Laboratory Update





March 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

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	Code Former Test Code Test Name Effective Date Page #					
1286		Gliadin (Deamidated Peptide) Antibody (IgA)	4/10/2012	1		
1261		Gliadin (Deamidated Peptide) Antibody (IgG)	4/10/2012	2		
1266		Gliadin (Deamidated Peptide) Antibody (IgG,IgA)	4/10/2012	3		
8944		Lyme Disease C6 Antibodies,Total, ELISA	4/17/2012	4		
3541		Vitamin D, 25-Hydroxy Total [LC/MS/MS]	4/17/2012	4		
8315UR		Histoplasma Antigen Urine	4/24/2012	5		
8157		Hypersensitivity Evaluation II	4/24/2012	5		
8156		Hypersensitivity Pneumonitis Evaluation	4/24/2012	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 Code Test Name Effective Date Page #					
EX1	Allergen IgE Mixes	4/17/2012	5			
2344	Candida albicans Evaluation	4/17/2012	7			
2343	Candida albicans IgG, IgM & IgA Antibodies	4/17/2012	7			
4891	Leptin	4/17/2012	8			
3830	Mannose-Binding Protein	4/17/2012	8			

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 #						
30440		4/17/2012	8				
90367	Leptin (90367) 4/17/2012 9						
16039		Mannose-binding Lectin (MBL) (16039)	4/17/2012	10			

Test Changes

The following test changes will be effective on the dates indicated below. **Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized.** Additional information, regarding the change, will be provided where applicable.

Gliadin (Deamidated Peptide) Antibody (IgA)				
Clinical Significance	Celiac disease or gluten sensitive entropathy is a chronic condition that damages the lining of the small intestine and results in a malabsorption syndrome. Detection of antibodies to gliadin, one of the major protein components of gluten, is useful in diagnosing celiac disease. However, gliadin antibodies may be found in individuals without celiac disease; thus gliadin antibody assays are less specific than assays measuring antibodies to endomysium and transglutaminase. Recent work has revealed that gliadin-reactive antibodies from celiac patients bind to a very limited number of specific epitopes on the gliadin molecule. Further, deamidation of gliadin results in enhanced binding of gliadin antibodies. Based on this information, assays using deaminated gliadin peptides bearing the celiac-specific epitopes have much			

	higher diagnostic	accurac	cy for celiac disease when compared to standard gliadin antibody assays.		
Effective Date	4/10/2012	4/10/2012			
Former Test Name	Gliadin Antibody (IgA				
Test Code	1286				
Specimen Requirements	1 mL serum (0.5 n	nL mini	mum)		
Reject Criteria	Gross hemolysis	or gros	s lipemia		
Reference Range	< 20 units Ant	Gliadin (Deamidated) Ab, (IgA) < 20 units Antibody Not Detected > or = 20 units Antibody Detected			
CPU Mappings	Result Code		Result Name		
	12461		Gliadin (Deamidated Peptide) Antibody (IgA)		
Tests Affected	Test Codes:	Na	me:		
	1076	Celiac Disease Autoantibodies Evaluation			
	1075	Celiac Disease EvaluatR™ with IgA			
	P6425A	CU	STOM QVMC CELIAC DISEASE PANEL		
	P48580A	CU	STOM VA ROSEBURG CELIAC COMPREHENSIVE AB PANEL		
	P433210	CU	STOM ADL CELIAC PANEL		
	P8019B	CUSTOM ETCH TRANSGLUTAMINASE & CELIAC PANEL			
	1077	Celiac Disease EvaluatR™			
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Gliadin (Deamidated Peptide) Antibody (IgG)			
Clinical Significance	Celiac disease or gluten sensitive entropathy is a chronic condition that damages the lining of the small intestine and results in a malabsorption syndrome. Detection of antibodies to gliadin, one of the major protein components of gluten, is useful in diagnosing celiac disease. However, gliadin antibodies may be found in individuals without celiac disease; thus gliadin antibody assays are less specific than assays measuring antibodies to endomysium and transglutaminase. Recent work has revealed that gliadin-reactive antibodies from celiac patients bind to a very limited number of specific epitopes on the gliadin molecule. Further, deamidation of gliadin results in enhanced binding of gliadin antibodies. Based on this information, assays using deaminated gliadin peptides bearing the celiac-specific epitopes have much higher diagnostic accuracy for celiac disease when compared to standard gliadin antibody assays.		
Effective Date	4/10/2012		
Former Test Name	Gliadin Antibody (IgG)		
Test Code	1261		
Specimen Requirements	1 mL serum (0.5 mL minimum)		
Reject Criteria	Gross hemolysis or gross lipemia		
Reference Range	Gliadin (Deamidated) Ab, (IgG) < 20 units		
CPU Mappings	Result Code Result Name 12456 Gliadin (Deamidated Peptide) Antibody (IgG)		

