Laboratory Update
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Quest Diagnostics Nichols Institute, Valencia

May 2011 Update

Dear Colleague,

We are pleased to offer our latest laboratory news in a new format designed for ease of use and review. The revised features of the update include a quick view of new test offerings, a summary of test changes and a new format for the specific updates. We've expanded the information provided for our referral tests as well. As we move forward with our laboratory update improvement project, we will be expanding our distribution of the update by email as we obtain your specific contact information.

We bring several new tests to market in this update, notably; test code 16983 - ColoVantage™ (methylated Septin 9), a molecular blood-based test for identifying a biomarker associated with colorectal cancer.

In this update, we would also like to draw your attention to Referral Test S51608, PTH-RP (34478Z) which we noted as a replacement in last month's update. Please note that the specimen requirement is Plasma: Sodium Heparin (green-top) and that Traysol tubes are no longer acceptable.

Please also note a correction to our last update in regard to CPT coding. Three of our new SureSwab assays, available on April 5th, should have shown CPT coding as follows:
15509 SureSwab™, Bacterial Vaginosis/Vaginitis: **87481x4, 87512, 87798, 87799x3**
16898 SureSwab™, Bacterial Vaginosis DNA, Quantitative RT-PCR: **87512, 87799x3**
19550 SureSwab™, Trichomonas vaginalis RNA, Qualitative TMA: **87798**

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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Summary of Test Changes

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8	AccuType® Metformin	5270											•			•
8	Benzodiazepines, Quant, Urine	4090U			•				•							
8	Cocaine Metabolite, Quant, Urine	4171U			•				•							
8	Creatinine	1320								•	•					•
9	Drugs Of Abuse Screen Urine w/Reflex Confirmation	4129U							•							
9	Fecal Fat, Qualitative	4426			•				•			•				•
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10	Hydrocodone and Metabolite, Serum	4490			•											
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12	Pain Management Opiates, Quant, Urine	4644U			•											
12	Pain Management Oxycodone, Quant, Urine	4648U			•											
12	Pain Management Phenycyclidine, Quant, Urine	4652U			•											
12	Pain Management Propoxyphene, Quant, Urine	4656U			•											
12	TBII (Thyrotropin-Binding Inhibitory Immunoglobulin)	1093			•						•					•
12	Magnesium RBC	4866R				•	•		•							•
13	Hepatitis C Viral RNA, Genotype, LiPA	7473			•											
13	Hepatitis C Viral RNA, Qualitative TMA	7516			•											•
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15	Hepatitis C Viral RNA, Quantitative bDNA	7486			•	•	•		•		•				•	•
16	Hepatitis C Viral RNA, Qualitative w/Rfx Quantitative bDNA	7518			•	•	•		•						•	•
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New Test Offerings

ColoVantage™ (methylated Septin 9) *** This test is not available for New York patient testing. ***		
Clinical Significance:	ColoVantage™ (methylated Septin 9) is a molecular blood-based test for identifying a biomarker associated with colorectal cancer. A patient whose ColoVantage test result is positive may have an increased likelihood of colorectal cancer and would be evalulated further.	
Effective Date:	**April 15, 2011**	
Test Code:	**16983**	
CPT Code(s):	**83891, 83896 (x3), 83898 (x3), 83912**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Plasma, EDTA** **10mL** **5mL** **To obtain this volume of plasma collect blood in two (2) 10 mL EDTA (lavender-top) tubes or five (5) standard EDTA (lavender-top) tubes. Centrifuge the blood samples, separate plasma and combine them. Send plasma in a single 10 mL pour-off tube. If a 10 mL pour-off tube is not available, two (2) 5 mL pour-off tubes can be used.**
Rejection Criteria:	**Non-frozen samples** **Samples with less than 5 mL of plasma**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room temperature: Not accepted** **Refrigerated: Not accepted** **Frozen: 28 days**	
Assay Category:	**LDT**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Reports: 3 days**	
Reference Ranges:	**Not Detected**	
Methodology:	**Real-Time Polymerase Chain Reaction**	
Always Message	**This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Methamphetamine and Metabolite, Quant, Urine		
Clinical Significance:	This panel is used for the detection of methamphetamine and amphetamine in urine.	
Effective Date:	**April 5, 2011**	
Test Code:	**4663U**	
CPT Code(s):	**82145**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Random Urine** **7.0 mL** **2.0 mL** **Collect 7 mL 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: Mon, Wed, Fri; Reports: 2-4 days**	
Reference Ranges:	**Amphetamine**	**Always Message: Limit of Quantitation: 200 ng/mL**
Reference Ranges:	**Methamphetamine**	**Always Message: Limit of Quantitation: 200 ng/mL**
Methodology:	**Liquid Chromatography Mass Spectrometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Pain Management, Alcohol Metabolites, with Confirm, Urine		
Clinical Significance:	Ethyl glucuronide and Ethyl sulfate are metabolites of ethanol (alcohol) that are present in urine for up to 80 hours post alcohol consumption.	
Effective Date:	**April 12, 2011**	
Test Code:	**16910**	
CPT Code(s):	**80101**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Random Urine** **20 mL** **5 mL** **Collect 20 mL of random urine, no preservatives**
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; Reports: 2-3 days**	
Reference Ranges:	**Alcohol Metabolites**	**<500 ng/mL**
	If screen is positive, it will reflex to:	
	Ethyl Glucuronide	**<500 ng/mL**
	Ethyl Sulfate	**<100 ng/mL**
Methodology:	**Liquid Chromatography Mass Spectrometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Region 1 Allergy Profile		
Effective Date:	**April 12, 2011**	
Test Code:	**3800**	
CPT Code(s):	**82785, 86003 (x25)**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Serum** **6 mL** **4 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Sun-Sat; Reports: 1-3 days**	
Reference Ranges:	**< .35 kU/L**	
Methodology:	**ImmunoCAP**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
Includes:	**Immunoglobulin E (1245)**	
	Allergen-*Alternaria alternata/tenuis* IgE (M6)	
	Allergen-*Aspergillus fumigatus* IgE (M3)	
	Allergen-Bermuda Grass IgE (G2)	
	Allergen-Box Elder IgE (T1)	
	Allergen-Cat Epithelium/Dander IgE (E1)	
	Allergen-*Cladosporium herbarum* IgE (M2)	
	Allergen-Cockroach, American IgE (I6)	
	Allergen-Common Silver Birch IgE (T3)	
	Allergen-Cottonwood IgE (T14)	
	Allergen-*Dermatophagoides farinae* IgE (D2)	
	Allergen-*Dermatophagoides pteronyssinus* IgE (D1)	
	Allergen-Dog Dander IgE (E5)	
	Allergen-Elm IgE (T8)	
	Allergen-Maple Leaf Sycamore IgE (T11)	
	Allergen-Mountain Juniper/Cedar IgE (T6)	
	Allergen-Mugwort IgE (W6)	
	Allergen-Mulberry IgE (T70)	
	Allergen-Oak IgE (T7)	
	Allergen-*Penicillium chrysogenum* IgE (M1)	
	Allergen-Pigweed IgE (W14)	
	Allergen-Sheep Sorrel IgE (W18)	
	Allergen-Short (Common) Ragweed IgE (W1)	
	Allergen-Timothy Grass IgE (G6)	
	Allergen-Walnut Tree Pollen IgE (T10)	
	Allergen-White Ash IgE (T15)	

