Laboratory Update
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Business Unit: Quest Diagnostics Nichols Institute, Valencia

August 2011 Update

Dear Colleague,

This is our first letter combining our laboratory update and database in one document. This format will simplify the process of building or revising your referral tests and eliminate the need for multiple sources of information. This is the next phase of our laboratory updates and our next improvement to our communication process.

Please note that we did not send a Laboratory Update during the month of June and therefore there may be a few more changes reflected in this letter. The changes have been scheduled to occur in early and late August to ensure minimal database maintenance.

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

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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	Reject Criteria	Other (see listing)
16	5' Nucleotidase	4174			x	x	x	x							
17	Acetaminophen	4100				x			x	x		x			x
17	ACTH, Plasma	3102			x			x	x		x	x			
16	Angiotensin Converting Enzyme, Serum	3114			x		x		x						
17	Apolipoprotein B	1903							x						x
18	B-Type Natriuretic peptide	7533			x	x	x		x			x			x
15	Buprenorphine and Naloxone, LC/MS/MS	90416		x	x	x	x	x							x
20	C3, Complement	1501			x							x			x
20	C4, Serum	1504			x							x			x
18	CA 125	3121				x	x	x	x			x			x
19	Calcitonin	3126				x	x		x		x	x			x
19	Calcium, Ionized	4831				x	x				x				x
32	CD Marker, T&B Cell Panels	1683													x
27	Coenzyme Q10	7534			x	x	x	x	x					x	x
28	Complement Functional Activity CH50	1600				x	x								x
20	Drugs of Abuse Screen Serum	4125													x
20	Endomysial Antibody Screen (IgA), Reflex to Titer	1191			x	x	x	x	x		x	x	x		x
28	Erythropoietin	1160													x
15	Ethyl Glucuronide with Confirmation, Urine	90418		x	x	x			x						x
29	Free Kappa & Lambda, with K/L Ratio, Serum	1760			x	x	x	x	x			x		x	x
21	Gabapentin	3364				x	x	x	x			x			x
16	Growth Hormone	3182													x
26	HIV-1 Abs [WB] w/Reflex HIV-2 Abs [WB] (Blood	3021BT													x
25	HIV-1 Abs + Bands [WB] w/Reflex HIV-2 Abs [EIA]	3013B													x
21	HIV-1 Abs + Bands [WB] w/Reflex HIV-2 Abs [WB]	3021B													
25	HIV-1 Genotyping, PR and RT, Sequencing	7480			x										x
25	HIV-1 RNA Quantitation [Real Time PCR] w/rfx HIV-1 Genotype	7482A			x	x	x		x					x	x
22	HIV-1 RNA Quantitative, bDNA	9874			x	x	x		x		x			x	x
23	HIV-1 RNA Quantitative, bDNA & CD4 Cell Count	9872			x	x	x		x		x			x	x
24	HIV-1 RNA Quantitative, bDNA, w/reflex HIV-1 Genotype	7482			x	x	x		x		x			x	x
29	HLA: B27 Typing	1350				x	x		x						x
30	Homocystine Cardiovascular	3334				x	x	x	x			x		x	x
26	Inhibin B	3982				x	x	x	x		x	x			x
31	Jo-1 IgG Autoantibodies	1208													x
16	Magnesium RBC	4866R				x									
31	QuantiFERON®-TB Gold (Incubated)	6110													x
31	Topiramate	4925				x	x	x	x		x				x
31	Von Willebrand Factor Ag	1907									x				

New Test Offerings

HIV-1 ABS + Bands [WB] & HIV-2 ABS [WB]		
Clinical Significance:	HIV-1 is the causative agent of AIDS (acquired immune deficiency syndrome) in humans. The HIV virus infects T-lymphocytes, resulting in immune deficiencies, manifested in such diseases as Kaposi's sarcoma, pneumonia, and various infections. HIV-2 is a comparable T-lymphocytic retrovirus that is less virulent, but is becoming more widespread worldwide. HIV-2 is more common outside of the United States, but cases have been reported in the U.S. HIV-2 antibody cross-reacts with HIV-1 antigen, requiring a specific HIV-2 western blot to confirm antibody positives. This test code provides HIV-1 and HIV-2 western blot results, as well as reports specific reactivity to HIV-1 bands.	
Effective Date:	**Immediate**	
Test Code:	**3081B**	
CPT Code(s):	**86689x2**	
Specimen Requirements:	Type: Alternates: Opt Volume: Min Volume:	**Serum** **Plasma Heparinized; Plasma Citrated; Plasma ACD; Plasma EDTA** **2.0 mL** **1.0 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 5 days** **Refrigerated: 14 days** **Frozen: 2 months**	
Set-Up/Analytic Time:	**Set-up: Tues, Thurs, Sat; Report Available: 1-2 days**	
Reference Ranges:	**ABS** **Bands**	**Negative** **Absent**
Methodology:	**Western Blot**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
Additional Information:	**EIA and Western Blot should be considered positive for HIV-1 or HIV-2 antibodies. HIV-2 IgG Abs: 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 should not be used for diagnosis without confirmation by other medically established means.**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	23490 **23491** **200722** **23493** **23494** **23495** **200723** **23496** **23497** **23498** **23511**	**HIV-1 IgG Antibodies -WB** **gp160/120** **p65** **p55** **p51** **gp41** **p40** **p31** **p24** **p18** **HIV-2 Antibodies-WB**

Pain Mgmt, Tapentadol, Qn, Urine			
Clinical Significance:	**The purpose of this test is to determine the presence of Tapentadol and N-Desmethyltapentadol (metabolite) in urine. The results of this test are used in specific therapeutic treatment programs and Pain Management settings to determine compliance with prescribed dosing schedules.**		
Effective Date:	**Immediate**		
Test Code:	**90243**		
CPT Code(s):	**83789**		
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Urine** **20 mL** **5 mL** **Collect 20 mL of random urine in urine container. No preservative.**	
Rejection Criteria:	**Urine specimens with preservative**		
Transport Temperature:	**Room temperature**		
Specimen Stability:	**Room Temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**		
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 3 days**		
Reference Ranges:	**Tapentadol**	**<50 ng/mL**	
	Nortapentadol	**<50 ng/mL**	
Methodology:	**LC/MS/MS**		
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**		
CPU Interface Mapping:	**Result Code:**	**Result Name:**	
	82090191 **82000670** **82000672**	**Report Comments** **Tapentadol** **Nortapentadol**	

Testosterone, Free, 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:	**Immediate**	
Test Code:	**3201**	
CPT Code(s):	**84402**	
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:	**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**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	211345	**Testosterone Free**

Lymphocyte Subset Panel 1		
Clinical Significance:	Immunophenotypic analysis may assist in evaluating cellular immunocompentency in suspected cases of primary and secondary immunodeficiency states.	
Effective Date:	**September 1, 2011**	
Test Code:	**71978**	
CPT Code(s):	**86355, 86357, 86359, 86360**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood EDTA (Lavender TOP)** **5.0 mL** **1.0 mL** **Maintain the specimen at ambient temperature. Do not refrigerate. It is recommended that the sample be drawn shortly before courier pick up and be received within 24 hours.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 72 hours** **Refrigerated: Unacceptable** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Sun thru Sat; Report Available: 1 days**	
Reference Ranges:	**CD3, Absolute**	**Infant - 29 Days: Not Established** **1 month - 12 months: 2160 - 5540 cells/uL** **1 year - 2 years: 2030 - 5150** **3 years - 6 years: 1220 - 3000** **7 years - 12 years: 920 - 2200** **13 years - 18 years: 860 - 2420** **19 years - Old Age: 840 - 3060**
	CD3, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 54 - 76 %** **1 year - 2 years: 49 - 75** **3 years - 6 years: 55 - 77** **7 years - 12 years: 58 - 80** **13 years - 18 years: 61 - 82** **19 years - Old Age: 57 - 85**
	CD4, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 1390 - 4080 cells/uL** **1 year - 2 years: 1220 - 3550** **3 years - 6 years: 670 - 1930** **7 years - 12 years: 520 - 1440** **13 years - 18 years: 510 - 1450** **19 years - Old Age: 490 - 1740**
	CD4, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 36 - 55 %** **1 year - 2 years: 30 - 60** **3 years - 6 years: 28 - 52** **7 years - 12 years: 29 - 52** **13 years - 18 years: 33 - 53** **19 years - Old Age: 30 - 61**
	CD8, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 600 -1490 cells/uL** **1 year - 2 years: 530 - 1590** **3 years - 6 years: 350 - 1160** **7 years - 12 years: 300 - 900** **13 years - 18 years: 240 - 890** **19 years - Old Age: 180 - 1170**
	CD8, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 12 - 24 %** **1 year - 2 years: 13 - 28** **3 years - 6 years: 16 - 34** **7 years - 12 years: 17 - 35** **13 years - 18 years: 17 - 36** **19 years - Old Age: 12 - 42**

	CD19, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 740 – 2560 cells/uL** **1 year - 2 years: 830 - 1880** **3 years - 6 years: 310 - 1120** **7 years - 12 years: 200 - 820** **13 years - 18 years: 130 - 800** **19 years - Old Age: 110 - 660**
	CD19, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 17 - 36 %** **1 year - 2 years: 20 - 38** **3 years - 6 years: 14 - 33** **7 years - 12 years: 12 - 34** **13 years - 18 years: 9 - 30** **19 years - Old Age: 6 - 29**
	CD3-CD16+CD56+, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 160 - 930 cells/uL** **1 year - 2 years: 95 - 620** **3 years - 6 years: 60 - 540** **7 years - 12 years: 70 - 500** **13 years - 18 years: 60 - 430** **19 years - Old Age: 70 - 760**
	CD3-CD16+CD56+, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 3 - 14 %** **1 year - 2 years: 2 - 16** **3 years - 6 years: 3 - 20** **7 years - 12 years: 3 - 19** **13 years - 18 years: 3 - 18** **19 years - Old Age: 4 - 25**
	Lymphocytes, Absolute	**Infant - 3 Days: 2000 - 11500 cells/uL** **4 Days - 6 Days: Not established** **7 Days - 20 Days: 2000 - 17000** **21 Days - 1 Month 6 Days: 2500 - 16500** **1 Month 7 Days - 2 Months 29 Days: 3300 – 15000** **3 Months 1 Day – 6 Months: 4000 - 13500** **7 Months 1 Day – 2 Years: 4000 - 10500** **3 Years - 6 Years: 2000 - 8000** **7 Years - 12 Years: 1500 - 6500** **13 Years - 18 Years: 1200 - 5200** **19 Years - Old Age: 850 - 3900**
	CD4/CD8 Ratio	**Infant - 29 Days: Not established** **1 Month - 1 Year: 1.70 - 3.90** **1 Year 1 Day - 2 Years: 1.40 - 3.90** **3 Years - 6 Years: 1.00 - 3.00** **7 Years - 12 Years: 1.00 - 2.80** **13 Years - 18 Years: 1.00 - 2.90** **19 Years - Old Age: 0.86 -5 .00**
Methodology:	**Flow Cytometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	85991069	**CD3, ABSOLUTE**
	85991070	**CD3, PERCENTAGE**
	86000756	**CD4, ABSOLUTE**
	86000757	**CD4, PERCENTAGE**
	86000758	**CD8, ABSOLUTE**
	86000759	**CD8, PERCENTAGE**
	85991067	**CD19, ABSOLUTE**
	85991068	**CD19, PERCENTAGE**
	86000760	**CD3-CD16+CD56+(ABS)**
	86000761	**CD3-CD16+CD56+ (%)**
	85991066	**LYMPHOCYTES, ABSOLUTE**
	86000762	**CD4/CD8 RATIO**

Lymphocyte Subset Panel 2		
Clinical Significance:	T and B lymphocyte count and helper/suppressor cell immune status assist in evaluating cellular immunocompetency.	
Effective Date:	**September 1, 2011**	
Test Code:	**36420**	
CPT Code(s):	**86355, 86359, 86360**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood EDTA (Lavender TOP)** **5.0 mL** **1.0 mL** **Maintain the specimen at ambient temperature. Do not refrigerate. It is recommended that the sample be drawn shortly before courier pick up and be received within 24 hours.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 72 hours** **Refrigerated: Unacceptable** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Sun thru Sat; Report Available: 1 days**	
Reference Ranges:	**CD3, Absolute**	**Infant - 29 Days: Not Established** **1 month - 12 months: 2160 - 5540 cells/uL** **1 year - 2 years: 2030 - 5150** **3 years - 6 years: 1220 - 3000** **7 years - 12 years: 920 - 2200** **13 years - 18 years: 860 - 2420** **19 years - Old Age: 840 - 3060**
	CD3, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 54 - 76 %** **1 year - 2 years: 49 - 75** **3 years - 6 years: 55 - 77** **7 years - 12 years: 58 - 80** **13 years - 18 years: 61 - 82** **19 years - Old Age: 57 - 85**
	CD4, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 1390 - 4080 cells/uL** **1 year - 2 years: 1220 - 3550** **3 years - 6 years: 670 - 1930** **7 years - 12 years: 520 - 1440** **13 years - 18 years: 510 - 1450** **19 years - Old Age: 490 - 1740**
	CD4, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 36 - 55 %** **1 year - 2 years: 30 - 60** **3 years - 6 years: 28 - 52** **7 years - 12 years: 29 - 52** **13 years - 18 years: 33 - 53** **19 years - Old Age: 30 - 61**
	CD8, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 600 -1490 cells/uL** **1 year - 2 years: 530 - 1590** **3 years - 6 years: 350 - 1160** **7 years - 12 years: 300 - 900** **13 years - 18 years: 240 - 890** **19 years - Old Age: 180 - 1170**
	CD8, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 12 - 24 %** **1 year - 2 years: 13 - 28** **3 years - 6 years: 16 - 34** **7 years - 12 years: 17 - 35** **13 years - 18 years: 17 - 36** **19 years - Old Age: 12 - 42**

