February 2013 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
90973	**Deoxycorticosterone, LC/MS/MS**	1/22/2013	3
91258	**Zolpidem Quantitation, Urine**	2/12/2013	4
19546	**Bile Acids, Fractionated and Total, Pregnancy**	2/26/2013	4
91307	***Echinococcus* Antibody (IgG), EIA with Reflex to Western Blot**	2/26/2013	5
16482	**BV Smear Nugent Score**	3/4/2013	5

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 #**
S51476		CA 125 w/HAMA Treatment [17717]	2/4/2013	6
S51387		CEA with HAMA Treatment [15018]	2/4/2013	6
S52476		TSH with HAMA Treatment [19537]	2/4/2013	7
19704		Activated Protein C Resistance with Reflex to Factor V (Leiden) Mutation	2/12/2013	7
17900		Factor V (Leiden) Mutation Analysis	2/12/2013	8
4175U		Fentanyl Screen, Urine W/Reflex Confirmation	2/12/2013	8
3021		HIV-1 Antibodies [WB] reflex to HIV-2 Antibodies [WB]	2/12/2013	9
17911		Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation Analysis	2/12/2013	9
17909		Prothrombin (Factor II) 20210G>A Mutation Analysis	2/12/2013	9
18041		SMA Carrier Screen	2/12/2013	10
S50070		SMA Diagnostic Test	2/12/2013	10
1513		**Alpha-1-Antitrypsin, Quantitative**	2/26/2013	11
5300		**Carbon Dioxide**	2/26/2013	11
4311		Cyclosporine A, Whole Blood [Immunoassay]	2/26/2013	12
1440		Fetal Fibronectin	2/26/2013	12
5301		**Glucose**	2/26/2013	13
4861W		Lead, Blood	2/26/2013	13
7745		**Pneumocystis jiroveci (carinii), DFA**	2/26/2013	14
799		RPR (Monitor) with Reflex to Titer	2/26/2013	14
5649		**Susceptibility, *Mycobacterium tuberculosis*, First-tier Drugs**	2/26/2013	14
3236		**T3, Reverse**	2/26/2013	15
3460		Tryptase	3/4/2013	15
5648		**AFB Identification Mycobacterium spp. by HPLC**	3/12/2013	15

2440		***Chlamydia trachomatis* Antigen, DFA**	3/12/2013	16
2400		*Chlamydia trachomatis* Culture	3/12/2013	16
3182		Growth Hormone	3/12/2013	17
2425		**Respiratory Virus Panel, DFA**	3/12/2013	17
9640		**Group B Strep, PCR**	3/18/2013	18
3170		Ferritin	3/19/2013	18

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 #
514	S51309	Hemoglobin, Free, Plasma	2/11/2013	19
36170	S51829N	Testosterone, Free and Total, LC/MS/MS	2/19/2013	19
391	S41147	Biotin (Vitamin B7)	2/26/2013	20
91030	S44445	Vitamin B5 (Pantothenic Acid)	2/26/2013	20
345	S50818	Cobalt, Serum/Plasma [345]	3/5/2013	21

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 #
S50604	Comprehensive Drug Screen Stool [1864ST]	1/7/2013	22
S49602	Bartonella DNA PCR, Tissue [47000]	1/22/2013	22
S51354	Deoxycorticosterone [6559X]	1/22/2013	22
7560	Treponema pallidum Total Antibodies, FTA-Antibodies Quant	1/22/2013	22
S44505	Vitamin B3 (Whole Blood Niacin)	2/25/2013	22
S49644	Zolpidem Screen Urine [9498]	2/26/2013	22

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

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90570	SureSwab™ Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR	22
S49825	Vitamin B2 [36399]	23
3231	Testosterone, Free, Total, and Sex Hormone Binding Globulin	23
3922	Testosterone, Total, LC/MS/MS	23

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 #
S52388		Lyme Disease Antibody Index for CNS Infection	1/22/2013	23

