Important Message!
Dear Colleague,

Please note that effective July 10, Immunohistochemistry (IHC) test ordering will be revised to be orderable by specific stain. Previous orderable panels 1854, 1859, and 1856 are being discontinued. The most commonly ordered tests may be viewed on our website under the search term IHC. Other IHC stains may be available by request.

Also effective July 10, our specimen retention policy will change from 28 days to 21 days. Our retention policy is designed to ensure adequate time for test additions after initial testing is completed. Our recent studies indicate that 21 days meets our customer needs. The change in policy will not affect short-term storage specimens such as Whole Blood or Urine, nor samples requiring extended storage such as Microbiology submissions. Please call Client Services at 1-800-421-4449 with any questions.

In addition, note that Palmetto GBA Medicare has instituted the Molecular Diagnostic Services (MolDx) program to assign Palmetto GBA Test Identifier (PTI) codes for all molecular diagnostic testing that is billed to them. Palmetto GBA's MolDx Program is designed to catalog molecular diagnostic tests to determine coverage and reimbursement policies. Beginning June 1, labs must use a Palmetto GBA PTI in the comment/narrative field in its claims for MolDx services. To assist our clients in billing submissions to Palmetto GBA for testing performed at Quest Diagnostics, we have posted the PTI codes for our offerings on our website www.nicholsinstitute.com/valencia. If you need additional information concerning the Palmetto GBA MolDx Program or PTI codes, please refer to the Palmetto GBA website.

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 #
91123	Chlordiazepoxide and Metabolites	7/9/2012	4
91114	Tapentadol, Quantitative, Urine	7/9/2012	4
19642	Tramadol, Screen with Reflex to Confirmation, Urine	7/9/2012	5
37127	DNA Cell Cycle Analysis, Hydatidiform Mole, Paraffin Block	7/10/2012	6
36158	DNA Cell Cycle Analysis, Paraffin Block	7/10/2012	7
10970	ER/PR/HER2 w/Reflex to HER2 FISH, Paraffin Block	7/10/2012	8
10529	Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations	7/10/2012	9
30316	HER-2, IHC, with Interpretation	7/10/2012	10
34949	HIV-1 Genotype	7/10/2012	11
10596	HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype	7/10/2012	12
34471	HIV-1 RNA, Quantitative PCR w/Reflex to Genotype	7/10/2012	13
29914	Ki-67, IHC with Interpretation	7/10/2012	14
36162	p53 Oncoprotein, IHC with Interpretation (36162X)	7/10/2012	15
16558	Vitamin D, 1,25-Dihydroxy, LC/MS/MS	7/10/2012	16
9429	Herpes Simplex Virus (HSV) 1/2 IgM Ab (EIA) with Reflex to IFA	7/17/2012	16
9435	Herpes Simplex Virus (HSV) 1/2 IgM Antibody, ELISA	7/17/2012	17
799	RPR (Monitor) with Reflex to Titer	7/17/2012	18
91029	Vitamin B3	8/13/2012	19
91030	Vitamin B5 (Pantothenic Acid)	8/13/2012	19

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 #
8517		**Influenza Virus A IgG Abs**	6/1/2012	20
8520		**Influenza Virus B IgG Abs**	6/1/2012	20
3970U		**Citrate 24 hour Urine**	7/10/2012	21
6110		**QuantiFERON®-TB Gold (Incubated)**	7/10/2012	21
4870R		**Copper, RBC**	7/16/2012	21
4875		**Selenium**	7/16/2012	22
4877R		**Zinc, RBC**	7/16/2012	22
5313		**Bilirubin, Total & Direct**	7/17/2012	22
2428		**Bordetella pertussis/parapertussis Antigen Detection**	7/17/2012	23
2416		**Bordetella pertussis/parapertussis Culture**	7/17/2012	23
2430		**Bordetella pertussis/parapertussis Evaluation**	7/17/2012	23
2418		**Cytomegalovirus Culture**	7/17/2012	24
7760		**Giardia lamblia Antigen Detection**	7/17/2012	24
2040		**HE4, Ovarian Cancer Monitoring**	7/17/2012	24
7736		**Helicobacter pylori IgM Antibody**	7/17/2012	25
8051		**Herpes Simplex Virus Type 1 & 2 IgG (HerpeSelect®) & IgM Abs**	7/17/2012	25
1821		**HPV DNA, High Risk**	7/17/2012	25
1821R		**HPV DNA, High Risk, Anal-Rectal**	7/17/2012	26
17333		**SureSwab(TM), Vaginosis/Vaginitis Plus**	7/24/2012	26

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 #
6399	5110	**CBC (Includes Differential and Platelets)**	7/10/2012	26
10479	1835	**Epidermal Growth Factor Receptor (EGFR), IHC**	7/10/2012	28
7037	1830	**ER/PR, Paraffin Block**	7/10/2012	28
7037	1830	**ER/PR, Paraffin Block**	7/10/2012	29
10969	1818	**ER/PR/DNA/HER2 w/Reflex to HER2 FISH, Paraffin Block**	7/10/2012	30
37811	7473	**Hepatitis C Viral RNA Genotype, LiPA**	7/10/2012	31
11348	7489	**Hepatitis C Viral RNA, Quantitative PCR with Reflex to Genotype, LiPA**	7/10/2012	32
35080		**Leukemia/Lymphoma Evaluation**	7/10/2012	33

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 #

RF264	Allergen-Eel IgE	6/1/2012	35
1082	Antiphospholipid Syndrome Evaluation, Expanded	6/11/2012	35
5651	AFB Suscept: MAI (MAC) by Radiometric Method	7/10/2012	35
5111	Complete Blood Count Without Differential	7/10/2012	35
7601	Dengue Virus Total Antibodies	7/10/2012	35
1874	Diagnostic Consultation by AP Specialist	7/10/2012	35
5400	DNA Cell Cycle Analysis, Breast Cancer	7/10/2012	36
5400P	DNA Cell Cycle Analysis, Products of Conception	7/10/2012	36
1831	ER (Estrogen Receptor), Breast Cancer	7/10/2012	36
1819	ER, PR, DNA CCA, HER-2/neu [IHC], Breast Cancer	7/10/2012	36
1840	ER, PR, HER-2/neu [IHC], Breast Cancer	7/10/2012	36
1842	ER, PR, HER-2/neu reflex FISH, Breast Cancer	7/10/2012	36
1839	ER, PR, Ki-67, HER-2/neu reflex to FISH, Breast Cancer	7/10/2012	36
1833	ER, PR, Ki-67, p53, HER-2/neu w/reflex to FISH, Breast Cancer	7/10/2012	37
1817	ER/PR/HER-2/Ki-67/DNA Cell Cycle Analysis, Breast Cancer	7/10/2012	37
5928	gp210 IgG Antibodies	7/10/2012	37
5118	Hematocrit	7/10/2012	37
5116	Hemoglobin	7/10/2012	37
5112	Hemoglobin & Hematocrit	7/10/2012	37
8144	Hepatitis B Virus Core/Precore Mutant DetectR™	7/10/2012	37
8132	Hepatitis B Virus Drug Resistance DetectR™	7/10/2012	37
8134	Hepatitis B Virus GenotypR™	7/10/2012	38
5846	HER-2/neu [IHC] w/reflex FISH, Breast Cancer	7/10/2012	38
1846	HER-2/neu [IHC], Breast Cancer	7/10/2012	38
7480	HIV-1 Genotyping, PR and RT, Sequencing	7/10/2012	38
7482A	HIV-1 RNA Quantitation [Real Time PCR] w/Rfx HIV-1 Genotype	7/10/2012	38
7482	HIV-1 RNA Quantitative, bDNA, w/Reflex HIV-1 Genotype	7/10/2012	38
1854	IHC STAIN & INTERPRETATION: CLIENT CHOOSES STAINS	7/10/2012	38
1859	IHC STAIN & INTERPRETATION: PATHOLOGIST CHOOSES 1-12 STAINS	7/10/2012	38
1856	IHC STAIN ONLY: CLIENT CHOOSES STAINS	7/10/2012	39
1845	Ki-67 (MIB-1), Breast Cancer	7/10/2012	39
4644U	Pain Management Opiates, Quant, Urine	7/10/2012	39
70236	Pain Mgmt, Opiates, Qn, with medMATCH, U	7/10/2012	39
5160	Platelet Count	7/10/2012	39
1832	PR (Progesterone Receptor), Breast Cancer	7/10/2012	39
5174	Reticulocyte Cell Count	7/10/2012	39

5172	Reticulocyte Count & Reticulocyte Hemoglobin Content	7/10/2012	40
5919	sp100 IgG Antibodies	7/10/2012	40
9456	Herpes Simplex Virus Type 1 IgM [EIA] w/reflex IFA	7/17/2012	40
2364	Rapid Plasma Reagin (RPR)	7/17/2012	40
2927	*Chlamydia trachomatis*/*Neisseria gonorrhoeae* [rRNA]	8/6/2012	40

New Test Offerings

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

Chlordiazepoxide and Metabolites	
Clinical Significance	For therapeutic drug monitoring of anxiolytic drug. Peak concentrations are reached several hours after oral administration. Elimination half-life is 24-48 hours.
Effective Date	**7/9/2012**
Test Code	**91123**
CPT Codes	80154
Specimen Requirements	2 mL (1 mL) serum collected in a red-top (no-gel) tube.
Reject Criteria	Room temperature specimens; Serum separator tubes.
Instructions	Patient Preparation: Collect at trough concentration, i.e., just before the administration of the next dose. Serum separator tubes are not acceptable; use polypropylene tubes and ship on cold pack by overnight courier.
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: Not acceptable Refrigerated: 5 days Frozen: 14 days
Set-up/Analytic Time	Set up: Friday; Report available: 1-6 days
Reference Range	Chlordiazepoxide: 100 - 3000 ng/mL Norchlordiazepoxide: 100 - 3000 ng/mL Nordiazepam: 100 -1500 ng/mL
Units Of Measure	ng/mL
Methodology	Liquid Chromatography/Tandem Mass Spectrometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 86008684 / Chlordiazepoxide 86008685 / Norchlordiazepoxide 86008686 / Nordiazepam

