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 #**
91919	**OncoVantage™**	3/24/2014	3
91995	**Colorectal Cancer, KRAS Mutation, Therascreen®**	4/21/2014	8
91664	***Clostridium difficile* Toxin/GDH with reflex to PCR**	5/5/2014	9
91971	**Amoxicillin, HPLC**	5/5/2014	10
34882	**Fluconazole, HPLC**	5/5/2014	11
91970	**Doxycycline, HPLC**	5/5/2014	11
34973	**Itraconazole, HPLC**	5/5/2014	12
16480	**Posaconazole, HPLC**	5/5/2014	13
19574	**Voriconazole, HPLC**	5/5/2014	14
17180	**17-Hydroxyprogesterone, LC/MS/MS**	5/12/2014	15
568	**Intrinsic Factor Blocking Antibody**	5/12/2014	16
8593	**Lyme Disease Antibodies (IgG, IgM) Immunoblot**	5/12/2014	16
6646	**Lyme Disease Antibody with Reflex to Blot (IgG, IgM)**	5/12/2014	18
36598	**T3, Free, Tracer Dialysis**	5/12/2014	19
35167	**T4, Free, Direct Dialysis**	5/12/2014	20
91998	**Tamoxifen and Metabolites, LC-MS/MS**	5/12/2014	21
14532	**ADAMTS13 Activity with Reflex to Inhibitor**	5/19/2014	22
91121	**Febrile Antibodies Panel**	5/19/2014	23

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 #**
91920		**Diabetes Risk Panel without Score**	5/5/2014	24
1208		Jo-1 IgG Autoantibodies	5/5/2014	24
3943		PTH, Intact and Calcium	5/5/2014	24
S51345		21-Hydroxylase Antibody	5/12/2014	25
A50927		*Rickettsia Conorii* Antibody Panel, IFA	5/12/2014	25
34966	2428	***Bordetella pertussis/parapertussis* Smear, DFA**	5/19/2014	25
5260	2416	*Bordetella pertussis/parapertussis*, Culture	5/19/2014	26
592	S50739	Creatine, 24-Hour Urine	5/19/2014	27
347		Factor VIII Activity, Clotting	5/19/2014	28
37811		**Hepatitis C Viral RNA Genotype, LiPA**	5/19/2014	28

16838	S52240	Histamine Release (Chronic Urticaria)	5/19/2014	29
19865	S52084	HPV Genotypes 16 and 18	5/19/2014	29
17171		HSV-2 Inhibition Study, ELISA	5/19/2014	29
688	2404	***Legionella* Culture**	5/19/2014	30
37357	S52108	***Legionella* Culture, Environmental**	5/19/2014	31
34475	2422	***Legionella pneumophila* Antigen, DFA**	5/19/2014	31
871	2408	***Mycoplasma hominis/Ureaplasma* Culture**	5/19/2014	32
34270	2406	*Mycoplasma pneumoniae* Culture	5/19/2014	33
10269		Protein Electrophoresis, Serum with Total Protein and Reflex to IFE, Serum	5/19/2014	34
16560	S52057	PTH, Intact, Fine Needle Aspirate	5/19/2014	35

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 #
7670	*Clostridium difficile* Toxin A and B, EIA	5/5/2014	35
S44060	Amoxicillin Level, BA	5/5/2014	36
S43490	Doxycycline Level, BA	5/5/2014	36
38226 [1440]	Fetal Fibronectin	5/5/2014	36
1146P	Humoral Immune Evaluation (Pneumo 14) & H. Flu B, Pre/Post	5/5/2014	36
1143P	Humoral Immune Evaluation (Pneumo 14) Pre/Post	5/5/2014	36
1088P	Humoral Immune Evaluation (Pneumo 23) & H. Flu B, Pre/Post	5/5/2014	36
1049P	Humoral Immune Evaluation (Pneumo 23) Pre/Post	5/5/2014	36
1087P	Humoral Immune Evaluation (Pneumo 7) & H. Flu B, Pre/Post	5/5/2014	36
1148P	Humoral Immune Status (Pneumo 14), Pre/Post	5/5/2014	36
1147P	Humoral Immune Status Survey (Pneumo 7), Pre/Post	5/5/2014	37
1047P	Humoral Immuno Evaluation (Pneumo 7), Pre/Post	5/5/2014	37
1149P	Humoral Immuno Status Survey (Pneumo 23), Pre/Post	5/5/2014	37
S51356	Substance P, EIA	5/5/2014	37
8941	*Borrelia burgdorferi* IgG & IgM Antibodies [EIA]	5/12/2014	37
7716	*Borrelia burgdorferi* IgG & IgM Antibodies EIA & Immunoblot	5/12/2014	37
8942	*Borrelia burgdorferi* IgG & IgM Abs w/reflex to Immunoblot + Bands [CDC]	5/12/2014	37
8951	*Borrelia burgdorferi* IgG Antibodies	5/12/2014	38
8947NY	*Borrelia burgdorferi* IgG Antibody with Reflex to IB + Bands [NY]	5/12/2014	38
8961	*Borrelia burgdorferi* IgM Antibodies	5/12/2014	38
8948NY	*Borrelia burgdorferi* IgM Antibody with Reflex IB + Bands [NY]	5/12/2014	38
3190	Hydroxyprogesterone, 17 Alpha	5/12/2014	38

3196	Intrinsic Factor Blocking Autoantibodies	5/12/2014	38
90523 [4168]	Kidney Stone Risk AssessR™	5/12/2014	39
3954	Thyroxine Free, Direct Dialysis	5/12/2014	39
3225	Triiodothyronine Free, Dialysis	5/12/2014	39
2430	*Bordetella pertussis* Culture and DFA	5/19/2014	39
2271	Epstein-Barr Virus Nuclear AG (EBNA) IgM ABS	5/19/2014	39
S50359	Febrile Agglutinins Panel	5/19/2014	39
2432	*Legionella* Culture and Antigen Detection, DFA	5/19/2014	39

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

Test Code	Former Test Code	Test Name	Effective Date	Page #
30333	S48484	Tiagabine, Serum/Plasma	5/5/2014	40
8331X	S49212	Titanium, Serum/Plasma	5/5/2014	40
S50352		ADAMTS13 Activity	5/19/2014	40
61716		**Neuromyelitis Optica (NMO)/Aquaporin-4-IgG Cell-Binding Assay, CSF**	5/19/2014	41
S51106		Neuromyelitis Optica IgG, CSF	5/19/2014	41

New Test Offerings

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

OncoVantage™	
Clinical Significance	**This multiplex panel will allow physicians to choose the most appropriate therapy for their patients based on the alterations found in the individual's tumor sample DNA. Guidelines exist for using results from many of these genes for selection of FDA approved therapies. By testing for other genes the physician can become aware of alternative treatments available to the patient based on presence of mutations in other genes the physicians might not have considered. Additional genes indicate prognosis of those patients with mutations, thus allowing physicians and patients to choose more or less aggressive therapies. Finally, mutations found in additional genes will qualify patients for ongoing or planned clinical trials.**
Effective Date	**3/24/2014**
Test Code	**91919**
CPT Codes	**81210, 81235, 81275, 81321, 81403 (x5), 81404 (x5), 81405 (x2), 81479**
Specimen Requirements	**Preferred:** **Formalin fixed, paraffin embedded tissue block** **Acceptable:** **7 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube** **2 mL (0.5 mL minimum) bone marrow collected in an EDTA (lavender-top) tube** **20 uL (10 uL minimum) Extracted DNA collected in a sterile, plastic microcentrifuge tube** **Cell pellet**
Reject Criteria	**Baked slides; received frozen**
Instructions	**For submission of paraffin block, tumor tissue type and block ID are required on the requisition form.** **A pathology report must be submitted.**

	For whole blood, EDTA specimens, sample type, collection time and date should be entered on tube and requisition form. **Ship immediately to maintain sample stability.**
Transport Temperature	**Room temperature**
Specimen Stability	

Formalin fixed, paraffin embedded tissue block	**Room temperature and Refrigerated: Indefinite** **Frozen: Unacceptable**
Whole blood and bone marrow	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: Unacceptable**
Extracted DNA	**Room temperature: 14 days** **Refrigerated: 90 days** **Frozen: Indefinite**
Cell pellet	**Room temperature and Refrigerated: 30 days** **Frozen: Unacceptable**

Set-up/Analytic Time	**Set up: Fri; Report available: 2 weeks after set up**
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	**Next Generation Sequencing/Ion Torrent Personal Genome Machine**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

OncoVantage(TM) 1

Result Code	Type	Result Name	Unit of Measure
86010176	Prompt-Result	Tumor Tissue Type:	
86007476	Prompt-Result	Block ID:	
85997341	Prompt-Result	Diagnosis:	
86010649	Prompt-Result	Source:	
86010178	Prompt-Result	Stage at Presentation:	
86010179	Prompt-Result	Grade:	
86010236		Overall Interpretation	
86010180		Gene Name #1	
86010181		Mutation #1	
86010182		Alteration Type #1	
86010183		Mutation Frequency #1	% Frequency
86010184		Tumor Type Drugs #1	
86010185		Non-Tumor Type Drugs #1	
86010186		Clinical Trials #1	

