December 2011 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
90801	**Trichomonas vaginalis RNA, Qualitative TMA, Males**	1/10/2012	3
90246	**Pain Management, Methylphenidate Metabolite, Quantitative, Urine**	1/17/2012	4
15780	**dRVVT Screen w/rfl dRVVT Confirm & dRVVT 1:1 Mix**	1/31/2012	5
35080	**Leukemia/Lymphoma Evaluation Panel**	2/14/2012	6

TEST CHANGES Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
3131		Adenosine Deaminase	1/10/2012	7
1515		Alpha-1-Antitrypsin GenotypR™	1/10/2012	7
1687		CD16/56 Surface Marker	1/10/2012	7
4884U		Cobalt 24hr Urine	1/10/2012	7
4884UR		Cobalt Random Urine	1/10/2012	7
4884W		Cobalt Whole Blood	1/10/2012	8
8141		Hepatitis B DNA Qualitative Real-Time PCR	1/10/2012	8
7485A		HIV-1 RNA Quantitation [Real Time PCR]	1/10/2012	8
9926		HIV-2 IgG Antibodies Western Blot	1/10/2012	8
1872		Natural Killer Cell Quantitation	1/10/2012	9
4100		Acetaminophen	1/17/2012	9
3102		ACTH, Plasma	1/17/2012	9
1904		Apolipoprotein A-1 & B	1/17/2012	9
7440U		*Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA] Urine w/ reflex Confirm	1/17/2012	9
4964		Clozapine & Norclozapine	1/17/2012	10
4202		D-Dimer Quantitative	1/17/2012	10
5779		Fungus Culture: Yeast Screen-Skin, Hair or Nail	1/17/2012	10
7489		HCV RNA, Quantitative PCR w/Reflex Genotype, LIPA	1/17/2012	10
2460		Hepatitis A Virus Total & IgM Antibodies	1/17/2012	11
7473		Hepatitis C Viral RNA, Genotype, LIPA	1/17/2012	11
7476		Hepatitis C Viral RNA, Quant bDNA w/Reflex Genotype, LIPA	1/17/2012	11
1101		Mitochondria M2 Antibody (IgG), EIA	1/17/2012	11
6100		Platelet Glycoprotein (Direct & Indirect) Abs	1/17/2012	12
7745		*Pneumocystis jiroveci (carinii)* Antigen Detection	1/17/2012	12

6110		QuantiFERON®-TB Gold (Incubated)	1/17/2012	12
90570		SureSwab™ Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR	1/17/2012	12
11363		SureSwab(TM), Chlamydia trachomatis/Neisseria gonorrhoeae RNA, TMA (11363)	1/17/2012	13
16492		SureSwab(TM), CT/NG, T vaginalis (16492)	1/17/2012	13
3360		Valproic Acid	1/17/2012	13
8169		West Nile Virus IgG & IgM Antibodies [EIA]	1/17/2012	13
5900		Activated Protein C Resistance	1/31/2012	14
3253		Antithrombin III Plasma Antigen	1/31/2012	14
3134		CA 27.29	1/31/2012	15
4836		Calcium, Total	1/31/2012	15
1320		Creatinine	1/31/2012	16
1426		Fibrinogen Activity, Clauss	1/31/2012	17
2455		Hepatitis Be Antibody	1/31/2012	17
2456		Hepatitis Be Antigen	1/31/2012	18
1741U		Kappa Lambda Light Chains w/Calculation 24hr Urine	1/31/2012	18
1741UR		Kappa Lambda Light Chains, Total, Random Urine	1/31/2012	19
1731U		Kappa Light Chain w/Calculation 24hr Urine	1/31/2012	19
1731UR		Kappa Light Chain, Total, Random Urine	1/31/2012	20
1736U		Lambda Light Chain w/Calculation 24hr Urine	1/31/2012	20
1736UR		Lambda Light Chain, Total, Random Urine	1/31/2012	20
5937		Protein S Antigen, Total	1/31/2012	21
4210		Thrombin Time	1/31/2012	21
3541		Vitamin D, 25-Hydroxy Total [LC/MS/MS]	1/31/2012	22
1907		von Willebrand Factor Antigen	1/31/2012	22
16910		Pain Management, Alcohol Metabolites with Confirmation, Urine	2/14/2012	22
90079		Pain Mgmt, Alcohol Metab, w/Conf, w/medMATCH™, U	2/14/2012	23
5924		Actin (Smooth Muscle) Antibody (IgA)	2/21/2012	23
5920		Actin (Smooth Muscle) Antibody (IgG)	2/21/2012	24

REDIRECTS
Please Note: Not all test codes assigned to each assay are listed in the table of contents.
Please refer to the complete listing on the page numbers indicated.

Test Code	Former Test Code	Test Name	Effective Date	Page #
S51992	**4163**	**Carnitine, LC/MS,MS [70107X]**	1/17/2012	24

DISCONTINUED TESTS
Please Note: Not all test codes assigned to each assay are listed in the table of contents.
Please refer to the complete listing on the page numbers indicated.

Test Code	Test Name	Effective Date	Page #
4163	Carnitines Evaluation	1/17/2012	26
1911	Lupus Anticoagulant: DRVVT reflex to Confirmation	1/31/2012	26
1795	Leukemia/Lymphoma Flow EvaluatR™	2/14/2012	26

SEND OUTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
S48767		Purine and Pyrimidine Panel, Urine (81420)	12/30/2011	26
S51635		Human Anti-Mouse AB (HAMA), ELISA(41882)	1/10/2012	26
S51884		HIV-1 Coreceptor Tropism (16710)	1/17/2012	27
S51667		Organic Acids, Full Panel, Quantitative, Urine (90561)	1/17/2012	27
S49453		Organic Acids, Qualitative, Urine(90404)	1/17/2012	28
S50070		Spinal Muscular Atrophy (SMA) - Diagnostic	1/17/2012	28
S51510		Hepatitis E Antibodies (IgG, IgM)(20173)	1/24/2012	29
S51511		Hepatitis E Antibody (IgG)(20171)	1/24/2012	29
S51512		Hepatitis E Antibody (IgM)(20172)	1/24/2012	30
S48851		Amylase, Random Urine (with Creatinine) (8464)	2/7/2012	30
S52424		Herpes Simplex Virus 1/2 (IgG) Type-Specific Antibodies, CSF (60555)	2/14/2012	31
S51518		Herpes Virus-6 DNA, Qualitative Real-Time PCR(43160)	2/14/2012	31
S52269		Herpes Virus-6 DNA, Quantitative Real-Time PCR (43660)	2/14/2012	31
S49015		Lymphocytic Choriomeningitis (LCM) Virus Antibody, IFA (CSF)(60625)	2/21/2012	31

New Test Offerings

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

Trichomonas vaginalis RNA, Qualitative TMA, Males	
Message	***** This test is not available for New York patient testing ** There is no alternative for New York patients***
Clinical Significance	**This test is used to detect Trichomonas vaginalis in clinical specimens. The test has greater analytical sensitivity than culture methods.**
Effective Date	**1/10/2012**
Test Code	**90801**
CPT Codes	**87798**
Specimen Requirements	**Male urethral swab in APTIMA® Unisex Swab Specimen Collection Kit or random urine (male) in APTIMA® Urine Specimen Collection Kit**
Reject Criteria	**Vaginal swabs; Female urine**
Instructions	Male urine: The patient should not have urinated for at least 1 hour prior to specimen collection. Patient to provide a first-catch urine (approximately 20-30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. 2 mL of urine MUST be transferred into the Gen-Probe Aptima Urine Transport Tube within 24 hours of collection and before being assayed.

