trypanosoma cruzi</i> infection) may be positive in this assay; thus, results should be used in conjunction with other clinical findings when considering a diagnosis of leishmaniasis. This assay was developed and its performance characteristics have been determined by Focus Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.				
Methodology	Enzyme Immunoassay				
Performing Site	Focus Diagnostics, Inc.				
CPU Mappings	<table border="1" style="width: 100%;"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011308</td> <td>Leishmania Antibody (IgG)</td> </tr> </tbody> </table>	Result Code	Result Name	86011308	Leishmania Antibody (IgG)
Result Code	Result Name				
86011308	Leishmania Antibody (IgG)				

NAbFeron® (IFNB-1) Neutralizing Antibody Test	
Clinical Significance	Detection of neutralizing antibodies to interferonB-1.
Effective Date	10/13/2014
Former Test Code	CHY 900581
Test Code	38007
CPT Codes	86382
Specimen Requirements	2 mL (2 mL minimum) serum

Instructions	Sample needs to be collected either before treatment with interferon or more than 24 hours following the most recent dose. Patient should not be on steroid therapy for at least two weeks prior to testing. Please label each specimen tube with two forms of patient identification. These forms of identification must also appear on the requisition form.									
Transport Temperature	Refrigerated									
Specimen Stability	Room temperature: 72 hours Refrigerated: 14 days Frozen: Unacceptable									
Set-up/Analytic Time	Set up: Wednesday; Report available: 7-14 days									
Reference Range	Normal titer: <1:20 Mild/Moderate Elevated titer: > or = 1:20 - < or = 1:100 Highly Elevated titer: >1:100									
Methodology	Viral Cytopathic Effect Assay									
Performing Site	Athena Diagnostics, Inc.									
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011382</td> <td>Interpretation</td> </tr> <tr> <td>86000688</td> <td>NAb Titer</td> </tr> <tr> <td>86011385</td> <td>Comments</td> </tr> </tbody> </table>		Result Code	Result Name	86011382	Interpretation	86000688	NAb Titer	86011385	Comments
Result Code	Result Name									
86011382	Interpretation									
86000688	NAb Titer									
86011385	Comments									

Test Changes

The following test changes will be effective on the dates indicated below. **Please note information that is changing appears in bold text in this update.** Former test names and test codes have been italicized.

TSI (Thyroid Stimulating Immunoglobulin)	
Effective Date	8/18/2014
Test Code	30551
Reference Range	< 140 % baseline
Units Of Measure	% baseline
Always Message	<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. TSI results greater than or equal to (\geq) 140% of the Reference Control are considered positive.</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> <p>Patients who are pregnant and are suspected of having hyperthyroidism should have both a TSI and human Chorionic Gonadotropin (hCG) tests measured. A serum hCG level greater than 40,625 mIU/mL can interfere with the TSI bioassay and may give false negative results. In these patients it is recommended that a second TSI is obtained when the hCG concentration falls below 40,625 mIU/mL (usually after approximately 20-weeks gestation).</p>
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

MuSK Quantitative Titers Antibody Test

8/5/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Effective Date	9/22/2014
Test Code	S50437
Reference Range	<1:10
Performing Site	Athena Diagnostics, Inc.
Additional Information	Results will be reported as a titer.

Neuromyelitis Optica (NMO)	
Effective Date	9/22/2014
<i>Former Test Name</i>	<i>Neuromyelitis Optica IgG Autoantibody Test</i>
Test Code	S52438
Reference Range	<3.0
Performing Site	Athena Diagnostics, Inc.
Additional Information	Negative results will be displayed on the report as <3.0

Sensory Neuropathy Profile-xp	
Effective Date	9/22/2014
Test Code	S49551
Reference Range	SGPG: <=1:3200 MAG: <=1:1600 Sulfatide: <1:2000
Performing Site	Athena Diagnostics, Inc.
Additional Information	The report format will be changed from portrait to landscape, the result table will be modified, results will be reported as a titer, sulfatide test has new reference ranges.

Sulfatide Autoantibody Test	
Effective Date	9/22/2014
Test Code	S48689
Reference Range	<1:2000
Performing Site	Athena Diagnostics, Inc.
Additional Information	The report format will be changed from portrait to landscape, the result table will be modified, and reference ranges will change.

Interferon-beta IgG, MAID (Reflex to Neutralization)									
Effective Date	10/13/2014								
Test Code	S51553								
Performing Site	Focus Diagnostics, Inc.								
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>110729</td> <td>Prompt-Result</td> <td>Interferon-Beta Used for Treatment:</td> </tr> </tbody> </table>	Result Code	Type	Result Name	110729	Prompt-Result	Interferon-Beta Used for Treatment:		
Result Code	Type	Result Name							
110729	Prompt-Result	Interferon-Beta Used for Treatment:							

	110730	Interferon-beta IgG
	<p><i>This test is a true reflex performed at Athena Diagnostics, Inc. Please build the unit code below separately. Orderable Reflex: 38007 NAbFeron (IFNB-1) Neutralizing Antibody</i></p>	
	Result Code	Result Name
	86011382	Interpretation:
	86000688	Nab Titer:
	86011385	Comments:
Additional Information	If the Interferon-beta IgG is > or = 4.0, NAbFeron® (IFNB-1) Neutralizing Antibody will be performed at an additional charge (CPT code(s): 86382).	