OncoVantage(TM) 2

Result Code	Result Name	Unit of Measure

86010187	Gene Name #2	
86010188	Mutation #2	
86010189	Alteration Type #2	
86010190	Mutation Frequency #2	% Frequency
86010191	Tumor Type Drugs #2	
86010192	Non-Tumor Type Drugs #2	
86010193	Clinical Trials #2	
OncoVantage(TM) 3		
Result Code	Result Name	Unit of Measure
86010194	Gene Name #3	
86010195	Mutation #3	
86010196	Alteration Type #3	
86010197	Mutation Frequency #3	% Frequency
86010198	Tumor Type Drugs #3	
86010199	Non-Tumor Type Drugs #3	
86010200	Clinical Trials #3	
OncoVantage(TM) 4		
Result Code	Result Name	Unit of Measure
86010201	Gene Name #4	
86010202	Mutation #4	
86010203	Alteration Type #4	
86010204	Mutation Frequency #4	% Frequency
86010205	Tumor Type Drugs #4	
86010206	Non-Tumor Type Drugs #4	
86010207	Clinical Trials #4	
OncoVantage(TM) 5		
Result Code	Result Name	Unit of Measure
86010208	Gene Name #5	
86010209	Mutation #5	
86010210	Alteration Type #5	
86010211	Mutation Frequency #5	% Frequency
86010212	Tumor Type Drugs #5	
86010213	Non-Tumor Type Drugs #5	
86010214	Clinical Trials #5	
OncoVantage(TM) 6		
Result Code	Result Name	Unit of Measure

86010215	Gene Name #6	
86010216	Mutation #6	
86010217	Alteration Type #6	
86010218	Mutation Frequency #6	% Frequency
86010219	Tumor Type Drugs #6	
86010220	Non-Tumor Type Drugs #6	
86010221	Clinical Trials #6	
OncoVantage(TM) 7		
Result Code	Result Name	Unit of Measure
86010222	Gene Name #7	
86010223	Mutation #7	
86010224	Alteration Type #7	
86010225	Mutation Frequency #7	% Frequency
86010226	Tumor Type Drugs #7	
86010227	Non-Tumor Type Drugs #7	
86010228	Clinical Trials #7	
OncoVantage(TM) 8		
Result Code	Result Name	Unit of Measure
86010229	Gene Name #8	
86010230	Mutation #8	
86010231	Alteration Type #8	
86010232	Mutation Frequency #8	% Frequency
86010233	Tumor Type Drugs #8	
86010234	Non-Tumor Type Drugs #8	
86010235	Clinical Trials #8	
Interacting Mutations		
Result Code	Result Name	
86010237	Interacting Mutations	
86010238	Additional Mutations	
Clinical Impact 1		
Result Code	Result name	
86010242	Gene Function #1	
86010243	Mutation Effect on Gene #1	
86010244	FDA Tumor Drugs #1	
86010336	FDA Non-Tumor Drugs #1	
86010245	Clinical Trials #1	

86010246	Companion Diagnostics #1
Clinical Impact 2	
Result Code	**Result Name**
86010247	Gene Function #2
86010248	Mutation Effect on Gene #2
86010249	FDA Tumor Drugs #2
86010337	FDA Non-Tumor Drugs #2
86010250	Clinical Trials #2
86010251	Companion Diagnostics #2
Clinical Impact 3	
Result Code	**Result Name**
86010252	Gene Function #3
86010253	Mutation Effect on Gene #3
86010254	FDA Tumor Drugs #3
86010338	FDA Non-Tumor Drugs #3
86010255	Clinical Trials #3
86010256	Companion Diagnostics #3
Clinical Impact 4	
Result Code	**Result Name**
86010257	Gene Function #4
86010258	Mutation Effect on Gene #4
86010259	FDA Tumor Drugs #4
86010339	FDA Non-Tumor Drugs #4
86010260	Clinical Trials #4
86010261	Companion Diagnostics #4
Clinical Impact 5	
Result Code	**Result Name**
86010262	Gene Function #5
86010263	Mutation Effect on Gene #5
86010264	FDA Tumor Drugs #5
86010340	FDA Non-Tumor Drugs #5
86010265	Clinical Trials #5
86010266	Companion Diagnostics #5
Clinical Impact 6	
Result Code	**Result Name**
86010267	Gene Function #6

86010268	**Mutation Effect on Gene #6**
86010269	**FDA Tumor Drugs #6**
86010341	**FDA Non-Tumor Drugs #6**
86010270	**Clinical Trials #6**
86010271	**Companion Diagnostics #6**
Clinical Impact 7	
Result Code	**Result Name**
86010272	**Gene Function #7**
86010273	**Mutation Effect on Gene #7**
86010274	**FDA Tumor Drugs #7**
86010342	**FDA Non-Tumor Drugs #7**
86010275	**Clinical Trials #7**
86010276	**Companion Diagnostics #7**
Clinical Impact 8	
Result Code	**Result Name**
86010277	**Gene Function #8**
86010278	**Mutation Effect on Gene #8**
86010279	**FDA Tumor Drugs #8**
86010343	**FDA Non-Tumor Drugs #8**
86010280	**Clinical Trials #8**
86010281	**Companion Diagnostics #8**
Gene Regions Passing QC	
Result Code	**Result Name**
86010241	**Gene Regions Passing QC**
86010240	**Always Statement**
86010239	**Publications**

Colorectal Cancer, KRAS Mutation, Therascreen®	
Clinical Significance	**The Therascreen® KRAS RGQ PCR kit is intended to aid in the identification of colorectal cancer patients for treatment with Erbitux® (cetuximab) based on a KRAS "No mutation detected" test result.**
Effective Date	**4/21/2014**
Test Code	**91995**
CPT Codes	**81275**
Specimen Requirements	**Formalin fixed, paraffin embedded tissue block**
Instructions	**Regular procedure for paraffin-embedded tissue block preparation. If frozen tissue block is received, call 1(800) 642-4657 ext. 2906.**

Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: Indefinite** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Tues; Report available: 4-11 days**
Reference Range	**KRAS Mutation Status**: **No mutation detected** **KRAS Mutation ID**: **No reference range**
Always Message	**The Therascreen® KRAS RGQ PCR test is a FDA approved companion diagnostic for the detection of the following seven somatic mutations: G12A, G12D, G12R, G12C, G12S, G12V, G13D in the human KRAS oncogene.**
Methodology	**Real time PCR-Qiagen Rotor Gene Q MDx**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **86010457** / **KRAS Mutation Status** **86010564** / **KRAS Mutation ID**

***Clostridium difficile* Toxin/GDH with reflex to PCR**	
Clinical Significance	**After treatment with antibiotics, many patients develop gastrointestinal problems ranging from mild diarrhea to severe pseudomembranous colitis. This organism is an opportunistic anaerobic bacterium that grows in the intestine once the normal flora has been altered by the antibiotic. For diagnosis of toxigenic *C. difficile*, current practice guidelines from the CDC recommend confirmation by Nucleic Acid Amplification Testing (NAAT) if the glutamate dehydrogenase of *C. difficile* (GDH) Antigen is positive, and toxin is not detected by Enzyme immunoassay. Additionally, if toxin is detected without the presence of GDH antigen, confirmation by NAAT is also recommended.**
Effective Date	**5/5/2014**
Test Code	**91664**
CPT Codes	**87449, 87324**
Specimen Requirements	**5 grams or 5 mL (1 gram or 1 mL minimum) unformed stool**
Reject Criteria	**Formed stool; stool submitted in transport media or swab; rectal swab; unfrozen stool greater than 72 hours old; received room temperature**
Instructions	**Collect fresh stool in sterile, leak-proof container without media, preservative, or metal ion. For patients requiring the use of diapers, first line the diaper with clean plastic to prevent absorption. Then transfer 5 grams or 5 mL of the stool specimen from the plastic lined diaper to the sterile container. Do not submit the diaper itself. Cap securely. Do not use any preservative, media or additive.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 72 hours** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Daily; Report available: 1-2 days**
Reference Range	**Not detected**
Always Message	**Direct PCR is for use only with liquid or non-formed stools. The clinical significance of toxin positive *C. difficile* in a non-symptomatic individual is not established.**

	Methodology: BD GeneOhm(TM) C. difficile Toxin B Gene (tcdB) Real-time PCR Qualitative Assay.
Methodology	**Immunoassay**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**GDH Antigen, Toxin A and B** **Result Code** / **Result Name** **86009745** / **GDH Antigen** **86009746** / **Toxin A and B** **This is a true reflex. Please build the unit code below separately** **Non-orderable Reflex: RRL Clostridium difficile Toxin B, Qualitative Real-time PCR** **Result Code** / **Result Name** **86006267** / **C difficile, QL PCR**
Additional Information	**If the GDH Antigen is detected and the Toxin A and B are not detected or the GDH Antigen is not detected and the Toxin A and B are detected, RRL- *Clostridium difficile* Toxin B, Qualitative Real Time PCR will be performed at an additional charge. (CPT code(s): 87493)** **New recommendations per the American Society for Microbiology recommend that screening assays for *C. difficile* toxin be combined with GDH antigen, with discordant results being confirmed by Nucleic Acid Amplification testing.**

Amoxicillin, HPLC	
Clinical Significance	**The concentration of antimicrobial agents in body fluids, most notably serum or plasma, are used to regulate therapy to ensure effective dosing (especially with oral agents where GI absorption is in question), to monitor accumulation to help minimize toxicity, and to help evaluate the pharmacokinetics of new agents. Both peak and trough levels obtained immediately after dosing or immediately prior to new dosing, respectively, may be monitored.**
Effective Date	**5/5/2014**
Test Code	**91971**
CPT Codes	**80299**
Specimen Requirements	**1 mL (0.5 mL minimum) serum collected in a red-top tube (no gel)**
Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Instructions	**Specimens collected just before or within 15 minutes of the next antibiotic dose represent the trough level. Specimens obtained within 15-30 minutes after the end of IV infusion, or 45-60 minutes after an IM injection, or 90 minutes after oral intake represent the peak level.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated and Frozen: 14 days**
Set-up/Analytic Time	**Set up: Wed, Sat; Report available: 1-5 days**
Reference Range	**<0.1 mcg/mL**
Always Message	**Average peak levels (1-2 hours post oral dosing)** **250 mg: 3.5-5.5 mcg/mL** **400 mg: 5.9 mcg/mL** **500 mg: 5.5-7.5 mcg/mL** **This assay tests amoxicillin alone since concentrations are equivalent for amoxicillin alone or amoxicillin clavulanate levels. This assay does not detect clavulanate levels.**