	Urine specimens must be refrigerated pending transfer into Aptima® transport medium.
Transport Temperature	**Room temperature**
Specimen Stability	<table><tr><td></td><td>**Urine**</td><td>**Swab**</td></tr><tr><td>**Room temperature:** **Refrigerated:** **Frozen:**</td><td>**30 days** **30 days** **6 months**</td><td>**60 days** **60 days** **6 months**</td></tr></table>
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 3 days**
Reference Range	**Not Detected**
Always Message	**This test was performed using the APTIMA® Trichomonas vaginalis Assay (GEN-PROBE®). The performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, Valencia. Performance characteristics refer to the analytical performance of the test.**
Methodology	**Transcription Mediated Amplification**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	<table><tr><td>**Result Code**</td><td>**Result Name**</td></tr><tr><td>**86008153**</td><td>**Tvaginalis RNA,QL TMA,Men**</td></tr></table>
Additional Information	**1. A “Detected” result (positive) indicates the presence of Trichomonas vaginalis RNA in a patient's specimen. A diagnosis of infection should not rely solely upon the result of a TMA assay. A positive TMA result should be interpreted along with clinical findings and other diagnostic results. 2. A “Not Detected” (negative) result indicates that Trichomonas vaginalis RNA was either not present in the specimen, or it is present at a level below the detection limit of the assay. A negative result does not exclude the diagnosis of disease.**

Pain Management, Methylphenidate Metabolite, Quantitative, Urine	
Effective Date	**1/17/2012**
Test Code	**90246**
CPT Codes	**83789**
Specimen Requirements	**20 mL random urine (clinical drug test transport vial)**
Reject Criteria	**Preserved samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days Refrigerated: 7 days Frozen: 30 days**
Set-up/Analytic Time	**Set Up: Tues-Sat; Report Available: 2-3 days**
Reference Range	<table><tr><td>**Ritalinic Acid**</td><td>**<100 ng/mL**</td></tr></table>
Methodology	**Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	<table><tr><td>**Result Code:**</td><td>**Result Name:**</td></tr><tr><td>**82090191**</td><td>**Report Comments**</td></tr></table>

82000676	**Ritalinic Acid**

dRVVT Screen w/rfl dRVVT Confirm & dRVVT 1:1 Mix	
Clinical Significance	**Diagnosis of a lupus anticoagulant (LA) requires testing with a least 2 screening reagents, followed by confirmatory testing. The dRVVT screen, confirm, and mix satisfy international guidelines for LA evaluations.**
Effective Date	**1/31/2012**
Test Code	**15780**
CPT Codes	**85613**
Specimen Requirements	**2.0 mL Frozen Citrated Plasma (minimum 1.0 mL)**
Reject Criteria	**Thawed plasma**
Instructions	**Please submit a separate, frozen vial for each special coagulation assay ordered. If the dRVVT Screen is prolonged (> 45 seconds), the dRVVT Confirmation will be performed at an additional charge (CPT: 85598). If the dRVVT Confirm is positive, a dRVVT 1:1 dilution will be performed at an additional charge (CPT: 85613).** **Platelet Poor Plasma for Lupus Anticoagulant Testing** **Perhaps the most important step in the diagnosis of the lupus anticoagulant (LA) is appropriate specimen collection and processing. It is imperative that the laboratory take extra precautions in preparing platelet-poor plasma (PPP). The more platelet-free the sample, the greater the sensitivity of most test systems to the presence of LA. Ideally, PPP should have a platelet count of less than 10 x 10^9 per liter (<10,000/uL). Although the sample collection process described in the Coagulation Specimens in the Specimen Collection section of Test Directory should yield PPP, the following double-spin technique can also be used:** **1. Spin down specimen at 1500 x g for 15 minutes.** **2. Transfer the plasma to a plastic tube with a plastic Pasteur pipette, staying away from the buffy coat layer. Spin down the plasma portion again at 1500 x g for 15 minutes. With another plastic Pasteur pipette, transfer the plasma to another plastic tube, staying clear of the bottom of the tube where the platelets lie. Alternatively, the plasma may be filtered using a 0.2 micron filter.** **3. Transfer plasma into a plastic tube using a plastic Pasteur pipette. Do not use glass tubes or glass Pasteur pipettes, as glass can activate the clotting cascade.** **4. Label each tube plasma. Submit a plasma aliquot for each and every coagulation assay requested (one tube for each test). If possible, submit one additional plasma aliquot for repeat and/or test additions.** **Reference: NCCLS guidelines H3-A3 and H21-A2**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 90 days**
Set-up/Analytic Time	**Set Up: Mon-Fri; Report Available: 1-4 days**
Reference Range	**< or = 45 sec**
Units Of Measure	**sec**
Methodology	**Clot Detection**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **30035405** / **dRVVT Screen** **Reflex Code ROB** / **Reflex dRVVT Confirm** **30035350** / **dRVVT Confirm** **Reflex Code: ROC** / **Reflex dRVVT 1:1 Mix**

	30035360 — **dRVVT 1:1 Mix** **30035380** — **dRVVT Mix Interpretation**
Additional Information	**Replaces test code 1911**

Leukemia/Lymphoma Evaluation Panel	
Clinical Significance	**Test is used to aid in the diagnosis of leukemia/lymphoma.**
Effective Date	**2/14/2012**
Former Test Name	*Leukemia/Lymphoma Flow EvaluatR™*
Former Test Code	*1795*
Test Code	**35080**
CPT Codes	**88184, 88189, 88185 (x21)**
Specimen Requirements	**Whole Blood: 3 mL Whole Blood Yellow Top ACD-A; Room Temperature** **Peripheral Blood: One green, yellow, or lavender-top (sodium heparin, ACD-A, or EDTA) tube. A minimum of 3 mL is required. Tube must be kept at room temperature and shipped immediately.** **Bone Marrow: A minimum of 1 mL (with maximum of 4 mL to prevent hemodilution of bone marrow) submitted in a green, yellow, or lavender-top (sodium heparin, ADC-A, or EDTA) tube. The tube must be kept at room temperature and shipped immediately.** **Tissue: Any tissue type is acceptable. Tissue size is dependent upon leukocyte cellularity. (The tissue is disaggregated into single cells so that a minimum of 50,000 cells of interest is harvested.) Ship tissue in sterile, plastic container with RPMI 1640 enriched with FBS (10%FBS RPMI). Absolutely no fixative should be added. Refrigerate and ship immediately.** **Body Fluids: Any body fluid is acceptable. Sample size is dependent upon cellularity of the sample (a minimum of 50,000 cells of interest in total volume of fluid). Place fluid in sterile, plastic, leakproof container. ABSOLUTELY NO FIXATIVE can be added. Refrigerate and ship immediately.**
Instructions	**A clinical summary or differential diagnosis is required with each specimen. If possible, submit CBC results with differential or an EDTA tube of peripheral blood. Initial markers evaluated: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD13, CD19, CD20, CD23, CD33, CD34, CD38, CD56, CD64, CD117, HLA-DR, sKappa, sLambda. CD 45 is used for gating. Additional markers may be performed, at an additional charge, if deemed medically necessary for proper evaluation by the reviewing Pathologist.**
Transport Temperature	**Peripheral Blood/Bone Marrow: Room temperature** **Tissue/Body Fluids: Refrigerate (Do NOT freeze.)**
Specimen Stability	**Whole Blood; Green Top Sodium Heparin; Yellow Top ACD-A; Bone Marrow** **Room Temperature: 72 hours** **Refrigerated: unacceptable** **Frozen: unacceptable** **Tissue; Body Fluid** **Room Temperature: unacceptable** **Refrigerated: 72 hours** **Frozen: unacceptable**
Methodology	**Flow Cytometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** — **Result Name** **40061410** — **Clinical Information** **40061420** — **Specimen Type**

40061430	**Viability**
40061440	**Interpretation**
40061450	**Sample Description**
40061460	**Gating Strategy**
40061470	**Markers**
40061480	**Number of Markers**

Test Changes

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

Adenosine Deaminase	
Effective Date	**1/10/2012**
Test Code	3131
Always Message	**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.**
Assay Category	**RUO**

Alpha-1-Antitrypsin GenotypR™	
Effective Date	**1/10/2012**
Test Code	1515
Instructions	**Frozen whole blood is now acceptable.**

CD16/56 Surface Marker	
Effective Date	**1/10/2012**
Test Code	1687
Assay Category	**FDA Approved**