Suboxone (Buprenorphine, Naloxone), Quant, Urine		
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:	**April 12, 2011**	
Test Code:	**4241U**	
CPT Code(s):	**83925 (x2)**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**Urine** **20mL** **10mL** **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,Thu,Sat; Reports: 2-4 days**	
Reference Ranges:	**Buprenorphine**	**<2 ng/mL**
	Norbuprenorphine	**<2 ng/mL**
	Naloxone	**Limit of quantitation: 2 ng/mL**
Methodology:	**Liquid Chromatography Mass Spectrometry**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	

Test Changes

The following test changes will be effective on the dates indicated below.
Please note that only the information that is changing appears in this update.
Former test codes and test names have been italicized.

AccuType® Metformin	
Clinical Significance:	The SNP rs2289669 G>A in the SLC47A1 gene, coding for the MATE1 protein, is associated with glucose lowering effect of metformin in patients with diabetes. The A allele is associated with higher levels of reduction in HbA1c. Genotyping patients with respect to these polymorphisms will determine the therapeutic response to metformin.
Effective Date:	**May 3, 2011**
Test Code:	**5270**
CPT Code(s):	**83891, 83892, 83898, 83909, 83912, 83914**
Component:	**OCT1 Locus Not Reported**

Benzodiazepines, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4090U**
Former Test Name:	*Benzodiazepines Confirmation Urine*
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 14 days (increased)** **Frozen: 30 days (increased)**

Cocaine Metabolite, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4171U**
Former Test Name:	*Cocaine Metabolite-Benzoylecgonine Urine*
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 14 days (increased)** **Frozen: 30 days (increased)**

Creatinine	
Effective Date:	**May 3, 2011**
Test Code:	**1320**
Add Component	**Glomerular Filtration Rate (GFR), Estimated**
Reference Ranges:	**>59 mL/min/1.73m^2**
Methodology:	**Calculation**
Additional Information	**Also affects: 1322, 5315, 5317, 5314** **Glomerular Filtration Rate (GFR) is calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.**

Drugs Of Abuse Screen Urine w/Reflex Confirmation	
Effective Date:	**May 3, 2011**
Test Code:	**4129U**
Specimen Stability:	**Room Temperature: 7 days (new)** **Refrigerated: 14 days (increased)** **Frozen: 30 days (increased)**
Additional Information	**Also affects: 4256U, 4252U, 4254U, 4121U, 4107U, 4109U, 4250U, 4101U, 4127U**

Fecal Fat, Qualitative	
Effective Date:	**May 3, 2011**
Test Code:	**4426**
Former Test Name:	*Fecal Fat (Lipids), Qualitative*
Transport Temperature:	**Frozen**
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 5 days** **Frozen: 30 days**
Set-Up/Analytic Time:	**Set-up: Sun – Sat; Reports 2 days**
Always Message:	**Normal – Tiny fat globules, <1 micron in diameter and too difficult to count, were observed microscopically under high power.** **Abnormal – Fat globules, 1 to 8 microns in diameter, and <100 globules per high power field were observed microscopically.** **Gross Abnormal – Large fat globules, 9 to 75 microns in diameter, and so numerous that there was very little fecal background observed microscopically under high power.**
Methodology:	**Sudan Stain (new)**

Glomerular Filtration Rate (GFR), Estimated	
Effective Date:	**May 3, 2011**
Test Code:	**1325**
Always Message	**Remove Always message**
Additional Information	**Glomerular Filtration Rate (GFR) is calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.**

Glutamic Acid Decarboxylase-65 Antibody	
Effective Date:	**May 3, 2011**
Test Code:	**1033**
Former Test Name:	*Glutamic Acid Decarboxylase (GAD) Autoantibodies*

Hemoglobin A1c AccuQuant®	
Effective Date:	**May 3, 2011**
Test Code:	**4972**
Always Message:	**% of Total Hemoglobin — Interpretation** **< 5.7 — Decreased risk of diabetes** **5.7 – 6.0 — Increased risk of diabetes** **6.1 – 6.4 — Higher risk of diabetes** **≥ 6.5 — Consistent with diabetes**
Additional Information	**Also affects: 4972SR, 4975, 4971**

HIV-1 RNA Quantitation [Real Time PCR]	
Effective Date:	**Immediate**
Test Code:	**7485A**
Always Message:	**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 vial 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.**
Additional Information	**Also affects: 7485ASR, 7482A**

Hydrocodone and Metabolite, Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4490**
Former Test Name:	*Hydrocodone Serum AccuQuant® (including Hydromorphone)*

