ANNOUNCEMENTS 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**	**Page #**
	HLA Typing	2

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 #**
91427	**Melanoma, Chromosomal Microarray, ClariSure® Oligo-SNP**	4/9/2013	3
91136	**Secretory Phospholipase A2, Type IIA (sPLA2)**	4/9/2013	4
91461	**Lynch Syndrome Panel**	4/16/2013	4
91584	**Lynch Syndrome, MLH1 Familial Deletion/Duplication**	4/16/2013	5
91460	**Lynch Syndrome, MLH1 Sequencing and Deletion/Duplication**	4/16/2013	6
91459	**Lynch Syndrome, MSH2 Familial Deletion/Duplication (Including EPCAM)**	4/16/2013	6
91471	**Lynch Syndrome, MSH2 Sequencing and Deletion/Duplication (Including EPCAM)**	4/16/2013	7
91458	**Lynch Syndrome, MSH6 Sequencing and Deletion/Duplication**	4/16/2013	8
91463	**Lynch Syndrome, PMS2 Familial Deletion/Duplication**	4/16/2013	9
91457	**Lynch Syndrome, PMS2 Sequencing and Deletion/Duplication**	4/16/2013	9
17303	**Chlamydia trachomatis DNA, SDA**	4/30/2013	10
17615	**Chlamydia trachomatis DNA, SDA, Pap Vial**	4/30/2013	11
17618	**Chlamydia/N. gonorrhoeae DNA, SDA, Pap Vial**	4/30/2013	12
17305	**Chlamydia/N.gonorrhoeae DNA, SDA**	4/30/2013	13
17304	**Neisseria gonorrhoeae DNA, SDA**	4/30/2013	14
17617	**Neisseria gonorrhoeae DNA, SDA, Pap Vial**	4/30/2013	15

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 #**
90521		Trichomonas vaginalis RNA, Qualitative TMA, Pap Vial	3/11/2013	15
10051		Hepatitis C Viral RNA, Quantitative Real-Time PCR w/Rflx to Qualitative TMA	3/26/2013	16
8137		**Hepatitis B Virus DNA, Quantitative, Real-Time PCR**	4/1/2013	16
7577		**Hepatitis C Viral RNA, Quantitative, Real-Time PCR**	4/1/2013	17
7485A		**HIV-1 RNA, Quantitative, Real-Time PCR**	4/1/2013	18
36712		**Sirolimus, LC/MS/MS**	4/1/2013	18
70007		Tacrolimus, Highly Sensitive, LC/MS/MS	4/1/2013	19

S51345		21-Hydroxylase Antibody [37916X]	4/8/2013	19
6399		CBC (Includes Differential and Platelets)	4/8/2013	19
S51491		Dihydrotestosterone, LC/MS/MS [90567]	4/8/2013	21
S49575		**Estriol, LC/MS/MS, Serum [34883]**	4/8/2013	21
S51290		**Muramidase (Lysozyme), Serum**	4/8/2013	21
S51657		**Porphobilinogen, Quantitative, 24-Hour Urine**	4/8/2013	21
S51658		**Porphobilinogen, Quantitative, Random Urine**	4/8/2013	22
S48558		**Porphyrins, Fractionated, Quantitative, Random Urine**	4/8/2013	22
S51406		**Porphyrins, Total, Plasma**	4/8/2013	22
4948		Protein C Antigen	4/8/2013	23
3060		Thyroid Abs Evaluation	4/16/2013	23
8761		Varicella-Zoster Virus Antibody (IgG)	4/30/2013	23

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 #
30551	*1092*	TSI (Thyroid Stimulating Immunoglobulin)	4/16/2013	24
5042X	*3515W*	**Vitamin B1 (Thiamine), Blood, LC/MS/MS**	4/23/2013	24
16500	*2040*	HE4, Ovarian Cancer Monitoring	5/6/2013	25

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 #
2445	Hepatitis C Antibody w/Reflex RIBA	4/16/2013	26
1091	Thyroid Stimulating Immunoglobulins w/TSH	4/16/2013	26
S51330	Chlamydia/N. gonorrhoeae DNA, SDA	4/30/2013	26

NY UPDATE
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	Page #
90569	Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR, PAP Vial	26

Announcements

HLA Typing	
Effective Date	**3/11/2013**

Reference Range	The HLA DNA Typing results will change to include a colon (:) as mandated by the WHO Nomenclature Committee. Example: for Test Code 17397X [17397] - HLA-A High Resolution SBT Typing: HLA-A* 02:01 HLA-A* 03:01 Additional details may be found in *http://hla.alleles.org/nomenclature/nomenc_reports.html* : *Nomenclature for factors of the HLA system, 2010,* Tissue Antigens 75, 291-455.
Performing Site	Quest Diagnostics Nichols Institute, Chantilly
Tests Affected	**Test Codes:** / **Name:** S51547 — HLA-A High Resolution SBT Typing [17397X] S51548 — HLA-B High Resolution SBT Typing [17396X] S52488 — HLA-DRB1 High Resolution SBT Typing [17393X] S51409 — HLA-DQB1 High Resolution SBT Typing [17394X]

New Test Offerings

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

Melanoma, Chromosomal Microarray, ClariSure® Oligo-SNP	
Clinical Significance	This assay detects alterations in copy number or allelic imbalance. It can be used in the differential diagnosis of melanocytic lesions (e.g., classifying indeterminate lesions as benign or malignant). The Illumina Infinium oligo-SNP array reveals copy number variations and loss of heterozygosity (LOH) across the whole genome. The allelic copy number alterations, often complex, are associated with malignant melanoma. The assay is performed using DNA extracted from FFPE samples.
Effective Date	**4/9/2013**
Test Code	**91427**
CPT Codes	**81406**
Specimen Requirements	**Formalin fixed paraffin embedded tissue block**
Instructions	**Formalin fixed paraffin-embedded block. Specimen must be fixed in 10% neutral buffered formalin. Fixation between 6 and 48 hours is recommended. Pathology report must accompany paraffin block. Information required in this report include: Physician identification, specimen identifiers (case and block number), specimen site and type, tissue processing used (routine or microwave), type of fixative, time and duration of fixation, and pathologic diagnosis.** **Ship at room temperature. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**See Instruction**
Set-up/Analytic Time	**Set up: As needed; Report available: within 22 days**
Methodology	**Microarray**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Type** / **Result Name** **86009049** / **Melanoma,ClariSure, Oligo**