Tapentadol, Quantitative, Urine

Clinical Significance	The purpose of this test is to determine the presence of tapentadol and Nortapentadol in urine. Results are used in specific treatment programs and Pain Management settings to determine compliance with prescribed dosing schedule.
Effective Date	**7/9/2012**
Test Code	**91114**
CPT Codes	83789
Specimen Requirements	20 mL (5 mL) random urine
Instructions	Collect 20 mL of random urine. No preservatives
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 5 days Refrigerated: 7 days Frozen: 30 days
Set-up/Analytic Time	Set up: Tue, Thu, Sat; Report available: 3-4 days
Reference Range	Tapentadol <50 ng/mL Nortapentadol <50 ng/mL
Units Of Measure	ng/mL
Methodology	Liquid Chromatography/Tandem Mass Spectrometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 86008665 / Tapentadol 86008666 / Nortapentadol

Tramadol, Screen with Reflex to Confirmation, Urine	
Clinical Significance	Tramadol is a common prescription analgesic medication. This test is used to monitor compliance with current drug therapy.
Effective Date	**7/9/2012**
Test Code	**19642**
CPT Codes	80101
Specimen Requirements	10 mL (2 mL) Random Urine
Instructions	Collect 10 mL of random urine.
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 28 days Refrigerated: 28 days Frozen: 28 days
Set-up/Analytic Time	Set up: Tue, Fri; Report available: 3-4 days
Reference Range	Cut-Off = 200 ng/mL
Units Of Measure	ng/mL
Always Message	This test was performed using a forensic kit that is intended for the qualitative and semi-quantitative determination of Tramadol in human urine and has not been cleared or approved by the FDA for diagnostic purposes. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute Valencia

	Laboratory. This test should not be used for diagnosis without confirmation by other, more specific, confirmatory analytical methodologies.
Methodology	Immunoassay
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 86008049 / Tramadol Screen Reflex: ROJ / Reflex Tramadol and Metabolite, Quant, Urine 86008562 / Tramadol 86008563 / O-Desmethyltramadol
Additional Information	If initial screen is positive, reflex to test code ROJ-Reflex Tramadol and Metabolite, Quant, Urine will occur at an extra charge and CPT code 83789 will be added.

DNA Cell Cycle Analysis, Hydatidiform Mole, Paraffin Block	
Message	Suggested replacement for discontinued test code 5400P DNA Cell Cycle Analysis, Products of Conception
Clinical Significance	DNA ploidy analysis measures the chromosome content of the cancer cells. Diploid tumors have chromosome numbers of 46 chromosomes. Tumors that are not diploid suggest a major chromosomal disruption that serves as a poor prognostic sign.
Effective Date	**7/10/2012**
Test Code	**37127**
CPT Codes	88182
Specimen Requirements	Formalin fixed paraffin embedded tissue Alternate: (4) 50 micron unstained sections
Reject Criteria	Refrigerated unacceptable; Frozen unacceptable
Instructions	See Specimen Collection Section, Oncology. Ship at room temperature. Specimen Container: Formalin fixed paraffin embedded tissue Formalin fixed, paraffin embedded tissue block (preferred) Paraffin Block Bag (preferred) 50 micron unstained sections Formalin fixed, paraffin embedded tissue block Paraffin Block Bag
Transport Temperature	Room temperature
Specimen Stability	Room temperature: Indefinite Refrigerated: Unacceptable Frozen: Unacceptable
Set-up/Analytic Time	Sets up 2 days a week; Report available: 3 to 4 days.
Reference Range	See Laboratory Report
Always Message	Interpretive Guide: Most partial moles are triploid and generally follow a benign clinical course. Complete moles are predominantly diploid and

	are associated with an increased risk of distant metastasis or choriocarcinoma. Normal tissues and hydropic abortuses, however, are also diploid and, therefore, do not carry the same risk of complications. If you have any questions, please call the Oncology Center at (800) 642-4657, ext. 2906. References: Lage, JM, et al. Am. J. of Clin. Path. 1988;89:596-600. Davis, JR, et al. Am J. Obstet. Gynecol. 1986;157:969-973. Hemming, R, et al. J. Clin. Path. 1987;40:615-620.
Methodology	Flow Cytometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 9658 / PARAFFIN BLOCK NUMBER: AOE 22556 / PRIMARY SITE: AOE 9647 / DNA INDEX/PLOIDY 22475 / DNA Prognostic Category

DNA Cell Cycle Analysis, Paraffin Block	
Message	Suggested replacement for discontinued test code 5400 DNA Cell Cycle Analysis, Breast Cancer
Clinical Significance	DNA ploidy analysis measures the chromosome content of the cancer cells. Diploid tumors have chromosome numbers of 46 chromosomes. Tumors that are not diploid suggest a major chromosomal disruption that serves as a poor prognostic sign.
Effective Date	**7/10/2012**
Test Code	**36158**
CPT Codes	88182
Specimen Requirements	Formalin fixed paraffin embedded tissue Alternate: (4) 4 micron unstained sections
Instructions	See Specimen Collection Section, Oncology. Ship at room temperature.
Transport Temperature	Room temperature preferred
Specimen Stability	Room temperature: Indefinite Refrigerated: Room Temperature Only Frozen: Room Temperature Only
Set-up/Analytic Time	Set up: Mon, Weds; Report available: 3 to 4 days.
Reference Range	See Laboratory Report
Always Message	In breast cancer, S-phase fractions greater than 10% are generally associated with worse disease-free and overall survival in both univariate and multivariate analyses. (Wenger CR, Clark GM S-phase fraction and breast cancer-a decade of experience. Breast Cancer Research and Treatment 51:255-265, 1998). For certain other types of tumors, interpretive information for S-phase fractions may be obtained by calling (800) 421-4449.
Methodology	Flow Cytometry
Assay Category	Laboratory Developed Test

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

Result Code	Result Name
9658	PARAFFIN BLOCK NUMBER: AOE
22496	PRIMARY TUMOR SITE: AOE
22555	DNA INDEX/PLOIDY
22469	DNA Prognostic Category
7315	S-PHASE FRACTION
22470	SPF Prognostic Category

ER/PR/HER2 w/Reflex to HER2 FISH, Paraffin Block	
Clinical Significance	Estrogen and progesterone receptor assays are routinely performed on breast carcinomas to assess responsiveness to endocrine therapy and prognosis. HER-2 is associated with cellular proliferation activity. Over-expression is observed in 25-30% of women with breast cancer. These patients are potential candidates for monoclonal therapy.
Effective Date	**7/10/2012**
Test Code	**10970**
CPT Codes	88360 (x3)
Specimen Requirements	Formalin fixed paraffin embedded tissue in IHC specimen transport kit Alternate: 5 4 micron unstained sections
Reject Criteria	Non-invasive tumors
Instructions	Tumor paraffin block (formalin-fixed only) or nine 4-micron unstained sections on Poly-L-Lysine or Silane coated slides. See Specimen Collection Section, Oncology. Please submit stained H & E slide and a copy of the pathology report. Ship at room temperature. Invasive or metastatic breast cancer formalin fixed paraffin embedded tissue or charged/+slides from formalin fixed paraffin embedded tissue. **Specimen MUST be fixed in 10% neutral buffered formalin.** Fixation between 6 and 48 hours is recommended. Pathology report must accompany paraffin block or slides. 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, pathologic diagnosis, and IHC score, if performed elsewhere. Ship at room temperature. **Do not freeze.**
Transport Temperature	Room temperature
Specimen Stability	**Formalin fixed paraffin embedded tissue** Room temperature: Indefinite Refrigerated: Indefinite Frozen: Not Established **4 micron unstained sections** Room temperature: Indefinite Refrigerated: Unacceptable Frozen: Unacceptable
Set-up/Analytic Time	Reports in 7-10 days
Reference Range	See Laboratory Report
Methodology	Immunohistochemical Assay
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name
ER/PR PARAFFIN BLOCK	

86007405	Paraffin Block Number: AOE
86007575	Primary Tumor Site: AOE
86003734	Quest Internal Number:
85985745	ESTROGEN RECEPTOR
85980083	ER Staining Intensity
86006615	ER Interpretation
85985747	PROGESTERONE RECEPTOR
86006696	PR Staining Intensity
86006616	PR Interpretation
HER2 (HercepTest),IHC Paraffin Block	
85980071	Sample fixed in Formalin? AOE
85980072	Fixed between 6-48 hours? AOE
86006609	Routine Tissue Processing? AOE
86007405	Paraffin Block Number: AOE
86007575	Primary Tumor Site: AOE
85985374	Staining Intensity
85993848	HER2 Overexpression
86003734	Quest Internal Number:
Reflex HER-2 FISH, Paraffin Block	
85985349	HER-2/neu, FISH

Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations	
Message	Suggested replacement for discontinued test codes 8132 Hepatitis B Virus Drug Resistance DetectR™, 8134 Hepatitis B Virus GenotypR™, 8144 Hepatitis B Virus Core/Precore Mutant DetectR™.
Clinical Significance	This test is used to: 1. Identify HBV genotype (A-H) for epidemiology or prognostic purposes. 2. Detect hepatitis B virus (HBV) mutations associated with resistance to antiviral agents.
Effective Date	**7/10/2012**
Test Code	**10529**
CPT Codes	83891, 83894, 83900, 83904 (x4), 83912
Specimen Requirements	Preferred: 1.0 mL (0.3 mL) plasma collected in a PPT potassium EDTA (white-top) tube Alternates: Plasma collected in EDTA (lavender-top) tube Serum
Reject Criteria	Unspun PPT tube
Instructions	Serum: Collect blood in sterile tubes with no anticoagulants; plastic serum separator tubes (SST ®) 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 refrigerated or frozen. Ship frozen. Plasma: Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K_3 (standard EDTA tube) or 9 mg spray-dried EDTA K_2 (plasma preparation tube or PPT tube with plasma separator-gel, preferred).