S49883		*Sporothrix* Antibody [9673]	1/22/2013	23
S41710		Acetone Blood [205]	1/29/2013	24
S47310		Acylglycines Quant [81249]	1/29/2013	24
S52567		IBD sgi Diagnostic (1800)	1/29/2013	25
S51162		Monogenic Diabetes (MODY) Eval [885]	1/29/2013	26
S51301		Phospholipids [717]	1/29/2013	26
S43665		Cimetidine [1262]	2/4/2013	26
S52175		Metoclopramide, Serum/Plasma [3041SP]	2/4/2013	27
S47815		Prostaglandins PG-D2	2/4/2013	27
S52011		CD57, CD3, CD8, Flow Cytometry	2/11/2013	27
S49112		D-Xylose Absorption Blood Fasting [1198X]	2/11/2013	28
S52113		HIV-1 Integrase Genotype [16868]	2/11/2013	29
S51368		Prekallikrein (Fletcher Factor) Activity [10334X]	2/11/2013	29
S51656		Serotonin, Blood	2/12/2013	30
S52578		Hexosaminidase A and Total, S	2/21/2013	30
S49273		Hexosaminidase A and Total, WBC	2/21/2013	30
S50740		Toxocara Antibody, ELISA (Fluid) [60945]	2/25/2013	31
S50345		Toxocara Antibody, ELISA (Serum) [40945]	2/25/2013	31
S41360		Legionella pneumophilia Antibodies (IgM)	2/26/2013	31

New Test Offerings

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

Deoxycorticosterone, LC/MS/MS	
Clinical Significance	**Deoxycorticosterone (DOC) is a weak mineralocorticoid derived from 21-hydroxylation of progesterone in the adrenal cortex.**
Effective Date	**1/22/2013**
Test Code	**90973**
CPT Codes	**82633**
Specimen Requirements	**0.5 mL serum collected in a red-top (no gel) tube** **Collect specimen in a non additive red top tube; spin down immediately and pour off into a 13x75 plastic transport tube.**
Reject Criteria	**Serum separator tubes,moderate hemolysis, gross hemolysis, gross lipemia, grossly icteric**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Sun, Tues, Thurs; Report available: 4-7 days**

Reference Range	**Male > or = 18 years:** < or = 15 ng/dL **Female:** Phase of Menstrual Cycle Mid Follicular: < or = 18 ng/dL Surge: < or = 23 ng/dL Mid Luteal: < or = 19 ng/dL **Pediatric 6-17 years:** < or = 35 ng/dL
Units Of Measure	**ng/dL**
Methodology	**Liquid Chromatography, Tandem Mass Spectrometry**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code:** 86007607 — **Result Name:** Deoxycorticosterone

Zolpidem Quantitation, Urine	
Clinical Significance	Zolpidem is used to treat patients with insomnia. This test is used to detect the presence of the drug as a therapeutic drug monitoring and to aide clinicians with the drug's dosage effectiveness.
Effective Date	**2/12/2013**
Test Code	**91258**
CPT Codes	**80299**
Specimen Requirements	**1 mL (0.5 mL minimum) random urine collected in a plastic, leakproof preservative-free container**
Reject Criteria	**Preserved urines and any other sample types that are not urine**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 7 days** **Refrigerated and Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon - Fri; Report available 4 days**
Reference Range	**None detected**
Methodology	**Liquid Chromatography, Tandem Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Chantilly**
CPU Mappings	**Result Code:** 86008832 — **Result Name:** Zolpidem Quantitation, Urine

Bile Acids, Fractionated and Total, Pregnancy	
Clinical Significance	**Intrahepatic cholestasis of pregnancy requires rapid TAT of results. Sample for this test will be run straight on dilution to improve TAT.**

Effective Date	**2/26/2013**
Test Code	**19546**
CPT Codes	**83789**
Specimen Requirements	**1 mL (0.5 mL) Serum**
Instructions	**Collect blood in a red top or SST tube. After clot formation centrifuge sample and pour off serum into a transport tube. Store sample refrigerated or frozen. Overnight fasting is preferred.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room Temperature: 7 Days** **Refrigerated: 14 Days** **Frozen: 30 Days**
Set-up/Analytic Time	**Tues-Sat; Report available: 2-4 days**
Reference Range	**Cholic Acid: < or = 3.1 umol/L** **Deoxycholic Acid: < or = 7.3 umol/L** **Chenodeoxycholic Acid: < or = 9.9 umol/L** **Total Bile Acids: 4.5 - 19.2 umol/L**
Units Of Measure	**umol/L**
Methodology	**Liquid Chomatography, Tandem Mass Spectrometry**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Result Name
86002132	**Cholic Acid**
86002133	**Deoxycholic Acid**
86002134	**Chenodeoxycholic Acid**
86002135	**Total Bile Acids**