86001293	**AOE**	**Specimen Source:**
86007540	**AOE**	**Diagnosis:**
86007541	**AOE**	**Physician Name:**
86007542	**AOE**	**Physician Phone #:**
86007543	**AOE**	**Physician NPI**

Secretory Phospholipase A2, Type IIA (sPLA2)	
Clinical Significance	Higher levels of sPLA2 (individually or combined with other risk factors) can be used for risk stratification in prediction of atherosclerosis/CVD and estimation for recurrent events after ACS.
Effective Date	**4/9/2013**
Test Code	**91136**
CPT Codes	**83520**
Specimen Requirements	**2 mL plasma collected in an EDTA (lavender-top) tube**
Reject Criteria	**Serum; heparin; other plasma samples; grossly icteric**
Instructions	**Separate plasma from cells as soon as possible after centrifugation. Transfer plasma to a Polypropylene transport tube for shipping.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 21 days** **Frozen -70 Degrees: 28 days**
Set-up/Analytic Time	**Set up: Wed; Report available: 7 days**
Reference Range	**Males: < or = 4.56 ng/mL** **Females: < or = 6.28 ng/mL**
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.**
Methodology	**Enzyme Immunoassay**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **86008762** / **sPLA2**

Lynch Syndrome Panel	
Clinical Significance	Germline mutations in DNA mismatch repair genes are the major cause of Hereditary Nonpolyposis Colorectal Cancer (HNPCC), also called Lynch Syndrome. HNPCC is typically inherited as autosomal dominant. The major genes involved in HNPCC are MLH1, MSH2, MSH6, and PMS2. HNPCC accounts for between 5% and 10% of colon cancers. Sequence analysis and deletion/duplication analysis of MLH1, MSH2, MSH6, and PMS2 are performed in this panel.
Effective Date	**4/16/2013**
Test Code	**91461**
CPT Codes	**81295, 81297, 81292, 81294, 81298, 81300, 81317, 81319, 81403**

Specimen Requirements	**4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube [x5]**
Reject Criteria	**Samples received frozen**
Instructions	**Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Sequencing, Multiplex Ligation-dependent Probe Amplification (MLPA), Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86009141	**Summary**
86009308	**MSH2 Sequencing**
86009137	**MSH2/EPCAM Del/Dup**
86009307	**MLH1 Sequencing**
86009138	**MLH1 Deletion, Duplication**
86009306	**MSH6 Sequencing**
86008784	**MSH6 Deletion, Duplication**
86009135	**PMS2 Sequencing**
86009136	**PMS2 Deletion, Duplication**

Lynch Syndrome, MLH1 Familial Deletion/Duplication	
Clinical Significance	This assay detects deletions and/or duplication involving one or more exons, as well as the entire MLH1 gene. This assay cannot detect smaller genetic alterations, such as point mutations affecting amino acid coding or mRNA splicing. The assay cannot detect mutations affecting MLH1 gene regions not examined in the assay (including most of the intronic regions). This assay cannot rule out the presence of germline mutations involving other mismatch repair genes.
Effective Date	**4/16/2013**
Test Code	**91584**
CPT Codes	**81294**
Specimen Requirements	**4 mL whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Samples received frozen**
Instructions	**Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**

Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **86009138** / **MLH1 Deletion, Duplication**

Lynch Syndrome, MLH1 Sequencing and Deletion/Duplication	
Clinical Significance	Sequencing: This test should be offered to patients with colorectal cancer who meet the Bethesda criteria established by the National Cancer Institute (NCI), and/or that their tumors display microsatellite instability (MSI) or replication error (RER) phenotype. Detection of a germline mutation in one or the mismatch repair genes helps to establish a clinical diagnosis of HNPCC in affected patients. Mutation detection in at risk family member allows predictive diagnosis of the disease and thus intensive screening and early intervention of cancer. Deletion/Duplication: This assay detects deletions and/or duplication involving one or more exons, as well as the entire MLH1 gene. This assay cannot detect smaller genetic alterations, such as point mutations affecting amino acid coding or mRNA splicing. The assay cannot detect mutations affecting MLH1 gene regions not examined in the assay (including most of the intronic regions). This assay cannot rule out the presence of germline mutations involving other mismatch repair genes.
Effective Date	**4/16/2013**
Test Code	**91460**
CPT Codes	**81292, 81294**
Specimen Requirements	**4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube [x2]**
Reject Criteria	**Samples received frozen**
Instructions	**Whole Blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Polymerase Chain Reaction and Dye-Terminator Sequencing Reaction; Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name**

86009307	**MLH1 Sequencing**
86009138	**MLH1 Deletion, Duplication**

Lynch Syndrome, MSH2 Familial Deletion/Duplication (Including EPCAM)	
Clinical Significance	This assay detects deletions and/or duplications involving one of more exons for the MSH2 gene, and exons 8 and 9 for the EPCAM gene. This assay cannot detect smaller genetic alterations, such as point mutations affecting amino acid coding or mRNA splicing. This assay cannot detect mutations affecting MSH2 and EPCAM gene regions not examined in the assay (including most of the intronic regions). This assay cannot rule out the presence of germline mutations involving other mismatch repair genes.
Effective Date	**4/16/2013**
Test Code	**91459**
CPT Codes	**81297, 81403**
Specimen Requirements	**5 mL whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Samples received frozen**
Instructions	**Whole Blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do Not Freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **86009137** / **MSH2/EPCAM Del/Dup**