	Store whole blood at room temperature and separate plasma from cells within 2 hours of collection. Transfer plasma to sterile, plastic, screw-capped aliquot tubes and store at -18 degrees or colder. If blood is collected in a PPT tube, centrifuge preferably within 2 hours of collection as before but it is not necessary to transfer plasma to aliquot tubes. Following centrifugation, a gel barrier maintains separation of plasma from cellular components during specimen transport and storage. The PPT is plastic and hence plasma can be stored and shipped frozen in the original tube. Avoid repeated freezing and thawing of specimen. Ship frozen. This test can only be performed reliably on specimens with a viral load of at least 600 IU/mL.
Transport Temperature	Frozen
Specimen Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 30 days
Set-up/Analytic Time	Set up Mon, Thurs; Report available: 1-2 days
Reference Range	See Laboratory Report
Always Message	The method used in this test is PCR and sequencing of the pol gene and BCP/precore region of HBV. A resistance profile for tenofovir has not yet been established. 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 (PCR), Sequencing
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 3037 / HBV Genotype 26011 / Polymerase Mutations 26958 / Precore Mutation 26959 / BCP Mutations

HER-2, IHC, with Interpretation	
Message	Also available test code 19214, HER-2, IHC, without Interpretation.
Effective Date	**7/10/2012**
Test Code	**30316**
CPT Codes	88360
Specimen Requirements	Formalin-fixed paraffin embedded tissue **or** ten 4-micron unstained sections in formalin-fixed, paraffin embedded tissue block or paraffin block bag • Zinkers • Bouin's
Reject Criteria	Non-invasive tumors
Instructions	Tumor paraffin block (formalin-fixed only) or five 4-micron unstained sections on Poly-L-Lysine or Silane coated slides. See Specimen Collection Section, Oncology. Please submit stained H & E slide and a copy of the pathology report. Do not place paper labels with adhesive backing on slides. Use pencil or xylene resistant pen to write on the frosted end of the slide only. Invasive or metastatic breast cancer formalin fixed paraffin embedded tissue or charged/+slides from formalin fixed paraffin embedded tissue. Specimen MUST be fixed in 10% neutral buffered formalin. Fixation between 6 and 48 hours is recommended. Pathology report must accompany paraffin block or slides. **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, pathologic diagnosis, and IHC score, if performed elsewhere. Ship at room temperature. **Do not freeze.**

Transport Temperature	Room temperature
Specimen Stability	**Formalin fixed paraffin embedded tissue or 4 micron unstained sections.** Room temperature: Indefinite Refrigerated: Indefinite Frozen: Unacceptable
Set-up/Analytic Time	Set up 5 days a week a.m.; Report available: 1 day
Reference Range	The sample was processed at Quest Diagnostics for technical-only immunohistochemistry staining as requested by the referring physician. The proper positive and negative controls were confirmed by a Quest Diagnostics pathologist(s) (see attached images), but staining of the test sample has not been evaluated by the Quest Diagnostics pathologist. Proper interpretation requires proper integration of clinical, morphologic, and immunologic information as well as proper staining and antibody selection. Fixation and processing of the tissue may interfere with the staining.
Always Message	The sample was processed at Quest Diagnostics for technical-only immunohistochemistry staining as requested by the referring physician. The proper positive and negative controls were confirmed by a Quest Diagnostics pathologist(s) (see attached images), but staining of the test sample has not been evaluated by the Quest Diagnostics pathologist. Proper interpretation requires proper integration of clinical, morphologic, and immunologic information as well as proper staining and antibody selection. Fixation and processing of the tissue may interfere with the staining.
Methodology	Immunohistochemical Assay (IHA)
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**HER-2, IHC, with Interpretation:**

Result Code	Result Name
85980071	Sample fixed in Formalin?
85980072	Fixed between 6-48 hours?
85985371	PARAFFIN BLOCK NUMBER:
85992359	PRIMARY TUMOR SITE:
85985373	QUEST INTERNAL NUMBER:
85985374	Staining Intensity
85993848	HER2 Overexpression

HER-2, IHC, without Interpretation:

Analyte Code	Result Name
29431	PARAFFIN BLOCK NUMBER:
29432	PRIMARY TUMOR SITE:
29433	QUEST INTERNAL NUMBER:
4639	HER-2
29434	Slides/Block mailed on:

HIV-1 Genotype	
Message	Suggested replacement for discontinued test code 7480 HIV-1 Genotyping, PR and RT, Sequencing and 7480NY HIV-1 Genotyping, PR and RT, Sequencing NY
Clinical Significance	The high replication rate of HIV-1 coupled with its rapid mutation rate drives the accumulation of mutations, some of

	which confer reduced susceptibility to antiretroviral agents. HIV-1 Genotyping identifies mutations in the HIV-1 reverse transcriptase and protease genes. Genotyping can be used to identify mutations associated with current or evolving resistance and monitor transmission of drug-resistant HIV-1.
Effective Date	**7/10/2012**
Test Code	**34949**
CPT Codes	87901
Specimen Requirements	Preferred: 2.0 mL (0.6 mL) plasma collected in an EDTA (lavender-top) tube Alternative: Plasma collected in a PPT Potassium EDTA (white top) or ACD-B (yellow-top) tube or Serum
Reject Criteria	Received room temperature, Unspun PPT tube, Frozen PPT tube, Heparinized plasma
Instructions	Plasma: Collect blood 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. Serum: Acceptable for Genotyping but may observe a reduced viral quantitation value. 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. **Ship frozen only.**
Transport Temperature	Frozen
Specimen Stability	Plasma: Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days Serum: Room temperature: 3 hours Refrigerated: 48 hours Frozen: 90 days
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 7 days
Reference Range	See Laboratory Report
Methodology	Reverse Transcriptase PCR and DNA Sequencing
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 86007864 / HIV-1 Genotype

HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype	
Message	Recommended replacement test for discontinued test 7482 HIV-1 RNA Quantitative, bDNA, w/Reflex HIV-1 Genotype
Effective Date	**7/10/2012**
Test Code	**10596**
CPT Codes	87536
Specimen Requirements	3.0 mL (2.0 mL) plasma collected in an EDTA (lavender-top) tube Alternates: Plasma collected in an ACD-A (yellow-top) tube Plasma in PPT Potassium EDTA (white-top) tube
Reject Criteria	Received thawed, Serum ,Heparnized Plasma ,Frozen PPT tubes, Unspun PPT tube
Instructions	Plasma only; no serum.

	Plasma: Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Blood collected in tubes containing ACD anticoagulant are acceptable but will yield results approximately 15% lower when compared to EDTA tubes due to the dilution effect of the 1.5 mL of anticoagulant used in the tube. Separate plasma from the cells by centrifugation within 4 hours after collection. (Note: If using a PPT tube, separate plasma within 2 hours of collection). Transfer the plasma to a separate plastic screw-cap vial, and ship frozen. Frozen PPT tubes are unacceptable.
Transport Temperature	Frozen
Specimen Stability	Plasma in EDTA (lavender-top) or ACD-A (yellow-top) tube Room temperature: 4 hours Refrigerated: 48 hours Frozen: 90 days Plasma in PPT Potassium EDTA (white-top) tube Room temperature: 4 hours Refrigerated: Unacceptable Frozen: 90 days
Set-up/Analytic Time	Set up: Mon-Fri; Report available: 10 days
Reference Range	See Laboratory Report
Always Message	This test was performed using the Versant (R) HIV-1 RNA 3.0 Assay (bDNA) kit by Siemens.
Methodology	Branch DNA Signal Amplication, if reflexed, Reverse Transcriptase PCR and DNA Sequencing
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name	
70043600	Copies/mL (VERSION 3.0)	
70011110	LogCopies/mL (VERSION 3.0)	
10596-2	Reflex HIV-1 Genotype	Reflex
86007864	HIV-1 Genotype	

HIV-1 RNA, Quantitative PCR w/Reflex to Genotype	
Message	Recommended replacement for discontinued test code 7482A HIV-1 RNA Quantitation [Real Time PCR] w/Rfx HIV-1 Genotype
Clinical Significance	Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA, quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy.
Effective Date	**7/10/2012**
Test Code	**34471**
CPT Codes	87536
Specimen Requirements	7.0 mL (3.1 mL) plasma collected in an EDTA (lavender-top) tube Alternate: Plasma collected in a PPT Potassium EDTA (white-top) tube
Reject Criteria	Specimen collected using heparin as anticoagulant, Leaking, uncapped or broken containers, Frozen plasma received in PPT in situ, ACD collection containers.
Instructions	Plasma: Collect blood 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 a plastic screw-cap vial and ship frozen.
Transport Temperature	Frozen

Specimen Stability	Room temperature: 24 hours Refrigerated: 6 days Frozen: 42 days
Set-up/Analytic Time	Set up: Mon-Fri; Report available: 7 days
Reference Range	See Laboratory Report
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.). If reflexed: 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	Real-Time Polymerase Chain Reaction (RT-PCR)
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 70011130 / Copies/mL: 70011135 / Log copies/mL: 34471-2 / Reflex HIV-1 Genotype / Reflex 86007864 / HIV-1 Genotype
Additional Information	Linear range: 20-10,000,000 copies/mL

Ki-67, IHC with Interpretation	
Message	Also available test code 19100, Ki-67, IHC without Interpretation.
Clinical Significance	Ki-67 is a tissue marker of anaplastic large cell non-Hodgkin's lymphoma.
Effective Date	**7/10/2012**
Test Code	**29914**
CPT Codes	88360
Specimen Requirements	Formalin-fixed paraffin embedded tissue **or** Five 4-micron unstained slides • Fixed tissue • Tissue in neutral buffered formalin
Instructions	Tumor paraffin block (formalin-fixed only) **or** five 4-micron unstained sections on Poly-L-Lysine **or** Silane coated slides. See Specimen Collection Section, Oncology. **Ship at room temperature. Do not place paper labels with adhesive backing on slides. Use pencil or xylene resistant pen to write on the frosted end of the slide only. Pathology report is required.**
Transport Temperature	Room temperature
Specimen Stability	Room temperature: Indefinite Refrigerated: Indefinite Frozen: Unacceptable
Set-up/Analytic Time	Set up: 6 days a week, a.m; Report available: 2 to 3 days
Reference Range	The sample was processed at Quest Diagnostics for technical-only immunohistochemistry staining as requested by the referring physician. The proper positive and negative controls were confirmed by a Quest Diagnostics pathologist(s) (see attached images), but staining of the test sample has not been evaluated by the Quest Diagnostics pathologist. Proper interpretation requires proper integration of clinical, morphologic, and immunologic information as well as proper staining and antibody selection. Fixation and processing of the tissue may interfere with the staining.

