Laboratory Update
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Business Unit: Quest Diagnostics Nichols Institute, Valencia

June 2011 Update

Dear Colleague,

This letter begins with a thank you for your very prompt response to our recent request to visit our website and update your contact information. If you have not already done so, please take the opportunity at your convenience. Beginning next month, we will begin sending this letter in electronic form only.

Please note this important update from our billing team. If you are located in a Direct Billing state, effective 5/30/11, Quest Diagnostics Nichols Institute of Valencia will only be able to bill Medicaid for tests performed in our facility. This is in accordance with Medicaid guidelines. Please send all tests with requested Medicaid billing directly to the referral lab that is performing the test.

Thank you for choosing Quest Diagnostics Nichols Institute, Valencia and for your continued support. For additional information, we invite you to visit our Web site at *www.NicholsInstitute.com/Valencia* or contact Client Relations at 800-421-4449.

Respectfully Yours,

Basel Kashlan

Basel Kashlan, MD, FCAP
Laboratory Director

Table of Contents

Summary of Test Changes

Page Number	Test Name	Test Code(s)	Change in Performing Site	Test Code	Test Name	Specimen Requirements	Minimum Volume	Shipping Temperature	Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Test Code	Reject Criteria	Other (see listing)
6	Phosphatidylglycerol IgG, IgM and IgA Autoantibodies	1775											x			
6	Rheumatoid Factor IgG, IgM & IgA Autoantibodies	1012											x			
6	SureSwab™, Bacterial Vaginosis/Vaginitis	15509														x
6	ANAlyzer®	1000									x					x
7	Inhibin B	3982									x					
7	Microalbumin Urine Random	3441UR														x
7	Neuron-Specific Enolase	3860														x
7	Nuclear Matrix Proteins (NMP)	9620														x
8	Sex Hormone Binding Globulin (SHBG)	3218									x					

New Test Offerings

Microalbumin, Random Urine		
Clinical Significance:	Microalbumin is albumin excreted in the urine and is a sensitive marker of nephropathy. It is used to screen for early renal disease in diabetic patients.	
Effective Date:	**June 7, 2011**	
Test Code:	**3450U**	
CPT Code(s):	**82043**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Urine unpreserved** **5 mL** **2 mL** **Collect 5 mL of random urine. No preservative.**
Rejection Criteria:	**Urine specimens with preservative**	
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 7 days** **Refrigerated: 7 days** **Frozen: 28 days**	
Set-Up/Analytic Time:	**Set-up: Mon-Sat; Report Available: 1-2 days**	
Always Message	**The ADA (Diabetes Care 26: S94-S98, 2003) defines abnormalities in albumin excretion as follows:** **Category Result (mcg/mg creat)** **Normal <30** **microalbuminuria 30-299** **clinical albuminuria > or = 300** **The ADA recommends that at least two of three specimens collected within 3-6 month period be abnormal before considering a patient to be within a diagnostic category.**	
Methodology:	**Turbidimetry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Testosterone, Free and Total, LC/MS/MS *** This test is not available for New York patient testing. *** Clinical Significance:	Helpful in assessing testicular function in males and managing hirsutism, virilization in females.	
Effective Date:	**June 7, 2011**	
Test Code:	**3922**	
CPT Code(s):	**84402, 84403**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum, Plasma (Sodium Heparin), Plasma (Lithium Heparin)** **0.9 mL** **0.45 mL** **Collect blood in a red-top tube (no gel).**
Rejection Criteria:	**Serum separator tubes are unacceptable.**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: 7 days** **Refrigerated: 7 days** **Frozen: 2 years**	
Set-Up/Analytic Time:	**Set-up: Mon- Fri; Report Available: 2 to 4 days**	
Reference Ranges: **Testosterone, Total** **Testosterone, Free**	**Always Message - consistent with Testosterone, Total (LC/MS/MS). Full table available at www.QuestDiagnostics.com/NicholsInstitute**	
	Pediatric Reference ranges for Testosterone, Free (pg/mL) **Age Males Females** **5-9.9 years 5.3 or less 0.2-5.0** **10-13.9 years 0.7-52.0 0.1-7.4** **14-17.9 years 18.0-111.0 0.5-3.9** **Adult Reference Ranges for Testosterone, Free (pg/mL)** **Age Males Females** **18-69 years 35.0-155.0 0.1-6.4** **70-89 years 30.0-135.0 0.2-3.7**	
Methodology:	**Liquid Chromatography/Tandem Mass Spectrometry, Tracer Equilibrium Dialysis, Calculation**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Testosterone, Total & Free and Sex Hormone Binding Globulin *** This test is not available for New York patient testing. **		
Clinical Significance:	Testosterone circulates almost entirely bound to transport proteins: normally less than 1% is free. Measurement of Free Testosterone may be useful when disturbances in Sex Hormone Binding Globulin (SHBG) are suspected such as when patients are obese or have excessive estrogen. Testosterone measurements are used to assess erectile dysfunction, infertility, gynecomastia, and osteoporosis and to assess hormone replacement therapy.	
Effective Date:	**June 7, 2011**	
CPT Code(s):	**84270, 84402, 84403**	
Test Code:	**3231**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum** **3 mL** **1.5 mL** **Specify age and sex on test request form.**
Rejection Criteria:	**Serum separator tubes are unacceptable.**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: 5 days** **Refrigerated: 7 days** **Frozen: 2 years**	
Set-Up/Analytic Time:	**Set-up: Mon – Fri; Report Available: 2 to 4 days**	
Reference Ranges:	**Testosterone, Total**	**Always Message - consistent with Testosterone, Total (LC/MS/MS). Full table available at www.QuestDiagnostics.com/NicholsInstitute**
	Testosterone, Free	**Refer to Free Testosterone in DOS Code 3922 above.**
	Sex Hormone Binding Globulin	**Refer to Sex Hormone Binding Globulin in DOS Code 3218 in Test Changes section.**
Methodology:	**Liquid Chromatography/Tandem Mass Spectrometry, Tracer Equilibrium Dialysis, Calculation, Immunoassay**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