Tests Affected	Test Codes:	Name:
	1076	Celiac Disease Autoantibodies Evaluation
	1075	Celiac Disease EvaluatR™ with IgA
	P6425A	CUSTOM QVMC CELIAC DISEASE PANEL
	P48580A	CUSTOM VA ROSEBURG CELIAC COMPREHENSIVE AB PANEL
	P433210	CUSTOM ADL CELIAC PANEL
	P8019B	CUSTOM ETCH TRANSGLUTAMINASE & CELIAC PANEL
	1077	Celiac Disease EvaluatR™

Gliadin (Deamidated Peptide) Antibody (IgG,IgA)					
Clinical Significance	intestine and resul protein componen found in individual measuring antibod reactive antibodies molecule. Further, information, assay	Celiac disease or gluten sensitive entropathy is a chronic condition that damages the lining of the small intestine and results in a malabsorption syndrome. Detection of antibodies to gliadin, one of the major protein components of gluten, is useful in diagnosing celiac disease. However, gliadin antibodies may be found in individuals without celiac disease; thus gliadin antibody assays are less specific than assays measuring antibodies to endomysium and transglutaminase. Recent work has revealed that gliadin-reactive antibodies from celiac patients bind to a very limited number of specific epitopes on the gliadin molecule. Further, deamidation of gliadin results in enhanced binding of gliadin antibodies. Based on this information, assays using deaminated gliadin peptides bearing the celiac-specific epitopes have much higher diagnostic accuracy for celiac disease when compared to standard gliadin antibody assays.			
Effective Date	4/10/2012				
Former Test Name	Gliadin Antibody (lgG,lg/	4)		
Test Code	1266				
Specimen Requirements	1 mL serum (0.5 m	L mini	imum)		
Reject Criteria	Gross hemolysis o	r gros	ss lipemia		
Reference Range	< 20 units Ant > or = 20 units Ant Gliadin (Deamidate < 20 units Ant	> or = 20 units Antibody Detected Gliadin (Deamidated) Ab, (IgG)			
CPU Mappings	Result Code		Result Name		
	12456		Gliadin (Deamidated Peptide) Antibody (IgG)		
	12461		Gliadin (Deamidated Peptide) Antibody (IgA)		
Tests Affected	Test Codes:	Na	ime:		
	1076	Се	eliac Disease Autoantibodies Evaluation		
	1075	Се	sliac Disease EvaluatR™ with IgA		
	P6425A	CU	ISTOM QVMC CELIAC DISEASE PANEL		
	P48580A	CU	ISTOM VA ROSEBURG CELIAC COMPREHENSIVE AB PANEL		
	P433210	CUSTOM ADL CELIAC PANEL			

March 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

P8019B	CUSTOM ETCH TRANSGLUTAMINASE & CELIAC PANEL
1077	Celiac Disease EvaluatR™

Lyme Disease C6 Antibodies,Total, ELISA					
Effective Date	4/17/2012	4/17/2012			
Former Test Name	Borrelia burgdorferi C	6 Pepti	de Antibodies DetectR™		
Test Code	8944				
Specimen Requirements	1 mL (0.3 mL) Serum I Acceptable: SST	Red top	(no gel)		
Transport Temperature	Room temperature				
Specimen Stability	Room temperature: 4 Refrigerated: 7 days Frozen:30 days				
Reference Range	<0.91 Negative				
Always Message	<0.91 Negative 0.91-1.09 Equivocal >1.09 Positive	0.91-1.09 Equivocal			
CPU Mappings	Result Code		Result Name		
	200583		Lyme Disease C6 Antibodies,Total, ELISA		
Tests Affected					
rests / triceted	Test Codes:	Nar	ne:		
	8954	Bori	relia burgdorferi IgG & IgM Antibodies [EIA] plus C6 Peptide		
	6906	Bor	relia burgdorferi Panel		
	0900	DOF	ielia bulguonen Fanei		

Vitamin D, 25-Hydroxy Total [LC/MS/MS]				
Effective Date 4/17/2012				
Test Code	3541			
Instructions	Collect blood in a standard red-top serum vacutainer tube. Allow blood to clot at room temperature. Centrifuge and separate the serum from the cells immediately. Alternatively, collect blood in an SST, allow to clot at room temperature, centrifuge and remove from the gel within 48 hours.			