	This test 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.
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
86010357	Amoxicillin, HPLC	mcg/mL

Fluconazole, HPLC	
Clinical Significance	**Fluconazole is commonly used in the treatment of various types of fungal infections. Due to the fact it is readily soluble in water it can be administered in relatively large amounts to patients. Measurement of serum drug levels may be helpful to optimize drug dosing regimens, particularly where there is non-compliance, concern about drug interactions, pharmacokinetic variability or suspected toxicity.**
Effective Date	**5/5/2014**
Test Code	**34882**
CPT Codes	**80299**
Specimen Requirements	**2 mL (1 mL minimum) serum collected in a red-top tube (no gel)**
Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 1-3 days**
Reference Range	**<0.5 mcg/mL**
Always Message	**Pharmacokinetics are similar after IV or oral administration.** **Adult, Peak (mean)** **Single 400 mg oral dose, 1-2 hr:** **4.1 to 8.1 mcg/mL** **Pediatric, Peak (mean)** **Single oral dose, 9 mo. to 13 yrs.** **2 mg/kg: 2.9 mcg/mL** **8 mg/kg: 9.8 mcg/mL** **Multiple IV doses, 5 to 15 yrs.** **2 mg/kg: 5.5 mcg/mL** **8 mg/kg: 14.1 mcg/mL** **This test 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.**
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
85976430	Fluconazole, HPLC	mcg/mL

Doxycycline, HPLC	
Clinical Significance	**The concentration of antimicrobial agents in body fluids, most notably serum or plasma, are used to regulate therapy to ensure effective dosing (especially with oral agents where GI absorption is in question), to monitor accumulation to help minimize toxicity, and to help evaluate the pharmacokinetics of new agents. Both peak and trough levels obtained immediately after dosing or immediately prior to new dosing, respectively, may be monitored.**
Effective Date	**5/5/2014**
Test Code	**91970**
CPT Codes	**80299**
Specimen Requirements	**1 mL (0.5 mL minimum) serum collected in a red-top tube (no gel)**
Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Instructions	**Specimens collected just before or within 15 minutes of the next antibiotic dose represent the trough level. Specimens obtained within 15-30 minutes after the end of IV infusion, or 45-60 minutes after an IM injection, or 90 minutes after oral intake represent the peak level.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Wed, Sat; Report available: 1-5 days**
Reference Range	**<0.1 mcg/mL**
Always Message	**Peak serum level (mean)** **200 mg dose: 2.7-4.5 mcg/mL** **Trough serum level (mean)** **200 mg dose: 12 hours post dose: 1.6 mcg/mL** **This test 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.**
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
86010356	Doxycycline, HPLC	mcg/mL

Itraconazole, HPLC	
Clinical Significance	**The antifungal drug itraconazole is active in the treatment of aspergillosis, blastomycosis, histoplasmosis, sporotrichosis, and onychomycosis. It is a protein-bound drug and thus has negligible CSF penetration. It may also be utilized in the treatment of systemic candidiasis and cryptococcosis, especially when other drugs are contraindicated or ineffective. The chronic nature of fungal infections demands constant monitoring of itraconazole levels within a patient to ensure that adequate therapeutic levels of the drug are administered, absorbed and subsequently excreted.**
Effective Date	**5/5/2014**
Test Code	**34973**
CPT Codes	**80299**
Specimen Requirements	**2 mL (1 mL minimum) serum collected in a red-top tube (no gel)**

Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 1-3 days**
Reference Range	**<0.05 mcg/mL**
Always Message	**Results are expressed in mcg/mL.** **Itraconazole is metabolized in humans to hydroxyitraconazole, a bioactive metabolite. Both itraconazole and hydroxyitraconazole levels are determined and reported. Levels may vary based on route and regimen of dosing (IV and Oral).** **200 mg dosing steady state ranges:** **IV, 7 days:** **Itraconazole: 1.0-4.8 mcg/mL** **Hydroxyitraconazole: 1.3-2.5 mcg/mL** **Oral, 36 days:** **Itraconazole: 0.6-3.4 mcg/mL** **Hydroxyitraconazole: 0.9-4.3 mcg/mL** **This test 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.**
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
85986920	Itraconazole, HPLC	mcg/mL
85986921	Hydroxyitraconazole, HPLC	mcg/mL

Posaconazole, HPLC	
Clinical Significance	**The antifungal drug posaconazole is indicated for prophylaxis of invasive aspergillus and candida infections in severely immunocompromised patients. It may also be used in the treatment of oropharyngeal candidiasis refractory to itraconazole and fluconazole. The chronic nature of fungal infections demands constant monitoring of posaconazole levels within a patient to ensure that adequate therapeutic levels of the drug are administered, absorbed and subsequently excreted.**
Effective Date	**5/5/2014**
Test Code	**16480**
CPT Codes	**80299**
Specimen Requirements	**2 mL (1 mL minimum) serum collected in a red-top tube (no gel)**
Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 14 days** **Frozen: 30 days**

Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 1-3 days**
Reference Range	**<0.02 mcg/mL**
Always Message	**Patient conditions such as underlying illness and nutritional status (fat intake) at the time of dosing may affect peak bloodstream concentration ranges (oral dosing):** **Serum Level Ranges:** **Single 200 mg dose, fasting: 0.05-0.27 mcg/mL** **Single 200 mg dose, high fat: 0.24-1.02 mcg/mL** **Steady state, 200 mg TID: 0.02-3.65 mcg/mL** **This test 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.**
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86006683** / **Posaconazole, HPLC** / **mcg/mL**

Voriconazole, HPLC	
Clinical Significance	**The antifungal drug voriconazole is commonly used in the treatment of various types of fungal infections. An increased fungal resistance to similar drugs of greater toxicity has promoted the use of voriconazole in treating infections caused by aspergillus and other fungal species. The chronic nature of fungal infections demands constant monitoring of voriconazole levels within a patient to ensure that adequate therapeutic levels of the drug are administered, absorbed and subsequently excreted.**
Effective Date	**5/5/2014**
Test Code	**19574**
CPT Codes	**80299**
Specimen Requirements	**Preferred:** **2 mL (1 mL minimum) serum collected in a red-top tube (no gel)** **Acceptable:** **2 mL (1 mL minimum) plasma collected in a Sodium Heparin (green-top) tube or 1 mL (1 mL minimum) CSF collected in a sterile screw cap container**
Reject Criteria	**Serum separator tubes; other body fluids; other specimen types**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature and Refrigerated: 5 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**<0.1 mcg/mL**
Always Message	**Steady state trough levels are achieved within 1 day when an IV loading dose is used and after approximately 5 days of oral or IV therapy without a loading dose.** **Targeted blood levels:** **Prophylaxis: trough >0.5 mcg/mL** **Therapy: trough >1.0 to 2.0 mcg/mL** **Safety: trough <5.5 mcg/mL** **Serum trough levels less than or equal to 1 mcg/mL are reported to be associated with lack of therapeutic response and serum trough levels >5.5 mcg/mL have been reported to be associated with**

	reversible neurological adverse events and hepatotoxicity. **Co-administration of drugs that metabolically induce or inhibit CYP2C19, or other conditions that affect CYP2C19 may alter voriconazole metabolism.** **This test 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.**
Methodology	**High Performance Liquid Chromatography**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86002228** / **Voriconazole, HPLC** / **mcg/mL**

17-Hydroxyprogesterone, LC/MS/MS	
Clinical Significance	**17-hydroxyprogesterone is elevated in patients with congenital adrenal hyperplasia (CAH). CAH is a group of autosomal recessive diseases characterized by a deficiency of cortisol and an excess of ACTH concentration. 17-hydroxyprogesterone is also useful in monitoring cortisol replacement therapy and in evaluating infertility and adrenal and ovarian neoplasms.**
Effective Date	**5/12/2014**
Test Code	**17180**
CPT Codes	**83498**
Specimen Requirements	**0.5 mL (0.25 mL minimum) serum collected in red-top (no gel) tube** **Acceptable:** **0.5 mL (0.25 mL minimum) plasma collected in an EDTA (lavender-top), or Heparin (green-top) tube**
Reject Criteria	**Samples collected in SST tubes**
Instructions	**SST tubes are unacceptable. Draw blood in a red-top tube (no gel). Separate serum after clotting. Ship serum refrigerated or frozen. Do not submit glass tubes.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 7 days** **Frozen: 2 years**
Set-up/Analytic Time	**Set up: Sun-Fri; Report available: 3 days**
Always Message	**Adult Reference Ranges for** **17-Hydroxyprogesterone, LC/MS/MS:** **Males:** **18-30 years: 32-307 ng/dL** **31-40 years: 42-196 ng/dL** **41-50 years: 33-195 ng/dL** **51-60 years: 37-129 ng/dL** **Females:** **Follicular Phase: < or = 185 ng/dL** **Luteal Phase: < or = 285 ng/dL** **Postmenopausal Phase: < or = 45 ng/dL** **Pregnancy:** **First Trimester: 78-457 ng/dL** **Second Trimester: 90-357 ng/dL** **Third Trimester: 144-578 ng/dL**

	Pediatric Reference Ranges for 17-Hydroxyprogesterone, LC/MS/MS: **1-12 months**: 11-170 ng/dL** **1-4 years**: 4-115 ng/dL** **5-9 years: 90 ng/dL or less** **10-13 years: 169 ng/dL or less** **14-17 years: 16-283 ng/dL** **Premature Infants: < or = 360 ng/dL (31-35 weeks)**** **Term Infants: < or = 420 ng/dL (3 days)**** **Tanner Stages**:** **II-III Males: 12-130 ng/dL** **II-III Females: 18-220 ng/dL** **IV-V Males: 51-190 ng/dL** **IV-V Females: 36-200 ng/dL** ****Includes data from J Clin Endocrinol Metab. 1991; 73:674-686; J Clin Endocrinol Metab. 1989; 69:1133-1136; and J Clin Endocrinol Metab. 1994; 78:266-270.**
Methodology	**Liquid Chromatography Tandem Mass Spectrometry**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86000324** / **17-OHProgesterone, LC/MS/MS** / **ng/dL**