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 codes and test names have been italicized.

Phosphatidylglycerol IgG, IgM and IgA Autoantibodies	
Effective Date:	**Immediate**
Test Code:	**1775**
CPT Code(s):	**83520 x 3**
Additional Information:	**Also affected 1776,1780, 1781, 1782**

Rheumatoid Factor IgG, IgM & IgA Autoantibodies	
Effective Date:	**Immediate**
Test Code:	**1012**
CPT Code(s):	**83520 x 3**
Additional Information:	**Also affected 1011, 1013, 1017, 1019**

SureSwab™, Bacterial Vaginosis/Vaginitis	
Effective Date:	**Immediate**
Test Code:	**15509**
Always Message	**One paragraph modification only:** **The concentration of Lactobacilli are collectively reported under the term "*Lactobacillus* spp.", as these species are among the peroxide producing Lactobacilli thought to be protective against bacterial vaginosis. *Atopobium vaginae*, *Megasphaera* spp., and *Gardnerella vaginalis* (greater than 6.0 log cells/mL) have been associated with vaginosis when present in the absence of peroxide producing Lactobacilli.**
Additional Information:	**Also affects 16491, 16898, 17333**

ANAlyzer®		
Effective Date:	**June 7, 2011**	
Test Code:	**1000**	
Reference Ranges:	**nRNP/Sm IgG Autoantibodies**	**< 11**
	Sm (Smith) IgG Autoantibodies	**< 11**
	SS-A IgG Autoantibodies	**< 11**
	SS-B IgG Autoantibodies	**< 11**
	Scl-70 IgG Autoantibodies	**< 11**
	Ribosomal P Protein Autoantibodies	**< 11**
Always Statement:	**REFERENCE RANGE for nRNP, SS-A, SS-B, Sm, Scl-70 & Ribo Abs:** **< 11 Units Negative** **11-20 Units Borderline** **> 20 Units Positive**	
Additional Information:	**1004, 1005, 1006, 1007, 1126, 1127, 1204, 1205, 1210, 1215, 1220, 1235, 1271, Reflexes for tests 1118, 1121**	