	CD19, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 740 – 2560 cells/uL** **1 year - 2 years: 830 - 1880** **3 years - 6 years: 310 - 1120** **7 years - 12 years: 200 - 820** **13 years - 18 years: 130 - 800** **19 years - Old Age: 110 - 660**
	CD19, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 17 - 36 %** **1 year - 2 years: 20 - 38** **3 years - 6 years: 14 - 33** **7 years - 12 years: 12 - 34** **13 years - 18 years: 9 - 30** **19 years - Old Age: 6 - 29**
	Lymphocytes, Absolute	**Infant - 3 Days: 2000 - 11500 cells/uL** **4 Days - 6 Days: Not established** **7 Days - 20 Days: 2000 - 17000** **21 Days - 1 Month 6 Days: 2500 - 16500** **1 Month 7 Days - 2 Months 29 Days: 3300 – 15000** **3 Months 1 Day – 6 Months: 4000 - 13500** **7 Months 1 Day – 2 Years: 4000 - 10500** **3 Years - 6 Years: 2000 - 8000** **7 Years - 12 Years: 1500 - 6500** **13 Years - 18 Years: 1200 - 5200** **19 Years - Old Age: 850 - 3900**
	CD4/CD8 Ratio	**Infant - 29 Days: Not established** **1 Month - 1 Year: 1.70 - 3.90** **1 Year 1 Day - 2 Years: 1.40 - 3.90** **3 Years - 6 Years: 1.00 - 3.00** **7 Years - 12 Years: 1.00 - 2.80** **13 Years - 18 Years: 1.00 - 2.90** **19 Years - Old Age: 0.86 -5 .00**
Methodology:	**Flow Cytometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	85991069	**CD3, ABSOLUTE**
	85991070	**CD3, PERCENTAGE**
	86000756	**CD4, ABSOLUTE**
	86000757	**CD4, PERCENTAGE**
	86000758	**CD8, ABSOLUTE**
	86000759	**CD8, PERCENTAGE**
	85991067	**CD19, ABSOLUTE**
	85991068	**CD19, PERCENTAGE**
	85991066	**LYMPHOCYTES, ABSOLUTE**
	86000762	**CD4/CD8 RATIO**

Lymphocyte Subset Panel 3		
Clinical Significance:	T-lymphocyte and helper/suppressor cell immune status assist in evaluating cellular immunocompetency.	
Effective Date:	**September 1, 2011**	
Test Code:	**71958**	
CPT Code(s):	**86359, 86360**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood EDTA (Lavender TOP)** **5.0 mL** **1.0 mL** **Maintain the specimen at ambient temperature. Do not refrigerate. It is recommended that the sample be drawn shortly before courier pick up and be received within 24 hours.**
Transport Temperature:	**Room temperature**	

Specimen Stability:	**Room Temperature: 72 hours** **Refrigerated: Unacceptable** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Sun thru Sat; Report Available: 1 days**	
Reference Ranges:	**CD3, Absolute**	**Infant - 29 Days: Not Established** **1 month - 12 months: 2160 - 5540 cells/uL** **1 year - 2 years: 2030 - 5150** **3 years - 6 years: 1220 - 3000** **7 years - 12 years: 920 - 2200** **13 years - 18 years: 860 - 2420** **19 years - Old Age: 840 - 3060**
	CD3, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 54 - 76 %** **1 year - 2 years: 49 - 75** **3 years - 6 years: 55 - 77** **7 years - 12 years: 58 - 80** **13 years - 18 years: 61 - 82** **19 years - Old Age: 57 - 85**
	CD4, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 1390 - 4080 cells/uL** **1 year - 2 years: 1220 - 3550** **3 years - 6 years: 670 - 1930** **7 years - 12 years: 520 - 1440** **13 years - 18 years: 510 - 1450** **19 years - Old Age: 490 - 1740**
	CD4, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 36 - 55 %** **1 year - 2 years: 30 - 60** **3 years - 6 years: 28 - 52** **7 years - 12 years: 29 - 52** **13 years - 18 years: 33 - 53** **19 years - Old Age: 30 - 61**
	CD8, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 600 -1490 cells/uL** **1 year - 2 years: 530 - 1590** **3 years - 6 years: 350 - 1160** **7 years - 12 years: 300 - 900** **13 years - 18 years: 240 - 890** **19 years - Old Age: 180 - 1170**
	CD8, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 12 - 24 %** **1 year - 2 years: 13 - 28** **3 years - 6 years: 16 - 34** **7 years - 12 years: 17 - 35** **13 years - 18 years: 17 - 36** **19 years - Old Age: 12 - 42**
	Lymphocytes, Absolute	**Infant - 3 Days: 2000 - 11500 cells/uL** **4 Days - 6 Days: Not established** **7 Days - 20 Days: 2000 - 17000** **21 Days - 1 Month 6 Days: 2500 - 16500** **1 Month 7 Days - 2 Months 29 Days: 3300 – 15000** **3 Months 1 Day – 6 Months: 4000 - 13500** **7 Months 1 Day – 2 Years: 4000 - 10500** **3 Years - 6 Years: 2000 - 8000** **7 Years - 12 Years: 1500 - 6500** **13 Years - 18 Years: 1200 - 5200** **19 Years - Old Age: 850 - 3900**
	CD4/CD8 Ratio	**Infant - 29 Days: Not established** **1 Month - 1 Year: 1.70 - 3.90** **1 Year 1 Day - 2 Years: 1.40 - 3.90** **3 Years - 6 Years: 1.00 - 3.00** **7 Years - 12 Years: 1.00 - 2.80**

		13 Years - 18 Years: 1.00 - 2.90 **19 Years - Old Age: 0.86 -5 .00**
Methodology:	**Flow Cytometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	85991069	**CD3, ABSOLUTE**
	85991070	**CD3, PERCENTAGE**
	86000756	**CD4, ABSOLUTE**
	86000757	**CD4, PERCENTAGE**
	86000758	**CD8, ABSOLUTE**
	86000759	**CD8, PERCENTAGE**
	85991066	**LYMPHOCYTES, ABSOLUTE**
	86000762	**CD4/CD8 RATIO**

Lymphocyte Subset Panel 4		
Clinical Significance:	Assists in evaluating helper/suppressor cell immune status in immunodeficiency diseases such as AIDS.	
Effective Date:	**September 1, 2011**	
Test Code:	**79248**	
CPT Code(s):	**86360**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood EDTA (Lavender TOP)** **5.0 mL** **1.0 mL** **Maintain the specimen at ambient temperature. Do not refrigerate. It is recommended that the sample be drawn shortly before courier pick up and be received within 24 hours.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 72 hours** **Refrigerated: Unacceptable** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Sun thru Sat; Report Available: 1 days**	
Reference Ranges:	**CD4, Absolute**	**Infant - 29 Days: Not Established** **1 month - 12 months: 1390 - 4080 cells/uL** **1 year - 2 years: 1220 - 3550** **3 years - 6 years: 670 - 1930** **7 years - 12 years: 520 - 1440** **13 years - 18 years: 510 - 1450** **19 years - Old Age: 490 - 1740**
	CD4, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 36 - 55 %** **1 year - 2 years: 30 - 60** **3 years - 6 years: 28 - 52** **7 years - 12 years: 29 - 52** **13 years - 18 years: 33 - 53** **19 years - Old Age: 30 - 61**
	CD8, Absolute	**Infant - 29 Days: Not Established** **1 month - 12 months: 600 -1490 cells/uL** **1 year - 2 years: 530 - 1590** **3 years - 6 years: 350 - 1160** **7 years - 12 years: 300 - 900** **13 years - 18 years: 240 - 890** **19 years - Old Age: 180 - 1170**
	CD8, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 12 - 24 %** **1 year - 2 years: 13 - 28** **3 years - 6 years: 16 - 34** **7 years - 12 years: 17 - 35** **13 years - 18 years: 17 - 36** **19 years - Old Age: 12 - 42**
	Lymphocytes,	**Infant - 3 Days: 2000 - 11500 cells/uL**

	Absolute	**4 Days - 6 Days: Not established** **7 Days - 20 Days: 2000 - 17000** **21 Days - 1 Month 6 Days: 2500 - 16500** **1 Month 7 Days - 2 Months 29 Days: 3300 – 15000** **3 Months 1 Day – 6 Months: 4000 - 13500** **7 Months 1 Day – 2 Years: 4000 - 10500** **3 Years - 6 Years: 2000 - 8000** **7 Years - 12 Years: 1500 - 6500** **13 Years - 18 Years: 1200 - 5200** **19 Years - Old Age: 850 - 3900**
	CD4/CD8 Ratio	**Infant - 29 Days: Not established** **1 Month - 1 Year: 1.70 - 3.90** **1 Year 1 Day - 2 Years: 1.40 - 3.90** **3 Years - 6 Years: 1.00 - 3.00** **7 Years - 12 Years: 1.00 - 2.80** **13 Years - 18 Years: 1.00 - 2.90** **19 Years - Old Age: 0.86 -5 .00**
Methodology:	**Flow Cytometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	86000756	**CD4, ABSOLUTE**
	86000757	**CD4, PERCENTAGE**
	86000758	**CD8, ABSOLUTE**
	86000759	**CD8, PERCENTAGE**
	85991066	**LYMPHOCYTES, ABSOLUTE**
	86000762	**CD4/CD8 RATIO**

Lymphocyte Subset Panel 5			
Clinical Significance:	Assists in evaluating helper cell immune status in immunodeficiency diseases such as AIDS.		
Effective Date:	**September 1, 2011**		
Test Code:	**83608**		
CPT Code(s):	**86361**		
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood EDTA (Lavender TOP)** **5.0 mL** **1.0 mL** **Maintain the specimen at ambient temperature. Do not refrigerate. It is recommended that the sample be drawn shortly before courier pick up and be received within 24 hours.**	
Transport Temperature:	**Room temperature**		
Specimen Stability:	**Room Temperature: 72 hours** **Refrigerated: Unacceptable** **Frozen: Unacceptable**		
Set-Up/Analytic Time:	**Set-up: Sun thru Sat; Report Available: 1 days**		
Reference Ranges:	**CD4, Absolute**	**Infant - 29 Days: Not Established** **1 month - 12 months: 1390 - 4080 cells/uL** **1 year - 2 years: 1220 - 3550** **3 years - 6 years: 670 - 1930** **7 years - 12 years: 520 - 1440** **13 years - 18 years: 510 - 1450** **19 years - Old Age: 490 - 1740**	
	CD4, Percentage	**Infant - 29 Days: Not Established** **1 month - 12 months: 36 - 55 %** **1 year - 2 years: 30 - 60** **3 years - 6 years: 28 - 52** **7 years - 12 years: 29 - 52** **13 years - 18 years: 33 - 53** **19 years - Old Age: 30 - 61**	
	Lymphocytes, Absolute	**Infant - 3 Days: 2000 - 11500 cells/uL** **4 Days - 6 Days: Not established** **7 Days - 20 Days: 2000 - 17000** **21 Days - 1 Month 6 Days: 2500 - 16500** **1 Month 7 Days - 2 Months 29 Days: 3300 – 15000** **3 Months 1 Day – 6 Months: 4000 - 13500** **7 Months 1 Day – 2 Years: 4000 - 10500** **3 Years - 6 Years: 2000 - 8000** **7 Years - 12 Years: 1500 - 6500** **13 Years - 18 Years: 1200 - 5200** **19 Years - Old Age: 850 - 3900**	
Methodology:	**Flow Cytometry**		
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**		
CPU Interface Mapping:	**Result Code:**	**Result Name:**	
	86000756 **86000757** **85991066**	**CD4, ABSOLUTE** **CD4, PERCENTAGE** **LYMPHOCYTES, ABSOLUTE**	

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.*

Immediate:

Buprenorphine and Naloxone, LC/MS/MS		
Clinical Significance:	Suboxone is medication used for the treatment of opiate addiction which contains both buprenorphine and naloxone. The test is used to monitor patient compliance with therapy.	
Effective Date:	**Immediate**	
Test Code:	**90416**	
Former Test Name:	*Suboxone (Buprenorphine, Naloxone), Quant, Urine*	
Former Test Code:	*4241U*	
CPT Code(s):	**83925x2**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Urine** **20 mL** **10 mL** **Collect 20 mL of random urine, no preservatives.**
Rejection Criteria:	**Urine specimens with preservative.**	
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 2-4 days**	
Reference Ranges:	**Buprenorphine** **Norbuprenorphine** **Naloxone**	**<2 ng/mL** **<2 ng/mL**
Methodology:	**LC/MS/MS**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	86007752 **86007753** **86007754**	**Buprenorphine** **Norbuprenorphine** **Naloxone**

Ethyl Glucuronide with Confirmation, Urine		
Effective Date:	**Immediate**	
Test Code:	**90418**	
Former Test Name:	*Ethyl Glucuronide and Ethyl Sulfate*	
Former Test Code:	*S52236*	
Rejection Criteria:	**Preserved specimens**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 30 days**	
Reference Ranges:	**Ethyl Glucuronide Screen:** **Ethyl Glucuronide Confirmation:** **Ethyl Sulfate Confirmation:**	**500 ng/mL** **500 ng/mL** **100 ng/mL**
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	86007755 **86007756** **86007757** **84999990**	**Ethyl Glucuronide** **Ethyl Glucuronide** **Ethyl Sulfate** **Please Note:**

Growth Hormone	
Effective Date:	**Immediate**
Test Code:	**3182**
Always Message:	**Effective July 11, 2011, Quest Diagnostics Human Growth Hormone assay will be standardized to the Recombinant Second International Standard (IS) 98/574. A shift to lower values (approx. 20%) will be observed, reflecting this standardization. Please interpret results accordingly.**
Additional Information:	**Also affected: 3171, 3175, 3185, 3195**

Magnesium RBC		
Effective Date:	**Immediate**	
Test Code:	**4866R**	
Specimen Requirements:	Type:	**Additional specimen type: Whole Blood Trace Metal Tube, EDTA**

Effective August 9, 2011

5' Nucleotidase		
Effective Date:	**August 9, 2011**	
Test Code:	**4174**	
Former Test Name:	*Nucleotidase, 5'*	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum** **1.0 mL** **0.2 mL** **Centrifuge and transfer serum specimens to clean, plastic screw-capped vial. Freeze and ship frozen.**
Transport Temperature:	**Frozen**	
Set-Up/Analytic Time:	**Set-up: Mon - Fri; Report Available: 1-3 days**	

Angiotensin Converting Enzyme, Serum		
Clinical Significance:	Increased in sarcoidosis, Gaucher's disease, and lymphoangiomyomatosis.	
Effective Date:	**August 9, 2011**	
Test Code:	**3114**	
Former Test Name:	*Angiotensin Converting Enzyme (ACE)*	
Specimen Requirements:	Opt Volume: Min Volume:	**1.0 mL** **0.2 mL**
Specimen Stability:	**Room temperature: 5 days** **Refrigerated: 7 days** **Frozen: 60 days**	
Set-Up/Analytic Time:	**Set-up: Mon - Sat; Report Available: 1-2 days**	

Acetaminophen		
Clinical Significance:	Acetaminophen is an analgesic/anti-inflammatory agent that may be hepatotoxic when ingested in quantities exceeding 150 mg/kg.	
Effective Date:	**August 9, 2011**	
Test Code:	**4100**	
Specimen Requirements:	Type:	**Additional specimen types: Plasma EDTA, Plasma Heparin, Plasma fluoride oxalate, Serum, Trace metal**
	Collection Instructions:	**Collect as a trough just before next dose.**
Specimen Stability:	**Room Temperature: 5 days Refrigerated: 7 days Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 3 days**	
Reference Ranges:	**Acetaminophen**	**10-20 mg/L**
Methodology:	**Immunoassay**	

ACTH, Plasma		
Clinical Significance:	Determination of ACTH is useful in differentiating between primary and secondary adrenocortical hypo- and hyperfunctional disorders: Addison's disease, Cushing's syndrome, adrenal carcinoma, ectopic ACTH syndrome, and nodular hyperplasia.	
Effective Date:	**August 9, 2011**	
Test Code:	**3102**	
Former Test Name:	*Adrenocorticotropic Hormone (ACTH)*	
Specimen Requirements:	Collection Instructions:	**Draw specimens between 7 a.m. and 10 a.m. If drawn during any other time, the reference ranges do not apply. Transfer the plasma to a plastic, transport tube and ship frozen. Do not thaw.**
Rejection Criteria:	**Grossly hemolyzed specimens**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room temperature: 16 hours Refrigerated: 24 hours Frozen: 28 days**	
Set-Up/Analytic Time:	**Set-up: Mon - Fri; Report Available: 1-2 days**	
Reference Ranges:	**ACTH, Plasma**	**<3 years Reference not established 3-17 years 9-57 pg/mL for both male/female > 17 years: Males: 7-50 pg/mL Females: 5-27 pg/mL**
Methodology:	**Immunoassay**	

Apolipoprotein B		
Effective Date:	**August 9, 2011**	
Test Code:	**1903**	
Specimen Requirements:	Collection Instructions:	**Fasting for at least 12 hours is required. Centrifuge, avoid hemolysis, and transfer serum specimens to clean, plastic, screw-capped vial(s).**
Specimen Stability:	**Room temperature: 72 hours Refrigerated: 10 days Frozen: 3 months**	

B-Type Natriuretic peptide		
Clinical Significance:	BNP is increased in congestive heart failure, left ventricular hypertrophy, acute myocardial infarction, coronary angioplasty, and hypertension. Elevations are also observed in pulmonary hypertension (indicating right ventricular dysfunction), acute lung injury, hypervolemic states, chronic renal failure and cirrhosis. Decreasing levels indicate therapeutic response to antihypertensive therapy. See Non-Lipid Markers of Cardiovascular Disease (CVD) and Congestive Heart Failure (BNP and NTproBNP) in the Cardiovascular chapter, Interpretive Information section.	
Effective Date:	**August 9, 2011**	
Test Code:	**7533**	
Former Test Name:	*BNP EvaluatR™*	
Specimen Requirements:	Opt Volume: Min Volume: Collection Instructions:	**1.0 mL** **0.5 mL** **Instructions: Use of glass EDTA tubes and glass transfer pipettes will affect accurate quantitation of BNP. Specimens collected or transported in glass will be rejected. Gross hemolysis is unacceptable. Gross lipemia is unacceptable. PPT (white-top EDTA) tubes are not acceptable for this test. Draw blood in pre-chilled plastic Vacutainer tube. Mix thoroughly by gentle inversion. Centrifuge in a refrigerated centrifuge as soon as possible after collection. Using plastic transfer pipette, immediately separate plasma from cells into clean, plastic, screw-capped vial(s).**
Rejection Criteria:	**Grossly hemolyzed or lipemic specimens.**	
Specimen Stability:	**Room Temperature: 1 hour** **Refrigerated: 24 hours** **Frozen: 9 months**	
Methodology:	**Immunoassay**	
Additional Information:	**Remove Always Message**	

CA 125		
Effective Date:	**August 9, 2011**	
Test Code:	**3121**	
Specimen Requirements:	Opt Volume: Min Volume: Collection Instructions:	**1.0 mL** **0.5 mL** **Centrifuge within 1 hour of collection and transfer serum specimens to sterile, plastic, screw-capped vial(s). Specimens must be refrigerated, or frozen, if received by the laboratory more than 24 hours after collection.**
Rejection Criteria:	**Grossly hemolyzed samples**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room temperature: 24 Hours** **Refrigerated: 7 Days** **Frozen: 60 Days**	
Methodology:	**Immunoassay**	

Always Message:	**This test was performed using the Siemens (DPC) chemiluminescent method. Values obtained from different assay methods cannot be used interchangeably. CA 125 levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**

Calcium, Ionized		
Clinical Significance:	Ionized calcium represents the true bioavailable calcium in the circulation. In situations where the total calcium is normal, but does not fit the clinical picture, a determination of the ionized calcium will, many times show an elevation in the bioavailable calcium.	
Effective Date:	**August 9, 2011**	
Test Code:	**4831**	
Specimen Requirements:	Opt Volume: Min Volume: Collection Instructions:	**2.0 mL** **0.6 mL** **Collect blood (2 mL serum) in a gel barrier tube. Let clot and spin immediately with cap on. Do not open tube. Ship the unopened gel barrier tube at room temperature. Do not freeze.**
Reference Ranges:	**Calcium, Ionized**	**<8 Months Not established** **8 Months-10 Years 4.9-5.4 mg/dL** **11-17 Years 4.8-5.3 mg/dL** **Adults 4.8-5.6 mg/dL**

Calcitonin		
Clinical Significance:	Calcitonin concentration is increased in patients with medullary thyroid carcinoma. Calcitonin concentrations may be used to monitor disease.	
Effective Date:	**August 9, 2011**	
Test Code:	**3126**	
Specimen Requirements:	Opt Volume: Min Volume: Collection Instructions:	**1.0 mL** **0.5 mL** **Overnight fasting sample is preferred.**
Rejection Criteria:	**Grossly hemolyzed specimens; Room temperature specimens**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Refrigerated: 24 hours (Added)** **Frozen: 28 days**	
Set-Up/Analytic Time:	**Set-up: Tues thru Fri; Report Available: 1-2 days**	
Reference Ranges:	**Calcitonin**	**Pediatric (Males and Females)** ***< 6 mos 41 pg/mL or less** ***6 mos-3 yrs 14 pg/mL or less** **3-17 yrs 6 pg/mL or less** **Adult Males 10 pg/mL or less** **Adult Females 5 pg/mL or less** ***Infant/toddler ranges obtained with the Nichols Institute Diagnostics Calcitonin-ICMA (Clinical Chemistry 2004; 50:1828-9).**
Methodology:	**Immunoassay**	
Always Message:	**This test was performed using the Siemens (DPC) Chemiluminescent method. Values obtained with different assay methods cannot be used interchangeably. Calcitonin levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of the disease.**	

C3, Complement		
Effective Date:	**August 9, 2011**	
Test Code:	**1501**	
Former Test Name:	**Complement C3**	
Specimen Requirements:	Collection Instructions:	**Overnight fasting preferred. Serum should be separated immediately from clot.**
Rejection Criteria:	**Gross hemolysis and lipemia.**	
Methodology:	**Immunoturbidimetric**	

C4, Serum		
Effective Date:	**August 9, 2011**	
Test Code:	**1504**	
Former Test Name:	**Complement C4**	
Specimen Requirements:	Collection Instructions:	**Overnight fasting preferred. Serum should be separated immediately from clot.**
Methodology:	**Immunoturbidimetric**	

Drugs of Abuse Screen Serum	
Effective Date:	**August 9, 2011**
Test Code:	**4125**
Removed Component	Propoxyphene
Additional Information:	**Also affected: 4149**
Remove result code	**37539**

Endomysial Antibody Screen (IgA), Reflex to Titer			
Clinical Significance:	Antiendomysial antibodies of the IgA class seem to be the most sensitive and specific markers for celiac disease and dermatitis herpetiformis, compared with antireticulin and antigliadin antibodies, which may also be present in these disorders.		
Effective Date:	**August 9, 2011**		
Test Code:	**1191**		
Former Test Name:	*Endomysial IgA Autoantibodies*		
CPT Code(s):	**86255 If reflexed, add 86256 at an additional charge.**		
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum** **1.0 mL** **0.3 mL** **Red-top tube (no gel); alternate SST**	
Transport Temperature:	**Refrigerated (cold packs)**		
Specimen Stability:	**Room Temperature: 4 days** **Refrigerated: 30 days** **Frozen: 30 days**		
Reference Ranges:	**Endomysial Ab (IgA) Screen** **Endomysial Ab (IgA) Titer**	**Negative** **< 1:5**	
Methodology:	**Immunofluorescence Assay**		
Classification:	**FDA-Modified**		
CPU Interface Mapping:	**Result Code:**	**Result Name:**	
	211378 **211379**	**Endomysial Ab (IgA) Screen** **Endomysial Ab (IgA) Titer**	

Gabapentin		
Clinical Significance:	Gabapentin is an anticonvulsant drug commonly used as adjunctive therapy to treat partial seizures. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity.	
Effective Date:	**August 9, 2011**	
Test Code:	**3364**	
Specimen Requirements:	Type:	**Lavender-Top (EDTA),** **Royal Blue-Top (EDTA),** **Royal Blue-Top (No Additive),** **Sodium Heparin (Green TOP),** **Lithium Heparin (Green TOP),** **Sodium Heparin Lead-Free (TAN- TOP),** **Serum collected in: Red-TOP (No Gel)**
	Opt Volume:	**3.0 mL**
	Min Volume:	**1.0 mL**
	Collection Instructions:	**Draw sample two hours after last dose at steady-state. Do not use gel barrier tubes. Centrifuge blood at 15-30 degrees C and 2000-2200 rpm (800-100 x g) for 5-6 minutes. Separate plasma from red cells as soon as possible; pipette or pour plasma into polypropylene or polyethylene tubes.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 5 days** **Refrigerated: 12 days** **Frozen: 1 month**	
Methodology:	**Mass Spectrometry**	