Always Message	The sample was processed at Quest Diagnostics for technical-only immunohistochemistry staining as requested by the referring physician. The proper positive and negative controls were confirmed by a Quest Diagnostics pathologist(s) (see attached images), but staining of the test sample has not been evaluated by the Quest Diagnostics pathologist. Proper interpretation requires proper integration of clinical, morphologic, and immunologic information as well as proper staining and antibody selection. Fixation and processing of the tissue may interfere with the staining.
Methodology	Immunohistochemical Assay (IHC)
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Ki-67, IHC with Interpretation:**

Analyte Code	Result Name
9658	PARAFFIN BLOCK NUMBER:
22496	PRIMARY TUMOR SITE:
10012	QUEST INTERNAL NUMBER:
6092	Ki-67,IHC w/ interp
31939	Ki-67 Staining Intensity

Ki-67, IHC without Interpretation:

Analyte Code	Result Name
27077	PARAFFIN BLOCK NUMBER:
22320	PRIMARY TUMOR SITE:
10012	QUEST INTERNAL NUMBER:
4447	Ki-67,IHC w/o interp
27136	Slides/Block mailed on:

p53 Oncoprotein, IHC with Interpretation (36162X)	
Clinical Significance	p53 is a tumor suppressor gene. Mutations of the p53 gene are detectable in approximately half of all carcinomas. Detection of p53 by Immunohistochemistry serves as a surrogate marker of the mutant p53 gene. Generally, the presence of mutant p53 gene expression is associated with a poorer prognosis.
Effective Date	**7/10/2012**
Test Code	**36162**
CPT Codes	88342
Specimen Requirements	Formalin fixed paraffin embedded tissue Alternates 4 micron unstained slides Fixed tissue Tissue in neutral buffered formalin
Instructions	Tumor paraffin block or five 4-micron unstained sections on Poly-L-Lysine **or** Silane coated slides. See Specimen Collection Section, Oncology. Please submit stained H & E slide and a copy of the pathology report. Ship at room temperature. **Pathology report is required.**
Transport Temperature	Room temperature
Specimen Stability	Room temperature: Indefinite Refrigerated: Indefinite

	Frozen: Unacceptable
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 2 to 3 days
Reference Range	See Laboratory Report
Methodology	Immunohistochemical Assay (IHC)
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name
9658	PARAFFIN BLOCK NUMBER: AOE
22496	PRIMARY TUMOR SITE: AOE
10012	QUEST INTERNAL NUMBER:
6035	p53
31938	p53 Staining Intensity

Vitamin D, 1,25-Dihydroxy, LC/MS/MS	
Clinical Significance	This test is used to measure the bio-active form of Vitamin D. This test is also used in the differential diagnosis of hypocalcemia and to monitor patients with renal osteodystrophy or chronic renal failure.
Effective Date	**7/10/2012**
Test Code	**16558**
CPT Codes	82652
Specimen Requirements	2.0 (1.1) mL Serum
Instructions	Collect blood in a non-gel barrier red-top tube. Allow blood to clot (30 minutes) at room temperature. Centrifuge and separate the serum from the cells. Note: If sample is submitted with less than 1.1 mL and needs to be repeated, the sample will be canceled with the comment TNP-Initial testing necessitated a repeat, but there was insufficient sample to perform repeat.
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 28 Days Refrigerated: 28 Days Frozen: 28 Days
Set-up/Analytic Time	Sets up 7 days a week; Report available: 3 days
Reference Range	Vitamin D, 1,25 (OH)2, Total: 1-9 years: 31-87 pg/mL 10-13 years: 30-83 pg/mL 14-17 years: 19-83 pg/mL Adults: 18-72 pg/mL Reference ranges are established for total 1,25-dihydroxy vitamin D. Values for subcomponents D2 (derived from plant or fungal sources) and D3 (derived from human or animal sources) are provided for informational purposes only.
Units Of Measure	pg/mL
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia. Performance characteristics refer to the analytical performance of the test.
Methodology	Liquid Chromatography Tandem Mass Spectrometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia

CPU Mappings	

Result Code	Result Name
86003320	Vitamin D,1,25 (OH)2,Total
86003321	Vitamin D3, 1,25 (OH)2
86003322	Vitamin D2, 1,25 (OH)2

Herpes Simplex Virus (HSV) 1/2 IgM Ab (EIA) with Reflex to IFA	
Message	Replacement test code for discontinued test code 9456 Herpes Simplex Virus Type 1 IgM [EIA] w/reflex IFA and 9466 Herpes Simplex Virus Type 2 IgM [EIA] w/reflex IFA
Clinical Significance	Clinical manifestations of HSV infections include genital tract infections, neonatal herpes, meningoencephalitis, keratoconjunctivitis, and gingivostomatitis. Most infections at non-genital sites are caused by HSV-1, whereas both HSV-1 and HSV-2 may cause genital herpes. Compared to HSV-1 genital infections, HSV-2 genital infections are associated with higher recurrence rates and asymptomatic transmission events; thus information on the HSV type causing genital infection is useful in guiding treatment and management options. Although HSV IgM is detectable in most cases of primary HSV infection, it may also be found in association with recurrences.
Effective Date	**7/17/2012**
Test Code	**9429**
CPT Codes	86694, if reflexed 86696x2
Specimen Requirements	1.0 mL (0.5 mL) Serum Red Top SST acceptable
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 1 month
Set-up/Analytic Time	Set up: Tues-Sat; Report available: 3 days
Always Message	Negative: <0.90 Equivocal: 0.90-1.09 Positive: >1.09 The following results were obtained with the Diamedix immunosimplicity Is-HSV 1 & 2 IgM EIA Test System. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody present. The magnitude of the reported IgM level cannot be correlated to an end-point titer.
Methodology	ELISA, if reflexed, IFA
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Result Name
211425	HSV Type 2 IgM Antibodies
Reflex RPA	Reflex Herpes Simplex Virus Type 1 and 2 IgM Abs [IFA]
210760	HSV 1 IgM Antibodies IFA
210761	HSV 2 IgM Antibodies IFA

Herpes Simplex Virus (HSV) 1/2 IgM Antibody, ELISA	
Clinical Significance	Clinical manifestations of HSV infections include genital tract infections, neonatal herpes, meningoencephalitis,

	keratoconjunctivitis, and gingivostomatitis. Most infections at non-genital sites are caused by HSV-1, whereas both HSV-1 and HSV-2 may cause genital herpes. Compared to HSV-1 genital infections, HSV-2 genital infections are associated with higher recurrence rates and asymptomatic transmission events; thus information on the HSV type causing genital infection is useful in guiding treatment and management options. Although HSV IgM is detectable in most cases of primary HSV infection, it may also be found in association with recurrences.
Effective Date	**7/17/2012**
Test Code	**9435**
CPT Codes	86694
Specimen Requirements	1.0 mL (0.5 mL) Serum Red Top SST acceptable
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 1 month
Set-up/Analytic Time	Set up: Tues-Sat; Report available: 3 days
Always Message	Negative: <0.90 Equivocal: 0.90-1.09 Positive: >1.09 The following results were obtained with the Diamedix immunosimplicity Is-HSV 1 & 2 IgM EIA Test System. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody present. The magnitude of the reported IgM level cannot be correlated to an end-point titer.
Methodology	ELISA
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 211424 / Herpes Simplex Virus 1/2 IgM
Additional Information	Specimens exhibiting equivocal or positive IgM ELISA results can be confirmed by HSV IgM 1and 2 IFA (DOS 9335& DOS 9337) for an additional charge.

RPR (Monitor) with Reflex to Titer	
Message	Replaces test code 2364 Rapid Plasma Reagin (RPR).
Clinical Significance	The RPR is a non-specific test for syphilis; therefore, all reactive nontreponemal tests should be confirmed using a standard treponemal test unless the patient has a known documented prior syphilis infection.
Effective Date	**7/17/2012**
Former Test Name	*Rapid Plasma Reagin (RPR)*
Former Test Code	*2364*
Test Code	**799**
CPT Codes	86592
Specimen Requirements	1.0 (0.2) mL Serum
Reject Criteria	Gross hemolysis, Gross lipemia, Gross Icteria, Bacterially contaminated specimens
Instructions	Serum: Collect whole blood into a clean, dry tube without anticoagulant. Allow to clot for 15 minutes at room temperature. Centrifuge at 1500-2000 RPM for 5 minutes to separate cells. Transfer the serum to a clean, dry test tube.
Transport Temperature	Room temperature

Specimen Stability	Room temperature: 4 Days Refrigerated: 7 Days Frozen: 30 Days -70 Degrees: Indefinite
Set-up/Analytic Time	Set up: Tues-Sat; Report available: 2-3 days
Reference Range	Nonreactive
Always Message	The RPR is a non-specific test for syphilis; therefore, all reactive nontreponemal tests should be confirmed using a standard treponemal test unless the patient has a known documented prior syphilis infection.
Methodology	Macroscopic Flocculation
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 8600747 / RPR Screen 799-2 / Reflex Test 86007408 / RPR Titer
Additional Information	If the RPR is Reactive, the RPR Titer will be added at an additional charge (CPT: 86593).