Levetiracetam	
Effective Date:	**May 3, 2011**
Test Code:	**4963**
Specimen Stability:	**Room temperature: 14 days (increased)** **Refrigerated: 28 days (increased)** **Frozen: 28 days (decreased)**
Reference Range	**Units mcg/mL**
Always Message:	**Therapeutic Levels:** **Drug Dosage — Trough (mcg/mL) — Peak (mcg/mL)** **500 mg BID — 3.1 – 10.0 — 10.0 – 25.0** **1000 mg BID — 4.9 – 37.1 — 30.0 – 40.0** **1500 mg BID — 7.0 – 34.0 — 36.1 – 70.0**

Myelin Basic Protein	
Effective Date:	**May 3, 2011**
Test Code:	**3900**
Former Test Name:	*Myelin Basic Protein CSF*
Reference Range	**mcg/L**
Always Message:	**MBP (mcg/L) Interpretation** **0 – 4.0 Negative** **4.1 – 6.0 Weakly positive** **> 6.0 Positive**
Additional Information	**Also affects: 1055**

Oxycodone and Metabolite, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4176U**
Former Test Name:	*Oxycodone And Metabolite Urine*
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 14 days (increased)** **Frozen: 30 days (increased)**

Pain Management Amphetamines, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4620U**
Former Test Name:	*Pain Management Amphetamine Confirmation, Urine*

Pain Management Barbiturates, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4624U**
Former Test Name:	*Pain Management Barbiturate Confirmation, Urine*

Pain Management Benzodiazepines, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4628U**
Former Test Name:	*Pain Management Benzodiazepines Confirmation, Urine*

Pain Management Cocaine Metabolite, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4636U**
Former Test Name:	*Pain Management Cocaine Metabolite Confirmation, Urine*

Pain Management Marijuana Metabolite, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4632U**
Former Test Name:	*Pain Management Marijuana Metabolite Confirmation, Urine*

Pain Management Methadone, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4640U**
Former Test Name:	*Pain Management Methadone Confirmation, Urine*

Pain Management Opiates, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4644U**
Former Test Name:	*Pain Management Opiates Confirmation, Urine*

Pain Management Oxycodone, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4648U**
Former Test Name:	*Pain Management Oxycodone Confirmation, Urine*

Pain Management Phencyclidine, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4652U**
Former Test Name:	*Pain Management Phencyclidine Confirmation, Urine*

Pain Management Propoxyphene, Quant, Urine	
Effective Date:	**May 3, 2011**
Test Code:	**4656U**
Former Test Name:	*Pain Management Propoxyphene Confirmation, Urine*

TBII (Thyrotropin-Binding Inhibitory Immunoglobulin)	
Effective Date:	**May 3, 2011**
Test Code:	**1093**
Former Test Name:	*Thyrotropin Receptor Autoantibody*
Reference Ranges:	**<17 % Inhibition**
Always Message:	Remove
Additional Information	**Also affects: 1090, 3060**

Magnesium RBC		
Effective Date:	**May 9, 2011**	
Test Code:	**4866R**	
Specimen Requirements:	Type: Opt Volume: Min Volume: Collection Instructions:	**EDTA (lavender-top or dark blue-top tube) packed cells** **EDTA (lavender-top tube) whole blood is acceptable.** **Sodium Heparin lead-free (tan-top tubes) are no longer acceptable.** **0.5 mL** **0.2 mL** **Leave packed cells in original collection tube.**
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: Unacceptable**	
Additional Information:	**Update specimen requirements, collection instructions, and stability.**	

Hepatitis C Viral RNA, Genotype, LiPA	
Effective Date:	**May 17, 2011**
Test Code:	**7473**
Former Test Name:	*Hepatitis C Virus SubtypR®*

Hepatitis C Viral RNA, Qualitative TMA	
Effective Date:	**May 17, 2011**
Test Code:	**7516**
Former Test Name:	*Hepatitis C Virus RNA DetectR™*
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Always Message:	**This test was performed using Versant® HCV Qualitative TMA Assay (Transcription Mediated Amplification).**
Additional Information	**Also affects: Reflex of 7492**

HCV RNA, Quantitative PCR w/Reflex Genotype, LiPA	
Effective Date:	**May 17, 2011**
Test Code:	**7489**
Former Test Name:	*Hepatitis C Virus RNA Quantitation (PCR) w/reflex SubtypR®*

Hepatitis C Viral RNA, Quant bDNA w/Reflex Genotype, LiPA		
Effective Date:	**May 17, 2011**	
Test Code:	**7476**	
Former Test Name:	*Hepatitis C Virus RNA AccuQuant® [bDNA] w/reflex SubtypR®*	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma EDTA, Plasma ACD, Plasma PPT, Serum** **3.0 mL** **2.0 mL**
Collection Instruction	**Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K3 (standard EDTA tube) or 9 mg spray-dried EDTA K2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Store whole blood at room temperature and centrifuge within 4 hours of collection. Transfer plasma collected in standard EDTA tubes to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen.** **Note: If blood is collected in a PPT tube, centrifuge within 2 hours of collection as before, but it is not necessary to remove the plasma and transfer to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components, during specimen transport and storage, and unlike standard VACUTAINER Brand blood collection tubes, the PPT tube is plastic and hence the plasma can be shipped and stored frozen in the original tube.** **Serum: Collect blood in sterile tubes with no anticoagulants; serum separator tubes (SSTs) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Avoid repeated freezing and thawing of specimen.**	
Rejection Criteria:	**Thawed or room temperature samples, Unspun PPT**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 2 months**	
Add Component	**HCV RNA (log 10)**	
Reference Ranges:	**<2.79 log IU/mL**	
Methodology:	**Calculation**	
Always Message:	**This test was performed using the Versant® HCV RNA ASSAY (bDNA) 3.0 kit by Siemens.**	