HIV-1 Abs + Bands [WB] w/Reflex HIV-2 Abs [WB]		
Effective Date:	**August 9, 2011**	
Test Code:	**3021B**	
Additional Information:	Replace Reflex Code RFS and associated Bands Result Codes with RNN below.	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping: Reflex RNN	**Result Code:**	**Result Name:**
	23511	**HIV-2 Antibodies-WB**

HIV-1 RNA Quantitative, bDNA		
Clinical Significance:	**Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy. The reportable range is 75 to 500,000 copies/mL.**	
Effective Date:	**August 9, 2011**	
Test Code:	**9874**	
Former Test Name:	*HIV-1 RNA UltraQuant® [bDNA]*	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma EDTA and Plasma ACD; Plasma PPT** **3.1 mL** **1.1 mL** **Collect peripheral blood in sterile tubes containing EDTA (K3, 0.15% v/v final; or K2 spray coated, 1.8 mg/mL final; or K2 Plasma Preparation Tubes (PPT), or ACD solution A, 17.6% solution v/v final). Note: Blood collected in tubes containing ACD anticoagulant are acceptable but will yield results approximately 15% lower when compared with EDTA tubes, due to the dilution effect of the 1.5 mL of anticoagulant used in the tube.** **EDTA or ACD – Store whole blood at room temperature (18 to 30°C) for up to 4 hours prior to centrifugation. Do not refrigerate. Remove plasma from cells within 4 hours of collection. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Do not clarify plasma by filtration or further centrifugation. Transfer the plasma to a separate plastic screw-capped vial, freeze and ship frozen.** **PPT – Store whole blood at room temperature (18 to 30°C) for up to 2 hours prior to centrifugation. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Aliquot to a sterile screw cap tube. Freeze samples (-60 to -80°C) immediately after centrifugation. Do not clarify plasma by filtration or further centrifugation. Do not submit original PPT tube.**
Rejection Criteria:	**Samples collected in heparin tubes; Frozen or refrigerated PPT tube; Serum samples; Samples in leaking, uncapped, or broken containers.**	
Specimen Stability:	**Plasma EDTA and Plasma ACD** **Refrigerated: 48 Hours** **Frozen: 90 Days** **Plasma PPT** **Frozen: 90 Days**	
Reference Ranges:	**HIV-1 RNA Quant bDNA** **HIV-1 RNA (log10)**	**copies/mL** **log copies/mL**
Additional Information:	**Also affects 9874SR**	
Always Message	**Add: A change in HIV-1 RNA level is likely significant only if the Log 10 difference is 0.5 or more. This test was performed using the Versant (R) HIV-1 RNA 3.0 Assay (bDNA) kit by Siemens.**	
CPU Interface Mapping: New components	**Result Code:** **63205** **200316**	**Result Name:** HIV-1 RNA Quantitative bDNA HIV-1 RNA (log 10)

HIV-1 RNA Quantitative, bDNA & CD4 Cell Count		
Clinical Significance:	**Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy. The reportable range is 75 to 500,000 copies/mL.**	
Effective Date:	**August 9, 2011**	
Test Code:	**9872**	
Former Test Name:	*HIV-1 RNA UltraQuant® [bDNA] & CD4 Cell Count*	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma EDTA and Plasma ACD; Plasma PPT** **3.1 mL** **1.1 mL** **For CD4 cell count, collect both EDTA and ACD whole blood samples for analysis. Ship the whole blood specimens ambient and separate from the plasma sample(s) collected for the HIV-1 RNA Quant bDNA. Do not refrigerate or freeze whole blood specimens.** **For HIV-RNA Quantitative bDNA, collect peripheral blood in sterile tubes containing EDTA (K3, 0.15% v/v final; or K2 spray coated, 1.8 mg/mL final; or K2 Plasma Preparation Tubes (PPT), or ACD solution A, 17.6% solution v/v final). Note: Blood collected in tubes containing ACD anticoagulant are acceptable but will yield results approximately 15% lower when compared with EDTA tubes, due to the dilution effect of the 1.5 mL of anticoagulant used in the tube.** **EDTA or ACD – Store whole blood at room temperature (18 to 30°C) for up to 4 hours prior to centrifugation. Do not refrigerate. Remove plasma from cells within 4 hours of collection. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Do not clarify plasma by filtration or further centrifugation. Transfer the plasma to a separate plastic screw-capped vial, freeze and ship frozen.** **PPT – Store whole blood at room temperature (18 to 30°C) for up to 2 hours prior to centrifugation. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Aliquot to a sterile screw cap tube. Freeze samples (-60 to -80°C) immediately after centrifugation. Do not clarify plasma by filtration or further centrifugation. Do not submit original PPT tube.**
Rejection Criteria:	**Samples collected in heparin tubes; Frozen or refrigerated PPT tube; Serum samples; Samples in leaking, uncapped, or broken containers.**	
Specimen Stability:	**Plasma EDTA and Plasma ACD** **Refrigerated: 48 Hours** **Frozen: 90 Days** **Plasma PPT** **Frozen: 90 Days**	
Reference Ranges:	**HIV-1 RNA Quant bDNA** **HIV-1 RNA (log10)**	**copies/mL** **log copies/mL**
Additional Information:	**Also affects 9872SR**	

Always Message	**Add: A change in HIV-1 RNA level is likely significant only if the Log 10 difference is 0.5 or more. This test was performed using the Versant (R) HIV-1 RNA 3.0 Assay (bDNA) kit by Siemens.**	
CPU Interface Mapping: New components	**Result Code:**	**Result Name:**
	63205	HIV-1 RNA Quantitative bDNA
	200316	HIV-1 RNA (log 10)

HIV-1 RNA Quantitative, bDNA, w/reflex HIV-1 Genotype		
Clinical Significance:	**Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy. The reportable range is 75 to 500,000 copies/mL.**	
Effective Date:	**August 9, 2011**	
Test Code:	**7482**	
Former Test Name:	*HIV-1 RNA ULTRAQUANT [BDNA] W/REFLEX GENOTYPR PLUS (RTI+PI)*	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma EDTA and Plasma ACD; Plasma PPT** **3.1 mL** **1.1 mL** **Collect peripheral blood in sterile tubes containing EDTA (K3, 0.15% v/v final; or K2 spray coated, 1.8 mg/mL final; or K2 Plasma Preparation Tubes (PPT), or ACD solution A, 17.6% solution v/v final). Note: Blood collected in tubes containing ACD anticoagulant are acceptable but will yield results approximately 15% lower when compared with EDTA tubes, due to the dilution effect of the 1.5 mL of anticoagulant used in the tube.** **EDTA or ACD – Store whole blood at room temperature (18 to 30°C) for up to 4 hours prior to centrifugation. Do not refrigerate. Remove plasma from cells within 4 hours of collection. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Do not clarify plasma by filtration or further centrifugation. Transfer the plasma to a separate plastic screw-capped vial, freeze and ship frozen.** **PPT – Store whole blood at room temperature (18 to 30°C) for up to 2 hours prior to centrifugation. Separate by centrifugation at 1000 xg for 10 to 15 minutes. Aliquot to a sterile screw cap tube. Freeze samples (-60 to -80°C) immediately after centrifugation. Do not clarify plasma by filtration or further centrifugation. Do not submit original PPT tube.**
Rejection Criteria:	**Samples collected in heparin tubes; Frozen or refrigerated PPT tube; Serum samples; Samples in leaking, uncapped, or broken containers.**	
Specimen Stability:	**Plasma EDTA and Plasma ACD** **Room temperature: Not acceptable** **Refrigerated: 48 Hours** **Frozen: 90 Days** **Plasma PPT** **Frozen: 90 Days**	

Reference Ranges:	**HIV-1 RNA Quant bDNA** **HIV-1 RNA (log10)**	**copies/mL** **log copies/mL**
Additional Information:	**The Siemens Trugene(R) HIV-1 Genotyping, PR and RT, Sequencing assay is reflexed for an additional fee when the viral load is greater than or equal to 1000 copies/mL. Add CPT code 87901. Add up to 10 days to the turnaround time.**	
Always Message	**Add: A change in HIV-1 RNA level is likely significant only if the Log 10 difference is 0.5 or more. This test was performed using the Versant (R) HIV-1 RNA 3.0 Assay (bDNA) kit by Siemens.**	
CPU Interface Mapping: New components	**Result Code:** **63205** **200316**	**Result Name:** HIV-1 RNA Quantitative bDNA HIV-1 RNA (log 10)

HIV-1 Genotyping, PR and RT, Sequencing	
Effective Date:	**August 9, 2011**
Test Code:	**7480**
Former Test Name:	*HIV-1 GenotypR™ PLUS (Reverse Transcriptase and Protease Inhibitors)*
Additional Information:	**Also affects 7480NY**
Always Message	**All HIV-1 Genotyping results must be interpreted in the context of both clinical and laboratory findings.** **This information is protected by various state laws specific to client location and, in such cases, cannot be further disclosed without the patient's specific written consent, or as otherwise permitted by law.** **This test was performed using the Trugene(R) HIV-1 Genotyping Test Kit by Siemens. The resistance report was generated using GuideLines(TM) Rules 16.0.**

HIV-1 RNA Quantitation [Real Time PCR] w/rfx HIV-1 Genotype	
Clinical Significance:	**Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy. The reportable range is 75 to 500,000 copies/mL.**
Effective Date:	**August 9, 2011**
Test Code:	**7482A**
Former Test Name:	*HIV-1 RNA Quantitation [Real Time PCR] w/rfx Genotypr Plus*
Specimen Stability:	**Plasma EDTA and Plasma ACD** **Room temperature: Not acceptable** **Refrigerated: 48 Hours** **Frozen: 90 Days**
Additional Information:	**Specimens collected in Plasma PPT tubes (separated from cells and frozen) and ACD anticoagulant have been validated at Quest Diagnostics Nichols Institute.** **If viral load quantitation result is greater than or equal to 1000 copies/mL, a reflex to the Siemens Trugene HIV-1 Genotyping, PR and RT, Sequencing assay will be ordered and performed for an additional fee. Add CPT code 87901 and add 7-10 days to the turnaround time.**

HIV-1 Abs + Bands [WB] w/Reflex HIV-2 Abs [EIA]	
Effective Date:	**August 9, 2011**
Test Code:	**3013B**
Additional Information:	**Currently when the HIV-1 WB assay is Negative or Indeterminate, HIV-2 Abs by EIA is reflexed (panel REH). If the HIV-2 Abs by EIA is Reactive, the panel further reflexes to HIV-2 Abs by WB + Bands (panel REK). Bands will no longer be reported for this reflex.** **Also affects 3013BT, Reflex Panel REK**

HIV-1 Abs [WB] w/Reflex HIV-2 Abs [WB] (Blood Bank)	
Effective Date:	**August 9, 2011**
Test Code:	**3021BT**
Former Test Name:	*HIV-1 Abs [WB] w/Reflex HIV-2 Abs + Bands [WB] (Blood Bank)*
Additional Information:	**Currently when the HIV-1 WB assay is Negative or Indeterminate, HIV-2 Abs by WB is reflexed (panel RFS). Reflexed panel RFS currently includes bands, however bands will no longer be reported for this reflex.** **Also affects Reflex Panel RFS**

Inhibin B		
Effective Date:	**August 9, 2011**	
Test Code:	**3982**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **1.0 mL** **0.5 mL**
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: 2 days** **Refrigerated: 7 days** **Frozen: 28 days**	
Set-Up/Analytic Time:	**Set-up: Tues,Thurs, Sat; Report Available: 2-3 days**	
Always Message	**REFERENCE RANGE for Inhibin B:** **Age: Male: Female:** **5-9.9 years 21-166 pg/mL < or = 18 pg/mL** **10-13.9 years 41-328 pg/mL < or = 86 pg/mL** **14-17.9 years 135-368 pg/mL < or = 123 pg/mL** **>18 years 47-308 pg/mL** **Female: Pre-menopausal <153 pg/mL** **Post-menopausal <10 pg/mL** ****This test was performed using the Beckman Coulter Inhibin-B Gen II ELISA method.** **Values obtained from different assay methods cannot be used interchangeably. Inhibin B levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.** **This test 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 should not be used for diagnosis without confirmation by other medically established means.**	
Methodology:	**Immunoassay**	