Cobalt 24hr Urine	
Clinical Significance	Cobalt is part of our diet. Approximately 85% of absorbed cobalt is excreted in the urine and the remainder eliminated in stool. Toxicity may occur in select industrial environments. Cobalt is not mined in the United States so primary supplies are imported.
Effective Date	**1/10/2012**
Test Code	4884U
Specimen Requirements	**7 mL from 24-hour urine (acid-washed urine container)**
Reject Criteria	**Received room temperature; grossly decomposed urine; use of a metal based preservative**
Instructions	**Patients should refrain from taking vitamins with mineral supplements, B-12 and B-complex at least one week prior to specimen collection.**
Set-up/Analytic Time	**Set Up: Mon-Fri; Report Available: 2 days**

Cobalt Random Urine	
Effective Date	**1/10/2012**
Test Code	4884UR
Set-up/Analytic Time	**Set Up: Mon-Fri; Report available: 2 days**
Always Message	**2nd voided AM urine for Non-Exposed Adults: <2.9 mcg/L.** **Biological Exposure Index (end of shift/work week): <or=15.0 mcg/L**

Cobalt Whole Blood	
Effective Date	**1/10/2012**
Test Code	4884W
Set-up/Analytic Time	**Set Up: Mon-Fri; Report available: 2 days**

Hepatitis B DNA Qualitative Real-Time PCR	
Clinical Significance	**Detects the presence of Hepatitis B Virus DNA down to 20 IU/mL (116 copies/mL) to aid in the diagnosis of HBV infection. In the absence of HbsAg, HBV DNA may still be detected, possibly indicative of the persistence of low-level viral replication.**
Effective Date	**1/10/2012**
Test Code	8141
Always Message	See Hepatitis B DNA, Quantitative, Real-Time PCR, #8137 for quantitation of HBV, if clinically indicated. The method used in this test is Real-Time PCR of the pre-core region of the circular HBV genome. This test was performed using the COBAS® AmpliPrep/COBAS® TaqMan® **HBVTest, v2.0** (Roche Molecular Systems, Inc.). The performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, Valencia. Performance characteristics refer to the analytical performance of the test.

HIV-1 RNA Quantitation [Real Time PCR]	
Effective Date	**1/10/2012**
Test Code	7485A
Always Message	**REMOVE:** On March 7, 2011, the Reference Range for this test was lowered from 48 to 20 copies/mL due to a more sensitive platform that detects all major HIV groups including Group O. Some patients previously thought to be completely suppressed may now have detectable virus. The clinical significance of a viral load between 20-48 copies/mL is currently unknown. Because studies confirm this test is equivalent to the previous version, no re-baseline testing is recommended; however, periodic re-testing is recommended to monitor for viral load changes.
Tests Affected	**Test Codes:** / **Name:** 7485ASR / HIV-1 RNA Quantitation [Real Time PCR] with serial reporting 7482A / HIV-1 RNA Quantitation [Real Time PCR] w/Rfx HIV-1 Genotype

HIV-2 IgG Antibodies Western Blot	
Effective Date	**1/10/2012**
Test Code	9926
Always Message	**REMOVE:**

	HIV-2 Ab tested with reagents by BBI Biotech product #PI-0511. **REPLACE WITH:** The HIV-2 IgG Antibodies Western Blot utilizes the Immunetics QualiCode(TM) HIV-1/2 Western Blot Kit.

Natural Killer Cell Quantitation	
Effective Date	**1/10/2012**
Test Code	1872
Assay Category	**FDA Approved**

Acetaminophen	
Effective Date	**1/17/2012**
Test Code	4100
Specimen Requirements	**1.0 mL (minimum 0.2 mL)**
Specimen Stability	Room Temperature: 5 days **Refrigerated: 10 days** **Frozen: Not acceptable**

ACTH, Plasma	
Effective Date	**1/17/2012**
Test Code	3102
Reference Range	< 3 years: — Reference range not established 3 – 17 years: — 9-57 pg/mL **> or = 18 years:** — **6-50 pg/mL**
Always Message	Reference range applies only to specimens collected between 7am-10am.

Apolipoprotein A-1 & B	
Effective Date	**1/17/2012**
Test Code	1904
Specimen Stability	Room Temperature: 72 hrs **Refrigerate: 10 days** **Frozen: 90 days**
Tests Affected	**Test Codes:** — **Name:** 1900 — Apolipoprotein A-1 & B

***Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA] Urine w/ reflex Confirm**	
Effective Date	**1/17/2012**
Test Code	7440U
Reject Criteria	**BD Probe Tec Vials**
Tests Affected	**Test Codes:** — **Name:**

7440SW	Chlamydia trachomatis/N. gonorrhoeae rRNA PLUS [TMA]w/ reflex Confirm
7435SW	Chlamydia trachomatis Confirmation [TMA]
7435U	Chlamydia trachomatis Confirmation [TMA] Assay Urine
7437SW	Chlamydia trachomatis rRNA Detection [TMA]
7437U	Chlamydia trachomatis rRNA Detection [TMA] Urine
7438U	Chlamydia trachomatis/N. gonorrhoeae rRNA PLUS [TMA] Urine
2937SW	Neisseria gonorrhoeae Confirmation [TMA]
2937U	Neisseria gonorrhoeae Confirmation [TMA] Assay Urine
2932U	Neisseria gonorrhoeae rRNA [TMA] Urine
2932SW	Neisseria gonorrhoeae rRNA Detection [TMA]
11363	SureSwab(TM), Chlamydia trachomatis/Neisseria gonorrhoeae RNA, TMA (11363)
16492	SureSwab(TM), CT/NG, T vaginalis (16492)
16491	SureSwab(TM), Vaginosis, CT/NG
17333	SureSwab(TM), Vaginosis/Vaginitis Plus - (17333)
P1159B	CUSTOM QDL WEST HILLS HPV-HIGH RISK/CT/NG/HSV PANEL
7438SW	Chlamydia trachomatis rRNA Detection [TMA]

Clozapine & Norclozapine	
Effective Date	**1/17/2012**
Test Code	4964
Always Message	**Clozapine Toxic Range: >900 ng/mL**

D-Dimer Quantitative	
Effective Date	**1/17/2012**
Test Code	4202
Set-up/Analytic Time	**Set Up: Weds, Sat; Report Available: 2-4 days**

Fungus Culture: Yeast Screen-Skin, Hair or Nail	
Effective Date	**1/17/2012**
Test Code	5779
Reject Criteria	**10% formalin containers are not acceptable**
Tests Affected	

Test Codes:	**Name:**
5779M	Yeast Screen- Miscellaneous
5322	Fungus Culture and stain :Skin, Hair or Nail
5322M	Fungus Culture & Stain - Miscellaneous

HCV RNA, Quantitative PCR w/Reflex Genotype, LIPA	
Clinical Significance	Quantitates Hepatitis C Virus RNA down to 43 IU/mL to monitor viral load in established Hepatitis C-infected individuals. The upper limit of detection is 69,000,000 IU/mL. Viral loads in excess of **300** IU/mL are automatically reflexed to a genotype assay to ascertain specific subtype. Clinical outcomes are genotype-dependent and differ with regard to disease severity and responses to (peg)interferon and ribivirin combination therapy. A better long-term response to therapy was observed with genotypes 2a and 2b (52%) and with 3a and 3b (74%) than with types 1a and 1b (29%). Other factors associated with favorable response are low pretreatment viral load and the absence of liver cirrhosis.
Effective Date	**1/17/2012**
Test Code	7489

Hepatitis A Virus Total & IgM Antibodies	
Effective Date	**1/17/2012**
Test Code	2460
Specimen Stability	**Room Temperature: 14 days** **Refrigerated: 14 days** Frozen: 2 months

Hepatitis C Viral RNA, Genotype, LIPA	
Effective Date	**1/17/2012**
Test Code	7473
Always Message	**Add prior to FDA message:** **The AccuType(R) IL28B test can help stratify HCV-infected individuals into those who are predisposed to respond more favorably and those who are predisposed to respond less favorably to standard HCV therapy. A favorable IL28B genotype (ie, CC) predicts improved treatment response for individuals infected with HCV genotype 1. Reference: Clin Gastroenterol Hepatol. 2011;9:344-350.** **To order the IL-28B test please submit a new whole blood sample for test code S52417.** **The method used in this test for HCV Genotyping is RT-PCR and reverse hybridization (Line Probe) of the 5' UTR and core region of the HCV genome,**
Additional Information	**Replace with:** **If the viral load is less than 300 IU/mL or the viral load has not been quantified in the last 1 to 2 months, test code #7578 (Hepatitis C Viral RNA, Quant bDNA w/reflexTMA/Genotype, LIPA or test code #7489 (HCV RNA, Quantitative PCR w/reflex genotype, LIPA) is recommended.** **This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. 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.**