Inhibin B		
Effective Date:	**June 7, 2011**	
Test Code:	**3982**	
Reference Ranges:	**Inhibin B**	**Male 47-308 pg/mL**
Always Message	**REFERENCE RANGE for Inhibin B:** **Male: 47-308 pg/mL** **Female: Pre-menopausal < 153 pg/mL** **Post-menopausal < 10 pg/mL**	

Microalbumin Urine Random		
Effective Date:	**June 7, 2011**	
Test Code:	**3441UR**	
Reference Ranges:	**Microalbumin (add)**	**Not Established mg/dL**
Methodology:	**Turbidimetry**	
Always Message	**The ADA (Diabetes Care 26: S94-S98, 2003) defines abnormalities in albumin excretion as follows:** **Category Result (mcg/mg creat)** **Normal < 30** **Microalbuminuria 30 – 299** **Clinical albuminuria > or = 300** **The ADA recommends that at least two of three specimens collected within 3-6 month period be abnormal before considering a patient to be within a diagnostic category.**	

Neuron-Specific Enolase	
Effective Date:	**June 7, 2011**
Test Code:	**3860**
Always Statement:	**This test was performed using EIA method. Values obtained with different assay methods cannot be used inter-changeably. NSE levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**
Additional Information:	**Also affects 3254, 3860C**

Nuclear Matrix Proteins (NMP)	
Test Code:	**9620**
Effective Date:	**June 7, 2011**
Always Statement	**This test was performed using EIA method. Values obtained with different assay methods cannot be used inter-changeably. NMP levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**

Sex Hormone Binding Globulin (SHBG)			
Effective Date:	**June 7, 2011**		
Test Code:	**3218**		
Reference Ranges:	**< 3 Years**	**Not established**	
		Male (nmol/L)	**Female (nmol/L)**
	3 – 9 Years	**32-158**	**32-158**
	10 – 13 Years	**10-166**	**24-120**
	14 – 17 Years	**20-87**	**12-150**
	18 – 55 Years	**10-50**	**17-124**
	> 55 Years	**22-77**	**14-73**
Rejection Criteria:	**Grossly hemolyzed specimens**		
Methodology:	**Immunoassay**		
Always Statement:	**Tanner Stages (7-17 Years)**	**Male (nmol/L)**	**Female (nmol/L)**
	Tanner I	**47-166**	**47-166**
	Tanner II	**23-168**	**25-129**
	Tanner III	**23-168**	**25-129**
	Tanner IV	**21-79**	**30-86**
	Tanner V	**9-49**	**15-130**
Additional Information:	**Also affects 3924**		

Test Discontinuations

Trisomy 13, 18 and 21 DetectR™ (PCR)	
Effective Date:	**Immediate**
Test Code:	**5857**
Additional Information:	No alternative available. Also affects 5857BK, 5855, 5855BK
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Hirsutism Evaluation (Female)	
Effective Date:	**June 7, 2011**
Test Code:	**3188**
Additional Information:	Suggested Alternate: : 3150 – Dehydroepiandrosterone-Sulfate (DHEA-S); 3190 – Hydroxyprogesterone, 17 alpha; 3112 – Androstenedione; 3921 – Testosterone, Total [LC-MS-MS]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Infertility: Endocrine Evaluation (Male)	
Effective Date:	**June 7, 2011**
Test Code:	**2017**
Additional Information:	Suggested Alternate: 2020 – Follicle-Stimulating Hormone & Luteinizing Hormone Eval; 3206 – Prolactin; 3922 – Testosterone, Free & Total
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Polycystic Ovary Evaluation	
Effective Date:	**June 7, 2011**
Test Code:	**2023**
Additional Information:	Suggested Alternate: 2020 – Follicle-Stimulating Hormone & Luteinizing Hormone Eval; 3150 – Dehydroepiandrosterone-Sulfate (DHEA-S); 3921 – Testosterone, Total [LC-MS-MS]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Recurrent Spontaneous Abortion: Endocrine Evaluation	
Effective Date:	**June 7, 2011**
Test Code:	**2025**
Additional Information:	Suggested Alternate: 3150 – Dehydroepiandrosterone-Sulfate (DHEA-S); 3250 – Thyroid Stimulating Hormone, 3rd Generation; 3206 – Prolactin; 3921 – Testosterone, Total [LC-MS-MS]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Testosterone, Free Dialysis Only	
Effective Date:	**June 7, 2011**
Test Code:	**3259**
Additional Information:	Suggested Alternate: 3922 – Testosterone, Free and Total, LC/MS/MS
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Testosterone, Free Dialysis w/Total Testosterone	
Effective Date:	**June 7, 2011**
Test Code:	**3249**
Additional Information:	Suggested Alternate: 3922 – Testosterone, Free and Total, LC/MS/MS
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Testosterone, Free & Total	
Effective Date:	**June 7, 2011**
Test Code:	**3248**
Additional Information:	Suggested Alternate: 3922 – Testosterone, Free and Total, LC/MS/MS
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