Effective August 23, 2011

Coenzyme Q10		
Clinical Significance:	Coenzyme Q10 (CoQ10) is a fat soluble cofactor that is essential for energy producing metabolic pathways and for the proper functioning of the mitochondrial oxidative system. With insufficient CoQ10, the electron transfer activity of the mitochondria decreases, resulting in a net failure to produce the energy necessary to run the cell. Tissues with high energy demand have even greater demands for CoQ10. For example, heart muscle, which continually exerts a pumping action for an entire lifetime, has an immense need for the cofactor. Studies demonstrate the effectiveness of supplemental coenzyme Q10 in cardiomyopathy, myocardial dysfunction, and congestive heart failure. CoQ10 is also a powerful antioxidant like vitamins E and C, and thus serves the role of neutralizing excess free radicals. It is now well established that the control of excessive free radical activity is key in preventing/delaying the progression of degenerative diseases.	
Effective Date:	**August 23, 2011**	
Test Code:	**7534**	
Former Test Name:	**Coenzyme Q10 (Co Q10) AssessR™**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum, foil wrap** **0.5 mL** **0.2 mL** **Samples received that are not protected from light will be rejected. Patient should fast 8-12 hours before collection. Patient may have water. It is not necessary to discontinue nutritional supplements before this test. Collect 0.5 mL serum from a (R, red-top tube, no additive). (SS, serum separator tube) is also accepted. Send serum in an amber vial or wrap a clear, plastic screw capped vial in foil. Freeze and ship frozen.**
Rejection Criteria:	**Specimens not light protected**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Frozen: 7 days**	
Always Message:	**Add: Detection limit 0.10 mg/L**	

Complement Functional Activity CH50		
Clinical Significance:	Total Complement (CH50) concentration is an overall measure of the complement system. Decreased concentrations are observed in patients with complement factor deficiencies and disease activity, e.g., systemic lupus erythematosus (SLE) and immune complex disease.	
Effective Date:	**August 23, 2011**	
Test Code:	**1600**	
Specimen Requirements:	Opt Volume: Min Volume: Collection Instructions:	**1.0 mL** **0.2 mL** **Please note: CSF, Pleural Fluid, Pericardial Fluid, and Synovial Fluid are unacceptable for this test.** **Avoid hemolysis. Centrifuge serum specimens within 1 hour of collection. Immediately pipette serum into sterile, plastic, screw-capped vial(s) and freeze solid -20 degrees C or lower. Do not allow samples to thaw. With multiple tests, submit a separate tube for each test. Send frozen samples on dry ice to the laboratory.**
Set-Up/Analytic Time:	**Set-up: Mon thru Sat; Report Available: 1-2 days**	

Erythropoietin	
Effective Date:	**August 23, 2011**
Test Code:	**1160**
Always Message:	**NOTE: Serum Thrombopoietin, the principal regulator of platelet production, is available when the cause of thrombocytopenia (or thrombocytosis) is unclear. If indicated, please order Test Code S52473, performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.**

Free Kappa & Lambda, with K/L Ratio, Serum		
Clinical Significance:	This test is a latex-enhanced, immunoassay that provides ultrasensitive detection and quantitation of free light chains (FLCs) in serum or urine earlier than electrophoresis. It is an aid in the diagnosis and treatment of multiple myeloma, lymphocytic neoplasms, Waldenstroms macroglobulinemia and connective tissue diseases, such as systemic lupus erythematosus. Approximately 15% of all cases of multiple myeloma produce only free kappa or lambda light chains in excess. These patients frequently show no abnormality on serum protein electrophoresis. Quite often urine is tested for the presence of these light chains, which are also called Bence Jones Proteins. However, the FLCs entering the urine are strongly influenced by renal tubular function. When clonal proliferation of plasma cells starts to develop, the FLC concentration increases in serum. Since these small particles are rapidly cleared by the renal tubules, urine tests for FLCs remain negative until the tumor mass expands, and the FLCs in serum exceed the resorptive capacity of the renal tubules. Therefore, the measurement of FLCs in serum is an alternative to less sensitive urine testing. Changing concentrations of FLCs in serum relate better to changing tumor load than to concentrations in urine.	
Effective Date:	**August 23, 2011**	
Test Code:	**1760**	
Former Test Name:	*Kappa/Lambda Light Chains, Free w/Ratio, Serum*	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum; Alternate SST** **2.0 mL** **1.0 mL**
Transport Temperature:	**Refrigerated**	
Rejection Criteria:	**Serum separator tubes (SST)**	
Specimen Stability:	**Room Temperature: 7 days** **Refrigerated: 21 days** **Frozen: 3 months**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 1-2 days**	
Methodology:	**Immunoturbidimetric**	
Additional Information:	**Also affects 1762**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	200746 **200747** **200748**	**Free Kappa, serum** **Free Lambda, serum** **Free Kappa/Lambda ratio**

HLA: B27 Typing		
Clinical Significance:	The B27 allele group of the HLA-B locus is present in 2 to 9% of the general population. About 20% of HLA-B27 carriers develop autoimmune disorders including ankylosing spondylitis (AS), reactive arthritis, psoriatic arthritis, undifferentiated oligoarthritis, uveitis, and inflammatory bowel disease. The highest association is with as, where approximately 95% of as patients are HLA-B27 positive.	
Effective Date:	**August 23, 2011**	
Test Code:	**1350**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Add: EDTA Whole Blood** **5.0 mL** **3.0 mL**
Specimen Stability:	**Room Temperature: 5 days**	
Reports As:	**HLA:B27**	**Positive or Negative**

Homocystine Cardiovascular		
Clinical Significance:	Homocysteine is a thiol-containing amino acid produced by the intracellular demethylation of methionine. Total homocysteine (tHcy) represents the sum of all forms of Hcy, including forms of oxidized, protein bound and free. Elevated levels of tHcy have emerged as an important risk factor in the assessment of cardiovascular disease. Excess Hcy in the bloodstream may cause injuries to arterial vessels due to its irritant nature, and result in inflammation and plaque formation, which may eventually cause blockage of blood flow to the heart. Elevated tHcy levels are caused by four major factors, including (a) genetic deficiencies in enzymes involved in Hcy metabolism such as cystathionine beta-synthase, methionine synthase and methylenetetrahydrofolate reductase; (b) nutritional deficiency in B vitamins such as B6, B12, and Folate; (c) renal failure resulting in defective amino acid clearance, and (d) drug interactions such as nitric oxide, methotrexate and phenytoin that interfere with Hcy metabolisms. Elevated levels of tHcy are also linked with Alzheimer's disease and osteoporosis.	
Effective Date:	**August 23, 2011**	
Test Code:	**3334**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma, EDTA, Plasma, Heparin, Serum** **1.0 mL** **0.5 mL** **Red top tubes: Place the specimen in a refrigerator or ice bath for 30 minutes after collection. Centrifuge the specimen as soon as possible after complete clot formation. Transfer the serum to a plastic screw capped vial. Mark the specimen type as serum on the transport tube.** **Barrier gel separator tubes: Place the specimen in a refrigerator for 30 minutes after collection. Do not place barrier tubes in an ice bath as freezing may prevent the barrier gel from adequately separating serum from cells. Centrifuge the specimen as soon as possible after complete clot formation, ensuring that the barrier gel completely separates serum from cells.** **EDTA or Heparin tubes: Place the specimen in a refrigerator or ice bath after collection. Centrifuge the specimen as soon as possible. Transfer the plasma to a plastic screw capped vial. Mark the specimen type as plasma on the transport tube. DO NOT submit whole blood.**
Rejection Criteria:	**Grossly hemolyzed or lipemic samples**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: 4 days** **Refrigerated: 14 days** **Frozen: 6 months**	
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 3 days**	
Methodology:	**Immunoassay**	

Jo-1 IgG Autoantibodies	
Effective Date:	**August 23, 2011**
Test Code:	**1208**
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 3 days**
Additional Information:	**Also affected: 1004**
Always Message:	**Negative: <1.0 Index Antibody Not Detected**

QuantiFERON®-TB Gold (Incubated)	
Effective Date:	**August 23, 2011**
Test Code:	**6110**
Always Message:	**The Nil value adjusts for patient sample background, heterophile antibody effects, or non-specific IFN. The Mitogen serves as a patient positive control. The result "Positive", "Negative", or "Indeterminate" is calculated from these values using an FDA-approved algorithm run on Quantiferon ® software.** **The performance of the Quantiferon ® TB Gold IT (QFT-GIT) test has not been extensively evaluated in children younger than 17 years of age. Therefore, there is limited published data to document the performance of QFT-GIT in this age group. According to the CDC, QFT-GIT should not be used for children <5 years of age.(MMWR 2010;59(RR-05);1-25)**

Topiramate		
Clinical Significance:	Topiramate is an antidepressant used as an adjunctive treatment of partial-onset epilepsy and Lennox-Gastaut syndrome in children. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity.	
Effective Date:	**August 23, 2011**	
Test Code:	**4925**	
Specimen Requirements:	Type:	**Additional Specimen Types:** **Plasma** **Sodium heparin (green-top)** **Lithium heparin (green-top)** **Sodium heparin lead-free (tan-top)** **Sodium heparin lead-free (royal blue-top)**
	Opt Volume:	**1.0 mL**
	Min Volume:	**0.5 mL**
	Collection Instructions:	**Draw at peak (2-4 hours after dose) or trough (0.5-1 hour before dose) at steady state.**
Rejection Criteria:	**Do not use gel barrier tubes.**	
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Room Temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Tues thru Sat; Report Available: 3 days**	
Reference Ranges:		**Units: mcg/mL**
Always Message:	**Remove: Pediatric patient have 50% higher clearance and shorter elimination half-life than adults. Consequently, plasma levels for the same dosage will be lower than adults.**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	37097	**Topiramate**

Von Willebrand Factor Ag		
Effective Date:	**August 23, 2011**	
Test Code:	**1907**	
Reference Ranges:	**Von Willebrand Antigen**	**61-164 %**

Effective September 1, 2011

CD Marker, T&B Cell Panels	
Clinical Significance:	Revised to match new individual components noted in new Panels.
Effective Date:	**September 1, 2011**
Test Code:	**1683, 1684, 1685, 1658, 1687, 1688**
Additional Information:	**Please see Lymphocyte Subsets Panels in New Test Section for detailed changes to components and reference ranges.**

Test Discontinuations

Babesia microti IgG & IgM Antibodies CSF	
Effective Date:	**August 1, 2011**
Test Code:	**2161C**
Additional Information:	No alternative available. Also affects 2162C, 2163C
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Cytochrome P450 2D6 GenotypR™	
Effective Date:	**August 1, 2011**
Test Code:	**5380**
Additional Information:	Suggested Alternate: 4565 AmpliChip™ CYP450 2D6 & 2C19 GenotypR™
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-2 IgG Antibodies reflex WB + bands	
Effective Date:	**August 9, 2011**
Test Code:	**9921B**
Additional Information:	Suggested Alternate: 9921 – HIV-2 IgG Abs w/Reflex WB
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-1 & 2 Antibodies + bands [WB]	
Effective Date:	**August 9, 2011**
Test Code:	**3015B**
Additional Information:	Suggested Alternate: 3081B – HIV-1 Abs + Bands [WB] & HIV-2 Abs [WB]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-2 IgG Abs w/Reflex WB + Bands [Blood Bank]	
Effective Date:	**August 9, 2011**
Test Code:	**9921BT**
Additional Information:	Suggested Alternate: 9921T - HIV-2 IgG Abs w/Reflex WB [Blood Bank]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-1/HIV-2 Antibodies [EIA] w/Reflex WB + Bands	
Effective Date:	**August 9, 2011**
Test Code:	**9915B**
Additional Information:	Suggested Alternate: 9915 – HIV-1/HIV- 2 Antibodies [EIA] w/Reflex WB
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-2 IgG Antibodies [WB] + bands	
Effective Date:	**August 9, 2011**
Test Code:	**9926B**
Additional Information:	Suggested Alternate: 9926 – HIV-2 IgG Abs Western Blot
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

HIV-2 IgG Antibody CSF	
Effective Date:	**August 9, 2011**
Test Code:	**9926C**
Additional Information:	No alternative available.
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Testosterone, Free	
Effective Date:	**August 9, 2011**
Test Code:	**3247**
Additional Information:	Suggested Alternate: 3201 - Testosterone, Free [LC-MS-MS]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Testosterone, Total (Pediatric & Female)	
Effective Date:	**August 9, 2011**
Test Code:	**3243**
Additional Information:	Suggested Alternate: 3921 – Testosterone, Total [LC-MS-MS]
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Lymphocyte Enumeration, T Cell	
Effective Date:	**September 1, 2011**
Test Code:	**1655**
Additional Information:	Suggested Alternate: 71958 – Lymphocyte Subset Panel 3
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Lymphocyte Enumeration, Helper/Suppressor	
Effective Date:	**September 1, 2011**
Test Code:	**1657**
Additional Information:	Suggested Alternate: 79248 - Lymphocyte Subset Panel 4
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Lymphocyte Enumeration, Helper/Suppressor - Limited	
Effective Date:	**September 1, 2011**
Test Code:	**1659**
Additional Information:	Suggested Alternate: 79248 - Lymphocyte Subset Panel 4
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Lymphocyte Enumeration, Basic & NK Cells	
Effective Date:	**September 1, 2011**
Test Code:	**1668**
Additional Information:	Suggested Alternate: 71978 - Lymphocyte Subset Panel 1
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Lymphocyte Enumeration, Basic	
Effective Date:	**September 1, 2011**
Test Code:	**1671**
Additional Information:	Suggested Alternate: 36420 - Lymphocyte Subset Panel 2
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