Histoplasma Antigen Urine				
Effective Date 4/24/2012				
Test Code	8315UR			
Always Message	This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.			
Assay Category	Laboratory Developed Test			

Hypersensitivity Evaluation II	
Effective Date	4/24/2012

Test Code	8157			
CRI Manniana				
CPU Mappings	Result Code	Result Name		
	23422	Saccharopolyspora rectivirgula		
		·		

Hypersensitivity Pneumonitis Evaluation			
Effective Date	4/24/2012		
Test Code	8156		
CPU Mappings			
	Result Code	Result Name	
	20191	Saccharopolyspora rectivirgula	

Discontinued Tests

Allergen IgE Mixes				
Message	There are no sugges	There are no suggested replacement tests.		
Effective Date	4/17/2012			
Test Code	EX1			
Tests Affected	Test Codes:	Name:		
	EX1	Allergen-Animal Epidermals & Proteins Mix IgE: EX1		
	EX2	Allergen-Animal Epidermals & Proteins Mix IgE: EX2		
	EX70	Allergen-Animal Epidermals & Proteins Mix IgE: EX70		
	EX71	Allergen - Mixed Feathers IgE: EX71		
	FX1	Allergen-Food Mix IgE - Nuts: FX1		
	FX2	Allergen-Food Mix IgE - Seafood: FX2		
	FX3	Allergen-Food Mix IgE - Cereal: FX3		
	FX5E	Allergen-Food Mix IgE - Children's: FX5E		
	FX7	Allergen-Food Mix IgE - Misc: FX7		
	FX8	Allergen-Food Mix IgE - Fruit & Nut: FX8		
	FX9	Allergen-Food Mix IgE - Fruit & Nut: FX9		
	FX10	Allergen-Food Mix IgE - Meat & Egg: FX10		
	FX13	Allergen-Food Mix IgE - Vegetables: FX13		
	FX14	Allergen-Food Mix IgE - Vegetables: FX14		
	FX15	Allergen-Food Mix IgE - Fruit: RFX15		
	FX16	Allergen-Food Mix IgE - Fruit: FX16		
	FX18	Allergen-Food Mix IgE - Vegetables: FX18		
	FX20	Allergen-Food Mix IgE - Grain: FX20		

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FX23	Allergen-Food Mix IgE - Meat: FX23
FX24	Allergen-Food Mix IgE - Misc: FX24
FX25	Allergen-Food Mix IgE - Misc: FX25
FX70	Allergen-Food Mix IgE - Spices: FX70
FX71	Allergen-Food Mix IgE - Spices: FX71
FX72	Allergen-Food Mix IgE - Spices: FX72
FX73	Allergen-Food Mix IgE - Meat: FX73
FX74	Allergen-Food Mix IgE - Fish: FX74
GX1	Allergen-Grass Mix IgE: GX1
GX2	Allergen-Grass Mix IgE: GX2
GX3	Allergen-Grass Mix IgE: GX3
GX4	Allergen-Grass Mix IgE: GX4
HX2	Allergen-House Dust Mix: HX2
MX1	Allergen-Molds & Yeasts Mix IgE: MX1
MX2	Allergen-Molds & Yeasts Mix IgE: MX2
PAX1	Allergen-Occupational Mix IgE: PAX1
PAX3	Allergen-Occupational Mix IgE: PAX3
PAX5	Allergen-Occupational Mix IgE: PAX5
PAX6	Allergen-Occupational Mix IgE: PAX6
RFX11	Allergen-Food Mix IgE - Vegetables: RFX11
RFX17	Allergen-Food Mix IgE - Fruit: RFX17
RFX21	Allergen-Food Mix IgE - Fruit: RFX21
RFX22	Allergen-Food Mix IgE - Nuts: RFX22
RGX6	Allergen-Grass Mix IgE: RGX6
RRX1	Allergen-Regional Mix IgE: RRX1
RRX2	Allergen-Regional Mix IgE: RRX2
RRX3	Allergen-Regional Mix IgE: RRX3
RRX4	Allergen-Regional Mix IgE: RRX4
RTX10	Allergen-Tree Pollen Mix IgE: RTX10
TX1	Allergen-Tree Pollen Mix IgE: TX1
TX2	Allergen-Tree Pollen Mix IgE: TX2
TX3	Allergen-Tree Pollen Mix IgE: TX3
TX4	Allergen-Tree Pollen Mix IgE: TX4
TX5	Allergen-Tree Pollen Mix IgE: TX5
TX6	Allergen-Tree Pollen Mix IgE: TX6
TX7	Allergen-Tree Pollen Mix IgE: TX7