Vitamin B3	
Clinical Significance	Nicotinic Acid occurs naturally in plants and animals and is also added to many foods as a vitamin supplement.
Effective Date	**8/13/2012**
Test Code	**91029**
CPT Codes	83925
Specimen Requirements	2.0 mL (1.0 mL) Serum (Red Top) Alternate: 2.0 mL (1.0 mL) Plasma (EDTA Lavender Top)
Instructions	Separate serum or plasma from cells and submit in plastic screw-capped vial.
Transport Temperature	Frozen
Specimen Stability	Room temperature and Refrigerated: Unacceptable Frozen: 30 days
Set-up/Analytic Time	Set up: Tues, Thurs; Report available: 2-6 days
Units Of Measure	ng/mL
Always Message	Due to the large variability in the metabolism of nicotinic acid, the dosing preparation used (immediate-release vs. extended release), and the mg doses used, the serum concentrations may range from <20 ng/mL to about 30,000 ng/mL. After oral administration of an immediate-release tablet, peak plasma concentrations occur in 4 to 5 hours. The plasma half-life of nicotinic acid is about one hour. In one study, fasting plasma concentrations were reported to be <20 ng/mL. In another study, it was reported that the administration of a single 1000 mg extended-release tablet resulted in mean nicotinic acid concentrations of <50 ng/mL. Nicotinamide is a metabolite of nicotinic acid. Due to the large variability in the metabolism of nicotinic acid, plasma concentrations of this metabolite are variable. In one study, fasting plasma concentrations were reported to be approximately 40 ng/mL. In another study it was reported that the administration of single 1000 mg of extended-release tablet of nicotinic acid resulted in a mean peak nicotinamide concentration of 400 ng/mL between 5 and 10 hours post dose, decreasing to about 100 ng/mL by 16 hours post dose.
Methodology	Liquid Chromatography, Tandem Mass Spectrometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia

CPU Mappings	**Result Code** / **Result Name** 86008460 — Nicotinic Acid 86008461 — Nicotinamide

Vitamin B5 (Pantothenic Acid)	
Clinical Significance	Vitamin B5 (Pantothenic Acid) is a component of coenzyme A and phosphopantetheine both of which are involved in fatty acid metabolism. It is essential to almost all forms of life and is widely distributed in food.
Effective Date	**8/13/2012**
Test Code	**91030**
CPT Codes	80299
Specimen Requirements	1.2 mL serum red-top (no gel) tube (minimum 0.6 mL) Also acceptable: Plasma collected in EDTA (lavender-top) or Heparin (green-top) tube
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 6 hours Refrigerated: 4 days Frozen: 30 days
Set-up/Analytic Time	Set up: Tues, Thurs, Sat: Report available: 2-4 days
Reference Range	<275 ng/mL
Units Of Measure	ng/mL
Methodology	Liquid Chromatography, Tandem Mass Spectrometry
Assay Category	Laboratory Developed Test
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** 86008462 — Vitamin B5

Test Changes

Influenza Virus A IgG Abs	
Effective Date	**6/1/2012**
Test Code	**8517**
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test should not be used for diagnosis without confirmation by other medically established means.
Assay Category	**Research Use Only**
Tests Affected	**Test Codes:** / **Name:** 8516 — Influenza Virus A & B IgG, IgM & IgA Antibodies

8519	Influenza Virus A IgG & IgM Abs

Influenza Virus B IgG Abs	
Effective Date	**6/1/2012**
Test Code	**8520**
Always Message	This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test should not be used for diagnosis without confirmation by other medically established means.
Assay Category	**Research Use Only**
Tests Affected	

Test Codes:	**Name:**
8523	Influenza Virus B IgG & IgM Abs

Citrate 24 hour Urine	
Effective Date	**7/10/2012**
Test Code	**3970U**
Assay Category	**FDA Approved/Cleared**
Tests Affected	

Test Codes:	**Name:**
3970UR	Citrate Urine Random
4168	Kidney Stone Risk AssessR™
5510	StoneRisk® Diagnostic Profile
5520	StoneTrack® Diagnostic Monitoring Test
5530	StoneRisk® Citrate Test
5515	UroRisk® Diagnostic Profile
90523	Kidney Stone Risk AssessR

QuantiFERON®-TB Gold (Incubated)	
Effective Date	**7/10/2012**
Test Code	**6110**
Always Message	**The Nil tube value is used to determine if the patient has a preexisting immune response which could cause a false-positive reading on the test. In order for a test to be valid, the Nil tube must have a value of ≤ 8.0 IU/mL.** **The mitogen control tube is used to assure the patient has a healthy immune status and also serves as a control for correct blood handling and incubation. It is used to detect false-negative readings. The mitogen tube must have a gamma interferon value ≥ 0.5 IU/mL higher than the value of the Nil tube.** **The TB Antigen tube is coated with the M tuberculosis specific antigens. For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be ≥ 0.35 IU/mL.** **For additional information, please refer to http://education.questdiagnostics.com/faq/QFT.**

Copper, RBC	
Effective Date	**7/16/2012**
Test Code	**4870R**
Specimen Requirements	Add acceptable: 3.0 mL (1.0 mL) whole blood Sodium heparin lead-free (tan-top)
Reject Criteria	Clotted and gross hemolysis
Transport Temperature	Room temperature
Specimen Stability	Room temperature: **10 days** Refrigerated: **10 days** Frozen: unacceptable
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Selenium	
Clinical Significance	Selenium is an element of parental nutrition. Monitoring the Selenium concentration is useful in assessing parental nutrition, especially recent intake. Concentrations are also monitored in children with propionic acidemia who require special diets with supplements.
Effective Date	**7/16/2012**
Test Code	**4875**
Specimen Requirements	**Absolute min (0.7 mL)**
Reject Criteria	Hemolysis
Instructions	**Carefully clean skin prior to venipuncture. Avoid worksite collection. Avoid hemolysis. Use the royal blue-top "Trace Metal" evacuated tube, which is available with EDTA, heparin or no additives. Do not use gel barrier tubes.** Centrifuge serum or plasma specimens within 1 hour of collection. Immediately separate serum and plasma specimens from the cells into trace element collection vial(s). **Patient should refrain from taking vitamins or mineral supplements at least three days prior to specimen collection.**
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: **8 hours** Refrigerated: **14 days** Frozen: **30 days**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Zinc, RBC	
Clinical Significance	Zinc is an essential element involved in a myriad of enzyme systems including wound healing, immune function, and fetal development. Zinc measurements are used to detect and monitor industrial, dietary, and accidental exposure to zinc. Also, Zinc measurements may be used to evaluate health and monitor response to treatment.
Effective Date	**7/16/2012**
Test Code	**4877R**
Specimen Requirements	Add acceptable: 3.0 mL (1.0 mL) whole blood Sodium heparin lead-free (tan-top) 3.0 mL (1.0 mL0 Sodium heparin (green-top) 3.0 mL (1.0 mL) Lithium heparin (green-top)
Reject Criteria	Clotted, Moderate hemolysis
Instructions	Red blood cells "Trace Metal": 1. Use the royal blue-top “Trace Metal” evacuated tube (Becton-Dickinson catalog #367736) with EDTA for RBC trace metal testing. Hemolysis is absolutely undesirable. 2. Send whole blood samples in the royal blue EDTA "Trace Metal" evacuated tube or pipette the well-mixed blood into a transfer tube closed tightly to avoid leakage. Royal blue "Trace Metal" evacuated tubes and transfer tubes are available

	from Client Supply. 3. Indicate "whole blood" on the tube. Red blood cells will be separated at the testing site.
Transport Temperature	Room temperature
Specimen Stability	Room temperature: **7 days** Refrigerated: **7 days** Frozen: unacceptable
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Bilirubin, Total & Direct	
Effective Date	**7/17/2012**
Test Code	**5313**
Specimen Requirements	**Plasma Heparin Foil Wrap not acceptable.**

Bordetella pertussis/parapertussis Antigen Detection	
Effective Date	**7/17/2012**
Test Code	**2428**
Specimen Requirements	Primary Specimen: ESwab 0.0 (0.0)
Instructions	1. Source of specimen is required. Indicate exact site where specimen was obtained. 2. Acceptable specimen: Nasopharyngeal secreations/swabs. Unacceptable specimen: Frozen specimen; Cotton tip swab; Dry swab/Culturette; Expired transport media; broken slides. 3. Ship swabs refrigerated or ambient. 4. Preparation of smears: Roll the nasopharyngeal swab over areas of the slide. Air dry. Heat fix the slide. Ship 2 slides in the slide holder at ambient temperature. 5. Smears will be prepared at the testing site if swabs are submitted.
Transport Temperature	Refrigerated
Specimen Stability	Eswab: Refrigerated 96 hours Amies w/Charcoal/swab Room Temperature: 24 hours Refrigerated: 7 days Regan-Lowe Media/Swab Room Temperature: 24 Hrs Refrigerated: 7 days Smear/ Slides Room Temperature: 72 hours Refrigerated: 7 days

Bordetella pertussis/parapertussis Culture	
Effective Date	**7/17/2012**
Test Code	**2416**
Specimen Requirements	**New Alternate:** **ESwab (modified Amies)**
Instructions	**1. Source of specimen is required. Indicate exact site where specimen was obtained.** **2. Acceptable specimens: Nasopharyngeal secretions/swabs.** **Unacceptable specimens: Frozen specimen; Cotton tip swab;** **Dry swab/culturette; Expired transport device; Anterior nasal or other specimen sources.**

	3. Ship Regan-Lowe transport media at ambient temperature if not pre-incubated; ship refrigerated if incubated. Ship ESwab refrigerated or ambient. **4. Pre-incubation of the inoculated Regan-Lowe medium at 36 degree C for 1-2 days before transit will increase survivability of Bordetella spp.**
Specimen Stability	**ESwab:** **Refrigerated: 96 hours** **Regan-Lowe Media/Swab:** **Room Temperature: 72 hours** **Refrigerated: 72 hours**

Bordetella pertussis/parapertussis Evaluation	
Effective Date	**7/17/2012**
Test Code	**2430**
Instructions	**1. Source of specimen is required. Indicate exact site where specimen was obtained.** **2. Acceptable specimens: Nasopharyngeal secretions/swabs.** **Unacceptable specimens: Frozen specimen; Cotton tip swab;** **Dry swab/culturette; Expired transport device; Broken slides.** **3. Ship Regan-Lowe transport media at ambient temperature if not pre-incubated; ship refrigerated if incubated. Ship ESwab refrigerated or ambient.** **4. Pre-incubation of the inoculated Regan-Lowe medium at 36 degree C for 1-2 days before transit will increase survivability of Bordetella spp.** **5. Preparation of smears: Roll the nasopharyngeal swab over areas of the slide. Air dry. Heat fix the slide. Ship 2 slides in the slide holder at ambient temperature.** **Please note: Bordetella culture cannot be performed on slide specimens! Slide specimens are for DFA only.** **6. Smears will be prepared at testing site if swabs are submitted.**
Specimen Stability	**Smear/slides:** **Room Temperature: 72 hours** **Refrigerated: 7 days**

Cytomegalovirus Culture	
Effective Date	**7/17/2012**
Test Code	**2418**
Specimen Requirements	Sputum is not acceptable
Reject Criteria	Sputum
Instructions	1. Specimens should be collected early in the acute phase of infection. The chance of viral recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many viruses. 2. Source of specimen is required, please include on requisition. **3. Place the following specimens into:** **a. sterile leak proof container: CSF, body fluids, urine, semen, saliva, biopsy or tissues, and bone marrow.** **b. viral transport media (M4, etc): respiratory samples (bronchial, lung, throat, nasal).** **4. Unacceptable specimens: Stool, whole blood, sputum, wooden swabs, and calcium alginate.** 5. All specimens except bone marrow, fluids and semen held more than 72 hours must be frozen at -70C (not -20C) or on dry ice. Do not freeze at -20C. Virus loses infectivity. 6. Ship specimens on cold pack or on dry ice. 7. M4 transport media (M4) and dacron-tipped swabs with plastic or fine-wire shafts available for use with M4 are provided. Please call Client Services, 800-421-4449 to request media.