Lynch Syndrome, MSH2 Sequencing and Deletion/Duplication (Including EPCAM)	
Clinical Significance	Sequencing: This test should be offered to patients with colorectal cancer who meet the Bethesda criteria established by the National Cancer Institute (NCI), and/or that their tumors display microsatellite instability (MSI) or replication error (RER) phenotype. Detection of a germline mutation in one or the mismatch repair genes helps to establish a clinical diagnosis of HNPCC in affected patients. Mutation detection in at risk family member allows predictive diagnosis of the disease and thus intensive screening and early intervention of cancer. Deletion/Duplication: This assay detects deletions and/or duplication involving one or more exons for the MSH2 gene, and exons 8 and 9 for the EPCAM gene. This assay cannot detect smaller genetic alterations, such as point mutations affecting amino acid coding or mRNA splicing. This assay cannot detect mutations affecting MSH2 and EPCAM gene regions not examined in the assay (including most of the intronic regions). This assay cannot rule out the presence of germline mutations involving other mismatch repair genes.
Effective Date	**4/16/2013**
Test Code	**91471**

CPT Codes	**81295, 81297, 81403**
Specimen Requirements	**4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube [x2]**
Reject Criteria	**Samples received frozen**
Instructions	**Whole Blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Polymerase Chain Reaction and Dye-Terminator Sequencing Reaction, Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86009308	**MSH2 Sequencing**
86009137	**MSH2/EPCAM Del/Dup**

Lynch Syndrome, MSH6 Sequencing and Deletion/Duplication	
Clinical Significance	Sequencing: This test should be offered to patients with colorectal cancer who meet the Bethesda criteria established by the National Cancer Institute (NCI), and/or that their tumors display microsatellite instability (MSI) or replication error (RER) phenotype. Detection of a germline mutation in one or the mismatch repair genes helps to establish a clinical diagnosis of HNPCC in affected patients. Mutation detection in at risk family member allows predictive diagnosis of the disease and thus intensive screening and early intervention of cancer. Deletion/Duplication: This assay detects deletion and/or duplication involving one or more exons, as well as the entire MSH6 gene. This assay cannot detect smaller alterations, such as point mutations affecting amino acid coding or mRNA splicing. The assay cannot detect mutations affecting gene regions not examined in the assay (including most of the intronic regions). This assay cannot rule out the presence of germline mutations involving other mismatch repair genes.
Effective Date	**4/16/2013**
Test Code	**91458**
CPT Codes	**81298, 81300**
Specimen Requirements	**4 mL (2mL minimum) whole blood collected in an EDTA (lavender-top) tube [x2]**
Reject Criteria	**Samples received frozen**
Instructions	**Whole Blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**

Reference Range	**Accompanies report**
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.**
Methodology	**Polymerase Chain Reaction, Dye Terminator Sequencing Reaction and Semi-quantitative Fluorescent Polymerase Chain Reaction**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86009306	**MSH6 Sequencing**
86008784	**MSH6 Deletion, Duplication**

Lynch Syndrome, PMS2 Familial Deletion/Duplication	
Clinical Significance	Hereditary non-polyposis colorectal cancer (HNPCC) is an autosomal dominant genetic disorder characterized by the familial accumulation of early onset colorectal, endometrial and other tumors, and accounts for approximately 3-5% of all colon cancer cases. HNPCC is caused by germline mutations in four genes involved in the DNA mismatch repair pathway: MLH1, MSH2, MSH6, and PMS2. MLH1 and MSH2 mutations account for approximately 90% of HNPCC cases, MSH6 accounts for approximately 7-10%, while PMS2 accounts for less than 5%. The prevalence of PMS2 mutations is not well established but some studies have shown that large deletions account for approximately 21-37% of PMS2 mutations.
Effective Date	**4/16/2013**
Test Code	**91463**
CPT Codes	**81319**
Specimen Requirements	**4 mL whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Samples received frozen**
Instructions	**Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**Multiplex Ligation-dependent Probe Amplification (MLPA)**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86009136	**PMS2 Deletion, Duplication**

Lynch Syndrome, PMS2 Sequencing and Deletion/Duplication

Clinical Significance	Hereditary non-polyposis colorectal cancer (HNPCC) is an autosomal dominant genetic disorder characterized by the familial accumulation of early onset colorectal, endometrial and other tumors, and accounts for approximately 3-5% of all colon cancer cases. HNPCC is caused by germline mutations in four genes involved in the DNA mismatch repair pathway: MLH1, MSH2, MSH6, and PMS2. MLH1 and MSH2 mutations account for approximately 90% of HNPCC cases, MSH6 accounts for approximately 7-10%, while PMS2 accounts for less than 5%. The prevalence of PMS2 mutations is not well established but some studies have shown that large deletions account for approximately 21-37% of PMS2 mutations. The prevalence of sequence variants is not well established.
Effective Date	**4/16/2013**
Test Code	**91457**
CPT Codes	**81317, 81319**
Specimen Requirements	**4 mL whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Samples received frozen**
Instructions	**Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Thurs; Report available: 15 days**
Reference Range	**Accompanies report**
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.**
Methodology	**DNA Sequencing and Multiplex Ligation-dependent Probe Amplification (MLPA)**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86009135	**PMS2 Sequencing**
86009136	**PMS2 Deletion, Duplication**

Chlamydia trachomatis DNA, SDA	
Clinical Significance	**C. trachomatis infections are the leading cause of sexually transmitted diseases in the United States. C. trachomatis is known to cause Cervicitis, Pelvic Inflammatory Disease (PID), Infant Conjunctivitis, Infant Pneumonia, Urethritis, Epididymitis and Proctitis. It is also the most frequent cause of non-gonococcal urethritis in men. Among women, the consequences of chlamydial infections are severe if left untreated. Approximately half of chlamydial infections are asymptomatic.**
Effective Date	**4/30/2013**
Test Code	**17303**
CPT Codes	**87491**
Specimen Requirements	**20 mL Urine, First void clean catch; Urethral swab or Endocervical swab or Vaginal swab**
Reject Criteria	**Only BD Collection Kits are acceptable. Overfilled or under filled Qx UPT; BD ProbeTec Qx CT/GC Amplified Kit w/o swab; BD ProbeTec Qx CT/GC Amp Kit w/cleaning swab. All other specimen types will be rejected.**
Instructions	**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 Qx UPT (Urine Preservative Transport Qx) within 8 hours of collection provided the urine has been stored at 2-30 degrees C. Urine can be held for up to 24 hours prior to transfer to the Qx UPT provided that the urine has been stored at 2-8 degrees C. 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 Qx Amplified Assay Collection Kit for Endocervical specimens.** **Male urethral: Submit swab in BD ProbeTec CT/GC Qx Amplified Assay Collection Kit for Male Urethral specimens.** **Vaginal: Submit swab in BD ProbeTec CT/GC Qx Amplified DNA Assay collection kit for Vaginal specimens.** **If a urine specimen is to be collected, the patient must not have urinated during the previous hour.**
Transport Temperature	**See instructions**
Specimen Stability	**Urine; Urethral or Endocervical swab** **Room temperature: 30 Days** **Refrigerated: 30 Days** **Frozen: 6 Months** **Vaginal swab:** **Room temperature: 14 Days** **Refrigerated: 14 Days** **Frozen: 6 Months**
Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays.**
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **70043703** / **C trachomatis DNA,SDA**