March 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

TX8	Allergen-Tree Pollen Mix IgE: TX8
TX9	Allergen-Tree Pollen Mix IgE: TX9
WX1	Allergen-Weed Pollen Mix IgE: WX1
WX2	Allergen-Weed Pollen Mix IgE: WX2
WX3	Allergen-Weed Pollen Mix IgE: WX3
WX5	Allergen-Weed Pollen Mix IgE: WX4
WX6	Allergen-Weed Pollen Mix IgE: WX5
WX7	Allergen-Weed Pollen Mix IgE: WX6
P6053E	CUSTOM DECATUR INHALANT PANEL # 1
P6271E	CUSTOM REGIONAL FOOD ALLERGY PANEL
P6271F	CUSTOM REGIONAL FULL ALLERGY PANEL
P6271G	CUSTOM REGIONAL OUTDOOR/ANIMAL PANEL
P6920C	CUSTOM SOUTH GEORGIA BLACHE FOOD ALLERGY PANEL
P7493H	CUSTOM ST. JOHN'S PEDIATRIC PANEL
RW209	Allergen-Weed Pollen Mix IgE: RW209

Candida albicans Evaluation	
Message	Suggested replacement test code 30440 Candida albicans Antibodies (IgG, IgA and IgM) (20125) and 9190 Candida Antigen Detection.
Effective Date	4/17/2012
Test Code	2344

Candida albicans IgG, IgM & IgA Antibodies		
Message	Suggested replacement test code 30440 Candida albicans Antibodies (IgG, IgA and IgM) (20125)	
Effective Date	4/17/2012	
Test Code	2343	

Leptin		
Message Suggested replacement test code 90367 Leptin (90367).		
Effective Date	4/17/2012	
Test Code	4891	

Mannose-Binding Protein		
Message Suggested replacement test 16039 Mannose-binding Lectin (MBL)		
Effective Date	4/17/2012	
Test Code	3830	

Referral Tests

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.**

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

Candida albicans Antibodies (IgG, IgA, IgM) (20125)			
Message	Suggested replacement for tests 2343 and 2344. *** This test is not approved for New York patient testing.***		
Clinical Significance	Systemic candidiasis is often characterized by markedly elevated levels of Candida-specific antibodies. However, interpretation of Candida antibody results is complicated by detection of these antibodies in healthy individuals, and blunted antibody responses in immunocompromised patients.		
Effective Date	4/17/2012		
Test Code	30440		
CPT Codes	86628 x 3		
Specimen Requirements	1.0 mL (0.2 mL) Serum Red Top Tube or Serum Separator Tube		
Transport Temperature	Room temperature		
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days		
Set-up/Analytic Time	Set up: Mon-Fri; Report available: 2-4 days		
Reference Range	C. Albicans IgG <1.0		
	C. Albicans IgA <1.0		
	C. Albicans IgM <1.0		
Always Message	INTERPRETIVE CRITERIA: <1.0 Antibody not detected > or = 1.0 Antibody detected Systemic candidiasis is often characterized by markedly elevated levels of IgG, IgA, and IgM recognizing Candida. However, interpretation of Candida antibody levels is complicated by detection of antibodies in 20-30% of healthy individuals, and blunted antibody responses in immunocompromised patients at risk for systemic candidiasis. Candida		
	antibody results should be considered within the context of clinical findings and results from other relevant laboratory tests, such as Candida antigen detection and/or culture.		
	This test 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	ELISA		
Assay Category	Laboratory Developed Test		
Performing Site	Focus Diagnostics, Inc.		
CPU Mappings	Result Code Result Name 86005287 C. Albicans IgG		
	86005288 C. Albicans IgA		
	86005289 C. Albicans IgM		