Giardia lamblia Antigen Detection	
Effective Date	**7/17/2012**
Test Code	**7760**
Specimen Requirements	**Stool Ecofix not acceptable.**

Instructions	**1. Collect fresh stool in clean, leak-proof plastic container. Store at 2 - 8 C. Ship within 48 hours of collection.** **2. Fresh stool that can not be tested within 48 hours, should be frozen at - 20 to - 70 C. Ship on dry ice.** **3. Stool collected in Cary Blair medium is acceptable. Ship refrigerated on cold pack.** **4. Preserved stools (10% Formalin, SAF, MF) may be refrigerated (2-8 C) or stored ambient (20-25 C). Ship ambient or refrigerated.** **5. Unacceptable specimen: Specimens other than stool, Frozen preserved specimens (e.g. formalin); Stool specimens in PVA or MIF; Duodenal or gastric aspirates; Swab specimens.**
Specimen Stability	**Stool:** **Refrigerated: 48 hours** **Frozen: 1 year** **Stool SAF Fixative:** **Room Temperature: 2 months** **Refrigerated: 2 months**

HE4, Ovarian Cancer Monitoring	
Effective Date	**7/17/2012**
Test Code	**2040**
Assay Category	**FDA Approved/Cleared**
Tests Affected	**Test Codes:** / **Name:** 2042 / HE4 & CA 125

Helicobacter pylori IgM Antibody	
Effective Date	**7/17/2012**
Test Code	**7736**
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.
Assay Category	Laboratory Developed Test
Tests Affected	**Test Codes:** / **Name:** 7741 / Helicobacter pylori Antibodies (IgG, IgA, IgM)

Herpes Simplex Virus Type 1 & 2 IgG (HerpeSelect®) & IgM Abs	
Message	Change to resulting codes only.
Effective Date	**7/17/2012**
Test Code	8051
CPU Mappings	**Result Code** / **Result Name** ADD / 211425 / Herpes Simplex Virus 1/2 IgM DELETE / 64362 / HSV Type 1 IgM Antibodies 64381 / HSV Type 2 IgM Antibodies

Tests Affected	

Test Codes:	Name:
9471	Herpes Simplex Virus 1 & 2 IgM Antibodies [EIA]
9901	TORCH IgG & IgM Antibodies Evaluation
2231	TORCH IgM Antibodies Evaluation

HPV DNA, High Risk	
Effective Date	**7/17/2012**
Test Code	**1821**
Always Message	**The analytical performance characteristics of this assay, when used to test SurePath or Vaginal specimens, have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Methodology: Hybrid Capture with Signal Amplification.**

HPV DNA, High Risk, Anal-Rectal	
Effective Date	**7/17/2012**
Test Code	**1821R**
Always Message	**The performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test. Methodology: Hybrid Capture with Signal Amplification.**

SureSwab(TM), Vaginosis/Vaginitis Plus	
Effective Date	**7/24/2012**
Test Code	**17333**
Reference Range	BV Risk Assessment: Low
Always Message	**LOW Risk for BV: 1) Presence of *Lactobacillus spp*., *G. vaginalis* levels less than 6.0 log cells/mL, and absence of *A. vaginae* and *Megasphaera spp*; or 2) absence of all targeted organisms; or 3) absence of *Lactobacillus spp*. plus *G. vaginalis* detected at levels less than 6.0 log cells/mL and absence of *A. vaginae* and *Megasphaera spp*.** **INTERMEDIATE Risk for BV: (possible transitional state): Presence of *Lactobacillus spp*. plus *G. vaginalis* (greater or equal to 6.0 log cells/mL) and/or one of the other BV-associated pathogens** **HIGH Risk for BV: (indicative of BV): Absence of *Lactobacillus spp*. and presence of *G. vaginalis* greater than or equal to 6.0 log cells/mL and/or one or both of the other BV-associated pathogens.** **Concentration for *Lactobacilli* (*L. acidophilus/crispatus, L. jensenii*) are collectively reported under the term "*Lactobacillus spp*.", as these species are among the peroxide producing *Lactobacilli* thought to be protective against bacterial vaginosis. *Atopobium vaginae*, *Megasphaera spp*., and *Gardnerella* (greater than 6.0 log cells/mL) have been associated with vaginosis when present in the absence of peroxidase producing *Lactobacilli*.** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia. Performance characteristics refer to the analytical performance of the test.**
CPU Mappings	

New Component before Lactobacillus species	
Result Code	**Result Name**

	86008580 | **BV Risk Assessment**
Tests Affected	

Test Codes:	Name:
16898	SureSwab(TM), Bacterial Vaginosis DNA, Quantitative RT-PCR
15509	SureSwab(TM), Bacterial Vaginosis/vaginitis
16491	SureSwab(TM), Vaginosis, CT/NG

Redirects

CBC (Includes Differential and Platelets)	
Effective Date	**7/10/2012**
Former Test Name	*Complete Blood Count & Differential*
Former Test Code	*5110*
Test Code	**6399**
Specimen Requirements	5.0 mL **(1.0 mL)** whole blood collected in EDTA (lavender-top) tube
Reject Criteria	**Clotted or frozen specimens.**
Specimen Stability	Room temperature: 48 hours Refrigerated: **Unacceptable** Frozen: **Unacceptable**
Set-up/Analytic Time	**Set up: Sun-Mon; Report available: 1 day**
Reference Range	See Laboratory Report
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**
20002500	**Eosinophils**
30002800	**Basophils**
30003400	**Blasts**
30003600	**Nucleated RBC**
30004200	**Comment(s)**

Epidermal Growth Factor Receptor (EGFR), IHC	
Clinical Significance	**To determine overexpression of EGFR in tumor cells. Efficacy of therapies depend on the expression of EGFR in tumor cells and has been reported to be associated with more aggressive diseases.**
Effective Date	**7/10/2012**
Former Test Name	*EGFR PHARMDX (EPIDERMAL GROWTH FACTOR RECEPTOR)*
Former Test Code	*1835*
Test Code	**10479**
CPT Codes	**88342**
Specimen Requirements	Tissue, formalin fixed, paraffin embedded tissue block Alternate: **(5)** 4 micron unstained sections
Instructions	Pathology report is required.
Specimen Stability	Room temperature: **Indefinite** Refrigerated: **Indefinite** Frozen: Unacceptable
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1 day**

Always Message	Interpretive guide: A specimen that is positive by Immunohistochemistry indicates cellular expression of EGFR (HER-1) protein. This experession has been reported to correlate with response to Erbitux (cetuximab) or other EGFR inhibitors.
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name
10855	Paraffin Block Number: AOE
22496	Primary Tumor Site: AOE
10012	Quest Internal Number
30414	Staining Intensity
6155	EGF, Receptor, IHC

ER/PR, Paraffin Block	
Clinical Significance	**Estrogen and progesterone receptor assays are routinely performed on breast carcinomas to assess responsiveness to endocrine therapy and prognosis.**
Effective Date	**7/10/2012**
Former Test Name	*ER, PR (Estrogen and Progesterone Receptors), Breast Cancer*
Former Test Code	*1830*
Test Code	**7037**
Specimen Requirements	**Formalin-fixed paraffin embedded tissue block, submitted in IHC specimen kit**
Instructions	Tumor paraffin block (formalin-fixed only) **or five 4-micron unstained sections on Poly-L-Lysine or Silane coated slides. Please submit stained H & E slide and a copy of the pathology report.** Ship at room temperature. **Do not place paper labels with adhesive backing on slides. Use pencil or xylene resistant pen to write on the frosted end of the slide only.**
Specimen Stability	Room temperature: **Indefinite** Refrigerated: **Indefinite** Frozen: Unacceptable
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1 to 3 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name
313357	Sample Fixed in Formalin? AOE
31942	Fixed Between 6-72 HRS? AOE
86006609	Routine Tissue Processing? AOE
10855	PARAFFIN BLOCK NUMBER: AOE
22496	PRIMARY TUMOR SITE: AOE
10012	QUEST INTERNAL NUMBER:
22548	ESTROGEN RECEPTOR
30165	ER Staining Intensity
31940	ER Interpretation
22549	PROGESTERONE RECEPTOR

30166	PR Staining Intensity
31941	PR Interpretation

ER/PR, Paraffin Block	
Clinical Significance	**Estrogen and progesterone receptor assays are routinely performed on breast carcinomas to assess responsiveness to endocrine therapy and prognosis.**
Effective Date	**7/10/2012**
Former Test Name	*ER, PR (Estrogen and Progesterone Receptors), Breast Cancer*
Former Test Code	*1830*
Test Code	**7037**
Specimen Requirements	**Formalin-fixed paraffin embedded tissue block, submitted in IHC specimen kit**
Instructions	Tumor paraffin block (formalin-fixed only) **or five 4-micron unstained sections on Poly-L-Lysine or Silane coated slides. Please submit stained H & E slide and a copy of the pathology report.** Ship at room temperature. **Do not place paper labels with adhesive backing on slides. Use pencil or xylene resistant pen to write on the frosted end of the slide only.**
Specimen Stability	Room temperature: **Indefinite** Refrigerated: **Indefinite** Frozen: Unacceptable
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1 to 3 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	**Result Name**
313357	Sample Fixed in Formalin? AOE
31942	Fixed Between 6-72 HRS? AOE
86006609	Routine Tissue Processing? AOE
10855	PARAFFIN BLOCK NUMBER: AOE
22496	PRIMARY TUMOR SITE: AOE
10012	QUEST INTERNAL NUMBER:
22548	ESTROGEN RECEPTOR
30165	ER Staining Intensity
31940	ER Interpretation
22549	PROGESTERONE RECEPTOR
30166	PR Staining Intensity
31941	PR Interpretation