Hepatitis C Viral RNA, Quant bDNA w/Reflex Genotype, LIPA	
Clinical Significance	Quantitates Hepatitis C Virus RNA down to 615 IU/mL to monitor viral load in established Hepatitis C infected individuals. Viral loads in excess of **300** IU/mL are automatically reflexed to a genotype assay to ascertain specific subtype. Clinical outcomes are genotype-dependent and differ with regard to disease severity and responses to interferon (IFN) therapy. A better long-term response to IFN was observed with genotypes 2a and 2b (52%) and with 3a and 3b (74%) than with types 1a and 1b (29%). Other factors associated with favorable interferon response are low pretreatment viral load and the absence of liver cirrhosis.
Effective Date	**1/17/2012**
Test Code	7476

Mitochondria M2 Antibody (IgG), EIA	
Effective Date	**1/17/2012**
Former Test Name	*Mitochondrial (M2) EP (MIT3) IgG Autoabs*

Test Code	1101
Specimen Requirements	**1.0 mL (0.3 mL) Serum** **Preferred: Red top (no gel)** **Acceptable: Serum Separator Tube**
Specimen Stability	Room temperature 7 days Refrigerated 14 days **Frozen: 30 days**
Tests Affected	

Test Codes:	Name:
1002	Tissue Total Autoantibodies Screen (TABS)
5906	Hepatitis Autoimmune EvaluatR™ PLUS
5908	Hepatitis Autoimmune EvaluatR™

Platelet Glycoprotein (Direct & Indirect) Abs	
Effective Date	**1/17/2012**
Test Code	6100
Set-up/Analytic Time	**Report Available: 6 days**
Tests Affected	

Test Codes:	Name:
6102	Platelet Glycoprotein (Indirect) Autoabs
6104	Platelet Associated Glycoprotein (Direct) Abs
5957	Platelet Glycoprotein Ia/IIa Total Autoantibodies
5955	Platelet Glycoprotein Ib/Ix Total Autoantibodies
5956	Platelet Glycoprotein IIb/IIIa Total Autoantibodies

***Pneumocystis jiroveci (carinii)* Antigen Detection**	
Effective Date	**1/17/2012**
Test Code	7745
Instructions	**Replace** 2nd instruction in collection instruction: **2. Respiratory specimens such as sputum, bronchial wash, bronchoalveolar lavage, or pleural fluid collected in sterile container are acceptable.**

QuantiFERON®-TB Gold (Incubated)	
Effective Date	**1/17/2012**
Test Code	6110
Instructions	**Collection Instruction Change to second step only, all other steps remain the same:** **2. Immediately after filling the tubes, shake them ten times just firmly enough to ensure the entire surface of the tube is coated with blood, to solubilize antigens in tube walls.**

SureSwab™ Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR	
Effective Date	**1/17/2012**
Test Code	90570

Transport Temperature	**Room Temperature: 14 days** **Refrigerated: 14 days** Frozen: 30 days

SureSwab(TM), Chlamydia trachomatis/Neisseria gonorrhoeae RNA, TMA (11363)	
Effective Date	**1/17/2012**
Test Code	11363
Specimen Requirements	Add: **2.0 mL Urethral swab**
Instructions	**Modify only:** Swab - Endocervical or **Urethral**: Swab MUST be submitted in Aptima(TM) Combo 2 Assay Unisex Swab Specimen Collection tube. Follow instructions in the Aptima(TM) Combo 2 Assay Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens package insert. In females, to ensure collection of an adequate specimen, columnar epithelial cells lining the endocervix should be obtained. To that effect, excess mucus should be removed prior to sampling by using the white shaft cleaning swab which is discarded after use.
Specimen Stability	**Endocervical swab** Room Temperature: 60 days Refrigerated: 60 days **Frozen: 1 year** **Urethral swab** **Room Temperature: 60 days** **Refrigerated: 60 days** **Frozen: 6 months** **Vaginal swab** Room Temperature: 60 days Refrigerated: 60 days **Frozen: 1 year**

SureSwab(TM), CT/NG, T vaginalis (16492)	
Effective Date	**1/17/2012**
Test Code	16492
Specimen Stability	Vaginal and Endocervial Swabs: **Frozen: 180 days**

Valproic Acid	
Effective Date	**1/17/2012**
Test Code	3360
Specimen Requirements	Optimal 1.0 mL **(minimum 0.2 mL)**
Reject Criteria	**Gel barrier tube (SST)**
Additional Information	**Do not use gel barrier tubes.**

West Nile Virus IgG & IgM Antibodies [EIA]	
Clinical Significance	**The West Nile Virus (WNV) is a single-stranded RNA virus of the Flaviviridae family. Like other arboviruses (e.g., St. Louis Encephalitis, Dengue Fever, and Yellow Fever), its main route of transmission to humans is through mosquitoes (primarily culex species) that have acquired the virus from infected birds. A single elevated WNV result, including IgM that may persist for many months, could represent past infection with WNV or infection with another flavivirus including Dengue and St. Louis Encephalitis. Diagnosis of suspected WNV infection is confirmed by isolation of WNV or detection of WNV antigen or nucleic acid sequences in clinical samples or detection of WNV-specific IgM in blood or spinal fluid,**

	confirmed with detection of WNV-specific neutralizing antibody in the same or a subsequent sample. See West Nile Virus: Detection with Immunologic and RT-PCR Assays in the Infectious Disease chapter, Interpretive Information section.
Effective Date	**1/17/2012**
Test Code	8169
Specimen Stability	**Room Temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Always Message	**West Nile Virus (WNV) IgM antibodies, in blood or cerebrospinal fluid, are positive in most infected people within 8 days of onset of symptoms and may remain detectable for months. In our laboratory, sera with reactive IgM are rerun in a modified test to rule out nonspecific reactions. IgG antibodies indicate either current or past exposure to the virus. Antibodies to WNV may cross-react with other viruses (e.g. Dengue, St. Louis Encephalitis, Eastern Equine Encephalitis, Yellow Fever, Enterovirus, CMV).**
Tests Affected	

Test Codes:	Name:
8169C	West Nile Virus IgG & IgM Antibodies CSF [EIA]
8168C	West Nile Virus IgM Antibodies CSF [EIA]

Activated Protein C Resistance	
Clinical Significance	**To screen for APC-R associated with venous thromboembolic disorders.**
Effective Date	**1/31/2012**
Test Code	5900
Specimen Requirements	**2.0 mL (1.0 mL) Plasma Citrated**
Instructions	**Freeze immediately**
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable **Frozen: 6 months**
Reference Range	**Normal >2.1 ratio** **Borderline 1.6-2.1 ratio** **Abnormal <1.6 ratio** **Ratios <1.6: It is recommended that any patient with an abnormal value have a Factor V Leiden R506Q Mutation Analysis, performed for confirmation.** **Ratios 1.6-2.1: Result equivocal; recommend repeat testing and/or genotype for Factor V Leiden.** **Ratios >2.1: Negative for the Factor V Leiden phenotype.**
Methodology	**dRVVT Based Clot Assay**
Tests Affected	

Test Codes:	Name:
5972	Thrombotic Risk Evaluation 1
5971	Thrombotic Risk Evaluation 2
5973	Thrombotic Risk Evaluation 3
5901	Activated Protein C Resistance w/reflex Factor V GenotypR™