Leptin (90367)				
Message	Suggested replacement for test code 4891.	Suggested replacement for test code 4891.		
Clinical Significance		Leptin is an adipocyte-derived hormone that is essential for normal body weight regulation. Leptin production is under neuroendocrine control so that serum concentrations vary directly with the amount of triglycerides stored in adipose tissue depots.		
Effective Date	4/17/2012			
Test Code	90367			
CPT Codes	82397			
Specimen Requirements	1.0 mL (0.2 mL) Serum Red Top Tube or Se	erum Separator Tube		
Reject Criteria	Hypericteric			
Transport Temperature	Refrigerated			
Specimen Stability	Room temperature: 8 hours Refrigerated: 14 days Frozen: 5 weeks	Refrigerated: 14 days		
Set-up/Analytic Time	Set up: Mon, Thur; Report available: 2-3 day	Set up: Mon, Thur; Report available: 2-3 days		
Units Of Measure	ng/mL	ng/mL		
Always Message	Males: 0.3-13.4 ng/mL Females: 4.7-23.7 ng/mL Adult Subjects (19-60 years) with BMI rang Males: 1.8-19.9 ng/mL Females: 8.0-38.9 ng/mL Pediatric Reference Ranges for Leptin: 5-9.9 years: 0.6-16.8 ng/mL 10-13.9 years: 1.4-16.5 ng/mL 14-17.9 years: 0.6-24.9 ng/mL This test was developed and its performance	Females: 4.7-23.7 ng/mL Adult Subjects (19-60 years) with BMI range of 25-30: Males: 1.8-19.9 ng/mL Females: 8.0-38.9 ng/mL Pediatric Reference Ranges for Leptin: 5-9.9 years: 0.6-16.8 ng/mL 10-13.9 years: 1.4-16.5 ng/mL		
Methodology	Electrochemiluminescence	Electrochemiluminescence		
Assay Category	Laboratory Developed Test	Laboratory Developed Test		
Performing Site	Quest Diagnostics Nichols Institute, San Jua	Quest Diagnostics Nichols Institute, San Juan Capistrano		
CPU Mappings	Result Code	Result Code Result Name		
	86007477	Leptin		
		ı		

Mannose-binding Lectin (MBL) (16039)		
Message	Suggested replacement for test code 3830.	
Clinical Significance	In conjunction with clinical findings and other laboratory tests, the deficiency of Mannose Binding Lectin (MBL) can be used to aid in the determination of susceptibility to infection.	
Effective Date	4/17/2012	
Test Code	16039	
CPT Codes	83520	

March 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

Specimen Requirements	1.0 mL (0.3 mL) Serum Red Top Tube or S	1.0 mL (0.3 mL) Serum Red Top Tube or Serum Separator Tube		
Reject Criteria	Hemolysis, Lipemia, Thawed Serum, Heat	Hemolysis, Lipemia, Thawed Serum, Heat treated, Specimens containing visible particulate matter		
Instructions	Overnight fasting is preferred. Do not submit specimens that have been Do not submit the sample in a glass tube.	Do not submit specimens that have been heat treated.		
Transport Temperature	Frozen	Frozen		
Specimen Stability	Room temperature: 4 hours Refrigerated: 4 hours Frozen: 21 days	Refrigerated: 4 hours		
Set-up/Analytic Time	Set up: Thu; Report available: 2-8 days	Set up: Thu; Report available: 2-8 days		
Units Of Measure	ng/mL	ng/mL		
Always Message	immune system. Clinical studies have use activate the classical complement pathwa deficiency has been associated with recu	DEFICIENT: <100 ng/mL		
Methodology	ELISA	ELISA		
Assay Category	Laboratory Developed Test	Laboratory Developed Test		
Performing Site	Quest Diagnostics Nichols Institute, San J	Quest Diagnostics Nichols Institute, San Juan Capistrano		
CPU Mappings	Result Code	Result Name		
	86000348	Mannose-binding lectin		