Discontinued Tests

Celiac Disease Panel #2	
Effective Date	8/11/2014
Test Code	18115
Additional Information	The recommended alternative is 12786 -Celiac Disease Serology in New Test Offering section.

HLA Typing for Celiac Disease	
Effective Date	8/11/2014
Test Code	S51543
Additional Information	The recommended alternative is test code 92545 - Celiac Genetics , in the Test Send Out Section.

Thyroid Stimulating IG (NY)	
Effective Date	8/18/2014
Test Code	S51609NY
Additional Information	The recommended alternative is test code 30551.

Leishmania Antibody, IFA					
Effective Date	9/8/2014				
Test Code	S51554				
Additional Information	The recommended alternative is test code 92480- Leishmania Antibody (IgG) in New Test Offering section.				
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>A49162</td> <td>ALT- Leishmania IFA</td> </tr> </table>	Test Codes:	Name:	A49162	ALT- Leishmania IFA
Test Codes:	Name:				
A49162	ALT- Leishmania IFA				

Focus Antifungal Susceptibility Test Deletions

8/5/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Effective Date	9/22/2014	
Additional Information	The following test codes will be discontinued. The recommended alternative is 92535-Mold Susceptibility, 5 Drug in the Test Send Out section.	
Tests Affected	Test Codes:	Name:
	S51044	Antifungal Susceptibility, Mold, Custom MIC (1)
	S52338	Antifungal Susceptibility, Mold, Custom MIC (2)
	S52384	Antifungal Susceptibility, Mold, Custom MIC (3)
	S50007	Antifungal Susceptibility, Mold, MIC Panel

Interferon-beta 1a (IFNB-1a) AB	
Effective Date	10/13/2014
Test Code	S52051
Additional Information	The recommended alternative is 38007- NAbFeron® (IFNB-1) Neutralizing Antibody Test in the New Test Offering section.

Interferon-beta 1b (IFNB-1b) Ab	
Effective Date	10/13/2014
Test Code	S52052
Additional Information	The recommended alternative is 38007- NAbFeron® (IFNB-1) Neutralizing Antibody Test in the New Test Offering section.

New York Patient Testing Update

Human Anti-mouse Antibody (HAMA)	
Message	**This test <i>is approved</i> for New York patient testing**
Test Code	1468

Test Send Out (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**.

Progensa® PCA3	
Effective Date	8/5/2014
Test Code	92028
Reference Range	PCA3 Score: 0-24 PCA3/PSA x 1000 Result: Negative Interpretation:

Units Of Measure	PCA3 Score: PCA3/PSA x 1000
Always Message	<p>Test Completed PCA3 and PSA mRNAs are quantitated by Nucleic Acid Amplification using Gen-Probe APTIMA technology. Clinical urine specimens are transported in solutions that preserve mRNA. Specific sequence DNA-coated magnetic beads are used to purify target mRNA, removing substances potentially inhibitory to amplification. Transcription-mediated amplification targets exon 3 and 4 of PCA3 and exon 2 and 3 of PSA. Amplicon products are detected by hybridization to complementary DNA probes labeled with acridinium esters that specifically target the PSA and PCA3 nucleic acid sequences. Diagnostic amplicons are quantitated with a luminometer. Detection of PSA verifies recovery of prostate cells in urine. PCA3 is highly overexpressed in prostate cancers. PCA3 expression is normalized to PSA and reported as a ratio of PCA3/PSA x 1000. The PCA3 score correlates with risk of prostate cancer on repeat biopsies.</p> <p>Test Limitations The ProgenSA PCA3 Assay is an In Vitro Diagnostic nucleic acid amplification test used to measure the concentration of prostate cancer gene 3 (PCA3) and prostate-specific antigen (PSA) RNA molecules and calculate the ratio of PCA3 RNA molecules to PSA RNA molecules (PCA3 Score) in post-digital rectal exam (DRE) first catch male urine specimens. Avero Diagnostics is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity testing. Testing performed at Avero Diagnostics, 6221 Riverside Drive, Suite 119, Irving TX, 75039. CLIA# 45D1069527.</p> <p>Removal of the below text: Reference Intervals Negative: 0-24 PCA3/PSA x 10(-3) Positive: >25 PCA3/PSA x 10(-3)</p> <p>Test References Groskopf, J., et.al <i>Clinical Chemistry</i> 2006:52 (6) 1089-1095 Marks, L.S., Y. Fradet, et.al. (2007). "PCA3 molecular urine assay for prostate cancer in men undergoing repeat biopsy <i>Urology</i> 69:532-535</p>

