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 #**
12786	**Celiac Disease Serology**	8/11/2014	2
92480	**Leishmania Antibody (IgG)**	9/8/2014	2
38007	**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 #**
30551		TSI (Thyroid Stimulating Immunoglobulin)	8/18/2014	4
S50437		MuSK Quantitative Titers Antibody Test	9/22/2014	4
S52438		**Neuromyelitis Optica (NMO)**	9/22/2014	4
S49551		Sensory Neuropathy Profile-xp	9/22/2014	5
S48689		Sulfatide Autoantibody Test	9/22/2014	5
S51553		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 #**
18115	Celiac Disease Panel #2	8/11/2014	5
S51543	HLA Typing for Celiac Disease	8/11/2014	6
S51609NY	Thyroid Stimulating IG (NY)	8/18/2014	6
S51554	Leishmania Antibody, IFA	9/8/2014	6
	Focus Antifungal Susceptibility Test Deletions	9/22/2014	6
S52051	Interferon-beta 1a (IFNB-1a) AB	10/13/2014	6
S52052	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 #**
1468	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 #**
92028		Progensa® PCA3	8/5/2014	7

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	

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	
This test is a true reflex. Please build the unit code below separately. ***Non-orderable Reflex: 18008 Endomysial Ab Titer***		
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 *Trypanosoma cruzi* 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 (Trypanosoma cruzi 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	**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	**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	**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 (>=) 140% of the Reference Control are considered positive.** **NOTE: A serum TSH level greater than 350 micro-International Units/mL can interfere with the TSI bioassay and potentially give false positive results.** **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).**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

MuSK Quantitative Titers Antibody Test

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**
Former Test Name	*Neuromyelitis Optica IgG Autoantibody Test*
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	

Result Code	Type	Result Name
110729	Prompt-Result	Interferon-Beta Used for Treatment:

	110730 | | Interferon-beta IgG ***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*** **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	**Test Codes:** | **Name:** A49162 | ALT- Leishmania IFA

Focus Antifungal Susceptibility Test Deletions

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 **is approved** 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	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. 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. **Removal of the below text:** **Reference Intervals** **Negative: 0-24 PCA3/PSA x 10(-3)** **Positive: >25 PCA3/PSA x 10(-3)** **Test References** **Groskopf, J., et.al Clinical Chemistry 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 Urology 69:532-535**

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 2nd 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	**Please note: report to follow by mail**

Result Code	Result Name
86011389	Celiac Genetics

Collection Instructions Update to BloodCenter of Wisconsin, Inc.	
Effective Date	**8/11/2014**
Instructions	**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.** **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.**
Tests Affected	

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	

Result Code	Type	Result Name
86011373	**Prompt-Result**	**Organism**
86011374		**Fluconazole**
86011375		**Amphotericin B**
86011376		**5-Fluorocytosine**
86011377		**Itraconazole**
86011378		**Voriconazole**