Hepatitis C Viral RNA, Quantitative bDNA		
Effective Date:	**May 17, 2011**	
Test Code:	**7486**	
Former Test Name:	*Hepatitis C Virus RNA AccuQuant® [bDNA]*	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma EDTA, Plasma ACD, Plasma PPT, Serum** **3.0 mL** **2.0 mL**
Collection Instructions:	**Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K3 (standard EDTA tube) or 9 mg spray-dried EDTA K2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Store whole blood at room temperature and centrifuge within 4 hours of collection. Transfer plasma collected in standard EDTA tubes to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen.** **Note: If blood is collected in a PPT tube, centrifuge within 2 hours of collection as before, but it is not necessary to remove the plasma and transfer to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components, during specimen transport and storage, and unlike standard VACUTAINER Brand blood collection tubes, the PPT tube is plastic and hence the plasma can be shipped and stored frozen in the original tube.** **Serum: Collect blood in sterile tubes with no anticoagulants; serum separator tubes (SSTs) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Avoid repeated freezing and thawing of specimen.**	
Rejection Criteria:	**Thawed or room temperature samples, Unspun PPT**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 2 months**	
Add Component	**HCV RNA (log 10)**	
Reference Ranges:	**<2.79 log IU/mL**	
Methodology:	**Calculation**	
Always Message:	**This test was performed using the Versant® HCV RNA ASSAY (bDNA) 3.0 kit by Siemens.**	
Additional Information:	**Also affected: Reflex of 7518**	

Hepatitis C Viral RNA, Qualitative w/Rfx Quantitative bDNA		
Clinical Significance:	Qualitative RNA by TMA is useful in confirming HCV infection and to assess response to therapy. The lower limit of detection is 10 IU/mL.	
Effective Date:	**May 17, 2011**	
Test Code:	**7518**	
Former Test Name:	*Hepatitis C Virus RNA DetectR™ with reflex AccuQuant®*	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma EDTA, Plasma ACD, Plasma PPT, Serum** **3.0 mL** **2.0 mL**
Collection Instructions:	**Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K3 (standard EDTA tube) or 9 mg spray-dried EDTA K2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Store whole blood at room temperature and centrifuge within 4 hours of collection. Transfer plasma collected in standard EDTA tubes to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen.** **Note: If blood is collected in a PPT tube, centrifuge within 2 hours of collection as before, but it is not necessary to remove the plasma and transfer to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components, during specimen transport and storage, and unlike standard VACUTAINER Brand blood collection tubes, the PPT tube is plastic and hence the plasma can be shipped and stored frozen in the original tube.** **Serum: Collect blood in sterile tubes with no anticoagulants; serum separator tubes (SSTs) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Avoid repeated freezing and thawing of specimen.**	
Rejection Criteria:	**Thawed or room temperature samples, Unspun PPT**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 14 days**	
Always Message:	**This test was performed using Versant® HCV Qualitative TMA Assay (Transcription Mediated Amplification).**	

Hepatitis C Viral RNA, Quant bDNA w/Reflex Qualitative TMA		
Effective Date:	**May 17, 2011**	
Former Test Name:	*Hepatitis C Virus RNA UltraQuant® [bDNA] w/reflex TMA*	
Test Code:	**7576**	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma EDTA, Plasma ACD, Plasma PPT, Serum** **3.0 mL** **2.0 mL**
Collection Instructions:	**Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K3 (standard EDTA tube) or 9 mg spray-dried EDTA K2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Store whole blood at room temperature and centrifuge within 4 hours of collection. Transfer plasma collected in standard EDTA tubes to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen.** **Note: If blood is collected in a PPT tube, centrifuge within 2 hours of collection as before, but it is not necessary to remove the plasma and transfer to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components, during specimen transport and storage, and unlike standard VACUTAINER Brand blood collection tubes, the PPT tube is plastic and hence the plasma can be shipped and stored frozen in the original tube.** **Serum: Collect blood in sterile tubes with no anticoagulants; serum separator tubes (SSTs) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Avoid repeated freezing and thawing of specimen.**	
Rejection Criteria:	**Thawed or room temperature samples, Unspun PPT**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 14 days**	
Add Component	**HCV RNA (log 10)**	
Reference Ranges:	**<2.79 log IU/mL**	
Methodology:	**Calculation**	
Always Message:	**This test was performed using the Versant® HCV RNA ASSAY (bDNA) 3.0 kit by Siemens.**	

Hepatitis C Viral RNA, Quant bDNA w/Rfx TMA/Genotype, LiPA		
Effective Date:	**May 17, 2011**	
Test Code:	**7578**	
Former Test Name:	*Hepatitis C Virus RNA UltraQuant® reflex to SubtypR®*	
Specimen Requirements:	Type: Opt Volume: Min Volume:	**Plasma EDTA, Plasma ACD, Plasma PPT, Serum** **3.0 mL** **2.0 mL**
Collection Instructions:	**Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K3 (standard EDTA tube) or 9 mg spray-dried EDTA K2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Store whole blood at room temperature and centrifuge within 4 hours of collection. Transfer plasma collected in standard EDTA tubes to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen.** **Note: If blood is collected in a PPT tube, centrifuge within 2 hours of collection as before, but it is not necessary to remove the plasma and transfer to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components, during specimen transport and storage, and unlike standard VACUTAINER Brand blood collection tubes, the PPT tube is plastic and hence the plasma can be shipped and stored frozen in the original tube.** **Serum: Collect blood in sterile tubes with no anticoagulants; serum separator tubes (SSTs) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic, screw-capped, aliquot tubes and store at -18 C or colder. Avoid repeated freezing and thawing of specimen.**	
Rejection Criteria:	**Thawed or room temperature samples, Unspun PPT**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 2 months**	
Add Component	**HCV RNA (log 10)**	
New Component Reference Ranges:	**<2.79 log IU/mL**	
New Component Methodology:	**Calculation**	
Always Message:	**This test was performed using the Versant® HCV RNA ASSAY (bDNA) 3.0 kit by Siemens.**	

Test Discontinuations

Benzodiazepines Screen Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4111**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: 4107 Benzodiazepine Screen Serum w/Rfx Confirmation

Cocaine Metabolites Screen Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4118**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: 4252 – Cocaine Metabolites Screen Serum w/Rfx Confirmation

Hepatitis C Virus RNA AccuQuant® bDNA reflex to SubtypR® with serial reporting	
Effective Date:	**May 17, 2011**
Test Code:	**7476SR, 7486SR, 7576SR, 7578SR**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	These HCV RNA bDNA serial graphic tests will be discontinued due to low volume. Recommended alternatives: 7476, 7486, 7576, 7578 (without serial reporting).