Celiac Genetics					
Effective Date	8/11/2014				
Test Code	92545				
CPT Codes	81382 (x2)				
Specimen Requirements	10 mL (3 mL minimum) whole blood collected in an ACD (yellow-top) tube				
Reject Criteria	Unlabeled tubes; samples past stability; improper specimen collection				
Instructions	Requisition and tube label must match with complete name and at least one 2 nd identifier				
Transport Temperature	Room temperature Note: Samples should not be shipped on Saturday or the day before a holiday to ensure viability. Please refer to UCLA Holiday Schedule Calendar.				
Specimen Stability	Room temperature: 5 days Refrigerated and Frozen: Not established				
Set-up/Analytic Time	Set up: As required; Report available: 8 days CHY Report available: 10 days				
Reference Range	See Laboratory Report				
Always Message	This test was developed and performance characteristics determined by the UCLA Immunogenetics Center, Department of Pathology and Laboratory Medicine. They have not been cleared or approved by the US Food and Drug Administration.				
Methodology	Polymerase Chain Reaction, Sequence Specific Oligonucleotide Probes				
CPU Mappings	<p>Please note: report to follow by mail</p> <table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011389</td> <td>Celiac Genetics</td> </tr> </tbody> </table>	Result Code	Result Name	86011389	Celiac Genetics
Result Code	Result Name				
86011389	Celiac Genetics				

Collection Instructions Update to BloodCenter of Wisconsin, Inc.																			
Effective Date	8/11/2014																		
Instructions	<p>For Adult patients: If requesting more than one panel for HLA Transplant Testing, no more than 14 mL whole blood collected in EDTA (lavender-top) tubes is required.</p> <p>For Pediatric patients: If requesting more than one panel for HLA Transplant Testing, follow drawing instructions according to age as specified. No more than what is specified by age is required.</p>																		
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>92158</td> <td>HLA- AB Intermediate Resolution Typing for Transplantation</td> </tr> <tr> <td>92157</td> <td>HLA- ABC Intermediate Resolution Typing for Transplantation</td> </tr> <tr> <td>92159</td> <td>HLA- DR, DQ Intermediate Resolution Typing for Transplantation</td> </tr> <tr> <td>92160</td> <td>HLA- DRB1 Intermediate Resolution Typing for Transplantation</td> </tr> <tr> <td>17397</td> <td>HLA-A High Resolution</td> </tr> <tr> <td>17396</td> <td>HLA-B High Resolution</td> </tr> <tr> <td>17394</td> <td>HLA-DQB1 High Resolution</td> </tr> <tr> <td>17393</td> <td>HLA-DRB1 High Resolution</td> </tr> </tbody> </table>	Test Codes:	Name:	92158	HLA- AB Intermediate Resolution Typing for Transplantation	92157	HLA- ABC Intermediate Resolution Typing for Transplantation	92159	HLA- DR, DQ Intermediate Resolution Typing for Transplantation	92160	HLA- DRB1 Intermediate Resolution Typing for Transplantation	17397	HLA-A High Resolution	17396	HLA-B High Resolution	17394	HLA-DQB1 High Resolution	17393	HLA-DRB1 High Resolution
Test Codes:	Name:																		
92158	HLA- AB Intermediate Resolution Typing for Transplantation																		
92157	HLA- ABC Intermediate Resolution Typing for Transplantation																		
92159	HLA- DR, DQ Intermediate Resolution Typing for Transplantation																		
92160	HLA- DRB1 Intermediate Resolution Typing for Transplantation																		
17397	HLA-A High Resolution																		
17396	HLA-B High Resolution																		
17394	HLA-DQB1 High Resolution																		
17393	HLA-DRB1 High Resolution																		

Mold Susceptibility, 5 Drug																						
Message	**This test is not approved for New York patient testing.**																					
Effective Date	9/22/2014																					
Test Code	92535																					
CPT Codes	87188 (X5)																					
Specimen Requirements	Pure isolate collected on a slant in a double walled container																					
Transport Temperature	Room temperature																					
Specimen Stability	Room temperature and Refrigerated: 30 days Frozen: Unacceptable																					
Set-up/Analytic Time	Set up: Mon; Report available: 2-7 days																					
Methodology	Broth Macrodilution																					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011373</td> <td>Prompt-Result</td> <td>Organism</td> </tr> <tr> <td>86011374</td> <td></td> <td>Fluconazole</td> </tr> <tr> <td>86011375</td> <td></td> <td>Amphotericin B</td> </tr> <tr> <td>86011376</td> <td></td> <td>5-Fluorocytosine</td> </tr> <tr> <td>86011377</td> <td></td> <td>Itraconazole</td> </tr> <tr> <td>86011378</td> <td></td> <td>Voriconazole</td> </tr> </tbody> </table>	Result Code	Type	Result Name	86011373	Prompt-Result	Organism	86011374		Fluconazole	86011375		Amphotericin B	86011376		5-Fluorocytosine	86011377		Itraconazole	86011378		Voriconazole
Result Code	Type	Result Name																				
86011373	Prompt-Result	Organism																				
86011374		Fluconazole																				
86011375		Amphotericin B																				
86011376		5-Fluorocytosine																				
86011377		Itraconazole																				
86011378		Voriconazole																				