Antithrombin III Plasma Antigen	
Clinical Significance	**Previously referred to as antithrombin III, antithrombin antigen is an inhibitor of several coagulation**

	factors. Patients with low concentrations of Antithrombin Antigen may have a hereditary or acquired prothrombotic state. The Antigenic test differentiates a Type I from Type II deficiency.
Effective Date	**1/31/2012**
Test Code	3253
Specimen Requirements	**1.0 mL (0.5 mL) Plasma Citrated**
Instructions	**Instructions: 3.8% sodium citrate (light blue-top) is not an acceptable collection container. Overnight fasting is preferred. Platelet Poor Plasma: Centrifuge light blue-top tube 15 minutes at approx. 1500 x g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the wbc/platelet buffy layer, and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (< 10,000/mcl). Freeze immediately and ship on dry ice. Do not thaw. Avoid freeze/thaw cycles.**
Specimen Stability	**Room Temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 21 days**
Methodology	**Immunoturbidimetric**
Tests Affected	**Test Codes:** / **Name:** 5973 – Thrombotic Risk Evaluation 3 5952 – Antithrombin III Evaluation

CA 27.29	
Effective Date	**1/31/2012**
Test Code	3134
Specimen Stability	Room Temperature: 7 days Refrigerated: 7 days **Frozen: 28 days**
Reference Range	**< 38 U/mL (whole number)**
Always Message	Assay by Chemiluminescence Microparticle Immunoassay on **Siemens** Centaur. Values obtained with different methods or kits cannot be used interchangeably for patient monitoring. Results cannot be interpreted as absolute evidence of the presence or absence of malignancy. The test is not interpretable in pregnancy.
Tests Affected	**Test Codes:** / **Name:** 3134SR – CA 27.29 with serial reporting

Calcium, Total	
Effective Date	**1/31/2012**
Test Code	4836
Reference Range	

	Males (mg/dL)	Females (mg/dL)
<1 month	8.4 – 10.6	8.4 – 10.6
1 – 11 months	8.7 – 10.5	8.7 – 10.5
1 – 3 years	8.5 – 10.6	8.5 – 10.6
4 - 19 years	8.9 – 10.4	8.9 – 10.4

20 - 49 years	**8.6 – 10.3**	8.6 – 10.2
> or = 50 years	**8.6 – 10.3**	**8.6 – 10.4**

Tests Affected

Test Codes:	**Name:**
3944	PTH, Intact, Including Ionized & Total Calcium
3943	PTH, Intact and Calcium
5315	Metabolic Panel, Basic
5317	Metabolic Panel, Comprehensive
3943SR	PTH, Intact, Including Total Calcium with serial reporting
5314	Renal Function Panel

Creatinine

Effective Date **1/31/2012**

Test Code 1320

Reference Range

Serum Creatinine:		
	Males (mg/dL)	Females (mg/dL)
0 - 2 days	0.79 - 1.58	0.79 - 1.58
3 – 28 days	**0.35 - 1.23**	**0.35 - 1.23**
1 month - 9 years	**0.20 - 0.73**	**0.20 - 0.73**
10 - 12 years	**0.30 - 0.78**	**0.30 - 0.78**
13 - 15 years	**0.40-1.05**	**0.40-1.00**
16 - 17 years	**0.60-1.20**	**0.50-1.00**
18 – 19 years	**0.60-1.26**	**0.50-1.00**
20 - 49 years	**0.60-1.35**	**0.50-1.10**
50 - 59 years	**0.70-1.33**	**0.50-1.05**
60 - 69 years	**0.70-1.25**	**0.50-0.99**
70 - 79 years	**0.70-1.18**	**0.60-0.93**
> or = 80 years	**0.70-1.11**	**0.60-0.88**

Always Message **For patients > or = 50 years of age: The upper reference limit for Creatinine is approximately 13% higher for people identified as African-American.**

Tests Affected

Test Codes:	**Name:**
1322	Creatinine Clearance
5315	Metabolic Panel, Basic
5317	Metabolic Panel, Comprehensive
5314	Renal Function Panel

1325	Glomerular Filtration Rate (GFR), Estimated

Fibrinogen Activity, Clauss	
Clinical Significance	**In dysfibrinogenemia, clotting activity may be lower than indicated by the fibrinogen concentration, because the fibrinogen is not fully functional. The Clotting Assay is also useful in determining the availability of substrate for clot formation.**
Effective Date	**1/31/2012**
Former Test Name	***Fibrinogen***
Test Code	1426
Instructions	**Platelet Poor Plasma: Centrifuge light blue-top tube 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcl). Freeze immediately and ship on dry ice. Grossly hemolyzed specimens are unacceptable.**
Specimen Stability	**Room Temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 30 Days**
Reference Range	**175-425 mg/dL**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	

Test Codes:	**Name:**
5991	Cardiovascular Thrombotic Risk AssessR™
5990	Thrombotic Risk AssessR™
5971	Thrombotic Risk Evaluation 2
5973	Thrombotic Risk Evaluation 3

Hepatitis Be Antibody	
Clinical Significance	**HBeAb appears in the early convalescence of HBV infection. With carrier state and chronic hepatitis, HbeAb may not develop.**
Effective Date	**1/31/2012**
Former Test Name	*Hepatitis B Virus e Antibodies*
Test Code	2455
Specimen Requirements	1.0 mL (0.5 mL) Serum
Reject Criteria	**Reject grossly hemolyzed or grossly lipemic samples**
Transport Temperature	**Room Temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: Indefinitely**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-2 days**
Reference Range	**Nonreactive**
Methodology	**Immunoassay**

Tests Affected	

Test Codes:	Name:
2463	Hepatitis A & B Virus Evaluation
2462	Hepatitis B Virus e Antigen/Antibody Evaluation
2479	Hepatitis B Virus MonitR™, Chronic

Hepatitis Be Antigen	
Clinical Significance	**HBeAg indicates active HBV replication. Infectivity is evaluated based on HBeAg and HBsAg. When HBeAg persists much longer than 10 weeks, the patient is likely to develop chronic hepatitis and be a carrier. See Hepatitis in the Infectious Disease chapter, Interpretive Information section.**
Effective Date	**1/31/2012**
Former Test Name	***Hepatitis B Virus e Antigen***
Test Code	2456
Specimen Requirements	**1.0 mL (0.5 mL) Serum**
Reject Criteria	**Gross hemolysis or gross Lipemia**
Transport Temperature	**Room temperature**
Specimen Stability	**Room Temperature: 7 Days** **Refrigerated: 14 Days** **Frozen: Indefinitely**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-2 days**
Reference Range	**Nonreactive**
Methodology	**Immunoassay**
Tests Affected	

Test Codes:	Name:
2463	Hepatitis A & B Virus Evaluation
2452	Hepatitis B Virus e Antigen/Antibody Evaluation
2479	Hepatitis B Virus MonitR™, Chronic

Kappa Lambda Light Chains w/Calculation 24hr Urine	
Clinical Significance	**Polyclonal immunoglobulin light chains (kappa and lambda) normally occur in a ratio of 2:1, whereas monoclonal immunoglobulin light chains exhibit only one type of light chain, either kappa or lambda. A kappa:lambda ratio outside of 2:1 is an indication of a monoclonal gammopathy.**
Effective Date	**1/31/2012**
Former Test Name	*Kappa & Lambda Light Chain, Quantitative 24 hour Urine*
Test Code	1741U
Specimen Requirements	**2.0 mL (0.5 mL) 24-Hour Urine**
Instructions	**Instructions: Collect without preservative. Please provide the 24-hour total volume on the request form and on the sample container (required for calculation).**
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 7 days**

	Frozen: not established
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Measured Kappa Chains** **< 2.00 mg/dL** **Measured Lambda Chains** **< 2.00 mg/dL**

Kappa Lambda Light Chains, Total, Random Urine	
Message	**Please note: This test measures primarily kappa and lambda light chains that are bound to the heavy chains of IgG, IgA, or IgM in urine; however, some free light chains can also be detected with this method. If free light chain multiple myeloma is suspected, please order free kappa and free lambda light chains for a more accurate measurement of the free light chains.**
Clinical Significance	**Polyclonal immunoglobulin light chains (kappa and lambda) normally occur in a ratio of 2:1, whereas monoclonal immunoglobulin light chains exhibit only one type of light chain, either kappa or lambda. A kappa:lambda ratio outside of 2:1 is an indication of a monoclonal gammopathy.**
Effective Date	**1/31/2012**
Former Test Name	*Kappa & Lambda Light Chain Urine Random*
Test Code	1741UR
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 1 week** **Frozen: not established**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Measured Kappa Chains** **< 2.00 mg/dL** **Measured Lambda Chains** **< 2.00 mg/dL**