Methadone Screen Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4113**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: 4109 – Methadone Screen Serum w/Reflex Confirmation

Opiates Screen Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4138**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: 4250 – Opiates Screen Serum w/Reflex Confirmation

Phencyclidine (PCP) Screen Serum	
Effective Date:	**May 3, 2011**
Test Code:	**4117**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: 4101 – Phencyclidine (PCP) Screen Serum w/Rfx Confirmation

BCL2/JH Gene Rearrangement [PCR]	
Effective Date:	**May 17, 2011**
Test Code:	**5049**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: S52422-Follicular Lymphoma, bcl-2/JH t (14;18), RT-PCR, CB (15007X), Performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

BCL2/JH Gene Rearrangement – Paraffin Block [PCR]	
Effective Date:	**May 17, 2011**
Test Code:	**5049BK**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: S52422-Follicular Lymphoma, bcl-2/JH t (14;18), RT-PCR, CB (15007X), Performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

BCL1/JH [T(11;14)] Translocation DetectR™	
Effective Date:	**May 17, 2011**
Test Code:	**5048**
Performing Site:	Quest Diagnostics Nichols Institute, Valencia
Additional Information:	This test will be discontinued. Recommended alternative: S52421-Mantle Cell Lymphoma, bcl-1/JH t (11;14), RT-PCR, CB (14991X), Performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

PTH-RP (34478Z)		
Clinical Significance:	Differential diagnosis of hypercalcemia; manage patients with solid tumors and hypercalcemia.	
Effective Date:	**Immediate**	
Test Code:	**S51608**	
CPT Code(s):	**83519**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:** **Collection Instructions:**	**Plasma: Sodium Heparin (green-top)** **0.5 mL** **0.3 mL** **Heparin Tubes: 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 unspun tubes.**
Rejection Criteria:	**Whole Blood; Plasma EDTA/Trasylol is not acceptable.**	
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 28 days**	
Set-Up/Analytic Time:	**Set-up: Tues; Reports: 2 to 3 days**	
Reference Ranges:	**PTH-RP**	**14-27 pg/mL**
Methodology:	**Immunoassay**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

DCP (Des-Gamma-Carboxy-Prothrombin (19982)		
Clinical Significance:	The DCP assay is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for progression to hepatocellular carcinoma (HCC) in conjunction with other laboratory findings and clinical assessment.	
Effective Date:	**Immediate**	
Test Code:	**S52398**	
CPT Code(s):	**83951**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:**	**Serum** **1 mL** **0.5 mL**
Rejection Criteria:	**Hemolysis; Lipemic specimens; Heavy, visible particulate matter.**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room temperature: 48 hours** **Refrigerated: 7 days** **Frozen: 21 days**	
Set-Up/Analytic Time:	**Set-up: Tues; Reports: 2 to 3 days**	
Reference Ranges:	**DCP**	**<7.6 ng/mL**
Methodology:	**Immunoassay**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Chromium, Blood (6085)		
Clinical Significance:	The assay is useful to 1. Monitor exposure to chromium; 2. Monitor progress of medical treatment; 3. Determine nutritional status.	
Effective Date:	**Immediate**	
Test Code:	**S52418**	
CPT Code(s):	**82495**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:** **Collection Instructions:**	**EDTA Trace-metal Whole blood** **4 mL** **2 mL** **To avoid contamination, use powderless gloves. DO NOT ALIQUOT SPECIMEN. Draw one vacutainer of blood (1-2 mL) and discard. Draw second vacutainer (2-4 mL in royal blue top, EDTA) for submission. Patient should refrain from taking mineral supplements, and multi-vitamin three days prior to specimen collection.**
Rejection Criteria:	**Moderate hemolysis; gross lipemia; clotted specimen**	
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room temperature: 48 hours** **Refrigerated: 5 days** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Mon – Fri; Reports: 2-3 days**	
Reference Ranges:	**Chromium, Blood**	**≤ 1.2 mcg/L**
Methodology:	**Inductively Coupled Plasma – Mass Spectrometry with Dynamic Reaction Cell (DRC-ICP-MS)**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Herpes Simplex Virus 1/2 (IgG) Type-Specific Abs, CSF [60555]		
Clinical Significance:	Detection of HSV type-specific IgG in CSF may indicate central nervous system (CNS) infection by that HSV type. However, interpretation of results may be complicated by a number of factors, including low antibody levels found in CSF, passive transfer of antibody across the blood-brain barrier, and serum contamination of CSF during CSF collection. PCR detection of type-specific HSV DNA in CSF is the preferred method for identifying HSV CNS infections.	
Effective Date:	**Immediate**	
Test Code:	**S52424**	
CPT Code(s):	**86695, 86696**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:**	**CSF** **1 mL** **0.1 mL**
Transport Temperature:	**Refrigerated**	
Specimen Stability:	**Room temperature: Unacceptable** **Refrigerated: 14 days** **Frozen: 30 days**	
Set-Up/Analytic Time:	**Set-up: Mon, Weds, Fri; Reports 2-3 days**	
Reference Ranges:	**HSV 1 IgG index** **HSV 2 IgG index**	**<1.01** **<1.01**
Methodology:	**Enzyme-linked immunosorbent assay**	
Performing Site:	**Focus Diagnostics**	