Chlamydia trachomatis DNA, SDA, Pap Vial	
Clinical Significance	**C. trachomatis infections are the leading cause of sexually transmitted diseases in the United States. C. trachomatis is known to cause Cervicitis, Pelvic Inflammatory Disease (PID), Infant Conjunctivitis, Infant Pneumonia, Urethritis, Epididymitis and Proctitis. It is also the most frequent cause of non-gonococcal urethritis in men. Among women, the consequences of chlamydial infections are severe if left untreated. Approximately half of chlamydial infections are asymptomatic.**
Effective Date	**4/30/2013**
Test Code	**17615**
CPT Codes	**87491**
Specimen Requirements	**Liquid Cytology(PreservCyt®) Preservative (ThinPrep®) or TriPath SurePath vials**
Reject Criteria	**PreservCyt material previously processed for cytology; SurePath material previously processed for cytology; Add-ons to samples for ThinPrep or SurePath; Specimens received after Pap Slide preparation.**
Instructions	**Liquid Based Cytology: Submit per manufacturer instructions. For samples that have the Pap performed outside of Quest Diagnostics:**

	SurePath(TM) - 0.5 mL pre-aliquot* of SurePath material. ThinPrep(R) Vial- 0.5 mL pre-aliquot* of PreservCyt(R) material.** *Aliquot before performance of liquid based cytology testing **Refer to manufacturer instructions Transfer aliquot to BD ProbeTec Qx CT/GC LBC diluent tube.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 30 Days Refrigerated: 30 Days Frozen: Unacceptable**
Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays.**
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code: 70043705 — Result Name: C trachomatis DNA,SDA,Vial**

Chlamydia/N. gonorrhoeae DNA, SDA, Pap Vial	
Clinical Significance	**C. trachomatis infections are the leading cause of sexually transmitted diseases in the United States. C. trachomatis is known to cause Cervicitis, Pelvic Inflammatory Disease (PID), Infant Conjunctivitis, Infant Pneumonia, Urethritis, Epididymitis and Proctitis. It is also the most frequent cause of non-gonococcal urethritis in men. Among women, the consequences of chlamydial infections are severe if left untreated. Approximately half of chlamydial infections are asymptomatic. Neisseria gonorrhoeae (Gonococci) is the causative agent of gonorrhoeae. In men, this disease generally results in anterior urethritis accompanied by purulent exudate. In women, the disease is most often found in the cervix, but the vagina and uterus may also be affected.**
Effective Date	**4/30/2013**
Test Code	**17618**
CPT Codes	**87491, 87591**
Specimen Requirements	**Liquid Cytology(PreservCyt®) Preservative (ThinPrep®) or TriPath SurePath vials**
Reject Criteria	**PreservCyt material previously processed for cytology; SurePath material previously processed for cytology; Add-ons to samples for ThinPrep or SurePath; Specimens received after Pap Slide preparation.**
Instructions	**Liquid Based Cytology: Submit per manufacturer instructions. For samples that have the Pap performed outside of Quest Diagnostics: SurePath(TM) - 0.5 mL pre-aliquot* of SurePath material.** ThinPrep(R) Vial- 0.5 mL pre-aliquot* of PreservCyt(R) material.** *Aliquot before performance of liquid based cytology testing **Refer to manufacturer instructions Transfer aliquot to BD ProbeTec Qx CT/GC LBC diluent tube.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 30 Days Refrigerated: 30 Days Frozen: Unacceptable**

Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**C trachomatis DNA,SDA,Vial: NOT DETECTED** **N gonorrhoeae DNA,SDA,Vial: NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays.**
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name
70043705	C trachomatis DNA,SDA,Vial
70043706	N gonorrhoeae DNA,SDA,Vial

Chlamydia/N.gonorrhoeae DNA, SDA	
Clinical Significance	**C. trachomatis infections are the leading cause of sexually transmitted diseases in the United States. C. trachomatis is known to cause Cervicitis, Pelvic Inflammatory Disease (PID), Infant Conjunctivitis, Infant Pneumonia, Urethritis, Epididymitis and Proctitis. It is also the most frequent cause of non-gonococcal urethritis in men. Among women, the consequences of chlamydial infections are severe if left untreated. Approximately half of chlamydial infections are asymptomatic.** **Neisseria gonorrhoeae (Gonococci) is the causative agent of gonorrhoeae. In men, this disease generally results in anterior urethritis accompanied by purulent exudate. In women, the disease is most often found in the cervix, but the vagina and uterus may also be infected.**
Effective Date	**4/30/2013**
Test Code	**17305**
CPT Codes	**87491, 87591**
Specimen Requirements	**20 mL Urine, First void clean catch; Urethral swab or Endocervical swab or Vaginal swab**
Reject Criteria	**Only BD Collection Kits are acceptable. Overfilled or under filled Qx UPT; BD ProbeTec Qx CT/GC Amplified Kit w/o swab; BD ProbeTec Qx CT/GC Amp Kit w/cleaning swab. All other specimem types will be rejected.**
Instructions	**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 Qx UPT (Urine Preservative Transport Qx) within 8 hours of collection provided the urine has been stored at 2-30 degrees C. Urine can be held for up to 24 hours prior to transfer to the Qx UPT provided that the urine has been stored at 2-8 degrees C. 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 Qx Amplified Assay Collection Kit for Endocervical specimens.** **Male urethral: Submit swab in BD ProbeTec CT/GC Qx Amplified Assay Collection Kit for Male Urethral specimens.** **Vaginal: Submit swab in BD ProbeTec CT/GC Qx Amplified DNA Assay collection kit for Vaginal specimens.** **If a urine specimen is to be collected, the patient must not have urinated during the previous hour.**
Transport Temperature	**See instructions**