Intrinsic Factor Blocking Antibody	
Clinical Significance	**Intrinsic Factor, produced by cells lining the stomach, binds vitamin B12 (cyanocobalamin) to facilitate absorption of the vitamin. Blocking antibody impedes the action of Intrinsic Factor as observed in approximately half of the patients who develop pernicious anemia.**
Effective Date	**5/12/2014**
Test Code	**568**
CPT Codes	**86340**
Specimen Requirements	**1 mL (0.3 mL minimum) serum**
Instructions	**Samples should not be collected from a patient who has received vitamin B12 injection therapy within the past week.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 28 days**
Set-up/Analytic Time	**Set up: Sun, Tue, Thu; Report available: 3-6 days**
Reference Range	**ADULTS: NEGATIVE**
Methodology	**Immunoassay**

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

Result Code	Result Name
85986180	Intrinsic Factor Block Ab

Lyme Disease Antibodies (IgG, IgM) Immunoblot	
Clinical Significance	**Lyme disease is transmitted by a tick vector carrying *Borrelia burgdorferi*. Immunoblot testing qualitatively examines, with high specificity, antibodies in a patient's specimen. Immunoblot testing is appropriate for confirming a detected EIA or IFA test result.**
Effective Date	**5/12/2014**
Test Code	**8593**
CPT Codes	**86617 (x2)**
Specimen Requirements	**1 mL (0.5 mL minimum) serum**
Reject Criteria	**Gross hemolysis; gross lipemia**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days**
Set-up/Analytic Time	**Set up: Daily; Report available: 1-3 days**
Reference Range	**Negative**
Always Message	**As per CDC criteria, a Lyme disease IgG immunoblot must show reactivity to at least 5 to 10 specific borrelial proteins to be considered positive; similarly, a positive Lyme disease IgM immunoblot requires reactivity to 2 of 3 specific borrelial proteins. Although considered negative, IgG reactivity to fewer specific borrelial proteins or IgM reactivity to only 1 protein may indicate recent *B. burgdorferi* infection and warrant testing of a later sample. A positive IgM but negative IgG result obtained more than a month after onset of symptoms likely represents a false-positive IgM result rather than acute Lyme disease. In rare instances, Lyme disease immunoblot reactivity may represent antibodies induced by exposure to other spirochetes.**
Methodology	**Immunoblot**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name
45059500	Lyme Disease Ab (IgG), Blot
45059600	18 kD (IgG) Band
45059700	23 kD (IgG) Band
45059800	28 kD (IgG) Band
45059900	30 kD (IgG) Band
45061300	39 kD (IgG) Band
45061400	41 kD (IgG) Band
45060500	45 kD (IgG) Band
45060600	58 kD (IgG) Band
45060700	66 kD (IgG) Band

45060800	**93 kD (IgG) Band**
45060900	**Lyme Disease Ab (IgM), Blot**
45061500	**23 kD (IgM) Band**
45061600	**39 kD (IgM) Band**
45061200	**41 kD (IgM) Band**

Lyme Disease Antibody with Reflex to Blot (IgG, IgM)	
Clinical Significance	**Lyme disease is caused by a bacterium *Borrelia burgdorferi* and is transmitted by ticks. EIA is the screening test with high sensitivity for antibody detection. Immunoblot testing qualitatively examines with high specificity antibodies in a patient's specimen. Immunoblot testing is appropriate for confirming a detected EIA test result.**
Effective Date	**5/12/2014**
Test Code	**6646**
CPT Codes	**86618**
Specimen Requirements	**1 mL (0.5 mL minimum) serum**
Reject Criteria	**Gross hemolysis; gross lipemia**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: daily; Report available: 1-3 days**
Reference Range	**< or = 0.90**
Always Message	**Reference Range:** **< or = 0.90 Negative** **0.91 - 1.09 Equivocal** **> or = 1.10 Positive** **The use of purified V1sE-1 and PepC10 antigens in this assay provides improved specificity compared to assays that utilize whole cell lysates of *B. burgdorferi,* the causative agent of Lyme disease, and slightly better sensitivity compared to the C6 antibody assay.** **As recommended by the Food and Drug Administration (FDA), all samples with positive or equivocal results in a *Borrelia burgdorferi* antibody EIA (screening) will be tested using a blot method. Positive or equivocal screening test results should not be interpreted as truly positive until verified as such using a supplemental assay (e.g. *B. burgdorferi* blot).** **The screening test and/or blot for *B. burgdorferi* antibodies may be falsely negative in early stages of Lyme disease, including the period when erythema migrans is apparent.**
Methodology	**Immunoassay and Immunoblot**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	**Result Name**
45054600	**Lyme Antibody Screen**
This test is a true reflex. Please build the unit code below separately. ***Non-orderable Reflex RRN-Lyme Disease Antibodies (IgG, IgM)***	
Result Code	**Result Name**

	45059500 — **Lyme Disease Ab (IgG), Blot** **45059600** — **18 kD (IgG) Band** **45059700** — **23 kD (IgG) Band** **45059800** — **28 kD (IgG) Band** **45059900** — **30 kD (IgG) Band** **45061300** — **39 kD (IgG) Band** **45061400** — **41 kD (IgG) Band** **45060500** — **45 kD (IgG) Band** **45060600** — **58 kD (IgG) Band** **45060700** — **66 kD (IgG) Band** **45060800** — **93 kD (IgG) Band** **45060900** — **Lyme Disease Ab (IgM), Blot** **45061500** — **23 kD (IgM) Band** **45061600** — **39 kD (IgM) Band** **45061200** — **41 kD (IgM) Band**
Additional Information	**If Lyme Ab Screen is "Equivocal" or "Positive" then the Lyme Disease Antibodies (IgG, IgM) by Immunoblot will be performed at an additional charge (CPT code(s): 86617 (x2)).**

T3, Free, Tracer Dialysis	
Clinical Significance	**T3 measurements are used to diagnose hyperthyroidism. This test can also be used to clarify thyroid status in the presence of possible protein-binding abnormalities.**
Effective Date	**5/12/2014**
Test Code	**36598**
CPT Codes	**84481; 84480**
Specimen Requirements	**1 mL (0.5 mL minimum) serum**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 7 days** **Frozen: 28 days**
Set-up/Analytic Time	**Set up: Sun-Thu; Report available: 4-7 days**
Always Message	**Adult Reference Range for T3, Free, Tracer Dialysis:** **210-440 pg/dL** **Pregnancy Reference Ranges for Free T3:** **200-380 pg/dL (all trimesters)** **Pediatric Reference Range for T3, Free, Tracer Dialysis:** **1-9 years: 282-518 pg/dL** **10-13 years: 286-556 pg/dL** **14-17 years: 242-501 pg/dL** **T3, Total:** **Reference Ranges for T3, Total:**

	<4 years: Reference Range Not Established **4-9 years: 104-190 ng/dL** **10-13 years: 94-213 ng/dL** **14-17 years: 84-179 ng/dL** **> or = 18 years: 76-181 ng/dL**
Methodology	**Equilibrium Dialysis by RIA, Immunochemiluminescence**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name	Unit of Measure
85990760	Free T3	pg/dL
55080300	T3, Total	ng/dL

T4, Free, Direct Dialysis	
Clinical Significance	**Free T4 by equilibrium dialysis is the most accurate measure of Free T4. Results are independent of the concentration of the T4-binding proteins, the presence of molecular variants of these proteins, or circulating autoantibodies. Free T4 is useful in the distinguishing euthyroidism from thyroid disease.**
Effective Date	**5/12/2014**
Test Code	**35167**
CPT Codes	**84439**
Specimen Requirements	**2 mL (0.5 mL mimimum) serum**
Instructions	**Fasting preferred**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 28 days**
Set-up/Analytic Time	**Set up: Sun-Thu; Report available: 4-7 days**
Always Message	**T4, Free Direct Dialysis:** **Reference Ranges for T4, Free, Direct Dialysis:** **Premature, 25-30 Weeks,** **Birth - 7 Days 0.5-3.3 ng/dL** **Premature, 31-36 Weeks,** **Birth - 7 Days 1.3-4.7 ng/dL** **Cord Blood, >37 Weeks 1.2-2.2 ng/dL** **Birth - 4 Days 2.2-5.3 ng/dL** **2 Weeks - 2 Years 0.8-2.0 ng/dL** **3-20 Years 1.0-2.4 ng/dL** **21-87 Years 0.8-2.7 ng/dL** **Pregnancy:** **First Trimester: 0.9-2.0 ng/dL** **Second Trimester: 0.8-1.5 ng/dL** **Third Trimester: 0.8-1.7 ng/dL** **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	**Direct Equilibrium Dialysis, Radioimmunoassay**

Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name	Unit of Measure
85986270	T4, Free Direct Dialysis	ng/dL

Tamoxifen and Metabolites, LC-MS/MS	
Clinical Significance	**Tamoxifen is a prodrug and undergoes biotransformation into a series of metabolites. N-desmethyl tamoxifen is the most abundant metabolite. 4-Hydroxy tamoxifen and N-desmethyl-4-hydroxy tamoxifen (endoxifen) are the most potent metabolites. Studies have shown that genetic variations in the CYP2D6 enzymes influence endoxifen levels. Due to this variability, monitoring endoxifen levels and phase one metabolite rather than CYP2D6 genotype testing is suggested to be a better approach for monitoring tamoxifen therapy.**
Effective Date	**5/12/2014**
Test Code	**91998**
CPT Codes	**83789**
Specimen Requirements	**0.5 mL (0.3 mL minimum) serum collected in red-top tube (no gel)**
Reject Criteria	**Plasma; serum separator tube; hemolysis**
Instructions	**Collect blood in a red-top vacutainer tube. Allow blood to clot (10-15 minutes) at room temperature before centrifugation. Separate serum from cells into a standard 13x100 mm tube.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 1 year**
Set-up/Analytic Time	**Set up: Wed, Fri; Report available: 2-5 days**
Reference Range	