Kappa Light Chain w/Calculation 24hr Urine	
Clinical Significance	**Polyclonal immunoglobulin light chains (kappa and lambda) normally occur in a ratio of 2:1, whereas monoclonal immunoglobulin light chains exhibit only one type of light chain, either kappa or lambda. A kappa:lambda ratio outside of 2:1 is an indication of a monoclonal gammopathy.**
Effective Date	**1/31/2012**
Test Code	1731U
Specimen Requirements	**2.0 mL (0.5 mL) 24-Hour Urine**
Instructions	**Instructions: Collect without preservative. Please provide the 24-hour total volume on the request form and on the sample container (required for calculation).**
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 7 days** **Frozen: not established**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Measured Kappa Chains** **< 2.00 mg/dL**

Kappa Light Chain, Total, Random Urine	
Message	**Please note: This test measures primarily kappa and lambda light chains that are bound to the heavy chains of IgG, IgA, or IgM in urine; however, some free light chains can also be detected with this method. If free light chain multiple myeloma is suspected, please order free kappa and free lambda light chains for a more accurate measurement of the free light chains.**
Clinical Significance	**Test is useful in monitoring myeloma patients with known kappa light chain disease.**
Effective Date	**1/31/2012**
Former Test Name	*Kappa Light Chain Urine Random*
Test Code	1731UR
Specimen Requirements	**2.0 mL (0.5 mL) Random Urine**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 1 week** **Frozen: not established**
Set-up/Analytic Time	**Set up: Mon-Sat; Report Available: 1-2 days**
Reference Range	**Measured Kappa Chains** : **< 2.00 mg/dL**

Lambda Light Chain w/Calculation 24hr Urine	
Clinical Significance	**Polyclonal immunoglobulin light chains (kappa and lambda) normally occur in a ratio of 2:1, whereas monoclonal immunoglobulin light chains exhibit only one type of light chain, either kappa or lambda. A kappa:lambda ratio outside of 2:1 is an indication of a monoclonal gammopathy.**
Effective Date	**1/31/2012**
Former Test Name	*Lambda Light Chain, Quant 24 hour Urine*
Test Code	1736U
Specimen Requirements	**2.0 mL (0.5 mL) 24-Hour Urine**
Instructions	**Instructions: Collect without preservative. Please provide the 24-hour total volume on the request form and on the sample container (required for calculation).**
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 7 days** **Frozen: not established**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Measured Lambda Chains** : **< 2.00 mg/dL**

Lambda Light Chain, Total, Random Urine	
Message	**Please note: This test measures primarily kappa and lambda light chains that are bound to the heavy chains of IgG, IgA, or IgM in urine; however, some free light chains can also be detected with this method. If free light chain multiple myeloma is suspected, please order free kappa and free lambda light chains for a more accurate measurement of the free light chains.**
Clinical Significance	**Test is useful in monitoring myeloma patients with known lambda light chain disease.**

Effective Date	**1/31/2012**
Former Test Name	*Lambda Light Chain Urine Random*
Test Code	1736UR
Specimen Requirements	**2.0 mL (0.5 mL) Random Urine**
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 12 hours** **Refrigerated: 1 week** **Frozen: not established**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Measured Lambda Chains** : **< 2.00 mg/dL**

Protein S Antigen, Total	
Clinical Significance	**The congenital or acquired deficiency of protein S increases the risk for thromboembolism, owing to a decrease of blood anticoagulant potential. It results in recurring thrombotic episodes. A decrease of protein S leads to a greater risk of thromboembolism.**
Effective Date	**1/31/2012**
Test Code	5937
Instructions	**Instructions: Hemolyzed samples are not acceptable. 3.8% sodium citrate (light blue-top tube) is not acceptable. Collection Instructions: Draw blood in light blue-top tube containing 3.2% sodium citrate, and mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.** **General Drawing Instructions: Refer to Quest Diagnostics Nichols Institute Directory of Services under Specimen Collection section, Coagulation Testing, for further information on specimen processing.**
Methodology	**Immunoturbidometric**
Tests Affected	**Test Codes:** : **Name:** 5973 : Thrombotic Risk Evaluation 3 5938 : Protein S Evaluation

Thrombin Time	
Clinical Significance	**Thrombin clotting time measures the rate of fibrin polymerzation. It detects the presence of a direct thrombin inhibitor such as hirudin. It is elevated when fibrin split products are elevated in dysfibrinogemias.**
Effective Date	**1/31/2012**
Test Code	4210
Specimen Requirements	**1.0 mL (0.5 mL) Plasma Citrated**
Instructions	**Instructions: Collect plasma by carefully mixing 1 part 3.2% sodium citrate with 9 parts venous blood. Gently mix but do not shake. Centrifuge immediately 1500 x g for 10 min., remove plasma using plastic pipette, and place into at least 2 polypropylene 10 x 75 mm tubes. Cap, promptly freeze, and ship frozen.** **General Drawing Instructions: Refer to Quest Diagnostics Nichols Institute Directory of Services under Specimen Collection section, Coagulation Testing, for further information on specimen processing.**
Reference Range	**16-23 sec**

Tests Affected	

Test Codes:	Name:
5976	Lupus Anticoagulant: Screen 2
5962	Lupus Anticoagulant: Screen 3

Vitamin D, 25-Hydroxy Total [LC/MS/MS]	
Effective Date	**1/31/2012**
Test Code	3541
Specimen Requirements	**0.5 mL (0.3 mL) Serum**

von Willebrand Factor Antigen	
Clinical Significance	**von Willebrand disease is the most common hereditary bleeding disorder; it may also be acquired. von Willebrand factor is necessary for platelet adhesion to injured endothelium. von Willebrand factor antigen is useful in assessing the quantity of von Willebrand factor. When combined with other tests, results are useful in categorizing the type of von Willebrand disease.**
Effective Date	**1/31/2012**
Test Code	1907
Specimen Requirements	Add: **Note: Storage of whole blood at refrigerated temperature before processing may lead to cryoprecipitate formation and falsely low Factor VIII and von Willebrand Factor studies.** **General Drawing Instructions: Refer to Quest Diagnostics Nichols Institute Directory of Services under Specimen Collection section, Coagulation Testing, for further information on specimen processing.**
Specimen Stability	**Room Temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 30 days**
Reference Range	**50 - 217 %**
Methodology	**Immunoturbidometric**
Tests Affected	

Test Codes:	Name:
5991	Cardiovascular Thrombotic Risk AssessR™
5981	von Willebrand Evaluation with Multimers
5961	von Willebrand Profile
1905	von Willebrand Factor Multimers Panel
5984	von Willebrand Evaluation without Multimers

Pain Management, Alcohol Metabolites with Confirmation, Urine	
Effective Date	**2/14/2012**
Test Code	16910
CPU Mappings	

Reporting Title: PAIN,ALCOHOL METAB W/CONF	
Result Code	**Result Name**
82090191	Report Comments

82000600	Alcohol Metabolites
82000610	**Ethyl Glucuronide (EtG)**
82000620	**Ethyl Sulfate (EtS)**
82000625	Please Note

Pain Mgmt, Alcohol Metab, w/Conf, w/medMATCH™, U	
Effective Date	**2/14/2012**
Test Code	90079
CPU Mappings	

Reporting Title: PAIN,ALCOHOL METAB W/CONF

Result Code	**Result Name**
82090100	Prescribed Drug 1
82090110	Prescribed Drug 2
82090120	Prescribed Drug 3
82090130	Prescribed Drug 4
82090140	Prescribed Drug 5
82090191	Report Comments
82000600	Alcohol Metabolites
82000601	medMATCH Alcohol Metabolites
82000610	**Ethyl Glucuronide (EtG)**
82000611	**medMATCH Ethyl Glucuronide (EtG)**
82000620	**Ethyl Sulfate (EtS)**
82000621	**medMATCH Ethyl Sulfate (EtS)**
82000625	Please Note