***Echinococcus* Antibody (IgG), EIA with Reflex to Western Blot**	
Clinical Significance	*Echinococcus* IgG detection is an important tool for diagnosing hydatid disease, since infected individuals do not exhibit fecal shedding of *E. granulosus* eggs.
Effective Date	**2/26/2013**
Test Code	**91307**
CPT Codes	**86682**
Specimen Requirements	**1 mL serum collected in a red-top tube (no gel) (0.2 mL minimum)**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues, Fri; Report available: 1-5 days**
Reference Range	**Negative**
Always Message	**REFERENCE RANGE: NEGATIVE**

	Detection of serum antibodies to *Echinococcus* plays an important role in the diagnosis of hydatid disease, since infected individuals do not exhibit fecal shedding of *Echinococcus* eggs. Serum antibodies may remain detectable for years after cyst removal. Serologic crossreactivity between *Echinococcus* and Cysticercus may occur.
Methodology	**Immunoassay**
Performing Site	**Focus Diagnostics, Inc.**
CPU Mappings	<table><tr><td>**Result Code**</td><td>**Result Name**</td></tr><tr><td>**85968630**</td><td>**Echinococcus IgG, EIA**</td></tr><tr><td colspan="2">***This is a true reflex. Please build the unit codes below separately.Non-Orderable Reflex 91307-2*** **Echinococcus Antibody (IgG), Western Blot**</td></tr><tr><td>**Result Code**</td><td>**Result Name**</td></tr><tr><td>**86008882**</td><td>**Echinococcus IgG, WB**</td></tr></table>
Additional Information	**If the Echinococcus IgG result is Positive, then the Echinococcus Ab (IgG), Western Blot will be performed at an additional charge (CPT code: 86682).**

BV Smear Nugent Score	
Clinical Significance	Bacterial vaginosis in the symptomatic patient is defined as a shift in the vaginal flora from predominately lactobacilli to a variety of other morphologies.
Effective Date	**3/4/2013**
Test Code	**16482**
CPT Codes	**87205**
Specimen Requirements	**Vaginal swab in Amies transport medium or similar. An air-dried smear is also acceptable.**
Reject Criteria	**Broken Slides**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 48 hours** **Frozen: Unacceptable**
Methodology	**Gram stained smears are examined microscopically using a scoring system based on the relative amounts of bacterial morphotypes present.**
Performing Site	**Quest Diagnostics Nichols Institute, Chantilly**
CPU Mappings	**CPU mapping available upon request.**

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*.

Note to Business Units: Please delete any information in blue and test codes that do not apply to your Business Unit.

CA 125 w/HAMA Treatment [17717]	
Effective Date	**2/4/2013**
Test Code	S51476
Reference Range	**CA 125, HAMA Treated <21 U/mL** **CA 125, Untreated <21 U/mL**
Always Message	**This test was performed using the Siemens chemiluminescent method. Values obtained from different assay methods cannot be used interchangeably. CA 125 levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 110417 / **CA 125, HAMA Treated** 110418 / **CA 125, Untreated**

CEA with HAMA Treatment [15018]	
Effective Date	**2/4/2013**
Test Code	S51387
Reference Range	**CEA, HAMA Treated See below** **CEA, Untreated Non-Smoker: <2.5 ng/mL** **Smoker: <5.0 ng/mL**
Always Message	**This test was performed using the Siemens chemiluminescent method. Values obtained from different assay methods cannot be used interchangeably. CEA levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 113011 / **CEA, HAMA Treated** 110264 / **CEA, Untreated**
Additional Information	Update report format

TSH with HAMA Treatment [19537]	
Effective Date	**2/4/2013**
Former Test Name	*TSH, 3rd Generation with HAMA Treatment [19537X]*
Test Code	S52476
Reference Range	**TSH, HAMA Treated** / **See below** **TSH, Untreated** / **Premature Infants (28-36 Weeks)** **1st Week of Life: 0.20-27.90 mIU/L** **Term Infants (>37 Weeks)** **Serum or Cord Blood: 1.00-39.00 mIU/L**

	< or = 4 Days: 3.20-35.00 mIU/L **5-6 Days: Not established** **1-4 Weeks: 1.70-9.10 mIU/L** **1-11 Months: 0.80-8.20 mIU/L** **1-19 Years: 0.50-4.30 mIU/L** **> or = 20 Years: 0.40-4.50 mIU/L** **Pregnancy** **First Trimester: 0.26-2.66 mIU/L** **Second Trimester: 0.55-2.73 mIU/L** **Third Trimester: 0.43-2.91 mIU/L** **TSH levels decline rapidly during the first week of life in most children, but may remain transiently elevated in a few individuals despite normal free T4 levels. For proper interpretation of an abnormal TSH from a newborn thyroid screen, a free (or total) T4 is usually required.**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 86002326 / **TSH, HAMA Treated** 86002327 / **TSH, Untreated**