Endoxifen:	**0.93-43.19 ng/mL**
Tamoxifen:	**12.54-233.07 ng/mL**
N-Desmethyl Tamoxifen:	**2.59-373.96 ng/mL**
4-Hydroxy Tamoxifen:	**0.24-5.05 ng/mL**
N-Desmethyl-4'-Hydroxy Tam:	**1.17-19.95 ng/mL**
4'-Hydroxy Tamoxifen:	**0.40-6.33 ng/mL**

Always Message	**The clinical interpretation of the quantitation of Tamoxifen and its metabolites is not yet fully established. The assay shows good agreement with published data from a clinical trial [1]. That study showed that women in the lowest quintile of values for Endoxifen had a 26% greater chance of recurrence than those in the upper 80% of values. Therefore we have used that quintile threshold for interpretation of results for this assay.** 1. **Tamoxifen metabolite concentrations, CYP2D6 genotype, and breast cancer outcomes., Madlensky L, Natarajan L, Tchu S et al., Clin PharmacolTher. 2011 May;89(5):718-25**
Methodology	**Liquid Chromatography Tandem Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings

Result Code	Type	Result Name	Unit of Measure
86010466	Prompt-Result	Menopausal Status	
86010467		Interpretation	
86010468		Endoxifen	ng/mL
86010469		Tamoxifen	ng/mL
86010470		N-Desmethyl Tamoxifen	ng/mL
86010471		4-Hydroxy Tamoxifen	ng/mL
86010472		N-Desmethyl-4'-Hydroxy Tam	ng/mL
86010473		4'-Hydroxy Tamoxifen	ng/mL
86010474		Always Comment	

ADAMTS13 Activity with Reflex to Inhibitor	
Clinical Significance	**ADAMTS-13 is a zinc metalloprotease that cleaves ultra large vWF multimers. Studies have shown that low levels of ADAMTS-13 activity are associated with thrombotic thrombocytopenic purpura (TTP), a life-threatening hematological condition characterized by low platelet count, microvascular thrombi, red cell fragmentation, and renal complications. Congenital TTP is a rare inherited disease caused by mutations within the ADAMTS-13 gene, which result in the production of non-functional protein. The acquired form of TTP is an autoimmune-like disorder caused by the development of autoantibodies to ADAMTS-13 that inhibits enzyme activity.**
Effective Date	**5/19/2014**
Test Code	**14532**
CPT Codes	**85397**
Specimen Requirements	**1 mL (0.5 mL minimum) plasma collected in 3.2% sodium citrate (light blue-top) tube**
Reject Criteria	**EDTA plasma**
Instructions	**Platelet Poor Plasma: Centrifuge light blue-top tube 15 minutes at approx. 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial.** **Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcl). Freeze immediately and ship on dry ice.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature and Refrigerated: Unacceptable** **Frozen -20° C: 21 days Frozen -70° C: 6 months**
Set-up/Analytic Time	**Set up: Sun, Tue, Thu; Report available: 4-7 days**
Reference Range	**ADAMTS13 Activity: 68-163 % Activity** **ADAMTS13 Inhibitor: <0.4 BEU**
Always Message	**Activity levels below 10% are seen in acquired and hereditary thrombotic thrombocytopenic purpura (TTP). Not all patients with TTP will exhibit low levels of ADAMTS13 activity with this assay, i.e., post bone marrow transplantation, drug-induced TTP, and mutations of ADAMTS13 at the CUB domain.** **Recent plasma exchange or immunosuppressive therapy may raise the observed activity levels. Mild decreases in ADAMTS13 activity are seen in a wide variety of conditions including metastatic cancer, neonates, serious infections and cirrhosis of the liver.** **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. **For more information on this test, go to: http://education.questdiagnostics.com/faq/FAQ112**
Methodology	**Immunoassay**
Assay Category	**Research Use Only**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**14532-1-ADAMTS13 Activity** **Result Code** / **Result Name** / **Unit of Measure** **85996860** / **ADAMTS13 Activity** / **% Activity** **This is a true reflex. Please build the unit code below separately** **Non-orderable Reflex 14532-2-ADAMTS13 Inhibitor** **Result Code** / **Result Name** / **Unit of Measure** **85996861** / **ADAMTS13 Inhibitor** / **BEU**
Additional Information	**If the ADAMTS13 Activity result is < or = 40%, then ADAMTS13 Inhibitor will be performed at an additional charge. (CPT code(s): 85335)**

Febrile Antibodies Panel	
Effective Date	**5/19/2014**
Test Code	**91121**
CPT Codes	**86768 (x5), 86757 (x4), 86622 (x2)**
Specimen Requirements	**3 mL (0.8 mL minimum) serum**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**
Methodology	**Immunoassay**
Performing Site	**Focus Diagnostics, Inc.**
CPU Mappings	10582 (10582X) {10582N} [3097]-Salmonella, Total Antibody, EIA (40450) **Result Code** / **Result Name** **86003281** / **Salmonella H, type a** **86003282** / **Salmonella H, type b** **86003283** / **Salmonella H, type d** **86003284** / **Salmonella O, type Vi** **86003285** / **Salmonella O, type D** **6419-Rickettsia (RMSF) Antibodies (IgG, IgM) with Reflex to Titers** **Result Code** / **Result Name** **70025900** / **RMSF IgG**

	70035700 — **RMSF IgM**
	37503-Rickettsia (Typhus Fever) Antibodies (IgG, IgM) with Reflex to Titers
	Result Code — **Result Name**
	70026000 — **R. typhi IgG**
	70026040 — **R. typhi IgM**
	91068-Brucella Antibodies (IgG, IgM), EIA with Reflex to Agglutination
	Result Code — **Result Name**
	86008608 — **Brucella IgG**
	86008609 — **Brucella IgM**
Additional Information	**If RMSF IgG is Detected, then RMSF IgG Titer will be performed at an additional charge (CPT code: 86757). If RMSF IgM is Detected, then RMSF IgM Titer will be performed at an additional charge (CPT code: 86757). If R. typhi IgG is Detected, then R. typhi IgG Titer will be performed at an additional charge (CPT code: 86757). If R. typhi IgM is Detected, then R. typhi IgM Titer will be performed at an additional charge (CPT code: 86757). If Brucella IgM result is > or = 1.10, then Brucella Antibody, Agglutination will be performed at an additional charge (CPT code: 86622)**

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.*

Diabetes Risk Panel without Score	
Effective Date	**5/5/2014**
Former Test Name	*Diabetes Risk Assessment*
Test Code	91920
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Jo-1 IgG Autoantibodies	
Effective Date	**5/5/2014**
Test Code	1208
Assay Category	**FDA Approved/Cleared**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** — **Name:** 1004 — Rheumatic Evaluation RMU — Reflex Analyzer 3242 — Myositis AssessR(TM) Plus Jo-1 Autoantibodies

<table>
<tr><th colspan="2">PTH, Intact and Calcium</th></tr>
<tr><td>Effective Date</td><td>5/5/2014</td></tr>
<tr><td>Test Code</td><td>3943</td></tr>
<tr><td>Reject Criteria</td><td>Plasma; received room temperature; received refrigerated</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature and refrigerated: Unacceptable
Frozen: 6 Months</td></tr>
<tr><td>Reference Range</td><td>
<table>
<tr><th colspan="2">Intact PTH</th></tr>
<tr><td><6 Years</td><td>Not established</td></tr>
<tr><td>6-9 Years</td><td>9-59 pg/mL</td></tr>
<tr><td>10-13 Years</td><td>11-74 pg/mL</td></tr>
<tr><td>14-17 Years</td><td>9-69 pg/mL</td></tr>
<tr><td>> or = 18 Years</td><td>14-64 pg/mL</td></tr>
</table>
</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, Valencia</td></tr>
<tr><td>Additional Information</td><td>Effective 5/5/14, Quest Diagnostics will replace the Siemens Immulite intact PTH assay with the Beckman Coulter intact PTH assay. Compared to the previous (Immulite) assay, the Beckman Coulter PTH assay generally gives similar values in the healthy subject range, but may run lower at very high levels of PTH. For patients whose PTH levels are being followed serially over time, a rebaselining code (test code 92110) is available to allow comparison of new and previous PTH assay results. This rebaseline code will be available from 5/6/2014 - 7/7/2014. This profile will include order code 3943 - intact PTH with Calcium (at regular price) plus an intact PTH measurement from the old Immulite method (at no additional charge).</td></tr>
<tr><td>Tests Affected</td><td>
<table>
<tr><th>Test Codes:</th><th>Name:</th></tr>
<tr><td>3941</td><td>PTH, Intact (Without Calcium)</td></tr>
<tr><td>3942</td><td>PTH Scattergraph (PTH Intact Incl Total Calcium)</td></tr>
<tr><td>3944</td><td>PTH, Intact, Including Ionized & Total Calcium</td></tr>
<tr><td>3943SR</td><td>PTH, Intact, Including Total Calcium w/Serial Reporting</td></tr>
</table>
</td></tr>
</table>

21-Hydroxylase Antibody	
Effective Date	**5/12/2014**
Test Code	S51345
Specimen Requirements	1 mL **(0.5 mL minimum)** serum
Reject Criteria	**Gross hemolysis; gross lipemia; gross icterus**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 28 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

***Rickettsia Conorii* Antibody Panel, IFA**

Effective Date	**5/12/2014**
Test Code	A50927
Transport Temperature	**Room temperature**
Specimen Stability	Room temperature: 7 days **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	Set up: Mon-Fri**; Report available: 1-4 days**
Performing Site	Focus Diagnostics, Inc.