Specimen Stability	**Urine; Urethral or Endocervical swab** **Room temperature: 30 Days** **Refrigerated: 30 Days** **Frozen: 6 Months** **Vaginal swab:** **Room temperature: 14 Days** **Refrigerated: 14 Days** **Frozen: 6 Months**
Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**C trachomatis DNA, SDA: NOT DETECTED** **N gonorrhoeae DNA, SDA: NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays.**
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **70043703** / **C trachomatis DNA,SDA** **70043704** / **N gonorrhoeae DNA,SDA**

Neisseria gonorrhoeae DNA, SDA	
Clinical Significance	**Neisseria gonorrhoeae (Gonococci) is the causative agent of gonorrhoeae. In men, this disease generally results in anterior urethritis accompanied by purulent exudate. In women, the disease is most often found in the cervix, but the vagina and uterus may also be affected.**
Effective Date	**4/30/2013**
Test Code	**17304**
CPT Codes	**87591**
Specimen Requirements	**20 mL Urine, First void clean catch; Urethral swab or Endocervical swab or Vaginal swab**
Reject Criteria	**Only BD Collection Kits are acceptable. Overfilled or under filled Qx UPT; BD ProbeTec Qx CT/GC Amplified Kit w/o swab; BD ProbeTec Qx CT/GC Amp Kit w/cleaning swab. All other specimen types will be rejected.**
Instructions	**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 Qx UPT (Urine Preservative Transport Qx) within 8 hours of collection provided the urine has been stored at 2-30 degrees C. Urine can be held for up to 24 hours prior to transfer to the Qx UPT provided that the urine has been stored at 2-8 degrees C. 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 Qx Amplified Assay Collection Kit for Endocervical specimens.** **Male urethral: Submit swab in BD ProbeTec CT/GC Qx Amplified Assay Collection Kit for Male Urethral specimens.** **Vaginal: Submit swab in BD ProbeTec CT/GC Qx Amplified DNA Assay collection kit for Vaginal specimens.** **If a urine specimen is to be collected, the patient must not have urinated during the previous hour.**

Transport Temperature	**See instructions**
Specimen Stability	**Urine; Urethral or Endocervical swab** **Room temperature: 30 Days** **Refrigerated: 30 Days** **Frozen: 6 Months** **Vaginal swab:** **Room temperature: 14 Days** **Refrigerated: 14 Days** **Frozen: 6 Months**
Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays.**
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **70043704** / **N gonorrhoeae DNA,SDA**

Neisseria gonorrhoeae DNA, SDA, Pap Vial	
Clinical Significance	**Neisseria gonorrhoeae (Gonococci) is the causative agent of gonorrhoeae. In men, this disease generally results in anterior urethritis accompanied by purulent exudate. In women, the disease is most often found in the cervix, but the vagina and uterus may also be affected.**
Effective Date	**4/30/2013**
Test Code	**17617**
CPT Codes	**87591**
Specimen Requirements	**Liquid Cytology(PreservCyt®) Preservative (ThinPrep®) or TriPath SurePath vials**
Reject Criteria	**PreservCyt material previously processed for cytology; SurePath material previously processed for cytology; Add-ons to samples for ThinPrep or SurePath; Specimens received after Pap Slide preparation.**
Instructions	**Liquid Based Cytology: Submit per manufacturer instructions. For samples that have the Pap performed outside of Quest Diagnostics:** **SurePath(TM) - 0.5 mL pre-aliquot* of SurePath material.**** **ThinPrep(R) Vial- 0.5 mL pre-aliquot* of PreservCyt(R) material.**** ***Aliquot before performance of liquid based cytology testing** ****Refer to manufacturer instructions** **Transfer aliquot to BD ProbeTec Qx CT/GC LBC diluent tube.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 30 Days** **Refrigerated: 30 Days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set-up: Mon-Sat; Report available: 2-3 days**
Reference Range	**NOT DETECTED**
Always Message	**This test was performed using the BD ProbeTec(TM) Chlamydia trachomatis and Neisseria gonorrhoeae**

	Amplified DNA Assays.
Methodology	**Strand Displacement Amplification**
Assay Category	**FDA Approved/Cleared**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name**: **70043706** / **N gonorrhoeae DNA,SDA,Vial**

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 names and test codes have been italicized.*

Trichomonas vaginalis RNA, Qualitative TMA, Pap Vial	
Effective Date	**3/11/2013**
Test Code	90521
Specimen Requirements	1 mL Liquid Cytology(PreservCyt(R)) Preservative (ThinPrep(R)) in Aptima(R) Vaginal Collection Kit (Orange label) or Aptima(R) Specimen Transfer tube (green label). **0.5 mL (0.5 mL minimum)**(SurePath(TM) preservative fluid collected in Aptima(R) Vaginal Collection Kit (Orange label), or Aptima(R) Specimen Transfer tube (green label), or APTIMA(R) Unisex Swab Specimen Collection Kit **Original SurePath (TM) vial is no longer acceptable**
Instructions	Labs performing cytology: Aliquot PreservCyt(R)or SurePath(TM) solution before performance of liquid based cytology testing. PreservCyt(R): Transfer 1 mL of PreservCyt(R) solution into APTIMA(R) Vaginal Collection Tube (orange label) or APTIMA(R) Specimen Transfer tube (green label). Ship to lab. **SurePath(TM): SurePath fluid must be transferred to APTIMA Specimen Transport Media within 4 days of collection. Tranfer 0.5 mL of SurePath(TM) preservative fluid into APTIMA(R) Vaginal Collection Tube (orange label), APTIMA(R) Specimen Transfer tube (green label), or APTIMA(R) Unisex Swab Specimen Collection Kit. Ship to lab.**
Specimen Stability	Liquid Cytology(PreservCyt(R)) Preservative (ThinPrep(R)): Room temperature: 14 days; Refrigerated: 30 days; Frozen: 6 months SurePath(TM) preservative fluid: Room temperature: 14 days; **Refrigerated: 14 days**; **Frozen: Not established**
Always Message	This test was performed using the APTIMA Trichomonas vaginalis Assay (GEN-PROBE). **The performance characteristics of this assay when used to test SurePath(R) specimens have been determined by Quest Diagnostics Nichols Institute, Valencia. Performance characteristics refer to the analytical performance of the test.**
Assay Category	**FDA Approved/Cleared/Modified FISH/Molecular assay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Hepatitis C Viral RNA, Quantitative Real-Time PCR w/Rflx to Qualitative TMA	
Effective Date	**3/26/2013**
Test Code	10051