Actin (Smooth Muscle) Antibody (IgA)	
Effective Date	**2/21/2012**
Former Test Name	*F-Actin IgA Autoantibodies*
Test Code	5924
Specimen Requirements	**0.5 mL (0.25 mL) Serum** **Preferred: Red top** **Acceptable: Serum separator tube**
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 14 days** **Refrigerated: 14 days** **Frozen: 30 days**
Reference Range	

<20 **> or = 20**	Negative **Positive**

Actin (Smooth Muscle) Antibody (IgG)	
Clinical Significance	**Actin is the major antigen to which smooth muscle antibodies react in autoimmune hepatitis. F-Actin IgG antibodies are found in 52-85% of patients with autoimmune hepatitis (AIH) or chronic active hepatitis and in 22% of patients with primary bilary cirrhosis (PBC). Anti-actin antibodies have been reported in 3-18% of sera from normal healthy controls.**
Effective Date	**2/21/2012**
Former Test Name	*F-Actin IgG Autoantibodies*
Test Code	5920
Specimen Requirements	**0.5 mL (0.25 mL) Serum** **Preferred: Red Top** **Acceptable: Serum Separator Tube**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 14 days** **Refrigerated: 14 days** **Frozen 30 days**
Reference Range	<20 Negative **> or = 20 Positive**
Always Message	**Antibodies recognizing actin are the main component of smooth muscle antibodies associated with autoimmune liver disease. Actin antibodies are found in approximately 75% of patients with autoimmune hepatitis (AIH) type 1, approximately 65% of patients with autoimmune cholangitis, approximately 30% of patients with primary biliary cirrhosis and approximately 2% of healthy controls. High values are closely correlated with AIH type 7.**
Tests Affected	**Test Codes:** / **Name:** 5908 / Hepatitis Autoimmune EvaluatR™ 5906 / Hepatitis Autoimmune EvaluatR™ PLUS RNW / Reflex Antinuclear AB ANA

Redirects

Carnitine, LC/MS,MS [70107X]	
Clinical Significance	**Serum carnitine analysis is useful in the diagnosis and monitoring of patients with carnitine deficiency (either primary or secondary). Primary carnitine deficiency is an autosomal recessively inherited genetic condition that affects carnitine uptake by cells and tissues through a defect in the plasma membrane carnitine transporter. Secondary carnitine deficiency can be seen in some disease states or in patients on carnitine-poor diets, but is also seen in a number of metabolic disorders. In these disorders, carnitine complexes with the accumulated substrate of the blocked metabolic step, and the resulting acylcarnitine ester is excreted in the urine, leading to a depletion of carnitine in the patient.**
Effective Date	**1/17/2012**
Former Test Code	***4163***
Test Code	**S51992**
CPT Codes	**82379**
Specimen Requirements	**1.0 mL (0.4 mL) Serum** **Alternate: Plasma collected in a sodium heparin (green-top) tube**

Instructions	**Collect blood sample in serum (red-top) tube. Separate serum by centrifugation. Avoid hemolysis. Remove serum and place in plastic tube. Freeze immediately after separation. Patient should be in a well-fed state.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 5 hours** **Refrigerated: 5 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: 4 days a week p.m.; Report available: 3 days**

Reference Range

Carnitine, Total	
Adult Male	**30-70 µmol/L**
Adult Female	**25-58 µmol/L**
Male ≤17 Years	**32-62 µmol/L**
Female ≤17 Years	**28-59 µmol/L**
Carnitine, Free	
Adult Male	**23-59 µmol/L**
Adult Female	**19-48 µmol/L**
Male ≤17 Years	**25-54 µmol/L**
Female ≤17 Years	**19-51 µmol/L**
Carnitine, Esters	
Adult Male	**4-15 µmol/L**
Adult Female	**4-13 µmol/L**
Male ≤17 Years	**4-12 µmol/L**
Female ≤17 Years	**3-16 µmol/L**
Esterified/Free Ratio	
Adult Male	**0.12-0.39**
Adult Female	**0.13-0.42**
Male ≤17 Years	**0.09-0.35**
Female ≤17 Years	**0.09-0.49**

Methodology	**Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

CPU Mappings

Result Code	Result Name
110729	CARNITINE, TOTAL
111730	CARNITINE, FREE
111731	CARNITINE, ESTERS
111732	ESTERIFIED/FREE RATIO

Discontinued Tests

Carnitines Evaluation	
Message	Suggested replacement test code **S51992 Carnitine, LC/MS,MS [70107X]**
Effective Date	**1/17/2012**
Test Code	4163

Lupus Anticoagulant: DRVVT reflex to Confirmation	
Message	Suggested replacement test code **15780 dRVVT Screen w/rfl dRVVT Confirm & dRVVT 1:1 Mix**
Effective Date	**1/31/2012**
Test Code	1911
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	

Test Codes:	**Name:**
1082	Antiphospholipid Syndrome Evaluation, Expanded
5963	Lupus Anticoagulant: Screen 1
5976	Lupus Anticoagulant: Screen 2
5962	Lupus Anticoagulant: Screen 3
1910	Lupus Anticoagulant: Screen 3

Leukemia/Lymphoma Flow EvaluatR™	
Message	Suggested replacement test code **35080 Leukemia/Lymphoma Evaluation Panel**
Effective Date	**2/14/2012**
Test Code	1795

Referral Tests

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION.**

Purine and Pyrimidine Panel, Urine (81420)	
Effective Date	**12/30/2011**
Test Code	S48767
Specimen Stability	**Frozen: 7 days**
Performing Site	Mayo Medical Labs

Human Anti-Mouse AB (HAMA), ELISA(41882)	
Effective Date	**1/10/2012**
Test Code	S51635

Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**
Reference Range	**<75 ng/mL**
Always Message	**REFERENCERANGE: <75 ng/mL** **INTERPRETIVE CRITERIA:** **<75 ng/mL Normal HAMA level** **>=75 ng/mL Increased HAMA level** **HAMA produced following therapeutic murine monoclonal antibody treatment may reduce the effectiveness of the monoclonal antibody therapy, or cause anaphylactic complications during subsequent rounds of treatment. HAMA may also be detected in a small percentage of the general population, and usually represent heterophilic antibodies or dietary exposure to murine proteins.**
Assay Category	**FDA Approved**
Performing Site	Focus Diagnostics, Inc.

HIV-1 Coreceptor Tropism (16710)	
Effective Date	**1/17/2012**
Test Code	S51884
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test. This test utilizes RT-PCR and DNA sequencing **performed in triplicate** to detect the presence of HIV-1 envelope V3 loop variants associated with CXCR4 (X4) coreceptor utilization. The use of CCR5 coreceptor antagonists to treat HIV-1 is not recommended for patients harboring X4-tropic virus. PLEASE NOTE: This information has been disclosed to you from records whose confidentiality may be protected by state law. If your state requires such protection, then the state law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is NOT sufficient for this purpose.
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Reporting Title: HIV-1 CORECEPTOR TROPISM** **Result Code:** / **Result Name:** **113761** / **MVC Activity Anticipated**
Additional Information	**Adding "MVC Activity Anticipated" reporting analyte.**

Organic Acids, Full Panel, Quantitative, Urine (90561)	
Effective Date	**1/17/2012**
Former Test Name	*Organic Acids, Quantitative, Random Urine, Full Panel*
Test Code	S51667
CPT Codes	83918,**82570**
Specimen Requirements	13 mL random urine, no preservative **submitted in 2 sterile urine transport containers** **To prevent delays in testing, the laboratory requests the receipt of two labeled containers:** **One standard urine transport container (or standard transport tube) containing specimen for organic acid analysis.** **One standard transport tube labeled for creatinine analysis- used for normalizing urine results.** **If volume is less than 4 mL- call the Biochemical Genetics Laboratory for instructions.**