***Bordetella pertussis/parapertussis* Smear, DFA**	
Clinical Significance	***Bordetella pertussis* is the cause of whooping cough. *Bordetella parapertussis* is a related organism and causes a similar but milder disease.**
Effective Date	**5/19/2014**
Former Test Name	*Bordetella pertussis/parapertussis Ag Detection*
Former Test Code	*2428*
Test Code	**34966**
Specimen Requirements	**Preferred:** **Nasopharyngeal swab collected in ESwab Mini-tip transport system (blue-cap)** **Acceptable:** **Nasopharyngeal swab or nasal aspirates collected in Amies or Stuart liquid bacterial transport system or 2 air-dried slides** **Remove all other specimen types and collection containers**
Reject Criteria	**Single slides will only have *B. pertussis* performed; broken slides; transport media containing charcoal**
Instructions	**Preferred specimen is nasopharyngeal swab collected in ESwab Mini-tip transport system (blue-cap). Mini-tip swabs with flexible shafts must be used to obtain nasopharyngeal specimens. Alternatively, two (2) air-dried slides with one or two smears on each, prepared from a nasopharyngeal swab or aspirate, packaged in slide carrier is acceptable. Single slides will only be stained for *B. pertussis*. Amies or Stuart transport without charcoal can also be used. Note that Amies or Stuart are not acceptable for culture. Transport temperature refrigerated (Cold-Pak) is preferred.**
Transport Temperature	**Nasopharyngeal slide:** — **Room temperature** **Nasopharyngeal swab:** — **Refrigerated**
Specimen Stability	**ESwab:** — **Room temperature: Unacceptable; Refrigerated: 4 days; Frozen: Unacceptable** **Swab:** — **Room temperature and Refrigerated: 48 hours; Frozen: Unacceptable** **Slides:** — **Room temperature and Refrigerated: 7 days; Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-4 days**
Reference Range	**Not detected**

Methodology	**Direct Immunofluorescence Assay (DFA)**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**SJC Reporting Title: B.PERTUSSIS/PARAPERTUSSISDFA** **Result Code** / **Type** / **Result Name** **86007404** / **Prompt-Result** / **Specimen Source:** **85991617** / / **B. pertussis, DFA** **85991618** / / **B. parapertussis, DFA**

***Bordetella pertussis/parapertussis*, Culture**	
Clinical Significance	***Bordetella pertussis* is the cause of whooping cough. *Bordetella parapertussis* is a related organism and causes a similar but milder disease.**
Effective Date	**5/19/2014**
Former Test Code	*2416*
Test Code	**5260**
CPT Codes	**87081**
Specimen Requirements	**Preferred:** **Nasopharyngeal swab collected in ESwab Mini-tip transport system (blue-cap)** **Acceptable:** **Nasopharyngeal swabs in Regan-Lowe transport media** **Remove all other specimen types and collection containers**
Reject Criteria	**Anterior nasal/nares; dry swab; Amies; Amies with charcoal culture swab**
Instructions	**Mini-tip swabs must be used for nasopharyngeal specimens and placed in ESwab or Regan-Lowe transport medium. For Regan-Lowe transport medium, collect specimen using mini-tip calcium alginate or dacron swab. Place swab in Regan-Lowe transport medium for culture.** **Pre-incubation of the inoculated Regan-Lowe medium at 36° C overnight before transit will increase survivability of *Bordetella* species.** **Transport pre-incubated Regan-Lowe refrigerated, preferable, or room temperature.** **Do not use rayon or cotton-tipped swabs, since they may be toxic to *Bordetella*.**
Transport Temperature	**Refrigerated**
Specimen Stability	**ESwabs:** — **Room temperature: Unacceptable** **Refrigerated: 4 days** **Frozen: Unacceptable** **Swab in Regan-Lowe:** — **Room temperature: 48 hours** **Refrigerated: 72 hours** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Daily; Report available: 7-10 days**
Reference Range	**Not isolated**
Methodology	**Culture**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

CPU Mappings	

Result Code	Type	Result Name
86007404	**Prompt-Result**	**Specimen Source:**
86010703		**Status**
85991362		**Bordetella Culture**

Creatine, 24-Hour Urine	
Effective Date	**5/19/2014**
Former Test Code	*S50739*
Test Code	**592**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: Next day**
Performing Site	**This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Quest Diagnostics Nichols Institute, Chantilly.**
CPU Mappings	

Result Code:	Type:	Result Name:
85993218	**Prompt-Result**	**Total Volume**
85988591		**Creatine, 24-Hour Urine**
25025900		**Creatinine, 24-Hour Urine**

Factor VIII Activity, Clotting	
Effective Date	**5/19/2014**
Test Code	347
Reject Criteria	Received room temperature, received refrigerated, hemolysis, received thawed **Remove: Thawed plasma**
Specimen Stability	**Room temperature and Refrigerated: Unacceptable** **Frozen -20° C: 14 days Frozen -70° C: 1 year**
Set-up/Analytic Time	Set up: Mon-Fri; **Report available: 2-4 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Hepatitis C Viral RNA Genotype, LiPA	
Effective Date	**5/19/2014**
Test Code	37811
Specimen Requirements	Preferred: 2 mL (0.6 mL minimum) plasma collected in PPT Potassium EDTA (white-top) tube **Acceptable:** **2 mL (0.6 mL minimum) serum**
Instructions	**Separate serum or plasma from whole blood within 24 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer the plasma to a properly identified, sterile, polyproprylene screw-cap vial and ship refrigerated or frozen.**

Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 14 days** **Frozen: 42 days**
Set-up/Analytic Time	Set up: Mon-Fri; **Report available: 3-6 days**
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 90251.** **http://education.questdiagnostics.com/faq/HCVGenotyping**
Assay Category	**Laboratory Developed Test ASR Class 1**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Histamine Release (Chronic Urticaria)	
Message	****This test is available for New York patient testing.****
Effective Date	**5/19/2014**
Former Test Code	*S52240*
Test Code	**16838**
Reject Criteria	**Gross hemolysis, lipemic or icteric specimen; Sample other than serum; SST**
Instructions	**Patients taking calcineurin inhibitors should stop their medication for 72 hours prior to draw.**
Set-up/Analytic Time	Set up: Tue, Thurs; **Report available: 4-9 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86004039** / **Histamine Release** / **%**

HPV Genotypes 16 and 18	
Clinical Significance	**Persistent infection with any of the 14 high-risk HPV types increases a woman's risk for progression to dysplasia or cervical cancer. The rate of progression or degree of risk depends on the HPV type. Of all 14 high-risk types, HPV Types 16 and 18 cause more than 60-65% od cervical cancers. This test will identify the presence or absence of HPV Type 16 DNA and /or Type 18 DNA in PreservCyt ThinPrep reflex specimens originally submitted for Digene High-Risk HPV Hybrid Capture 2. Knowledge of the HPV genotype will help physicians diagnose the type of HPV infection and its risk of delevoping into dysplasia or cervical cancer.**
Effective Date	**5/19/2014**
Former Test Code	*S52084*
Test Code	**19865**

Specimen Requirements	Preferred: 4 mL (2 mL minimum) Residual (PreservCyt®) fluid collected in a liquid cytology (PreservCYT®) Preservative (Thin Prep®) **Acceptable:** **2 mL (1 mL minimum) Residual SurePath® fluid collected in a TriPath SurePath® vials - post processing of the PAP smear**
Reject Criteria	**Cervical swabs in Digene HC Cervical Sampler, Cytyc media w/o cervical brush/broom, Swabs, Digene vials are not acceptable, Unprocessed SurePath vials are not acceptable, Vaginal Swabs**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 2-5 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** **86005017** / **HPV16 DNA, Invader(R)** **86005018** / **HPV18 DNA, Invader(R)**

HSV-2 Inhibition Study, ELISA	
Effective Date	**5/19/2014**
Former Test Name	*S51626*
Test Code	**17171**
CPT Codes	**86696**
Specimen Stability	**Room temperature: 7 days** Refrigerated: 14 days Frozen: 30 days
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-5 days**
Reference Range	**Negative**
Always Message	**This assay is intended only for samples giving a positive index in the HerpeSelect HSV-2 type-specific IgG screening ELISA. A Positive inhibition study interpretation indicates true HSV-2 specific reactivity, whereas a Negative inhibition study interpretation indicates that the positive screening index was falsely positive.**
Methodology	**Enzyme Linked Immunosorbent Immunoassay**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	**Result Code** / **Result Name** **86000393** / **HSV2 IgG Inhibition,ELISA**

***Legionella* Culture**	
Clinical Significance	**Bacteria in the genus *Legionella* primarily cause respiratory illness, i.e. either Legionnaires' disease, a systemic illness manifested primarily by pneumonia, or Pontiac fever, a nonpneumonic, influenza-like illness. *Legionellae* may also cause a variety of other illnesses.**
Effective Date	**5/19/2014**
Former Test Name	*Legionella SPP. Culture*