AccuType® IL28B (90251) *****New York State approval pending. This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing at this time.*****		
Clinical Significance:	The C polymorphism in rs12979860 is strongly associated with a two fold greater sustained virological response in European, African American, and Hispanic populations following treatment with Interferon. Knowledge of host genotype patients infected with HCV will aid in the clinical decision whether to initiate treatment with PegIFN and RBV (a 48 week course of interferon and ribavirin which has limited efficacy and is often poorly tolerated due to side effects that prevent patients from finishing treatment).	
Effective Date:	**April 4, 2011**	
Test Code:	**S52417**	
CPT Code(s):	**83891, 83898, 83896 (x2), 83912**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume**	**EDTA (lavender-top) whole blood** **5 mL** **2 mL**
Rejection Criteria:	**Do not freeze whole blood.**	
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: unacceptable**	
Set-Up/Analytic Time:	**Set up: Tues; Reports: 2-3 days**	
Reference Ranges:	**AccuType IL28B**	**Accompanies report**
Methodology:	**Real-Time Polymerase Chain Reaction**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

HIV-1 RNA, Qualitative TMA with Reflex to Quantitative Real-Time PCR (18967)		
Clinical Significance:	Early detection and treatment monitoring of chronic HIV-1 infection.	
Effective Date:	**April 11, 2011**	
Test Code:	**S52416**	
CPT Code(s):	**87535**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:** **Collection Instructions:**	**EDTA K2 plasma submitted in 2 transport containers** **4.6 mL** **3.1 mL** **Collect plasma in EDTA (lavender-top) or a (white-top) PPT Vacutainer™ plasma preparation tube. Separate plasma from the cells by centrifugation within 6 hours after collection. Transfer the plasma to two plastic screw-cap vials and ship frozen.**
Rejection Criteria:	**Whole blood; Unspun PPT, PPT with plasma frozen in-situ; Specimen collected using heparin as anticoagulant, leaking, uncapped or broken containers**	
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room temperature: 24 hours** **Refrigerated: 5 days** **Frozen: 35 days**	
Set-Up/Analytic Time:	**Set-up: Weds Reports: 3 to 4 days**	
Reference Ranges:	**HIV-1 RNA, QL TMA:**	**Not Detected**
Methodology:	**Transcription-Mediated Amplification (Reflex Real-Time Polymerase Chain Reaction)**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	
Additional Information:	**If HIV-1 RNA, Qualitative TMA result is Detected, HIV-1 RNA Quantitative, Real-Time PCR will be performed at an additional charge (CPT code: 87536).**	

Beta-2 Transferrin (10640)		
Clinical Significance:	The presence of Beta-2 Transferrrin in nasal or ear fluid or in wound drainage, following head trauma, surgery, or from tumors or congenital malformation, clearly indicates CSF leaking into these passages or fluids creating a pathway for life-threatening, central nervous system infection.	
Effective Date:	**April 30, 2011**	
Test Code:	**S52419**	
CPT Code(s):	**86335**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume** **Collection Instructions:**	**Body Fluid** **0.5 mL** **0.2 mL** **CSF is not acceptable. Nasal, otic, and other Non-CSF fluids are acceptable.**
Transport Temperature:	**Frozen**	
Specimen Stability:	**Room temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 14 days**	
Assay Category:	**RUO**	
Reference Ranges:	**Beta-2 Transferrin**	**Not detected**
Methodology:	**Electrophoresis; Immunofixation Electrophoresis**	
Performing Site:	**Quest Diagnostics Nichols Institute, Chantilly**	

FISH, Melanoma, Deletion 9p21 (CDKN2A/P16) (16863)		
Clinical Significance:	The deletion of 9p21 (CDKN2A/p16) is present in both early and late stages of the primary melanoma. Studies suggest that 9p21 deletion might be a highly informative marker in common and dysplastic nevi with high risk of malignant transformation (Casorzo, et al. Melanoma Res. 2005;15:155-160).	
Effective Date:	**May 2, 2011**	
Test Code:	**S52423**	
CPT Code(s):	**88271 (x2); 88275; 88291**	
Specimen Requirements:	**Type:**	**Formalin fixed paraffin embedded tissue**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room temperature: Indefinite** **Refrigerated: Indefinite** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Monday-Sat 5-6 days**	
Reference Ranges:	**FISH, Melanoma, del19p21**	**Attached report**
Methodology:	**Fluorescence in situ Hybridization**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS) (18902)		
Clinical Significance:	This panel, detecting tumor-associated somatic mutations in 4 different oncogenes, can predict response to EGFR-targeted immunotherapy in patients with metastatic colorectal cancer. Tumors with mutations in KRAS, NRAS, BRAF, and PI3KCA (exons 9 and 20) are associated with inferior response to anti-EGFR immunotherapy, and are variably associated with more aggressive clinical behavior compared to unmutated cases.	
Effective Date:	**May 9, 2011**	
Test Code:	**S52415**	
CPT Code(s):	**83891, 83898 (x2), 83892 (x2), 83909 (x4), 83904 (x4), 83912, 83898 (x3), 83904 (x3), 83907, 83909 (x3), 83912, 83898 (x3), 83894 (x3), 83892 (x3), 83909 (x6), 83904 (x3), 83912, 83898 (x2), 83892 (x2), 83909 (x4), 83904 (x4), 83912**	
Specimen Requirements:	**Type:** **Collection Instructions:**	**Paraffin block** **Formalin fixed paraffin embedded tissue**
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Room temperature: Indefinite** **Refrigerated: Indefinite** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Tues; Reports: 2 to 3 days**	
Reference Ranges:	**Colorectal Cancer Mut Pnl (KRAS,PIK3CA,BRAF,NRAS)**	**Accompanies report**
Methodology:	**Polymerase Chain Reaction, Sequencing**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Mantle Cell Lymphoma, bcl-1/JH t(11;14), RT-PCR, CB (14991X)		
Clinical Significance:	Bcl-1/JH t(11;14) is highly specific for mantle cell lymphoma (MCL). The t(11;14) can be found in approximately 70% to 95% cases of MCL. Half of these translocations fall within the BCL-1 major translocation cluster (MTC). The t(11;14) real time PCR assay can be used to monitor minimal residual disease in NHL. Ideally, recent patient samples should be tested side by side with the previous sample to better illustrate the quantitative changes.	
Effective Date:	**May 17, 2011**	
Test Code:	**S52421**	
CPT Code(s):	**83891, 83912, 83896 (x2), 83898 (x2)**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:** **Collection Instructions:**	**Bone marrow: EDTA (lavender-top) or EDTA (lavender-top) whole blood or Formalin fixed paraffin embedded tissue** **5 mL** **1 mL** **Collect whole blood or bone marrow in an EDTA (lavender-top) tube ship refrigerated or room temperature.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Whole blood or Bone marrow** **Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: Unacceptable** **Formalin fixed paraffin embedded tissue** **Room temperature: Indefinite** **Refrigerated: Indefinite** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Monday; Reports 5-6 days**	
Reference Ranges:	**Bcl-1/JH, t(11;14)**	**0/Negative**
Methodology:	**Real-Time Polymerase Chain Reaction**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Follicular Lymphoma, bcl-2/JH t(14;18), RT-PCR, CB (15007X)		
Clinical Significance:	Follicular lymphoma is the most common type of non-Hodgkin's lymphoma in the United States. Up to 90% of follicular lymphomas carry bcl-2/JH t(14;18)(q32;q21) chromosome translocation. The presence of the bcl-2 translocation has been associated with poor prognosis in one group of diffuse large-cell and follicular lymphoma patients. Analysis of bcl-2 translocations provides an important marker for detection and monitoring of malignancy during patient treatment and follow up.	
Effective Date:	**May 17, 2011**	
Test Code:	**S52422**	
CPT Code(s):	**83891, 83896 (x3), 83898 (x3), 83912**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:** **Collection Instructions:**	**Bone marrow: EDTA (lavender-top) or EDTA (lavender-top) whole blood or Formalin fixed paraffin embedded tissue** **5 mL** **1 mL** **Collect whole blood or bone marrow in an EDTA (lavender-top) tube ship refrigerated or room temperature.**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Whole blood or Bone marrow** **Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: Unacceptable** **Formalin fixed paraffin embedded tissue** **Room temperature: Indefinite** **Refrigerated: Indefinite** **Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Monday; Reports 5-6 days**	
Reference Ranges:	**Bcl-2,t(14;18)**	**0/Negative**
Methodology:	**Real-Time Polymerase Chain Reaction**	
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**	