ER/PR/DNA/HER2 w/Reflex to HER2 FISH, Paraffin Block	
Clinical Significance	**Estrogen and progesterone receptor assays are routinely performed on breast carcinomas to assess responsiveness to endocrine therapy and prognosis. DNA Analysis is used to estimate tumor aggressiveness and patient prognosis. HER-2 is associated with cellular proliferation activity. Over-expression is observed in 25-30% of women with breast cancer. These patients are potential candidates**

	for monoclonal therapy.
Effective Date	**7/10/2012**
Former Test Name	*ER, PR, DNA CCA, HER-2/neu reflex to FISH, Breast Cancer*
Former Test Code	*1818*
Test Code	**10969**
Specimen Requirements	Formalin-fixed paraffin embedded tissue submitted in IHC specimen kit Alternate: **4 micron unstained sections and 50 micron shavings**
Reject Criteria	**Non-invasive tumors**
Instructions	**Please submit stained H & E slide and a copy of the pathology report. Ship at room temperature.** **Do not place paper labels with adhesive backing on slides. Use pencil or xylene resistant pen to write on the frosted end of the slide only.** **Invasive or metastatic breast cancer** formalin-fixed paraffin embedded tissue **or charged/+slides from formalin-fixed paraffin embedded tissue. Specimen MUST be fixed in 10% neutral buffered formalin. Fixation between 6 and 48 hours is recommended.** Pathology report must accompany paraffin block or slides. **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, pathologic diagnosis, and IHC score, if performed elsewhere. Ship at room temperature. Do not freeze.**
Specimen Stability	Formalin fixed paraffin embedded tissue Room temperature: **Indefinite** Refrigerated: **Indefinite** Frozen: Not Established **4 micron unstained sections and 50 micron shavings** **Room temperature: Indefinite** **Refrigerated: Unacceptable** **Frozen: Unacceptable**
Set-up/Analytic Time	Report available: **7-10 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name	
86007405	Paraffin Block Number:	AOE
86007575	Primary Tumor Site:	AOE
86003734	Quest Internal Number:	
85985745	ESTROGEN RECEPTOR	
85980083	ER Staining Intensity	
86006615	ER Interpretation	
85985747	PROGESTERONE RECEPTOR	
86006696	PR Staining Intensity	
86006616	PR Interpretation	
85986532	DNA INDEX/PLOIDY	

85986533	DNA Prognostic Category	
85986534	S-PHASE FRACTION	
85986535	SPF Prognostic Category	
85980071	Sample fixed in Formalin?	AOE
85980072	Fixed between 6-48 hours?	AOE
86006609	Routine Tissue Processing?	AOE
85985374	Staining Intensity	
85993848	HER2 Overexpression	
9508-2	Reflex HER-2, FISH, Paraffin Block	REFLEX
85985349	HER-2/neu, FISH	

Hepatitis C Viral RNA Genotype, LiPA	
Effective Date	**7/10/2012**
Former Test Code	*7473*
Test Code	**37811**
CPT Codes	87902
Specimen Requirements	2 (0.**6**) mL plasma collected in PPT Potassium EDTA (white top) tube Alternates: Plasma collected in ACD solution B (yellow-top) tube Serum
Reject Criteria	Unspun PPT tube
Instructions	**Plasma:** Collect blood in sterile tubes containing EDTA anticoagulant; either 0.15% solution v/v final EDTA K_3 (standard EDTA tube) or 9 mg spray-dried EDTA K_2 (Plasma Preparation Tube or PPT tube with plasma separator-gel, preferred). Blood collected in tubes containing ACD anticoagulant are acceptable but will yield results approximately 15% lower when compared to EDTA tubes due to the dilution effect of the 1.5 mL of anticoagulant used in the tube. Blood collected in tubes with heparin anticoagulant are unsuitable for this test. Store whole blood at room temperature and separate plasma from cells within 6 hours of collection. Transfer plasma 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 6 hours of collection as before, but it is not necessary to transfer the plasma 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 (SST®) are recommended. Allow blood to clot at room temperature and separate serum from cells within 6 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.
Transport Temperature	Frozen **Do not thaw**
Specimen Stability	Room temperature: 3 hours Refrigerated: 7 days Frozen: 90 days
Set-up/Analytic Time	Set up Mon-Fr9i; Report available: 2-3 days
Reference Range	See Laboratory Report
Always Message	The method used in this test is RT-PCR and reverse hybridization (Line Probe) of the 5' UTR and core region of the HCV genome. This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test. Quest Diagnostics also offers the AccuType(R) IL28B test, which can help stratify HCV-infected individuals into those who are predisposed to respond more favorably and those who are predisposed to respond less favorably to standard HCV therapy. A favorable IL28B genotype (ie, CC) predicts improved treatment response for individuals infected with HCV genotype 1. Reference: Clin Gastroenterol Hepatol. 2011;9:344-350. To order the IL-28B test please submit a new whole blood sample for test code S52417.
Methodology	Multi-Probe Reverse Hybridization
Assay Category	ASR Class I
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 85996222 / HCV Genotype, LiPA

Hepatitis C Viral RNA, Quantitative PCR with Reflex to Genotype, LiPA	
Effective Date	**7/10/2012**
Former Test Name	*HCV RNA, Quantitative PCR w/Reflex Genotype, LIPA*
Former Test Code	*7489*
Test Code	**11348**
Specimen Requirements	5.0 mL **(3.0 mL)** plasma **[x2]** collected in an EDTA (lavender-top) tube Alternate: Plasma collected in a PPT Potassium EDTA (white-top) tube, Serum
Reject Criteria	Unspun PPT tube**, Received room temp,** 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.
Specimen Stability	Plasma: Room temperature: Unacceptable **Refrigerated: 72 hours** Frozen: 6 weeks Serum: **Room temperature: 3 hours** **Refrigerated: 72 hours** Frozen: **90 days**
Set-up/Analytic Time	Set up: **Mon**-Sat; Report available: **7** days

Reference Range	**See Laboratory Report**
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) HCVTest Kit (Roche Molecular Systems, Inc.). If reflexed: The method used in this test is RT-PCR and reverse hybridization (Line Probe) of the 5' UTR and core region of the HCV genome. This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test. Quest Diagnostics also offers the AccuType(R) IL28B test, which can help stratify HCV-infected individuals into those who are predisposed to respond more favorably and those who are predisposed to respond less favorably to standard HCV therapy. A favorable IL28B genotype (ie, CC) predicts improved treatment response for individuals infected with HCV genotype. 1. Reference: Clin Gastroenterol Hepatol. 2011;9:344-350. To order the IL-28B test please submit a new whole blood sample for test code S52417.
Methodology	Real-Time Polymerase Chain Reaction, **Multi-Probe Reverse Hybridization**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name	
55194255	HCV RNA, PCR, Quant	
55194250	HCV RNA, PCR, Quant	
11348-2	Reflex Hepatitis C Viral RNA Genotype, LiPA	Reflex
85996222	HCV Genotype, LiPA	

Leukemia/Lymphoma Evaluation	
Effective Date	**7/10/2012**
Former Test Name	*Leukemia/Lymphoma Evaluation Panel*
Test Code	**35080**
CPT Codes	88184, 88185 (x21), 88189
Specimen Requirements	**10 mL** (3.0 mL) **PERIPHERAL** blood collected in an EDTA (lavender-top) tube Alternate: **Peripheral blood collected in: ACD solution B (yellow-top) or sodium heparin (green-top), Bone marrow, Biopsy, CSF, Pericardial fluid, Pleural fluid, Peritoneal fluid, Cyst fluid, Gastric fluid, Synovial fluid, Viscous fluid, Amniotic fluid, Buffy coat**
Instructions	**Peripheral blood:** One green, yellow, or lavender-top (sodium heparin, ACD-A or EDTA) tube. A minimum of 3 mL is required. The tube must be kept at room temperature and shipped to the lab immediately. Bone marrow: A minimum of 1 mL (with a maximum of 4 mL to prevent hemodilution of bone marrow) submitted in a green, yellow, or lavender-top (sodium heparin, ACD-A or EDTA) tube. The tube must be kept at room temperature and shipped immediately.