Always Message	Please note: the guidelines for the use of new anti- HCV therapies (boceprevir and telaprevir) recommend using a test method that detects plasma viral nucleic acid levels as low as 10 IU/ml. This assay has a lower Limit of Detection of 7.1 IU/ml for genotype 1 and conforms to the recommendation. Quantitation of plasma HCV nucleic acid levels below 43 IU/ml (the Lower Limit of Quantitation for this test) may not be linear, and in this circumstance are reported as "<43 IU/mL HCV RNA Detected". **This test was performed using the COBAS(R) AmpliPrep / COBAS(R) TaqMan(R) HCV.** **http://education.questdiagnostics.com/faq/HCV-RNA-PCR** **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.**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Hepatitis B Virus DNA, Quantitative, Real-Time PCR	
Clinical Significance	**Chronic carriers will persist in producing detectable HBV. Patients with chronic liver disease of unknown origin most commonly have HBV that is detected by Viral DNA testing. Quantitative measurement of HBV Viral DNA may be used to monitor progression of disease.**
Effective Date	**4/1/2013**
Former Test Name	*Hepatitis B DNA Quantitative Real-Time PCR*
Test Code	8137
Specimen Requirements	**3 mL (2.5 mL minimum) Plasma, EDTA (lavender-top) preferred; Plasma, PPT Potassium EDTA (white top) and Serum acceptable.**
Reject Criteria	**Unspun PPT tube**
Instructions	**Separate plasma from whole blood within 1 day of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature. Recommend collecting two tubes per patient to avoid QNS.**
Transport Temperature	**Frozen**
Always Message	**The method used in this test is Real-Time PCR of the pre-core region of the circular HBV genome.** **The test was performed using the COBAS(R) AmpliPrep/COBAS(R) TaqMan(R) HBV Test, v2.0 (Roche Molecular Systems, Inc.)**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 210594 / **Hepatitis B Virus DNA** 63203 / **Hepatitis B Virus DNA**
Tests Affected	**Test Codes:** / **Name:** 2479 / Hepatitis B Virus MonitR, Chronic

Hepatitis C Viral RNA, Quantitative, Real-Time PCR	
Clinical Significance	**Quantitative RNA by Real-Time PCR is useful in confirming HCV infection assessing prognosis (prior to the initiation of therapy), prescribing individualized therapy, predicting response to therapy, and monitoring response to therapy.**
Effective Date	**4/1/2013**

Former Test Name	*HCV RNA, Quantitative Real-Time PCR*
Test Code	7577
Specimen Requirements	**3 mL (2.5 mL minimum) Plasma, EDTA (lavender-top) preferred; Plasma, PPT Potassium EDTA (white top) and Serum acceptable.**
Reject Criteria	**Received room temperature; Unspun PPT tube; Samples collected using heparin as anticoagulant.**
Instructions	**Separate serum or plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer the plasma to a properly identified, sterile, polypropylene screw-cap vial and ship frozen.**
Transport Temperature	**Frozen**
Units Of Measure	HCV RNA, PCR, Quant: IU/mL **HCV RNA, PCR, Quant: LogIU/mL**
Always Message	**Please note: the guidelines for the use of new anti HCV therapies (boceprevir and telaprevir) recommend using a test method that detects plasma viral nucleic acid levels as low as 10 IU/ml. This assay has a lower Limit of Detection of 7.1 IU/ml for genotype 1 and conforms to the recommendation. Quantitation of plasma HCV nucleic acid levels below 43 IU/ml (the Lower Limit of Quantitation for this test) may not be linear, and in this circumstance are reported as "<43 IU/mL HCV RNA Detected".** **This test was performed using the COBAS(R) AmpliPrep / COBAS(R) TaqMan(R) HCV Test Kit (Roche Molecular Systems, Inc.).** **http://education.questdiagnotics.com/faq/HCV-RNA-PCR**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 200357 / **HCV RNA, PCR, Quant** 210944 / **HCV RNA, PCR, Quant**
Tests Affected	**Test Codes:** / **Name:** 5906 / Hepatitis Autoimmune EvaluatR Plus RJA / Reflex Hepatitis C Viral RNA, Quantitative Real-Time PCR

HIV-1 RNA, Quantitative, Real-Time PCR	
Clinical Significance	**This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.** **This test is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.**
Effective Date	**4/1/2013**
Former Test Name	*HIV-1 RNA Quantitation [Real Time PCR]*
Test Code	7485A
Specimen Requirements	**3 mL (2.5 mL minimum) Plasma, EDTA (lavender-top) preferred; Plasma, PPT Potassium EDTA (white top) acceptable.**
Reject Criteria	**Specimen collected using heparin as anticoagulant; Leaking, uncapped or broken containers; Frozen**

	plasma received in PPT.
Instructions	**Collect plasma in EDTA (lavender-top) or a (white-top) PPT Vacutainer(TM) plasma preparation tube. Separate plasma from the cells by centrifugation within 6 hours after collection. Transfer the plasma to a plastic screw-cap vial and ship frozen.**
Transport Temperature	**Frozen**
Always Message	**This test was performed using the Cobas(R) AmpliPrep/Cobas(R) Taqman(R) HIV-1 test kit version 2.0 (Roche Molecular Systems, Inc.).**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 55132 / **HIV-1 RNA, QN PCR** 55134 / **HIV-1 RNA, QN PCR**
Tests Affected	**Test Codes:** / **Name:** 7485ASR / HIV-1 RNA Quantitation [Real Time PCR] w/Serial Reporting