New Referral Tests

Digitoxin, Serum/Plasma (1613SP)		
Effective Date:	**Immediate**	
Test Code:	**S52434**	
CPT Code(s):	**80299**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum, Alternate Plasma, EDTA** **1.0 mL** **0.5 mL**
Rejection Criteria:	**Thawed serum/plasma or received at room temperature.**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: 5 days** **Refrigerated: 7 days** **Frozen: 2 months**	
Set-Up/Analytic Time:	**Set-up: Tues,Thurs; Report Available: 2-4 days**	
Reference Ranges:	**Digitoxin**	**10-30 ng/mL**
Methodology:	**Immunoassay**	
Performing Site:	**National Medical Services**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	110127	**Digitoxin**

HLA-A29 DNA Typing (16773)		
Clinical Significance:	Birdshot retinochoroidopathy (BSCR) is a rare posterior uveitis, characterized by distinctive, multiple, hypopigmented choroidal and retinal lesions. At least 96% of patients, if not all, share the major histocompatibility antigen, HLA-A29. However, most HLA-A29 positive individuals do not have this disease. Together with clinical manifestations, HLA-A29 typing is used for diagnosis of BSCR.	
Effective Date:	**Immediate**	
Test Code:	**S52431**	
CPT Code(s):	**83891, 83900, 83912, 83896x30**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Whole blood, ACD or EDTA** **10.0 mL** **5.0 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 8-10 days**	
Reference Ranges:	**HLA-A29 DNA Typing**	**Accompanies report**
Methodology:	**PCR followed by Sequence Specific Oligonucleotide Probes**	
Performing Site:	**Quest Diagnostics Nichols Institute, Chantilly**	
CPU Interface mapping	**Result Code:**	**Result Name:**
	113321	**HLA-A29 DNA Typing**

SMA Carrier Screen (18041)		
Clinical Significance:	Spinal muscular atrophy is a severe neuromuscular disease characterized by degeneration of motor neurons in the spinal cord which results in progressive muscle weakness and paralysis. SMA is often fatal in childhood. The carrier rate of SMA is comparable to that of Cystic Fibrosis. Population studies have determined the frequency of SMA Carriers to be 1 in 34-50 persons and can be found in any gender or ethnicity.	
Effective Date:	**Immediate**	
Test Code:	**S52456**	
CPT Code(s):	**83891, 83900, 83909, 83914(x16), 83912, 83901(x14)**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole blood, EDTA or ACD** **4.0 mL** **2.0 mL** • **If submitted with any other Genetics test requiring an EDTA (lavender-top) tube, please submit a separate tube for this test.** • **Signed consent form is required. Results will not be released from Athena until consent is received.** • **Please label each specimen tube with two forms of patient identification. These forms of identification must also appear on the requisition form.** **For assistance with interpretation of these results, please call 866-GENEINFO (866-436-3463).**
Rejection Criteria:	**Clotted specimen; Received frozen**	
Transport Temperature:	**Room temperature**	
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 14 days**	
Set-Up/Analytic Time	**Set-up: Mon-Sun; Report available: 7 days**	
Reference Range	**SMA Carrier Screen**	**Accompanies report**
Methodology:	**Multiplex-Ligation-dependent Probe Amplification (MLPA)**	
Assay Category:	**Laboratory Developed Test**	
Performing Site:	**Athena Diagnostics, Inc.**	
CPU Interface mapping:	**Result Code:**	**Result Name:**
	113386	**SMA Carrier Screen**

Cytomegalovirus DNA, Qualitative Real-Time PCR (45000)		
Clinical Significance:	The detection of cytomegalovirus (CMV) DNA is based upon the real-time amplification and detection of specific CMV genomic DNA sequences by PCR from total DNA extracted from the specimen.	
Effective Date:	**Immediate**	
Test Code:	**S49983**	
CPT Code:	**87496**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Urine, Tissue** **1.0 mL** **0.3 mL**
Set-Up/Analytic Time:	**Set-up: Sun-Mon; Report Available: 2-3 days**	
Specimen Stability:	Urine: Tissue:	**Room temperature: 2 days** **Refrigerated: 8 days** **Frozen: 30 days** **Room temperature: 2 days** **Refrigerated: 8 days** **Frozen: 30 days**
Always Message:	**Peak serum concentrations, 2-4 hrs2 g dose: 30-40 mcg/mL. Any undisclosed antimicrobials might affect the results.**	
Reference Range:	**CMV DNA**	**Not detected**
Method:	**Real-Time PCR**	
Performing Site:	**Focus Diagnostics**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	104775	**CMV DNA**

NMO-IgG Autoantibody Test (193)		
Clinical Significance:	Confirm suspected cases of NMO and assist in making a differential diagnosis and identifying the cause of MS-like symptoms in the patient. An accurate diagnosis will further help predict disease course and provide direction in treatment options.	
Effective Date:	**Immediate**	
Test Code:	**S52438**	
CPT Code(s):	**83520**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **2.0 mL** **1.0 mL**
Rejection Criteria:	**Frozen samples**	
Transport Temperature:	**Refrigerated**	
Specimen Stability	**Room temperature: 3 days** **Refrigerated: 14 days** **Frozen: Unacceptable**	
Set-Up/Analytic Time	**Set-up: Tues; Report available: 8-15 days**	
Reference Range	**Interpretation:** **Technical Result:** **Comments:**	 **Accompanies report**
Methodology:	**ELISA**	
Assay Category:	**Laboratory Developed Test**	
Performing Site:	**Athena Diagnostics, Inc.**	

Always Statement:	**Neuromyelitis optica (NMO)-specific autoantibodies are also found in patients with relapsing optic neuritis (rON)1, or longitudinally extensive transverse myelitis (LETM) without optic neuritis, which is thought to be a precursor to NMO in some cases 2.The main target antigen for this immunoreactivity has been identified as aquaporin-4 (AQP4) 3. An antibody-mediated pathogenesis for NMO is supported by several observations, including the characteristics of the AQP4 antibodies, the distinct NMO pathology (including IgG and complement deposition, and loss of AQP4 from spinal cord lesions) 2. However, many aspects of the pathogenesis remain unclear 2.** **Although Neuromyelitis Optica (NMO or Devic syndrome) has been classified as a subtype of multiple sclerosis for many years, the disease is classically restricted to the optic nerves and spinal cord, and it is now clear that it has distinct clinical and pathological features 2. The average age of onset for NMO is 34.5 years, with a range of 4-66 yrs of age 4. In caucasian populations, females develop the disease 3 times more frequently than males (3:1 ratio), and in one report, 22% of cases had a severe residual visual loss after the first episode of optic neuritis 4.** **Methods** **Detection of NMO-specific autoantibodies was performed by ELISA using free biotinylated Aquaporin-4 (AQP4), and plates that were coated with purified AQP4. Compared to the results of a cell-based assay designed to detect NMO-autoantibodies, the sensitivity and specificity of this ELISA test has been calculated as 73% and greater than 99%, respectively.** **References** **1. Jarius S, et al. Nat Rev Neurol (2010) 6:383-392.** **2. Jarius S, et al. Nat Clin Pract Neurol. (2008) 4:202-214.** **3. Lennon VA, et al. J Exp Med (2005) 202:473-477.** **4. Collongues N, et al, Neurology (2010) 74:736-742.** ***** FINAL REPORT *** ver 1.0** **This test was developed and its performance characteristics determined by Athena Diagnostics, Inc. 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. This test is used for clinical purposes and should not be regarded as investigational or for research only. Athena Diagnostics is licensed under the Clinical Laboratory improvement Amendments of 1988 (CLIA) to perform high complexity clinical testing. Athena Diagnostics has performed assay validation studies and has developed its laboratory protocols and operating procedures in consultation with experts in the field and in accordance with the standards of the National Committee on Clinical Laboratory Standards (NCCLS).**	
CPU Interface mapping:	**Result Code**:	**Result Name:**
	113358	**Interpretation**
	113359	**Technical Result**
	113360	**Comments**

Thrombopoietin (TPO) (16336)		
Clinical Significance:	This test will be used to measure serum TPO level in patients with thrombocytopenia of unknown cause. ITP (Idiopathic Thrombocytopenia purpura) is a common cause of thrombocytopenia. The diagnosis is based on exclusion criteria. Serum TPO levels are normal or only slightly elevated in ITP so that if TPO level is markedly elevated the diagnosis of ITP is strongly in doubt. Markedly elevated TPO levels may occur in individuals with genetic mutations of CD110. New Drugs, non peptide thrombopoietin receptor agonist (CD110) are becoming increasingly used in patients with thrombocytopenia of ITP. The cost of these new drugs is very high. That is why it is important to know levels of TPO. Patients with elevated TPO levels do not respond to treatment with thrombopoietin receptor agonist. Knowing levels of TPO may help in predicting efficacy of response to an extremely expensive stimulating drug used in a wide variety of hematologic disorders. May reduce the need for platelet transfusions with all known complications and reduced cost of blood products by hospital.	
Effective Date:	**Immediate**	
Test Code:	**S52473**	
CPT Code(s):	**83520**	
Assay Category:	**RUO**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum** **1.0 mL** **0.5 mL** **Cytokine levels may demonstrate diurnal variation. Recommend cytokine levels be determined at the same time of day for improved longitudinal comparison**
Rejection Criteria:	**Thawed Serum**	
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Thu; Report Available: 6-7 days**	
Reference Ranges:	**Thrombopoietin (TPO)**	**7-99 pg/mL**
Methodology:	**Immunoassay**	
Always Message:	**This test was performed using a kit that has not been approved or cleared by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. This test should not be used for diagnosis without confirmation by other medically established means.**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	113413	**Thrombopoietin (TPO)**

Aspirin Resistance (11-Dehydrothromboxane B2) (16174)		
Clinical Significance:	Aspirin (which inhibits platelet cyclo-oxygenase) reduces the risk of thrombosis in cardiovascular disease by impairing platelet function. Patients who do not respond to the platelet inhibitory effects of aspirin are designated as 'ASPIRIN RESISTANT'. The measurement of 11-DEHYDRO THROMBOXANE B-2 in urine (the principal metabolite of platelet cyclo-oxygenase derived thromboxane B-2) indicates lack of aspirin responsiveness.	
Effective Date:	**August 9, 2011**	
Test Code:	**S52243**	
CPT Code(s):	**84431, 82570**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Preserved urine in BD C&S Urine Vacutainer ® Tube** **4.0 mL** **3.0 mL** **Sample must be collected in BD C&S Vacutainer ® tube**
Transport Temperature:	**Room temperature**	
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 3 months**	
Set-Up/Analytic Time	**Set-up: Thu; Report available: 2-3 days**	
Reference Range	**11-Dehydrothromboxane B2**	**>1500 pg/mg creat**
Always Statement:	**A urine level of 11-Dehydro Thromboxane B2 above 1500 pg/mg creatinine should be expected in healthy, aspirin-free individuals. A urine level of 11-Dehydro Thromboxane B2 equal or below 1500 pg/mg creatinine in individuals taking aspirin indicates an aspirin-like effect. A urine level of 11-Dehydro Thromboxane B2 above 1500 pg/mg creatinine in individuals taking aspirin indicates a lack of aspirin-like effect.**	
Methodology:	**Enzyme Immunoassay**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	
CPU Interface mapping:	**Result Code:**	**Result Name:**
	113369	**11-Dehydrothromboxane B2**

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.

SMA Diagnostic Test (16869)		
Clinical Significance:	Spinal muscular atrophy is characterized by progressive muscle weakness caused by the degeneration of lower motor neurons that are responsible for controlling voluntary muscle movement including walking, crawling, swallowing, and head and neck control. Age of onset ranges from before birth to adolescence or young adulthood. The most common type of SMA is associated with respiratory failure and death before the age of two.	
Effective Date:	**Immediate**	
Test Code:	**S50070**	
Former Test Name:	*Spinal Muscular Atrophy DNA (111D)*	
CPT Code(s):	**83891, 83900, 83909, 83914(x16) 83912, 83901(x14)**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole blood, EDTA or ACD** **4.0 mL** **2.0 mL** • **If submitted with any other Genetics test requiring an EDTA (lavender-top) tube, please submit a separate tube for this test.** • **Signed consent form is required. Results will not be released from Athena until consent is received.** • **Please label each specimen tube with two forms of patient identification. These forms of identification must also appear on the requisition form.** **For assistance with interpretation of these results, please call 866-GENEINFO (866-436-3463).**
Rejection Criteria:	**Clotted specimen; Received frozen**	
Transport Temperature:	**Room temperature**	
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 14 days**	
Set-Up/Analytic Time	**Set-up: Mon-Sun; Report available: 7 days**	
Reference Range	**SMA Diagnostics**	**Accompanies report**
Methodology:	**Multiplex-Ligation-dependent Probe Amplification (MLPA)**	
Assay Category:	**Laboratory Developed Test**	
CPU Interface mapping:	**Result Code:**	**Result Name:**
	113387	**SMA Diagnostics**

Mineral Profile RBC (3066R)		
Effective Date:	**Immediate**	
Test Code:	**S49802**	
Specimen Requirements:	Type: Opt Volume: Min. Volume:	**Red Blood Cells** **9.0 mL** **5.0 mL**

17-Hydroxy-Progesterone, 24hr Urine	
Effective Date:	**Immediate**
Test Code:	**S43550**
Always Statement	**This test was performed using a kit that has been approved by the FDA for an alternative matrix. The analytic performance characteristics of this test for the submitted matrix have been determined by Inter Science Institute.**

Rabies Vaccine Response End-Point Titer	
Effective Date:	**Immediate**
Test Code:	**S52235**
Reference Ranges:	**In humans, a result of 0.5 IU/mL or higher is considered acceptable according to the World Health Organization (WHO) guidelines; see WHO and Advisory Committee on Immunization Practices documents for additional guidance. Also, there is more information at www.vet.ksu.edu/rabies.** **(Note: the symbol ">/=" means greater than or equal to")** **Results are confidential, personal health information. All disclosures must be in accordance with HIPAA.**

Amino Acid Analysis, LC/MS, Plasma (646N)		
Effective Date:	**Immediate**	
Test Code:	**S51335**	
Specimen Requirements:	Collection Instructions:	**Collect plasma specimens after an overnight fast (or at least 4 hours after a meal). Non-fasting samples are acceptable for pediatric patients**.