	Tissue: Any tissue type is acceptable. Tissue size is dependent upon leukocyte cellularity. (Tissue is disaggregated into single cells so that a minimum of 50,000 cells of interest are harvested.) . Ship tissue in sterile plastic container with RPMI 1640 enriched with FBS (10%FBS RPMI). Absolutely no fixative should be added. Refrigerate and ship immediately. Body fluids: Any body fluid is acceptable. Sample size is dependent upon cellularity of the smaple. Minimum of 50, 000 cells of interest in total volume of fluid. Place fluid in sterile plastic container. Absolutely no fixative should be added. Refrigerate and ship immediately.
Transport Temperature	Peripheral Blood: Room temperature
Specimen Stability	Room temperature: 72 hours Refrigerated: **Call lab** Frozen: **Call lab**
Set-up/Analytic Time	Set up: **7** days a week; Report available: **2-3 days**
Reference Range	See Laboratory Report
Always Message	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.
Methodology	Flow Cytometry
Assay Category	ASR Class I
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	Result Name	
29130	**CLINICAL INFORMATION:**	**AOE**
29131	**SPECIMEN TYPE:**	**AOE**
29132	**VIABILITY:**	
29133	**INTERPRETATION:**	
29134	**SAMPLE DESCRIPTION:**	
29135	**GATING STRATEGY:**	
29136	**MARKERS:**	
29186	**NUMBER OF MARKERS:**	
35080-2	**Leukemia/Lymphoma Evaluation - 1 Additional Marker**	**TEST ADD**
29137	**1 Additional Marker**	
35080-3	**Leukemia/Lymphoma Evaluation - 2 Additional Markers**	**TEST ADD**
29138	**2 Additional Markers**	
35080-4	**Leukemia/Lymphoma Evaluation - 3 Additional Markers**	**TEST ADD**
29139	**3 Additional Markers**	

Additional Information	Includes: CD2, CD3, CD5, CD4, CD7, CD8, CD10, CD11c, CD13, CD19, CD20, CD23, CD33, CD34, CD38, CD56, CD64, CD117, HLADR, Kappa, Lambda, CD45

Discontinued Tests

Allergen-Eel IgE	
Message	Test discontinued due to reagent discontinuation. There is no replacement available.
Effective Date	**6/1/2012**
Test Code	**RF264**

Antiphospholipid Syndrome Evaluation, Expanded	
Message	Suggested replacement tests 1711 Phosphatidylserine IgG, IgM & IgA Autoantibodies and 1771 Phosphatidic Acid Antibodies (IgG, IgA, IgM) and 1791 Phosphatidylethanolamine Antibodies (IgG, IgA, IgM) and 1751 Phosphatidylcholine Antibodies (IgG, IgA, IgM) and 7352 Cardiolipin Antibodies (IgG, IgA, IgM) [7352] and 15780 DRVVT Screen w/Rfl DRVVT Confirm & DRVVT 1:1 Mix
Effective Date	**6/11/2012**
Test Code	**1082**

AFB Suscept: MAI (MAC) by Radiometric Method	
Message	Test discontinued due to manufacturer discontinuance. Suggested replacement test codes 5659 AFB Suscept: MAI Complex (MAC) by Agar Proportion Method or S52393 Mycobacterium Avium Complex MIC Panel.
Effective Date	**7/10/2012**
Test Code	**5651**

Complete Blood Count Without Differential	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5111**

Dengue Virus Total Antibodies	
Message	Suggested replacement test code S49605, Dengue Fever IgM Ab [40410].
Effective Date	**7/10/2012**
Test Code	**7601**

Diagnostic Consultation by AP Specialist	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**1874**

DNA Cell Cycle Analysis, Breast Cancer	
Message	Suggested replacement test code 36158 DNA Cell Cycle Analysis, Paraffin Block
Effective Date	**7/10/2012**
Test Code	**5400**

DNA Cell Cycle Analysis, Products of Conception	
Message	Suggested replacement test code 37127 DNA Cell Cycle Analysis, Hydatidiform Mole, Paraffin Block
Effective Date	**7/10/2012**

Test Code	**5400P**
Tests Affected	**Test Codes:** / **Name:** 5400T / DNA Cell Cycle Analysis, Non-Breast

ER (Estrogen Receptor), Breast Cancer	
Message	Suggested replacement test codes 36160 Estrogen Receptor (ER), IHC with Interpretation or 19197 Estrogen Receptor (ER), IHC without Interpretation
Effective Date	**7/10/2012**
Test Code	**1831**

ER, PR, DNA CCA, HER-2/neu [IHC], Breast Cancer	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**1819**

ER, PR, HER-2/neu [IHC], Breast Cancer	
Message	Suggested replacement tests 7037 ER/PR, Paraffin Block (7037X) and 30316 HER-2, IHC, with Interpretation
Effective Date	**7/10/2012**
Test Code	**1840**

ER, PR, HER-2/neu reflex FISH, Breast Cancer	
Message	Suggested replacement test code 10970 ER/PR/HER2 w/Reflex to HER2 FISH, Paraffin Block
Effective Date	**7/10/2012**
Test Code	**1842**

ER, PR, Ki-67, HER-2/neu reflex to FISH, Breast Cancer	
Message	Suggested replacement tests 10970 ER/PR/HER2 w/Reflex to HER2 FISH, Paraffin Block and 29914 Ki-67, IHC with Interpretation (29914X)
Effective Date	**7/10/2012**
Test Code	**1839**

ER, PR, Ki-67, p53, HER-2/neu w/reflex to FISH, Breast Cancer	
Message	Suggested replacement test codes 10970 ER/PR/HER2 w/Reflex to HER2 FISH, Paraffin Block,and 29914 Ki-67, IHC with Interpretation (29914X),and 36162 p53 Oncoprotein, IHC with Interpretation (36162X)
Effective Date	**7/10/2012**
Test Code	**1833**

ER/PR/HER-2/Ki-67/DNA Cell Cycle Analysis, Breast Cancer	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**

Test Code	**1817**

gp210 IgG Antibodies	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5928**

Hematocrit	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5118**

Hemoglobin	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5116**

Hemoglobin & Hematocrit	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5112**

Hepatitis B Virus Core/Precore Mutant DetectR™	
Message	Suggested replacement test code 10529 Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations
Effective Date	**7/10/2012**
Test Code	**8144**

Hepatitis B Virus Drug Resistance DetectR™	
Message	Suggested replacement test code 10529 Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations
Effective Date	**7/10/2012**
Test Code	**8132**

Hepatitis B Virus GenotypR™	
Message	Suggested replacement test code 10529Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations
Effective Date	**7/10/2012**
Test Code	**8134**

HER-2/neu [IHC] w/reflex FISH, Breast Cancer	
Message	Suggested replacement test code 15547 HER-2, IHC with Reflex to FISH
Effective Date	**7/10/2012**

Test Code	**5846**

HER-2/neu [IHC], Breast Cancer	
Message	Suggested replacement test codes 30316 HER-2, IHC, with Interpretation or 19214 HER-2, IHC, without Interpretation
Effective Date	**7/10/2012**
Test Code	**1846**

HIV-1 Genotyping, PR and RT, Sequencing	
Message	Suggested replacement test code 34949 HIV-1 Genotype
Effective Date	**7/10/2012**
Test Code	**7480**
Tests Affected	**Test Codes:** / **Name:** 7480NY / HIV-1 Genotyping, PR and RT, Sequencing [NY]

HIV-1 RNA Quantitation [Real Time PCR] w/Rfx HIV-1 Genotype	
Message	Suggested replacement test code 34471 HIV-1 RNA, Quantitative PCR w/Reflex to Genotype
Effective Date	**7/10/2012**
Test Code	**7482A**

HIV-1 RNA Quantitative, bDNA, w/Reflex HIV-1 Genotype	
Message	Suggested replacement test code 10596 HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype
Effective Date	**7/10/2012**
Test Code	**7482**

IHC STAIN & INTERPRETATION: CLIENT CHOOSES STAINS	
Message	Test discontinued. To order specific IHC, please refer to website for list of IHC-specific test codes.
Effective Date	**7/10/2012**
Test Code	**1854**

IHC STAIN & INTERPRETATION: PATHOLOGIST CHOOSES 1-12 STAINS	
Message	Test discontinued. To order specific IHC, please refer to website for list of IHC-specific test codes.
Effective Date	**7/10/2012**
Test Code	**1859**

IHC STAIN ONLY: CLIENT CHOOSES STAINS	
Message	Test discontinued. To order specific IHC, please refer to website for list of IHC-specific test codes.
Effective Date	**7/10/2012**
Test Code	**1856**

Ki-67 (MIB-1), Breast Cancer	
Message	Test discontinued. To order specific IHC, please refer to website for list of IHC-specific test codes.
Effective Date	**7/10/2012**
Test Code	**1845**

Pain Management Opiates, Quant, Urine	
Message	*Includes: Codeine, Morphine, Hydrocodone, Hydromorphone*
Effective Date	**7/10/2012**
Test Code	**4644U**
Additional Information	Effective July 10, 2012 all requests for test code 4644U will be replaced by test code 4645U Pain Management Opiates Expanded, Quant, Urine. Includes drug components: Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, Oxymorphone

Pain Mgmt, Opiates, Qn, with medMATCH, U	
Message	*Includes: Codeine, Morphine, Hydrocodone, Hydromorphone*
Effective Date	**7/10/2012**
Test Code	**70236**
Additional Information	Effective July 10, 2012 all requests for test code 70236 will be replaced by test code: • 70237 Pain Mgmt, Opiates Expanded, Qn, with medMATCH, U • Includes drug components: Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, Oxymorphone

Platelet Count	
Message	Test discontinued. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5160**

PR (Progesterone Receptor), Breast Cancer	
Message	Suggested replacement test codes 36159 Progesterone Receptor (PR), IHC with Interpretation or 19261 Progesterone Receptor (PR), IHC without Interpretation
Effective Date	**7/10/2012**
Test Code	**1832**

Reticulocyte Cell Count	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5174**

Reticulocyte Count & Reticulocyte Hemoglobin Content	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5172**

sp100 IgG Antibodies	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	**7/10/2012**
Test Code	**5919**

Herpes Simplex Virus Type 1 IgM [EIA] w/reflex IFA	
Message	Replacement test cope 9429 Herpes Simplex Virus (HSV) 1/2 IgM Ab (EIA) with Reflex to IFA
Effective Date	**7/17/2012**
Test Code	**9456**
Tests Affected	**Test Codes:** 9466 — **Name:** Herpes Simplex Virus Type 2 IgM [EIA] w/reflex IFA

Rapid Plasma Reagin (RPR)	
Message	Suggested replacement test code 799 RPR (Monitor) with Reflex to Titer
Effective Date	**7/17/2012**
Test Code	**2364**

***Chlamydia trachomatis*/*Neisseria gonorrhoeae* [rRNA]**	
Message	Test discontinued due to reagent discontinuation. Suggested replacement test codes 7438SW Chlamydia Trachomatis/N. Gonorrhoeae rRNA Plus [TMA], 2932SW Neisseria Gonorrhoeae rRNA Detection [TMA], 7437SW Chlamydia Trachomatis rRNA DETECTION [TMA], 7440SW Chlamydia Trach/N. Gonorrhoeae rRNA Plus [TMA] W/Rfx Confirm
Effective Date	**8/6/2012**
Test Code	**2927**
Tests Affected	**Test Codes:** 2925, 2930 — **Name:** Chlamydia trachomatis Detection [rRNA]; Neisseria gonorrhoeae Antigen Detection [rRNA]