New Referral Tests

Biotinidase (70132X)		
Clinical Significance:	Detect biotinidase deficiency. Children born with biotinidase deficiency develop mental retardation; it is a very treatable disorder once diagnosed.	
Effective Date:	**June 7, 2011**	
Test Code:	**S52428**	
CPT Code(s):	**82261**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum, Plasma EDTA, Plasma Heparinized** **2 mL** **1 mL** **Separate serum/plasma within one hour of collection and store at minimum of -20 degrees or below. Use dry ice for shipment.**
Rejection Criteria:	**Thawed serum/plasma or received at room temperature.**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Tues,Thurs; Report Available: 4-5 days**	
Reference Ranges:	**Biotinidase**	**5.1-11.9 nmol/mL/min**
Methodology:	**Enzymatic,Colorimetric**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Referral 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.

Galactose-1-Phosphate RBC [80337] NY		
Effective Date:	**May 18, 2011**	
Test Code:	**S48547NY**	
Reference Ranges:	**Erythrocytes**	**mcg/g Hb**
	Galactose-1-Phosphate Conversion (new)	**mg/dL**
Always Statement	**<1.0 (non-galactosemic)** **1.0-4.0 (galactosemic on galactose restricted diet)** **>4.0 (galactosemic on unrestricted diet)**	

IGF-I, LC/MS (16293)			
Effective Date:	**June 13, 2011**		
Test Code:	**S51997**		
Former Test Name:	*IGF-I [16293]*		
Reference Ranges:	**New table as Always Message**		
	Z-Score (Male)		**-2.0 - +2.0**
	Z-Score (Female)		**-2.0 - +2.0**
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum, Plasma EDTA, Plasma Heparinized** **0.5 mL** **0.3mL**	
Rejection Criteria:	**SST (red-top/glass) tubes are not acceptable.**		
Specimen Stability:	**Room Temperature: 48 hours** **Refrigerated: 5 days** **Frozen (-20): 72 hours** **Frozen (-70): 21 days**		
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 3-4 Days**		
Methodology:	**Liquid Chromatography/Mass Spectrometry**		
Always Statement:	**Pediatric:**		

Age (Years)	Female	Age (Years)	Male
<1*	17-185	<1*	<or =142
1-1.9*	15-175	1-1.9	< or = 134
2-2.9*	16-178	2-2.9	< or =135
3 – 3.9	38-214	3-3.9	30-155
4 – 4.9	34-238	4-4.9	28-181
5 – 5.9	37-272	5-5.9	31-214
6 – 6.9	45-316	6-6.9	38-253
7 – 7.9	58-367	7-7.9	48-28
8 – 8.9	76-424	8-8.9	62-347
9 – 9.9	99-483	9-8.9	80-398
10 – 10.9	125-541	10-10.9	100-449
11 – 11.9	152-593	11-11.9	123-497
12 – 12.9	178-636	12-12.9	146-541
13 – 13.9	200-664	13-13.9	168-576
14 -14.9	214-673	14-14.9	187-599
15 -15.9	218-659	15-15.9	201-609
16 – 16.9	208-619	16-16.9	209-602
17 – 17.9	185-551	17-17.9	207-576