Former Test Code	*2404*
Test Code	**688**
Specimen Requirements	**1 g Lung tissue, fresh (unfixed) tissue, 3 mL (2 mL minimum) bronchial washings, sputum, bronchial alveolar lavage, pleural fluid, nasopharyngeal lavage/wash or tracheal lavage/wash collected in a sterile leak-proof container** **Remove all other specimen types and collection containers**
Reject Criteria	**Expired transport device; environmental sources, received in viral transport media**
Instructions	**Lung Biopsy: Place lung biopsy into sterile container.** **Sputum: Instruct patient to gargle with water and cough deeply to collect deep respiratory specimen in sterile container.** **Aspirate: Place aspirate or washing into sterile container.** **Tissue: Add small amount of sterile, non-bacteriostatic, distilled water to prevent drying, if necessary. Do not add saline, because it may be inhibitory.**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 7 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Daily; Report available: 7-10 days**
Reference Range	**Not isolated**
Methodology	**Culture**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Type** / **Result Name** **86007404** / **Prompt-Result** / **Specimen Source:** **86010701** /	**Status** **85996827** /	**Legionella Culture**
Tests Affected	**Test Codes:** / **Name:** P6102E / Custom Mission Legionella DFA Panel

***Legionella* Culture, Environmental**	
Clinical Significance	***Legionellae* are found widespread in water sources, especially in warmer waters of plumbing systems and cooling towers. Infection often occurs through aerosol inhalation of contaminated water.**
Effective Date	**5/19/2014**
Former Test Name	*Legionella, Environmental Culture*
Former Test Code	*S52108*
Test Code	**37357**
CPT Codes	**99199**
Specimen Requirements	**Preferred:** **250 mL (100 mL minimum) water collected in a sterile leak-proof container** **Acceptable:** **Culture swab of environmental water-related surface in liquid Amies (red-cap) or gel Amies (blue-cap) transport medium.**

	Remove all other specimen types and collection containers. Remove message from acceptable sample type information.
Instructions	**Transport at refrigerated temperatures preferred.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 7 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 7-10 days**
Reference Range	**Not isolated**
Methodology	**Culture**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	

Result Code	Type	Result Name
86007404	**Prompt-Result**	**Specimen Source:**
86010706		**Status**
85991838		**Legionella Culture**

***Legionella pneumophila* Antigen, DFA**	
Clinical Significance	**Bacteria in the genus *Legionella* primarily cause respiratory illness, i.e. either Legionnaires' disease, a systemic illness manifested primarily by pneumonia, or Pontiac fever, a nonpneumonic, influenza-like illness. *Legionellae* may also cause a variety of other illnesses.**
Effective Date	**5/19/2014**
Former Test Name	*Legionella Pneumophila Ag Detection*
Former Test Code	*2422*
Test Code	**34475**
Specimen Requirements	**1 g Lung tissue or fresh (unfixed) tissue, 3 mL (2 mL minimum) bronchial washings, sputum, bronchial alveolar lavage, pleural fluid, nasopharyngeal lavage/wash or tracheal lavage/wash collected in sterile leak-proof container** **Remove all other specimen types and collection containers**
Reject Criteria	**Expired transport device; environmental sources, received in viral transport media**
Instructions	**Lung Biopsy: Place lung biopsy into sterile container.** **Sputum: Instruct patient to gargle with water and cough deeply to collect deep respiratory specimen in sterile container.** **Aspirate: Place aspirate or washing into sterile container.** **Tissue: Add small amount of sterile, non-bacteriostatic, distilled water to prevent drying, if necessary. Do not add saline, because it may be inhibitory.**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated 7 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Daily; Report available 1-2 days**
Reference Range	**Not detected**
Methodology	**Direct Immunofluorescence Assay (DFA)**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

CPU Mappings	<table><tr><th>Result Code</th><th>Type</th><th>Result Name</th></tr><tr><td>86007404</td><td>Prompt-Result</td><td>Specimen Source:</td></tr><tr><td>45058310</td><td></td><td>L. pneumophila Ag, DFA</td></tr></table>
Tests Affected	<table><tr><th>Test Codes:</th><th>Name:</th></tr><tr><td>P6102E</td><td>Custom Mission Legionella DFA Panel</td></tr></table>

***Mycoplasma hominis/Ureaplasma* Culture**	
Clinical Significance	***Ureaplasma urealyticum* and *Mycoplasma hominis* are primarily associated with genital tract colonization and disease in adults and respiratory tract colonization and disease in newborns. Though controversial, these organisms have been associated with endometritis, chorioamnionitis, premature rupture of membranes, stillbirth, premature birth, low birth weight, post-partum infections, and infertility. Of particular concern is the causal relationship between central nervous system infections in the premature newborn and *U. urealyticum*.**
Effective Date	**5/19/2014**
Former Test Name	*Ureaplasma Urealyticum/Mycoplasma hominis Culture*
Former Test Code	*2408*
Test Code	**871**
Specimen Requirements	**Preferred:** **(1 mL or 1 swab minimum) Urogenital (vaginal, cervical, urethral swabs or vaginal secretions) collected in VCM medium (green-cap) tube or equivalent (UTM) container.** **Acceptable:** **Urine, sterile body fluids, tissue, wounds (swab), respiratory (sputum, bronchial washing, tracheobronchial secretions, bronchial alveolar lavage, nasopharyngeal or throat swabs) collected in a VCM medium (green-cap) tube or equivalent (UTM) container (see instructions).** **Remove all other specimen types and collection containers**
Reject Criteria	**Specimens collected on wooden shafted swabs, or cotton swabs; specimens received in expired transport medium; tissue specimens in formalin; urine containing any preservatives; specimens received in M4RT transport medium; raw specimens**
Instructions	**Ship on dry ice.** **Urine: Client should centrifuge urine at 3000 rpm for 15 minutes. Suspend sediment in VCM or equivalent transport media. If the specimen is not centrifuged, submit a 1:1 volume of urine in VCM or equivalent transport media.** **Submit a 1:1 volume of sterile body fluids, tissue, respiratory (sputum, bronchial washing, tracheobronchial secretions, bronchial alveolar lavage) in VCM or equivalent transport media.** **Respiratory samples are only acceptable from children under 1 year old.** **NOTE: Do not use M4RT; the room temperature formula cannot be used for *mycoplasma.***
Transport Temperature	**Frozen -70° C on dry ice**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen -20° C: Unacceptable** **Frozen -70° C: 30 days**
Reference Range	**Not isolated**
Methodology	**Culture**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

CPU Mappings	

Result Code	Type	Result Name
86007404	**Prompt-Result**	**Specimen Source:**
86010702		**Status**
86010707		**Mycoplasma hominis**
86010708		**Ureaplasma species**

Tests Affected	

Test Codes:	Name:
2399	Mycoplasma hominis Culture
2429	Ureaplasma urealyticum Culture

***Mycoplasma pneumoniae* Culture**	
Clinical Significance	***Mycoplasma pneumoniae* is one of the principal etiologic agents responsible for primary atypical pneumonia (often called walking pneumonia) as well as more mild forms of upper respiratory illness. Primary atypical pneumonia may be a severely debilitating disease and may infect otherwise healthy individuals.**
Effective Date	**5/19/2014**
Former Test Code	*2406*
Test Code	**34270**
Specimen Requirements	**Preferred:** **Throat swab collected in VCM medium (green-cap) tube or equivalent (UTM) container** **Acceptable:** **Lung tissue, pleural fluid, pericardial fluid collected in VCM medium (green-cap) tube or equivalent (UTM) container, nasopharyngeal aspirate or swab, bronchial lavage/wash (1 mL or 1 swab minimum) collected in a VCM medium (green-cap) tube or equivalent (UTM) container.** **Remove all other specimen types and collection containers**
Reject Criteria	**Received in M4RT; sputum**
Instructions	**Ship on dry ice.** **Submit a 1:1 volume of lung tissue, pleural, pericardial, nasopharyngeal aspirate or swab, bronchial lavage/wash in VCM or equivalent transport media.** **For genital specimens refer to test 871- *Mycoplasma hominis/Ureaplasma* Culture.** **Note: PCR is the optimal method for detection of *Mycoplasma pneumoniae.***
Transport Temperature	**Frozen -70° C on dry ice**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen -20° C: Unacceptable** **Frozen -70° C: 30 days**
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 weeks**
Reference Range	**Not isolated**
Methodology	**Culture**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Type	Result Name

	86007404	**Prompt-Result**	**Specimen Source:**
	86010705		**Status**
	85993084		**M. pneumoniae Culture**

Protein Electrophoresis, Serum with Total Protein and Reflex to IFE, Serum	
Effective Date	**5/19/2014**
Test Code	10269
Set-up/Analytic Time	**Set up: Sun-Fri;** Report available: 5-7 days
Reference Range	

Protein, Total, Serum:	**Males (g/dL)**	**Females (g/dL)**
<1 month:	4.1-6.3	4.2-6.2
1-5 months:	4.7-6.7	4.4-6.6
6-11 months:	5.5-7.0	5.6-7.9
1-19 years:	6.3-8.2	6.3-8.2
>19 years:	**6.1-8.1**	**6.1-8.1**
Protein Electrophoresis, Serum		
Albumin:	3.5-4.7 g/dL	
Alpha-1-Globulin:	0.1-0.3 g/dL	
Alpha-2-Globulin:	0.5-1.0 g/dL	
Beta Globulin:	0.8-1.4 g/dL	
Gamma Globulin:	0.6-1.6 g/dL	
Abnormal Protein Band 1:	None Detected	
Abnormal Protein Band 2:	None Detected	
Abnormal Protein Band 3:	None Detected	
Interpretation:	No Reference Range available	
Immunofixation, Serum:	No monoclonal proteins detected	

Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

PTH, Intact, Fine Needle Aspirate	
Effective Date	**5/19/2014**
Former Test Code	*S52057*
Test Code	**16560**
Specimen Requirements	**Preferred:** **1 mL (0.8 mL minimum)** Fine needle aspirate collected in a sterile transport tube **Acceptable:** **1 mL (0.8 mL minimum)** Node washings collected in a sterile transport tube or Saline node washings

Reject Criteria	**Glass tubes**
Instructions	**A 25-gauge needle is inserted obliquely within the transducer plane of view and moved back and forth through the nodule to compensate for patient movement and needle deflection. There is no suction device; cells move into the needle via capillary action. Three to six separate passes are performed, each with a new needle. After collection of the cytology samples, each FNA needle is then washed with 0.1-0.5 mL of normal saline; the washes from all needles are pooled (final volume 1 mL) and immediately frozen, and then transported to the laboratory directly. If the mass is determined a priori cystic, there is no need to use normal saline in the syringe as the cyst contents are directly aspirated, pooled into a tube and frozen for transport to the laboratory.**
Set-up/Analytic Time	Set up: Tue-Sat; **Report available: 2-5 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86003412** / **PTH, Intact, FNA** / **pg/mL**

Discontinued Tests

***Clostridium difficile* Toxin A and B, EIA**	
Effective Date	**5/5/2014**
Test Code	7670
Additional Information	**Please note:** Orders for 7670- *Clostridium difficile* Toxin A and B, EIA, will automatically be replaced with test code 91664- *Clostridium difficile* Toxin/GDH with Reflex to PCR

Amoxicillin Level, BA	
Effective Date	**5/5/2014**
Test Code	S44060
Additional Information	The recommended alternative is test code 91971 Amoxicillin, HPLC in the New Test Offerings section.