Activated Protein C Resistance with Reflex to Factor V (Leiden) Mutation	
Effective Date	**2/12/2013**
Test Code	19704
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 days**
Reference Range	**Accompanies report**
Always Message	**19704 Factor V (Leiden) Mutation Analysis** **Mutation Analysis:** **The Factor V Leiden (R506Q) mutation [NM 000130.2: c.1601G>A (p.R534Q)] in the Factor V gene is one of the most common causes of inherited thrombophilia. This mutation causes resistance to degradation of activated Factor V protein by activated protein C (APC). The Factor V Leiden (R506Q) mutation is detected by amplification of the selected region of Factor V gene by polymerase chain reaction (PCR) and fluorescent probe hybridization to the targeted region, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.** **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.** **Health care providers, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.**
Methodology	RVTT-Based Assay (Clot-Based), **Hybeacons**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** 26703 / APC Resistance **19704-2 Reflex Factor V (Leiden) Mutation Analysis** **Result Code** / **Result Name** **85985660** / **Factor V (Leiden) Mutation**

Factor V (Leiden) Mutation Analysis	
Effective Date	**2/12/2013**
Test Code	17900
CPT Codes	**81241**
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 days**
Reference Range	**Accompanies report**
Always Message	**Mutation Analysis:** **The Factor V Leiden (R506Q) mutation [NM 000130.2: c.1601G>A (p.R534Q)] in the Factor V gene is one of the most common causes of inherited thrombophilia. This mutation causes resistance to degradation of activated Factor V protein by activated protein C (APC). The Factor V Leiden (R506Q) mutation is detected by amplification of the selected region of Factor V gene by polymerase chain reaction (PCR) and fluorescent probe hybridization to the targeted region, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.** **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.** **Health care providers, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.**
Methodology	**Hybeacons**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** **85985660** / **Factor V Leiden Mutation**
Tests Affected	**Test Codes:** / **Name:** 19704 / Activated Protein C Resistance with Reflex to Factor (Leiden) Mutation

Fentanyl Screen, Urine W/Reflex Confirmation	
Effective Date	**2/12/2013**
Test Code	4175U
Assay Category	**Laboratory Developed Test**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 4472U / Expanded Drugs Of Abuse Screen Urine + Fentanyl W/Reflex Confirmation

HIV-1 Antibodies [WB] reflex to HIV-2 Antibodies [WB]	
Effective Date	**2/12/2013**
Test Code	3021

Performing Site	Quest Diagnostics Nichols Institute, Valencia
Additional Information	If HIV-1 Abs Western Blot is Negative or Indeterminate, HIV-2 Abs Western Blot, is performed for **an** additional fee, **adding CPT code 86689.**
Tests Affected	**Test Codes:** / **Name:** 3021B / HIV-1 Antibodies + bands [WB] reflex HIV-2 Antibodies [WB] 3021BT / HIV-1 Abs [WB] w/Reflex HIV-2 Abs [WB] (Blood Bank)

Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation Analysis	
Effective Date	**2/12/2013**
Test Code	17911
CPT Codes	**81291**
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 days**
Reference Range	**Accompanies report**
Always Message	**Hyperhomocysteinemia is a risk factor for arterial disease and venous thrombosis. Homocysteine levels are affected by nutritional and genetic factors. Since MTHFR is involved in methylation of homocysteine to methionine, individuals with MTHFR gene mutations that reduce enzyme activity may develop hyperhomocysteinemia and thus be at elevated risk for vascular disease.** **The C677T [NM 005957.3: c.665C>T (p.A222V)] and A1298C [c. 1286A>C (p.E429A)] mutations are detected by amplification of the selected regions of MTHFR gene by polymerase chain reaction (PCR) and fluorescent probes hybridization to the targeted regions, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.** **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.** **Health care providers, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.**
Methodology	**Hybeacons**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** **85986610** / **MTHFR**

Prothrombin (Factor II) 20210G>A Mutation Analysis	
Effective Date	**2/12/2013**
Test Code	17909
CPT Codes	**81240**
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 days**
Reference Range	**Accompanies report**
Always Message	**The G20210A mutation [AF478696.1: g.21538G>A (c.*97G>A)] in the Prothrombin/Factor II gene is the second most common inherited risk factor for thrombosis occurring in approximately 2% of Caucasians. Presence of the mutation is associated with an elevation of prothrombin levels to about 30% above normal in heterozygotes and to 70% above normal in homozygotes.**