Sirolimus, LC/MS/MS	
Effective Date	**4/1/2013**
Former Test Name	*Sirolimus*
Test Code	36712
Units Of Measure	**mcg/L**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 70006 / Tacrolimus and Sirolimus, LC/MS/MS

Tacrolimus, Highly Sensitive, LC/MS/MS	
Effective Date	**4/1/2013**
Test Code	70007
Reference Range	**No definitive therapeutic or toxic ranges have been established. Optimal blood drug levels are influenced by type of transplant, patient response, time post-transplant, co-administration of other drugs, and drug formulation. The following trough range is a suggested guideline:** 5.0-20.0 **mcg/L**
Units Of Measure	**mcg/L**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 70006 / Tacrolimus and Sirolimus, LC/MS/MS

21-Hydroxylase Antibody [37916X]	
Effective Date	**4/8/2013**
Test Code	S51345
Reference Range	**Negative**
Always Message	**Patient with indeterminate result may benefit from serial testing to confirm positivity.** This test was performed using a kit that has not been approved or cleared by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. This test should not be used for diagnosis without confirmation by other medically established means.
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

CBC (Includes Differential and Platelets)	
Effective Date	**4/8/2013**
Test Code	6399
Specimen Stability	**Refrigerated: 48 hours**
Reference Range	**Remove the reference ranges from the following components within the CBC**: % Neutrophilic Bands % Neutrophils % Lymphocytes % Monocytes % Eosinophils % Basophils Reference ranges will continue to be reported for the absolute cell counts.
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	**Result Name**
30000000	WBC
30000100	RBC
30000200	HGB
30000300	HCT
30000400	MCV
30000500	MCH
30000600	MCHC
30000800	PLT
30004600	MPV
30000700	RDW
30001700	Absolute Neutrophils
30001110	Absolute Band Neutrophils
30001310	Absolute Metamyelocytes
30001510	Absolute Myelocytes

	30001530	Absolute Promyelocytes
	30002110	Absolute Lymphocytes
	30002400	Absolute Monocytes
	30002700	Absolute Eosinophils
	30003000	Absolute Basophils
	30003500	Absolute Blasts
	30003610	Absolute Nucleated RBC
	30000900	Neutrophils
	30001100	Band Neutrophils
	30001300	Metamyelocytes
	30001500	Myelocytes
	30001520	Promyelocytes
	30001800	Lymphocytes
	30002000	Reactive Lymphocytes
	30002200	Monocytes
	30002500	Eosinophils
	30002800	Basophils
	30003400	Blasts
	30003600	Nucleated RBC
	30004200	Comment(s)
Additional Information	Update report format.	

Dihydrotestosterone, LC/MS/MS [90567]	
Effective Date	**4/8/2013**
Test Code	S51491
Specimen Requirements	**1 mL (0.6 mL minimum)** serum collected in a red-top tube (no gel)
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Estriol, LC/MS/MS, Serum [34883]	
Effective Date	**4/8/2013**
Former Test Name	*Estriol Serum Total [22517P]*
Test Code	S49575
Specimen Requirements	0.5 mL (0.3 mL minimum) serum collected in red-top tube (no gel) **Plasma is unacceptable**

Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
Tests Affected	**Test Codes:** 36742 — **Name:** Estrogens, Fractionated, LC/MS/MS

Muramidase (Lysozyme), Serum	
Effective Date	**4/8/2013**
Former Test Name	*Lysozyme, Serum [619X]*
Test Code	S51290
Specimen Requirements	**2 mL (0.5 minimum)** serum
Instructions	**Centrifuge serum specimens within 1 hour of collection. Transfer serum to sterile, plastic, screw-capped vial(s). Freeze and ship frozen samples on dry ice.**
Transport Temperature	**Frozen**
Set-up/Analytic Time	Set up: Mon, Thurs; **Report available: 1-5 days**
Reference Range	**7.0-15.0 mcg/mL**
Methodology	**Enzymatic**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code:** 110202 — **Result Name:** **Muramidase (Lysozyme), Serum**

Porphobilinogen, Quantitative, 24-Hour Urine	
Effective Date	**4/8/2013**
Former Test Name	*Porphobilonogen 24hr Urine [7294N]*
Test Code	S51657
Always Message	**Remove Always Message**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Type** / **Result Name**: 110939 / AOE / Total Volume 110940 / / **Porphobilinogen, 24 hr Ur** **86008983** / / **Interpretation**
Additional Information	Update report format to add interpretation analyte.
Tests Affected	**Test Codes:** S48559 — **Name:** Porphyrins, Fractionated, Quantitative and Porphobilinogen, 24-Hour Urine

Porphobilinogen, Quantitative, Random Urine	
Effective Date	**4/8/2013**
Former Test Name	*Porphobilinogen Random Urine [84889N]*
Test Code	S51658
Always Message	**Remove Always Message**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 110941 / **Porphobilinogen, Rand Ur** **86008984** / **Interpretation**
Additional Information	Update report format to add interpretation analyte.

Porphyrins, Fractionated, Quantitative, Random Urine	
Effective Date	**4/8/2013**
Former Test Name	*Porphyrins Fractionated Urine Random [9324N]*
Test Code	S48558
Specimen Requirements	2 mL **(1.5 mL minimum)** random urine, no preservative
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Porphyrins, Total, Plasma	
Effective Date	**4/8/2013**
Former Test Name	*Porphyrins, Total Plasma [10290X]*
Test Code	S51406
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 110328 / Total Porphyrins **86009304** / **Interpretation**
Additional Information	Update report format to add interpretation analyte.