***Brabant G, et al. Serum insulin-like growth factor I reference values for an automated chemiluminescence immunoassay system: Results from a multicenter study. Horm. Res. 2003;60:53-60**

Female Tanner Stages (based on breast stage)

Age (Years)	1	2	3	4,5
8-8.9	80-307	84-414	197-642	388-871
9-9.9	92-332	91-432	197-642	358-823
10-10.9	105-359	99-451	197-642	330-776
11-11.9	118-387	107-470	197-642	304-731
12-12.9	133-416	115-490	197-642	278-688
13-13.9	148-447	123-510	197-642	254-646

	Male Tanner Stages (based on testicular volume) **Age (Years) 1 2,3 4,5** **10-10.9 84-315 78-418 349-817** **11-11.9 96-341 101-478 318-765** **12-12.9 109-368 127-543 289-716** **13-13.9 123-396 158-614 262-668** **14-14.9 138-426 192-689 236-622** **15-15.9 153-457 230-769 212-578** **Adults:** **Age (Years)** **18-19.9 108-548** **20-24.9 83-456** **25-29.9 63-373** **30-39.9 53-331** **40-49.9 52-328** **50-59.9 50-317** **60-69.9 41-279** **70-79.9 34-245** **>80 34-246**

Cytomegalovirus (CMV) DNA, Quant RT PCR [45050]	
Effective Date:	**June 13, 2011**
Test Code:	**S52333**
Always Statement	**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.**

Influenza A/B RT-PCR RFX TO INFLNZ A H1N1 (09) RT-PCR [42699]	
Effective Date:	**June 20, 2011**
Test Code:	**S52074**
Additional Information:	**Throat swabs in M4, VCM or UTM are acceptable but are not approved for New York patient testing.**

Influenza A H1N1 (2009) Real Time RT-PCR [46585]	
Effective Date:	**June 20, 2011**
Test Code:	**S51886**
Additional Information:	**Throat swabs in M4, VCM or UTM are acceptable but are not approved for New York patient testing.**

***Clostridium difficile* Cytotoxin Ab Neutraliz [81055]**		
Effective Date:	**June 27, 2011**	
Test Code:	**S44785**	
Rejection Criteria:	**Stool, other sterile body fluids, specimens beyond stability or received in inappropriate container.**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 14 days** **Frozen: 30 days**	
Reference Ranges:	***Clostridium difficile* Cytotoxin Ab Neutraliz**	**< or = 1:2 titer**

Herpes Simplex Virus, Type 1&2 DNA Real-Time PCR [43200][NY]		
Effective Date:	**June 27, 2011**	
Test Code:	**S51676NY**	
Specimen Requirements:	Type:	**Alternate sample:** **Vaginal swab submitted in Aptima Vaginal swab collection kit.**

Porphobilinogen 24hr Urine (7294N)		
Effective Date:	**June 27, 2011**	
Test Code:	**S51657**	
Reference Ranges:	**Porphobilinogen, 24hr Ur**	**< 2.4 mg/24 h**
Additional Information:	**Also affects S48559**	

Porphobilinogen Random Urine [84889N]		
Effective Date:	**June 27, 2011**	
Test Code:	**S51658**	
Reference Ranges:	**Porphobilinogen Random Urine**	**1-8 Years: 0.9-2.8 mg/g creat** **9-17 Years:0.5-2.0 mg/g creat** **>=18 Years: <2.0 mg/g creat**

Referral Test Discontinuations

Biotinidase [9359]	
Effective Date:	**June 7, 2011**
Test Code:	**S40690**
Additional Information:	Suggested Alternate: **S52428 – Biotinidase [70132X]**
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

New York Patient Testing Update

Adenosine Deaminase	
Effective Date:	**Immediate**
Test Code:	**3131**
Additional Information:	**This test is not approved for the testing of patient samples from New York State.**

Aspergillus DNA, PCR [48003]	
Effective Date:	**Immediate**
Test Code:	**S50959**
Additional Information:	**This test is not approved for the testing of patient samples from New York State.**