Testosterone, Free and Total LC/MS/MS (NY) (36170)		
Effective Date:	**Immediate**	
Test Code:	**S51829N**	
Former Test Name:	*Testosterone, Free and Total LC/MS/MS (NY) (36170)*	
Former Test Code:	*S51829*	
Notes:	**NY patient testing only**	
Remove Component:	**% Free Testosterone**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	111519	**% Free Testosterone**

Metformin, Urine Test (2740U)	
Former Test Name:	*Glucophage Urine (2740)*
Effective Date:	**Immediate**
Test Code:	**S49627**
CPT Code:	**80299**
Transport Temperature:	**Refrigerated (preferred and may help improve isolate viability).**
Specimen Stability:	**Room Temperature: 1 month** **Refrigerated: 1 month** **Frozen: 1 month**
Methodology:	**LC-MS/MS**

Metformin Serum, Plasma (2740SP)		
Former Test Name:	*Glucophage (2740)*	
Effective Date:	**Immediate**	
Test Code:	**S48679**	
CPT Code:	**80299**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum, Plasma-EDTA** **1.0 mL** **0.5 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 1 month** **Refrigerate: 1 month** **Frozen: 1 month**	
Methodology:	**LC-MS/MS**	

CellSearch® Circulating Tumor Cells, Breast (16011)		
Effective Date:	**Immediate**	
Test Code:	**S51755**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Whole Blood Cellsave ™ preservative tube** **20 mL** **10 mL** **1. Draw at least one CellSave™ 10 ml tube. It is highly recommended that two 10 ml tubes be drawn due to the possibility of repeat due to carry over or system malfunction.** **2. Collect blood aseptically by venipuncture or from a venous port into a CellSave™ Preservative Tube only. Circulating tumor cells (CTC) are fragile and require preservation for accurate analysis.** **3. Fill the tube until blood flow stops to ensure correct ratio of sample to anticoagulant and preservative. Immediately mix by gently inverting the tube eight times. Tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results.** **4. Process samples within 96 hours of collection.** **5. Blood samples may be stored or transported in CellSave™ Preservative Tubes for up to 96 hours at room temperature (15 to 30C) prior to processing. Draw date and time must be provided with the whole blood specimen. Draw samples prior to intravenous therapy. After initiation of therapy, blood can be drawn at the first follow-up visit, which is usually 3-4 weeks after initiation of therapy. If the patient is on doxorubicin therapy, allow at least 7 days following administration of a dose of therapy before blood draw.**
Always Message:	**Interpretation/Comment:** **A circulating tumor cell (CTC) count of 5 or more per 7.5ml of blood at any time during the course of the disease has been reported to be associated with a poor prognosis and is predictive of shorter Progression Free Survival (PFS) and Overall Survival (OS) in patients with metastatic breast cancer. The table lists median PFS and OS based on CTC counts.** **Number of CTC PFS(months) OS(months)At all time <5 7.2 22.6Baseline <5; at final draw >5 5.9 10.6Baselne >5; at final draw <5 6.1 19.8At all time points >5 1.8 4.1** **CellSearch™ results should be used in conjunction with all clinical information derived from diagnostics tests (i.e., imaging, laboratory tests), physical examination and complete medical history in accordance with appropriate patient management procedures. This prognostic study does not demonstrate that any current line of therapy is any more or less effective than any other or no therapy.** **Method: The test was performed using Veridex Circulating Tumor Cell Kit.** **References:** **1. Veridex product insert, document LBL50058, Rev. 6, 2009-05. 2. Circulating Tumor Cells versus Imaging-Predicting Overall Survival in Metastatic Breast Cancer. Clin Cancer Res. 2006 Nov 1;12(21) 6403-9. 3. Circulating Tumor Cells: A Novel Prognostic Factor for Newly Diagnosed Metastatic Breast Cancer. J Clin Oncol. 2005 Mar 1;23(7): 1420-30.**	

Titanium (4486SP)		
Effective Date:	**Immediate**	
Test Code:	**S49212**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum-Trace metal, Plasma-EDTA Trace metal** **3.0 mL** **1.0 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 14 days** **Refrigerate: 14 days** **Frozen: 14 days**	

Beryllium Urine (0638U)		
Effective Date:	**Immediate**	
Test Code:	**S50371**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Urine** **1.0 mL** **0.5 mL** **Avoid exposure to gadolinium-based contrast media for 48 hours prior to sample collection.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 14 days**	
Set-Up/Analytic Time:	**Set-up: Mon-Sat; Report Available: 2-3 days**	

Mineral Profile Serum (3066SP)		
Effective Date:	**Immediate**	
Test Code:	**S50376**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Serum-Trace metal, Plasma-EDTA/Sodium Heparin-Trace metal** **7.0 mL** **4.0 mL** **Entire sample volume must be submitted in one container.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 14 days**	

Barbiturates Confirmation, Serum (8620SP)		
Effective Date:	**Immediate**	
Test Code:	**S47570**	
Set-Up/Analytic Time:	**Set-up: Tue,Thu; Report Available: 3-5 days**	
Remove Component:	**Mephobarbital**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	47574	**Mephobarbital**

Modafinil Serum/Plasma (3045SP)	
Effective Date:	**Immediate**
Test Code:	**S50570**
CPT Code:	**80299**
Set-Up/Analytic Time:	**Set-up: Tue,Thu; Report Available: 3-6 days**

Thiothixene (4469SP)		
Effective Date:	**Immediate**	
Test Code:	**S40755**	
CPT Code:	**80299**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum, Plasma-EDTA** **5.0 mL** **2.5 mL**
Set-Up/Analytic Time:	**Set-up: Mon, Wed, Fri; Report Available: 3-5 days**	

Free Copper (1333SP)		
Effective Date:	**Immediate**	
Test Code:	**S48616**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum-Trace metal, Plasma EDTA-Trace metal** **3.0 mL** **1.5 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 14 days**	
Set-Up/Analytic Time:	**Set-up: Thu; Report Available: 2-3 days**	

Cyclohexanone (1409SP)		
Effective Date:	**Immediate**	
Test Code:	**S41385**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum, Plasma-EDTA** **2.0 mL** **0.7 mL**
Specimen Stability:	**Room temperature: 4 days** **Refrigerate: 14 days** **Frozen: 1 month**	

Glutathione		
Effective Date:	**Immediate**	
Test Code:	**S52169**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**K3EDTA** **7.0 mL** **5.0 mL**
Transport Temperature:	**Refrigerated**	
Notes:	**Collection tubes can be ordered through client supply**	

Methemoglobin Reductase Blood (9322)	
Effective Date:	**Immediate**
Test Code:	**S50583**
CPT Code:	**84311**
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 2-6 days**

Adenosine Deaminase, Blood (80649)		
Effective Date:	**Immediate**	
Test Code:	**S46075**	
CPT Code:	**84311**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Whole Blood-EDTA, ACD** **4.0 mL** **1.0 mL**
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 22 days** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 10-12 days**	
Reference Range:	**Adenosine Deaminase, Blood**	**0.5-1.7 IU/g Hb**

Lipoprotein Profile (83673)	
Effective Date:	**Immediate**
Test Code:	**S40390**
CPT Codes:	**83718, 82465, 84478, 82172, 82664**
Transport Temperature:	**Refrigerated**
Specimen Stability:	**Room temperature: Unacceptable** **Refrigerated: 7 days** **Frozen: 14 days**

Chlamydia Group Antibody Screen, IFA, Serum (40265)	
Effective Date:	**Immediate**
Test Code:	**S52342**
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 2-4days**
Always Message	**CHLAMYDIA IgG <1:8** **CHLAMYDIA IgM <1:20** **INTERPRETATION: ANTIBODY NOT DETECTED** **REFERENCE RANGE: IgG <1:8** **IgM <1:20** **This assay detects antibody to L1, L2, L3 (LGV), various serotypes of C. trachomatis and possibly other species of Chlaymdia due to antibody crossreactivity to L1/L2.The presence of antibody to L1/L2 infected cells indicates infection with Chlamydia species. Single titers are difficult to interpret; however, the presence of IgM, four-fold increases in IgG titers between acute and convalescent specimens, or single IgG titers greater than 1:128 indicate recent exposure. Low IgG titers (1:8 - 1:128) indicate probable past exposure.** **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.**

IgA Fibronectin Aggregates & Serum IgA (4320)		
Effective Date:	**Immediate**	
Test Code:	**S49748**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **2.0 mL** **1.0 mL**
Specimen Stability:	**Room temperature: 7 days** **Refrigerate: 14 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Mon, Wed, Thu; Report Available: 2-9 days**	

5-Fluorocytosine Level, BA (51590)		
Former Test Name:	*Antifungal Serum Level, 5-Fluorocytosine, BA (51590)*	
Effective Date:	**Immediate**	
Test Code:	**S49887**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **1.0 mL** **0.5 mL**
Rejection Criteria:	**SST tubes are not acceptable**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 4-6 days**	
Notes:	**Specimens collected just before or within 15 minutes of the next dose represent the THROUGH levels. Specimens obtained within 15-30 minutes after the end of I.V. infusion or 45-60 minutes after an IM injection or 90 minutes after oral intake represent the PEAK level.**	
Always Message:	**Peak serum concentrations, 2-4 hrs 2g dose: 30-40 mcg/mL. Any undisclosed antimicrobials might affect the results.**	

Ketoconazole Level, BA (51685)	
Former Test Name:	*Ketoconazole Serum Level (51685)*
Effective Date:	**Immediate**
Test Code:	**S48645**
Specimen Stability:	**Room temperature: Unacceptable** **Refrigerate: Unacceptable** **Frozen: 30 days**
Rejection Criteria:	**SST tubes are not acceptable**
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 4-5 days**
Always Message:	**Peak levels (mean)** **Single 200 mg dose PO, 1-2 hrs: 3.5 mcg/mL** **Any undisclosed antimicrobials might affect the results.**

Neocomplete Paraneoplastic Profile with Recombxt (437)		
Effective Date:	**Immediate**	
Test Code:	**S49555**	
CPT Code:	**83516, 83519 x 3, 83520, 84181, 84182 x 6, 86255**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **5.0 mL** **2.0 mL**
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room Temperature: 3 days** **Refrigerated: 14 days** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri Report Available: 28-30 days**	
Notes:	**Profile Includes:** **Amphiphysin Antibody Test, GAD Antibody Test, Ganglionic nAChR Antibody Test, LEMS Antibody Test, NMDA Receptor (NR1) Antibody Test, Recombx™ CAR (Anti-Recoverin) Autoantibody Test , Recombx™ MaTa Autoantibody Test, Recombx™ CV2 Antibody Test, Recombx™ Hu Autoantibody Test, Recombx™ Ri Autoantibody Test, Recombx™ Yo Autoantibody Test, Recombx™ Zic4 Antibody Test, VGKC Antibody Test.**	

Complement Split Factor Bb (BBLL)		
Effective Date:	**Immediate**	
Test Code:	**S49959**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma-EDTA** **1.0 mL** **0.5 mL**
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 4 weeks**	
Reference Range:	**Complement Split Factor BB**	**0.41-1.49 mcg/mL**

Complement Split SC5B-9 (SC5B9)		
Effective Date:	**Immediate**	
Test Code:	**S49961**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma-EDTA** **1.0 mL** **0.5 mL**
Set-Up/Analytic Time:	**Set-up: Wed; Report Available: 4 weeks** ***Test is Batched 1x monthly depending on volume**	
Reference Range:	**Complement Split SC5B-9**	**Male: 72-244 ng/mL** **Female: 27-244 ng/mL**

Plasmalogens	
Effective Date:	**Immediate**
Test Code:	**S41212**
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 14-16 days**