Protein C Antigen	
Effective Date	**4/8/2013**
Test Code	4948
Reject Criteria	Received room temperature; received refrigerated; **gross hemolysis**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Tests Affected	

Test Codes:	Name:
8757	Protein C Activity and Antigen

Thyroid Abs Evaluation	
Effective Date	**4/16/2013**
Test Code	3060
Always Message	**Remove:** **ReferenceRange: <140% of baseline of Reference Control** **Thyroid Stimulating Immunoglobulins (TSI) can engage the TSH receptors resulting in hyperthyroidism in Graves' disease patients. TSI levels can be useful in monitoring the clinical outcome of Graves' disease as well as assessing the potential for hyperthyroidism from maternal-fetal transfer. TSI results greater than or equal to (>=) 140% of the Reference Control are considered positive.** **NOTE: A serum TSH level greater than 350 micro-International Units/mL can interfere with the TSI bioassay and potentially give false positive results.** **Patients who are pregnant and are suspected of having hyperthyroidism should have both a TSI and human Chorionic Gonadotropin (hCG) tests measured. A serum hCG level greater than 40,625 mIU/mL can interfere with the TSI bioassay and may give false** **negative results. In these patients it is recommended that a second TSI is obtained when the hCG concentration falls below 40,625 mIU/mL (usually after approximately 20-weeks gestation).**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Result Name
11165	Thyroglobulin Autoantibodies
30876	Thyroid Peroxidase Autoantibodies
32490	TBII
32525	TSH

Additional Information	**Remove TSI from test offering, result code 32516.**

Varicella-Zoster Virus Antibody (IgG)	
Effective Date	**4/30/2013**
Test Code	8761
Reject Criteria	**Gross hemolysis; gross lipemia; grossly icteric**
Reference Range	**< or = 0.90** **Interpretive Criteria** **< or = 0.90 Negative-No VZV IgG Antibody Detected** **0.91-1.09 Equivocal** **> or = 1.10 Positive-VZV IgG Antibody Detected**
Always Message	**A positive result indicates that the patient has antibody to VZV but does not differentiate between an active or past infection. The clinical diagnosis must be interpreted in conjunction with the clinical signs and symptoms of the patient. This assay reliably measures immunity due to previous infection but may not be sensitive enough to detect antibodies induced by vaccination. Thus, a negative result in a vaccinated individual does not necessarily indicate susceptibility to VZV infection.**

Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 8756 / Varicella-Zoster Virus Antibodies (IgG, IgM)

Redirects

TSI (Thyroid Stimulating Immunoglobulin)	
Effective Date	**4/16/2013**
Former Test Code	*1092*
Test Code	**30551**
Reject Criteria	**Gross hemolysis; Gross lipemia; Gross icteria**
Set-up/Analytic Time	**Set-up: Tues-Sat; Report available: 1-5 days**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **85986240** / TSI

Vitamin B1 (Thiamine), Blood, LC/MS/MS	
Clinical Significance	**Vitamin B1 is required for branched-chain amino acid and carbohydrate metabolism. Vitamin B1 deficiency is most often due to alcoholism or chronic illness. In the early stage, patients with Vitamin B1 deficiency exhibit anorexia, irritability, apathy, and generalized weakness. Prolonged deficiency causes beriberi.**
Effective Date	**4/23/2013**
Former Test Name	*Vitamin B1 (Thiamine) Whole Blood*
Former Test Code	*3515W*
Test Code	**5042X**
Specimen Requirements	**2 mL (1 mL) whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Received room temperature; Received refrigerated**
Instructions	**Transfer whole blood to a plastic shipping vial to prevent breakage.** **Wrap tube in aluminum foil to protect from light.** **Freeze immediately.** **Samples received frozen but not protected from light are acceptable. Wrap sample in foil before sending to lab, no disclaimer is required. Samples received refrigerated but not protected from light are unacceptable and should be rejected.** **Overnight fasting is recommended**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 5 days** **Frozen: 5 weeks**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 3-6 days**

	This assay has an overnight incubation period
Reference Range	**78-185 nmol/L**
Units Of Measure	**nmol/L**
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code**: **85987120** — **Result Name**: **Vitamin B1, Blood**

HE4, Ovarian Cancer Monitoring	
Effective Date	**5/6/2013**
Former Test Code	*2040*
Test Code	**16500**
Specimen Requirements	0.5 mL **(0.3 mL minimum)** serum
Reject Criteria	**Gross hemolysis**; lipemia; icteria; **presence of fibrin, red blood cells, or other particulate matter; obvious microbial contamination**
Instructions	**Sample collected in red-top tube must be allowed to clot for at least 30 minutes but no longer than 1 hour.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 72 hours** **Frozen: 28 days**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 2-5 days**
Reference Range	**Female Premenopausal < or = 70 pmol/L** **Female Postmenopausal < or = 140 pmol/L**
Units Of Measure	**pmol/L**
Methodology	**Chemiluminescent Microparticle Immunoassay (CMIA)**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano.**
CPU Mappings	**Result Code**: **55005776** — **Result Name**: HE4, Ovarian CA Monitoring

Discontinued

Hepatitis C Antibody w/Reflex RIBA	
Effective Date	**4/16/2013**
Test Code	2445
Additional Information	The recommended alternative is 7493 Hepatitis C Antibody w/Rfx to RNA Quantitation performed at Quest Diagnostics

	Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 2445B / Hepatitis C Antibody w/Reflex RIBA + Bands

Thyroid Stimulating Immunoglobulins w/TSH	
Effective Date	**4/16/2013**
Test Code	1091
Performing Site	Quest Diagnostics Nichols Institute, Valencia and San Juan Capistrano
Additional Information	The recommended alternatives are: 3250 TSH performed at Quest Diagnostics Nichols Institute, Valencia and 30551 TSI (Thyroid Stimulating Immunoglobulin) performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

Chlamydia/N. gonorrhoeae DNA, SDA	
Effective Date	**4/30/2013**
Test Code	S51330
Additional Information	The replacement test is 17305 Chlamydia/N. gonorrhoeae DNA, SDA performed at Quest Diagnostics Nichols Institute, Valencia

New York Update

Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR, PAP Vial	
Message	**Test is now approved for New York patients.**
Effective Date	**3/26/2013**
Test Code	90569
Performing Site	Quest Diagnostics Nichols Institute, Valencia