	Do not use preservatives. Avoid fecal contamination of urine. Patient age is required for correct reference range.
Specimen Stability	**Room temperature and Refrigerated: Unacceptable** **Frozen: 28 days**
Reference Range	**Creatinine, Random Urine:** **0-6 months** **0.18-2.86** **mmol/L** **7-11 months** **0.18-3.19** **mmol/L** **1-2 years** **0.18-11.33** **mmol/L** **3-8 years** **0.18-13.19** **mmol/L** **9-12 years** **0.18-16.19** **mmol/L** **>12 years** **2.38-26.55** **mmol/L**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Reporting Title: ORGANIC ACIDS, QUANTITATIVE** **Result Code:** / **Result Name:** **113760** / **Creatinine, Random Urine**
Additional Information	**Adding Creatinine analyte.**

Organic Acids, Qualitative, Urine(90404)	
Effective Date	**1/17/2012**
Test Code	S49453
CPT Codes	83919,**82570**
Specimen Requirements	13 mL random urine, no preservative **submitted in 2 sterile urine transport containers** **If volume is less than 4 mL- call the Biochemical Genetics Laboratory for instructions. To prevent delays in testing, the laboratory requests the receipt of two labeled containers: One standard urine transport container (or standard transport tube) containing specimen for organic acid analysis. One standard transport tube labeled for creatinine analysis- used for normalizing urine results.** Do not use preservatives. Avoid fecal contamination of urine.**Patient age is required for correct reference range.**
Specimen Stability	**Room temperature and Refrigerated: Unacceptable** **Frozen: 28 days**
Reference Range	**Creatinine, Random Urine:** **0-6 months** **0.18-2.86** **mmol/L** **7-11 months** **0.18-3.19** **mmol/L** **1-2 years** **0.18-11.33** **mmol/L** **3-8 years** **0.18-13.19** **mmol/L** **9-12 years** **0.18-16.19** **mmol/L** **>12 years** **2.38-26.55** **mmol/L**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	Reporting Title: ORGANIC ACIDS, QUALITATIVE **Result Code:** / **Result Name:** **113759** / **Creatinine, Random Urine**
Additional Information	**Adding Creatinine analyte.**

Spinal Muscular Atrophy (SMA) - Diagnostic	
Effective Date	**1/17/2012**
Test Code	S50070
Specimen Requirements	4 mL whole blood collected in EDTA (lavender-top) tube **Prenatal Preferred Specimen: Cultured cells of chorionic villus sample (CVS) or amniocytes. Minimum volume: 2 confluent T-25 flasks (please keep back-up cultured cells until testing is complete)** **Prenatal Alternate Specimen: Direct chorionic villus sample (CVS) or Amniotic fluid (please keep back-up cultured cells until testing is complete). Minimum Volume: 7-10 mL direct amniotic fluid or 7-10 mgs of direct CVS (For CVS only, villi should be stored and transported in 10 mL sterile saline or RPMI tissue culture medium)** **For Maternal Cell Contamination Studies: Please provide a lavender or yellow top tube with 10 mL of maternal peripheral blood. The maternal sample may arrive separately.** **All prenatal samples must be coordinated with an Athena genetic counselor prior to sending. Please call 1-800-394-4493 to speak to one of our genetic counselors.** **Storage Conditions: Incubation of cultures at 37°C; Send direct samples immediately.** **Notes: Athena Diagnostics does not have a cell culture facility; direct specimen accepted if client agrees to provide backup cell culture, which may be needed for additional testing.** ***Please call with questions**
Transport Temperature	**Room temperature, overnight**
Set-up/Analytic Time	**Prenatal samples are not processed on weekends, therefore no shipments on Fridays and no arrivals on Saturday and Sundays.** **Reports: 7 days**
Performing Site	Athena Diagnostics, Inc.

Hepatitis E Antibodies (IgG, IgM)(20173)	
Effective Date	**1/24/2012**
Test Code	S51510
Always Message	**REFERENCE RANGE: NOT DETECTED** **Hepatitis E virus (HEV) is a major cause of enteric non-A hepatitis worldwide. Both HEV IgM and IgG are typically detected within one month after infection; IgM persists for about two months, whereas IgG levels persist for months to years after recovery. Approximately 20% of the US population is positive for HEV IgG, indicating that HEV exposure is more common than previously thought.** **This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.**
Assay Category	**Laboratory Developed Test**
CPU Mappings	**Result Code** / **Result Name** **110599** / **Remove Interpretation result code.**

Hepatitis E Antibody (IgG)(20171)	
Effective Date	**1/24/2012**
Test Code	S51511
Always Message	**REFERENCE RANGE: NOT DETECTED** **Hepatitis E virus (HEV) is a major cause of enteric non-A hepatitis worldwide. HEV IgG is typically detected within one month after infection, and persists for months to years after recovery. Approximately 20% of the US population is positive for HEV IgG, indicating that HEV exposure is more common than previously thought.** **This test was developed and its performance characteristics have been determined by Focus**

	Diagnostics. Performance characteristics refer to the analytical performance of the test.
Assay Category	**Laboratory Developed Test**
Performing Site	Focus Diagnostics, Inc.

Hepatitis E Antibody (IgM)(20172)	
Effective Date	**1/24/2012**
Test Code	S51512
Always Message	**REFERENCE RANGE: NOT DETECTED** **Hepatitis E Virus (HEV) is a major cause of enteric non-A hepatitis worldwide. HEV IgM is typically detected within 2-4 weeks after infection, and then persists for about two months.** **This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.**
Assay Category	**Laboratory Developed Test**
Performing Site	Focus Diagnostics, Inc.

Amylase, Random Urine (with Creatinine) (8464)

Effective Date	**2/7/2012**
Former Test Name	*Amylase, Random Urine*
Test Code	S48851
Specimen Requirements	10 mL random urine no preservative **(minimum: 2 mL)**
Reject Criteria	**Acidified urine**
Specimen Stability	**Refrigerated: 7 days** **Frozen: 28 days**
Reference Range	

Amylase/Creatinine Ratio	40-440 U/g Creatinine	
Amylase, Random Urine	ReferenceRangeNot Established	
Creatinine, Random Urine	< or =6 months	2-32 mg/dL
	7-11 months	2-36 mg/dL
	1-2 years	2-128 mg/dL
	3-8 years	2-149 mg/dL
	9-12 years	2-183 mg/dL
	> or = 13 years	Male: 20-370 mg/dL Female: 20-320 mg/dL

Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code:	**Result Name:**
38450 **113762** **105678**	**Amylase/Creat Ratio** **Amylase, Random U** **Creatinine, Random Urine**

Herpes Simplex Virus 1/2 (IgG) Type-Specific Antibodies, CSF (60555)	
Message	***This test is **not** available for New York patient testing at Focus Diagnostics Inc.*
Effective Date	**2/14/2012**
Test Code	S52424
Performing Site	Focus Diagnostics, Inc.
Additional Information	**This test is not available for New York patient testing. For NY patient testing please order S51676NY Herpes Simplex Virus, Type 1 & 2 DNA, Quantitative Real-Time PCR performed at Focus Diagnostics, Inc.**

Herpes Virus-6 DNA, Qualitative Real-Time PCR(43160)	
Message	***This test is **not** available for New York patient testing at Focus Diagnostics Inc.*
Effective Date	**2/14/2012**
Test Code	S51518
Specimen Requirements	**Amniotic fluid is no longer an acceptable specimen type. Other acceptable specimens: Bone marrow (EDTA, ACD), bronchoalveolar lavage, and tissue.**
Performing Site	Focus Diagnostics, Inc.

Herpes Virus-6 DNA, Quantitative Real-Time PCR (43660)	
Effective Date	**2/14/2012**
Test Code	S52269
Specimen Requirements	**Amniotic fluid is no longer an acceptable specimen type. Other acceptable specimens: Bone marrow (EDTA, ACD) and bronchoalveolar lavage**
Performing Site	Focus Diagnostics, Inc.

Lymphocytic Choriomeningitis (LCM) Virus Antibody, IFA (CSF)(60625)	
Effective Date	**2/21/2012**
Former Test Name	*Lymphocytic Choriomeningitis Virus CSF*
Test Code	S49015
Specimen Stability	**Room temperature: Unacceptable Refrigerated: 14 days Frozen: 30 days**
Performing Site	Focus Diagnostics, Inc.