Referral Test Changes

The following test changes will be effective on the dates indicated below.
Please note that only the information that is changing appears in this update.
Former test codes and test names have been italicized.

Sulfonylurea Drug Screen [19102]		
Effective Date:	**Immediate**	
Test Code:	**S42270**	
CPT Code(s):	**83788**	
Specimen Requirements:	**Type:** **Opt Volume:** **Min Volume:**	**Serum, Plasma Heparinized** **3 mL** **2 mL**
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Room temperature: 72 hrs** **Refrigerated: 14 days** **Frozen: 14 days**	
Set-Up/Analytic Time:	**Reports 6 days**	
Methodology:	**Liquid Chromatography Mass Spectrometry**	
Performing Site:	**MedTox**	

Thyroid Stimulating Immunoglobulin [30551][NY]	
Effective Date:	**Immediate**
Test Code:	**S51609NY**
Former Test Name:	*Thyroid Stimulating Immunoglobulin [30551X][NY]*
Reference Ranges:	**< 140 % baseline**

EGFR Pathway (KRAS with reflex to NRAS, BRAF)[16819]	
Effective Date:	**Immediate**
Test Code:	**S51882**
Always Message:	**KRAS: Activating KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog) mutations can be found in 30-40% of colorectal cancer, 15-20% of lung cancer, and 60% of pancreatic cancer. Presence of KRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy such as cetuximab.** **Nucleic acid was extracted from either paraffin embedded tissue, whole blood or bone marrow. For each example, 2 PCR reactions were performed to detect mutations at exon 1 (codon 12 & 13) and exon 2 (codon 61) of the KRAS gene. The PCR products are then purified and sequenced in both forward and reverse directions. Sequencing data is analyzed and compared to a KRAS reference. The presence of the mutation(s) and its location(s) will be reported.** **For cases in which the tumor represents less than 10% of the analyzed tissue, this assay may not be able to detect mutations. However, we microdissect all tissues and selectively analyze the tumor cells in the provided specimen.** **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.** **NRAS: Activating NRAS (neuroblastoma RAS viral (v-ras) oncogene homolog) mutations can be found in 3% of colorectal cancer, 1% of lung cancer, and 25% of small intestine cancer. Presence of NRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy.** **Total nucleic acid was extracted from paraffin-embedded tissue. For each sample, 2 PCR reactions were performed to detect mutations at exon 1 (codon 12 & 13) and exon 2 (codon 61) of the NRAS gene. The PCR products are then purified and sequenced in both forward and reverse directions. Sequencing data is analyzed and compared to a NRAS reference. The presence of the mutation(s) and its location(s) will be reported.** **For cases in which the tumor represents less than 10% of the analyzed tissue, this assay may not be able to detect mutations. However, we microdissect all tissues and selectively analyze the tumor cells in the provided specimen.** **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.**

HTLV I/II, Confirmatory Assay (8511)	
Effective Date:	**April 11, 2011**
Test Code:	**S52044**
Former Test Name:	*HTLV I/II, Western Blot [8511X]*
Methodology:	**Line Immunoassay**
Additional Information:	**Specimen Types no longer accepted: Plasma Potassium Oxalate, Plasma ACD Sol B**

Cysticercus Ab [40350]	
Effective Date:	**April 18, 2011**
Test Code:	**S50069**
Always Message:	**Cysticercosis is caused by infection with the larval form (cysticercus) of the pork tapeworm, Taenia solium. A negative test result does not exclude the diagnosis of neurocysticercosis, particularly if only a single brain lesion is present. Test sensitivity increases from 50% or less for a solitary brain cyst to greater than 90% if 3 or more cysts are present. Antibodies from other parasitic infections, particularly echinococcosis, may crossreact in the Cysticercus antibody ELISA. Confirmation of positive ELISA results by the cysticercus IgG antibody Western blot is thus recommended.**