Essential and Metabolic Fatty Acid in Erythrocytes (0041)			
Effective Date:	**Immediate**		
Test Code:	**S49187**		
Specimen Stability:	**Room temperature: 3 days** **Refrigerate: 8 weeks** **Frozen: Unacceptable**		
Reference Range:	**Alpha Linolenic (18:3n3)**		**1.6-11.6 uM**
	Eicosapentaenoic (20:5n3)		**6-102 uM**
	Docosapentaenoic (22:5n3)		**38-165 uM**
	Docosahexaenoic (22:6n3)		**53-215 uM**
	Linoleic (18:2n6)		**143-408 uM**
	Gamma Linolenic (18:3n6)		**0.8-5.5 uM**
	Eicosadienoic (20:2n6)		**3.4-9.1 uM**
	Dihomogamma Linolenic (20:3n6)		**18-66 uM**
	Arachidonic (20:4n6)		**206-509 uM**
	Docosadienoic (22:2n6)		**0.20-1.40 uM**
	Docosatetraenoic (22:4n6)		**24-149 uM**
	Mead (20:3n9)		**<=7.4 uM**
	Myristoleic (14:1n5)		**<=0.78 uM**
	Palmitoleic (16:1n7)		**2.7-18.3 uM**
	Vaccenic (18:1n7)		**15-33 uM**
	Oleic (18:1n9)		**201-410 uM**
	11-Eicosenoic (20:1n9)		**3.8-9.4 uM**
	Nervonic (24:1n9)		**1.0-3.2 uM**
	Capric (10:0)		**<=1.03 uM**
	Lauric (12:0)		**<=2.58 uM**
	Myristic (14:0)		**2.3-13.6 uM**
	Palmitic (16:0)		**345-642 uM**
	Stearic (18:0)		**306-564 uM**
	Arachidic (20:0)		**1.3-3.2 uM**
	Behenic (22:0)		**0.72-1.79 uM**
	Lignoceric (24:0)		**1.1-3.2 uM**
	Hexacosanoic (26:0)		**<=0.58 uM**
	Pentadecanoic (15:0)		**<=5.2 uM**
	Heptadecanoic (17:0)		**<=11.1 uM**
	Nonadecanoic (19:0)		**<=1.28 uM**
	Heneicosanoic (21:0)		**<=0.18 uM**
	Tricosanoic (23:0)		**<=0.22 uM**
	Total C:18 Trans		**<=28.1 uM**
	LA/DGLA		**<=14.4 uM**
	EPA/DGLA		**0.1-4.8 uM**
	AA/EPA		**2-69 uM**
	Stearic/Oleic		**>=1.13 uM**
CPT Code:	**82726**		
Remove Component:	**Palmitelaidic (16:1n7t)**		
CPU Interface Mapping:	**Result Code:**	**Result Name:**	
	102347	**Palmitelaidic (16:1n7t)**	

PIVKA-II (Protein-Induced Vit K Antagonist (300726)		
Clinical Significance:	PIVKA (proteins induced by vitamin K absence) are immunologically similar to the naturally occurring factors but are dysfunctional since they lack the vitamin K dependent carboxyglutamyl residues that are required for calcium and phospholipid binding during clotting. PIVKA-II is prothrombin (factor II) produced in vitamin K's absence and lacks normal coagulant activity.	
Effective Date:	**Immediate**	
Test Code:	**S43090**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma-Citrated** **1.0 mL** **0.5 mL**
Set-Up/Analytic Time:	**Set-up: Tue; Report Available: 3-8 days** ***Test sets up every other week.**	

Acetone Blood (205)		
Clinical Significance:	Excessive formation of ketone bodies (acetone) results in increased blood levels (ketonemia) and increased excretion in the urine (ketonuria). This condition is associated with a decreased availability of carbohydrates, such as dieting or decreased use of carbohydrates. Diabetes and alcohol consumption are common causes of ketoacidosis. Acetone is one ketone body formed from acetoacetate. Ingestion of isoproply alcohol also leads to the formation of acetone.	
Effective Date:	**Immediate**	
Test Code:	**S41710**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Whole Blood-Fluoridated/Oxalate** **1.0 mL** **0.5 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 14 days** **Refrigerated: 14 days** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Tue-Sat; Report Available: 2-5 days**	

Allergen – Cinnamon IgG (45920)		
Effective Date:	**Immediate**	
Test Code:	**S51975**	
Reference Range:	**Cinnamon IgG**	**<2.0 mcg/mL**

Allergen – Pecan Food IgG (52120)		
Effective Date:	**Immediate**	
Test Code:	**S52216**	
Reference Range:	**Pecan IgG**	**<2.0 mcg/mL**

Allergen – Clam IgG (50820)		
Effective Date:	**Immediate**	
Test Code:	**S52016**	
Reference Range:	**Clam IgG**	**<2.0 mcg/mL**

Allergen – Oyster IgG (43120)		
Effective Date:	**Immediate**	
Test Code:	**S52158**	
Reference Range:	**Oyster IgG**	**<2.0 mcg/mL**

Allergen – Sulfamethoxazole IgE (87610E)	
Effective Date:	**Immediate**
Test Code:	**S51966**
Specimen Stability:	**Room temperature: 4 weeks** **Refrigerate: 4 weeks** **Frozen: 12 months**
Always Message:	**Conventional RAST Scoring Guide** **Class IgE (ku/L) Comment** **0 <0.10 Negative** **0/1 0.1-0.34 Equivocal** **1 0.35-0.69 Low Positive** **2 0.7-3.4 Moderate Positive** **3 3.5-17.4 Positive** **4 >=17.5 Strong Positive**

Epstein-Barr Virus DNA (PCR) (47510)	
Effective Date:	**July 11, 2011**
Test Code:	**S49990**
Always Message:	**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.**

Epstein-Barr Virus DNA, Quantitative Real-Time PCR (48453)	
Effective Date:	**July 11, 2011**
Test Code:	**S51739**
Assay Category:	**ASR Class I**
Always Message:	**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.**

Organic Acids, Quant, Random Urine, Full Panel (38067)	
Effective Date:	**July 11, 2011**
Test Code:	**S51667**
Always Message:	**If you have any questions regarding these results, please contact the Quest Diagnostics Biochemical Genetics laboratory at 1-800-642-4657 Ext. 4817 or Ext. 4423 and ask to speak with the laboratory director on call. For general questions about Quest Diagnostics genetic testing, please call the Gene info line at 1-866-GENE-INFO.**

Organic Acids Qualitative Urine (10049N)	
Effective Date:	**July 11, 2011**
Test Code:	**S49453**
Always Message:	**This test is a qualitative screen for identification of organic acids that are at least moderately increased. It is recommended that elevated organic acids be confirmed by quantitative urine organic acid analysis (SOC 41335N). This screen may miss disorders characterized by minimal or intermittent metabolite excretion, especially if the patient is asymptomatic at the time of collection. The following metabolites are also poorly extracted from urine by this method, and may result in a missed diagnosis: 3-hydroxyisovaleric acid, 4-hydroxybutyric acid, glutaconic acid, glyoxylic acid, mevalonic acid, pyruvic acid, and suberylglycine.** **If you have any questions regarding these results, please contact the Quest Diagnostics Biochemical Genetics laboratory at 1-800-642-4657 Ext. 4817 or Ext. 4423 and ask to speak with the laboratory director on call. For general questions about Quest Diagnostics genetic testing, please call the Gene info line at 1-866-GENE-INFO.**

Digoxin (418X)		
Effective Date:	**July 18, 2011**	
Test Code:	**S51669**	
Specimen Requirements:	Collection Instructions:	**Collect as trough just prior to next dose.**
Set-Up/Analytic Time:	**Mon-Sat; Report Available: 2-3 days**	
Reference Range:	**0.8-2.0 mcg/L**	
Always Message	**FAB Anti-Digoxin (Digibind®) in serum, plasma under toxicity therapy may interfere with the digoxin immunoassay.**	

Pentobarbital (700X)	
Effective Date:	**July 18, 2011**
Test Code:	**S51464**
Specimen Stability:	**Frozen: Not established**

Phenobarbital (708X)		
Effective Date:	**July 18, 2011**	
Test Code:	**S52035**	
Specimen Requirements:	Collection Instructions:	**Collect just prior to next dose.**
Specimen Stability:	**Room temperature: 5 days** **Refrigerate: 7 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Mon-Sat; Report Available: 2-3 days**	

Influenza A Virus H1/H3 Subtyping by Real-Time RT-PCR (42690)	
Effective Date:	**July 25, 2011**
Test Code:	**S52347**
Set-Up/Analytic Time:	**Set-up: Tues,Thurs, Sat; Report Available: 2-3 days**
Always Message:	**This assay detects and differentiates between seasonal influenza A H3 viruses. This assay does not detect the presence of 2009 H1N1 influenza A virus.** **This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.**

Susceptibility Anaerobic Bacteria,1 Drug, MIC (51480)		
Former Test Name:	*Antimicrobial Susceptibility, Anaerobic Cefotetan (51480)*	
Effective Date:	**July 25, 2011**	
Test Code:	**S51157**	
CPT Code:	**87186**	
Specimen Requirements:	Type: Collection Instructions:	**Pure culture of anaerobic isolate on a slant, plate or swab.** **Swabs transport in an appropriate Amies agar gel transport medium (or equivalent). Organism identification and drug must be supplied.**
Transport Temperature:	**Refrigerated (preferred and may help improve isolate viability).**	
Specimen Stability:	**Room Temperature: Determined by viability** **Refrigerated: Determined by viability**	
Rejection Criteria:	**Isolate in Thioglycollate brothAerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable).**	
Methodology:	**Etest Gradient**	

Susceptibility Panel, Anaerobic Bacteria, MIC (Gradient) (51477)		
Former Test Name:	*Antimicrobial Suscep Anaerobic Bacteria, Routine MIC (51477)*	
Effective Date:	**July 25, 2011**	
Test Code:	**S49970**	
Specimen Requirements:	Type: Collection Instructions:	**Pure culture of anaerobic isolate on a slant, plate or swab.** **Swabs transport in an appropriate Amies agar gel transport medium (or equivalent)**
Transport Temperature:	**Refrigerated (preferred and may help improve isolate viability).**	
Specimen Stability:	**Room Temperature: Determined by viability** **Refrigerated: Determined by viability**	
Rejection Criteria:	**Isolate in Thioglycollate broth, Aerobic slant, plate or swab Frozen isolates (unless <-70 C in Glycerol broth (acceptable).**	
Always Message:	**Drug concentrations are expressed in mcg/mL.** **S=Susceptible I=Intermediate R=Resistant** **Although most antimicrobials are reported for all anaerobes, several antimicrobials have limited testing and reporting based on identification of the isolate: Cefoxitin and Cefotetan are reported only for Clostridium species (not C. perfringens); Meropenem is reported only for Bacteroides fragilis group and Clostridium species (not C. perfringens); Penicillin is not reported for Bacteroides fragilis group.**	

Somatostatin (34480)		
Effective Date:	**August 1, 2011**	
Test Code:	**S49916**	
Assay Category:	**Laboratory Developed Test**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma-EDTA** **1.8 mL** **0.6 mL** **Draw in a pre-chilled lavender-top tube. Separate and freeze plasma immediately. Do not thaw.**
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: 8 hours** **Refrigerated: 8 hours** **Frozen: 28 days**	
Rejection Criteria:	**Gross lipemia and gross icterus specimen**	
Reference Range:	**Adult: < or = 30 pg/mL**	

Everolimus, Blood Test (2066B)		
Effective Date:	**September 12, 2011**	
Test Code:	**S18883**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Whole blood-EDTA** **1.0 mL** **0.4 mL**

Referral Test Discontinuations

CA 125, Peritoneal Fluid (17545X)	
Effective Date:	**Immediate**
Test Code:	**S51839**
Additional Information:	Suggested Alternate: 3121 - CA 125
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

Digitoxin, Serum/Plasma (417Z)	
Effective Date:	**Immediate**
Test Code:	**S51315**
Additional Information:	Suggested Alternate: S52434 - Digitoxin, Serum/Plasma (1613SP), Performed at National Medical Services
Performing Site:	**Quest Diagnostics Nichols Institute, Chantilly**

Botulinum Toxin Type A Antibody (113)	
Effective Date:	**Immediate**
Test Code:	**S50476**
	No replacement available
Performing Site:	**Athena Diagnostics**

Trichomonas *vaginalis* RNA, Qualitative TMA (19550X)	
Effective Date:	**Immediate**
Test Code:	**S52017**
	Recommended replacement:19550-Sureswab®, Trichomonas *vaginalis* RNA, Qualitative TMA, Performed at Quest Diagnostics Nichols Institute, Valencia
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Anaerobic Susceptibility: Gatifloxacin MIC	
Effective Date:	**July 25, 2011**
Test Code:	**S49192**
	Recommended replacement: S51157- Susceptibility Anaerobic Bacteria,1 Drug, MIC (51480), Performed at Focus Diagnostics
Performing Site:	**Focus Diagnostics**

Aspirinworks (300353)	
Effective Date:	**August 9, 2011**
Test Code:	**S50742**
Additional Information:	Suggested Alternate: S52243 - Aspirin Resistance (11-Dehydrothromboxane B2) (16174), Performed at Quest Diagnostics, Nichols Institute San Juan Capistrano
Performing Site:	**Esoterix Endocrine**