Doxycycline Level, BA	
Effective Date	**5/5/2014**
Test Code	S43490
Additional Information	The recommended alternative is test code 91970 Doxycycline, HPLC in the New Test Offerings section.

Fetal Fibronectin	
Effective Date	**5/5/2014**
Test Code	38226 [1440]
Additional Information	This test will be discontinued, there is no recommended alternative.

Humoral Immune Evaluation (Pneumo 14) & H. Flu B, Pre/Post

Effective Date	**5/5/2014**
Test Code	1146P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Evaluation (Pneumo 14) Pre/Post	
Effective Date	**5/5/2014**
Test Code	1143P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Evaluation (Pneumo 23) & H. Flu B, Pre/Post	
Effective Date	**5/5/2014**
Test Code	1088P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Evaluation (Pneumo 23) Pre/Post	
Effective Date	**5/5/2014**
Test Code	1049P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Evaluation (Pneumo 7) & H. Flu B, Pre/Post	
Effective Date	**5/5/2014**
Test Code	1087P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Status (Pneumo 14), Pre/Post	
Effective Date	**5/5/2014**
Test Code	1148P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immune Status Survey (Pneumo 7), Pre/Post	
Effective Date	**5/5/2014**
Test Code	1147P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immuno Evaluation (Pneumo 7), Pre/Post	
Effective Date	**5/5/2014**
Test Code	1047P

Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Humoral Immuno Status Survey (Pneumo 23), Pre/Post	
Effective Date	**5/5/2014**
Test Code	1149P
Additional Information	This test is being discontinued due to low volume. There is no recommended alternative.

Substance P, EIA	
Effective Date	**5/5/2014**
Test Code	S51356
Additional Information	The recommended alternative is Substance P, performed by Cambridge Biomedical, Inc., please send directly to Cambridge Biomedical Inc.

***Borrelia burgdorferi* IgG & IgM Antibodies [EIA]**	
Effective Date	**5/12/2014**
Test Code	8941
Additional Information	The recommended alternative is test code 6646-Lyme Disease Ab with Reflex Blot (IgG, IgM) in the Test Change section.

***Borrelia burgdorferi* IgG & IgM Antibodies EIA & Immunoblot**	
Effective Date	**5/12/2014**
Test Code	7716
Additional Information	The recommended alternative is test code 6646-Lyme Disease Ab with Reflex Blot (IgG, IgM) in the Test Change section.
Tests Affected	**Test Codes:** / **Name:** 7716B / Borrelia burgdorferi IgG & IgM Antibodies EIA & Immunoblot+Bands

***Borrelia burgdorferi* IgG & IgM Abs w/reflex to Immunoblot + Bands [CDC]**	
Effective Date	**5/12/2014**
Test Code	8942
Additional Information	The recommended alternative is test code 6646-Lyme Disease Ab with Reflex Blot (IgG, IgM) in the Test Change section.
Tests Affected	**Test Codes:** / **Name:** 8942NY / Borrelia burgdorferi IgG & IgM w/reflex IB+Bands [NY]

***Borrelia burgdorferi* IgG Antibodies**	
Effective Date	**5/12/2014**
Test Code	8951

Additional Information	The recommended alternative is test code 6646-Lyme Disease Ab with Reflex Blot (IgG, IgM) in the Test Change section.

***Borrelia burgdorferi* IgG Antibody with Reflex to IB + Bands [NY]**	
Effective Date	**5/12/2014**
Test Code	8947NY
Additional Information	The recommended alternative is test code 6646-Lyme Disease Ab with Reflex Blot (IgG, IgM) in the Test Change section.

***Borrelia burgdorferi* IgM Antibodies**	
Effective Date	**5/12/2014**
Test Code	8961
Additional Information	There is no recommended alternative.

***Borrelia burgdorferi* IgM Antibody with Reflex IB + Bands [NY]**	
Effective Date	**5/12/2014**
Test Code	8948NY
Additional Information	There is no recommended alternative.

Hydroxyprogesterone, 17 Alpha	
Effective Date	**5/12/2014**
Test Code	3190
Additional Information	The recommended alternative is 17180 - Hydroxyprogesterone, LC/MS/MS in the New Test section.
Tests Affected	**Test Codes:** / **Name:** P9105BE / Custom NMH 17-OH Progesterone 60 min Post Stimulation P36981J / Custom SML Hydroxyprogesterone 3 Specimens

Intrinsic Factor Blocking Autoantibodies	
Effective Date	**5/12/2014**
Test Code	3196
Additional Information	The recommended alternative is 568 - Intrinsic Factor Blocking Antibody, in the New Test Section

Kidney Stone Risk AssessR™	
Effective Date	**5/12/2014**
Test Code	90523 [4168]
Additional Information	The recommended alternatives are: • 5510-StoneRisk® Diagnostic Profile • 5515-UroRisk® Diagnostic Profile

Thyroxine Free, Direct Dialysis	
Effective Date	**5/12/2014**
Test Code	3954
Additional Information	The recommended alternative are both: 35167 - T4, Free, Direct Dialysis in the New Test section and 3226 - Thyroxine (T4)
Tests Affected	**Test Codes:** / **Name:** P35859C / Custom CLM Thyroxine Free, Direct Dialysis w/o T4

Triiodothyronine Free, Dialysis	
Effective Date	**5/12/2014**
Test Code	3225
Additional Information	The recommended alternative is 36598 - T3, Free, Tracer Dialysis in the New Test section

***Bordetella pertussis* Culture and DFA**	
Effective Date	**5/19/2014**
Test Code	2430
Additional Information	The recommended alternatives are: • 5260-Bordetella pertussis/parapertussis, Culture • 34966-Bordetella pertussis/parapertussis Smear, DFA

Epstein-Barr Virus Nuclear AG (EBNA) IgM ABS	
Effective Date	**5/19/2014**
Test Code	2271
Additional Information	The recommended alternative is test code 2121- Epstein-Barr Virus Viral Capsid Ag (VCA) IgM Abs.

Febrile Agglutinins Panel	
Effective Date	**5/19/2014**
Test Code	S50359
Additional Information	The recommended alternative is test code 91121- Febrile Antibodies Panel in the New Test Offering section.

***Legionella* Culture and Antigen Detection, DFA**	
Effective Date	**5/19/2014**
Test Code	2432
Additional Information	The recommended alternatives are:

	• 688 - *Legionella* Culture • 34475 - *Legionella pneumophila*, DFA

Test Send Outs (Referrals)

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

Tiagabine, Serum/Plasma	
Effective Date	**5/5/2014**
Former Test Code	*S48484*
Test Code	**30333**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 30 days** **Frozen: 48 months**
CPU Mappings	**Result Code** / **Result Name** **85981860** / **Tiagabine, Serum/Plasma**

Titanium, Serum/Plasma	
Effective Date	**5/5/2014**
Former Test Code	*S49212*
Test Code	**8331X**
Transport Temperature	**Room temperature**
Set-up/Analytic Time	**Set up: Tues;** Report available: 1 day
Reference Range	**The normal value for titanium is generally less than 5 mcg/L. In patients with a titanium-based implant/prosthesis, a serum concentration greater than 10 mcg/L may be indicative of wear. However, a reported titanium value alone is not predictive of prosthesis wear or failure.**
CPU Mappings	**Result Code** / **Result Name** **85358600** / **Titanium, Serum/Plasma**

ADAMTS13 Activity	
Effective Date	**5/19/2014**
Test Code	S50352
Additional Information	This test will be discontinued, the recommended alternative is test code 14532- ADAMTS13 Activity with Reflex to Inhibitor in the New Test Offering section.

Neuromyelitis Optica (NMO)/Aquaporin-4-IgG Cell-Binding Assay, CSF	
Clinical Significance	**Diagnosis of a neuromyelitis optica spectrum disorder (NMOSD). Distinguishing NMOSD from multiple sclerosis early in the course of disease.**
Effective Date	**5/19/2014**
Test Code	**61716**
CPT Codes	**86255**
Specimen Requirements	**1 mL (0.5 mL minimum) CSF collected in a sterile vial**
Reject Criteria	**Gross hemolysis; grossly icterus**
Instructions	**Include relevant clinical information, name, phone number, mailing address, and e-mail address (if applicable) of ordering physician.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated and Frozen: 28 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 3-6 days**
Reference Range	**Negative**
Methodology	**CBA, IFA**
CPU Mappings	**Result Code** / **Result Name** **113833** / **NMO/AQP4-IgG CBA, CSF**

Neuromyelitis Optica IgG, CSF	
Effective Date	**5/19/2014**
Test Code	S51106
Additional Information	This test will be discontinued, the recommended alternative is test code 61716- Neuromyelitis Optica (NMO)/Aquaporin-4 IgG Cell-Binding, CSF