Chlamydia/N. gonorrhoeae DNA, SDA [17305]		
Effective Date:	**May 2, 2011**	
Test Code:	**S51330**	
Specimen Requirements:	**Type:** **Collection Instructions:**	**Urine, Endocervical/Urethral swab, or Vaginal swab** • **Urine: Patient should not have urinated for at least 1 hour. Collect the specimen in a sterile, preservative-free collection cup. The patient should collect the first 20-60 mL of voided urine (the first part of the stream – Not Midstream) into a urine collection cup. Urine should be transferred from collection cup to Q^x UPT (Urine Preservative Transport Q^x) within 8 hours of collection provided the urine has been stored at 2-30°. Urine can be held for up to 24 hours prior to transfer to the Q^xUPT provided that the urine has been stored at 2-8°. The correct volume of urine has been added when fluid level is in the fill window. This volume corresponds to 2-3 mL of urine. DO NOT overfill or under fill the tube.** • **Female endocervix: Submit swab in BD Probetec CT/GC Q^x Amplified Assay Collection Kit for Endocervical specimens.** • **Male urethral: Submit swab in BD Probetec CT/GC Q^x Amplified Assay Collection Kit for Male Urethral specimens.** **Vaginal: Submit swab in BD Probetec CT/GC Q^x Amplified DNA Assay collection kit for Vaginal specimens.**
Transport Temperature:	**Room Temperature**	
Specimen Stability:	**Urine in Qx UPT or Endocervial/Urethral swab** **Vaginal swab**	**Room temperature: 30 days** **Refrigerated: 30 days** **Frozen: 6 months** **Room temperature: 6 days** **Refrigerated: 14 days** **Frozen: 6 months**
Rejection Criteria:	**Only BD Collection Kits are acceptable. Any other manufacturer's collection transport containers will be rejected. Overfilled or underfilled urine preservative transport (Q^x UPT) will be rejected; BD Probetec Q^x CT/GC Amplified Assay without a swab will be rejected. BD Probetec Q^x CT/GC Amplified Assay collection kit with cleaning swab will be rejected.**	

Magnesium RBC, New York [623Z] NY		
Effective Date:	**May 9, 2011**	
Test Code:	**S49785NY**	
Specimen Requirements:	**Type:**	**EDTA (lavender-top or dark blue-top tube) packed cells** **EDTA (lavender-top tube) whole blood is acceptable.** **Sodium Heparin lead-free (tan-top tubes) are no longer acceptable.**
	Opt Volume:	**0.5 mL**
	Min Volume:	**0.2 mL**
	Collection Instructions:	**Leave packed cells in original collection tube. Patient should refrain from taking vitamins, or mineral herbal supplements for at least one week before sample collection. Do no centrifuge whole blood.**
Specimen Stability:	**Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: Unacceptable**	
Methodology:	**Inductively Coupled Plasma-Mass Spectrometry**	
Additional Information:	**Update specimen requirements, collection instructions, method and stability.**	

Histamine Release (Chronic Urticaria) [16838]	
Effective Date:	**May 9, 2011**
Test Code:	**S52240**
Additional Information:	**Update units to %.**

Referral Test Discontinuations

Amino Acid, Individual (9233)	
Effective Date:	**Immediate**
Test Code:	**S44285**
Additional Information	Recommended replacement: For Plasma-S51335-Amino Acid Analysis, LC/MS, Plasma (646N) For Urine-S48385-Amino Acid Quant Urine (5983N) For CSF-S50398-Amino Acid Analysis Quant CSF (42630N)
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Glycine CSF (9233)	
Effective Date:	**Immediate**
Test Code:	**S48733**
Additional Information	Recommended replacement: For CSF-S50398-Amino Acid Analysis Quant CSF (42630N)
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Glycine Plasma (9233)	
Effective Date:	**Immediate**
Test Code:	**S48737**
Additional Information	Recommended replacement: For Plasma-S51335-Amino Acid Analysis, LC/MS, Plasma (646N)
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Herpes Simplex I/II Ab, CSF [60524]	
Effective Date:	**Immediately**
Test Code:	**S51059**
Additional Information	Suggested Alternate: S52424 Herpes Simplex Virus 1/2 (IgG) Type-Specific Abs, CSF [60555]
Performing Site:	**Focus Diagnostics**

Beta Glucuronidase CSF [8640]	
Effective Date:	**April 12, 2011**
Test Code:	**S48607**
Additional Information	Suggested Alternate: S52083-CEA, CSF [17420X]
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Neuromyelitis Optica IgG, Serum (83185)	
Effective Date:	**April 20, 2011**
Test Code:	**S50931**
Additional Information	Test will no longer be orderable as a stand alone code.
Performing Site:	**Mayo Medical Laboratories**

Genomic Alterations, Postnatal Clarisure(tm) CGH [16135X]	
Effective Date:	**May 2, 2011**
Test Code:	**S51332**
Additional Information	Suggested Alternate: S52307 Genomic Alterations, Postnatal, Oligo-SNP Array [16478]
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Chromium, Blood	
Effective Date:	**May 3, 2011**
Test Code:	**S47245**
Additional Information	Recommended replacement: S52418-Chromium, Blood (6085)
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Beta 2 Transferrin	
Effective Date:	**May 3, 2011**
Test Code:	**S48873**
Additional Information	Suggested Alternate: S52419-Beta-2 Transferrin (10640)
Performing Site:	**Quest Diagnostics Nichols Institute, Chantilly**

ColoVantage™ (methylated Septin 9) (16983)	
Effective Date:	**May 5, 2011**
Test Code:	**S52104**
Additional Information	Suggested Alternate:16983 ColoVantage™ (methylated Septin 9
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**

EGFR Pathway (KRAS with reflex to NRAS, BRAF)[16819]	
Effective Date:	**May 9, 2011**
Test Code:	**S51882**
Additional Information	Suggested Alternate: S52415 Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS) (18902)
Performing Site:	**Quest Diagnostics Nichols Institute, San Juan Capistrano**