	The G20210A mutation is detected by amplification of the selected region of Factor II gene by polymerase chain reaction (PCR) and fluorescent probe hybridization to the targeted region, followed by melting curve analysis with a real time PCR system. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data. **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.** **Health care providers, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with interpretation of these results.**
Methodology	**Hybeacons**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code**: **85994504** — **Result Name**: **Prothrombin (Factor II)**

SMA Carrier Screen	
Effective Date	**2/12/2013**
Test Code	18041
CPT Codes	**81401**
Specimen Requirements	**Chorionic villi samples are no longer acceptable**
Instructions	**Whole blood: Normal phlebotomy procedure. Store and ship ambient immediately. Do not freeze.**
Set-up/Analytic Time	**Set up: Daily; Report available: 3-4 days**
Methodology	**Allele Specific Real-Time Polymerase Chain Reaction, ddCt Method**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name**: 86008027 — Technical Results 86008021 — SMN1 86008026 — SMN2 86008020 — Interpretation
Additional Information	Updated CPU mapping to remove analytes for Comments, Methods and References.

SMA Diagnostic Test	
Effective Date	**2/12/2013**
Test Code	S50070
CPT Codes	**81401**
Specimen Requirements	4 mL whole blood collected in EDTA (lavender-top) tube **or cultured cells from amniotic fluid collected in two T-25 flasks.** **Chorionic villi samples and cultured amniocytes are no longer acceptable**
Instructions	**For prenatal diagnosis with a fetal specimen:**

	1) parents must be documented carriers of one of the mutations tested; **2) maternal blood or DNA must be available to rule out maternal cell contamination (order test code 10262X);** **3) contact the laboratory genetic counselor before submission. Amniotic Fluid: Normal collection procedure. Specimen stability is crucial. Store and ship ambient immediately. Amniocyte or chorionic villus culture: Two sterile T25 flasks, filled with culture medium. Specimen stability is crucial. Store and ship ambient immediately. Do not refrigerate or freeze.**
Specimen Stability	Whole blood **Room temperature: 8 days** Cultured cells from amniotic fluid, amniotic fluid and cultured cells from CVS **Room temperature: 48 hours** **Refrigerated and Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Daily; Report available: 7-8 days** **Prenatal samples require added time for confirmatory testing**
Methodology	**Allele Specific Real-Time Polymerase Chain Reaction, ddCt Method**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Result Name** **86008027** / **Technical Results** 86008021 / SMN1 86008026 / SMN2 86008020 / Interpretation
Additional Information	Updated CPU mapping to remove analytes for Comments, Methods and References.

Alpha-1-Antitrypsin, Quantitative	
Clinical Significance	**Alpha-1-Antitrypsin level may be increased in normal pregnancy and in several diseases including chronic pulmonary disease; hereditary angioedema; renal, gastric, liver and pancreatic diseases; diabetes; carcinomas and rheumatoid diseases. Alpha-1-Antitrypsin may be decreased in emphysema, hepatic cirrhosis, respiratory distress syndrome of the newborn, nephrosis, malnutrition and cachexi**a.
Effective Date	**2/26/2013**
Former Test Name	***Alpha-1-Antitrypsin***
Test Code	1513
Reject Criteria	**Gross hemolysis,gross lipemia,gross icteria**
Instructions	**Overnight fasting is preferred. Centrifuge and transfer serum specimens to clean, plastic, screw-capped vial(s).**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 2 days** **Refrigerated: 7 days** **Frozen: 3 monts**
Reference Range	**83-199 mg/dL**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 1614 / Alpha-1-Antitrypsin PhenotypR™ PLUS

Carbon Dioxide	
Effective Date	**2/26/2013**
Former Test Name	***Bicarbonate***
Test Code	5300
Specimen Stability	**Room Temperature: 48 hours** **Refrigerated: 72 hours** **Frozen: 30 days**
Reference Range	**19-30 mmol/L**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 5316 / Electrolyte Panel 5315 / Metabolic Panel, Basic 5317 / Comprehensive Metabolic Panel 5314 / Renal Function Panel

Cyclosporine A, Whole Blood [Immunoassay]	
Clinical Significance	**Cyclosporine (Cyclosporin A) is an immunosuppressant therapeutic agent used in the prevention of organ graft rejection. Measurement of blood levels is recommended due to the inter-individual variability of metabolism as well as the toxicity associated with excessive dosage.**
Effective Date	**2/26/2013**
Test Code	4311
Specimen Requirements	**2 mL (1 mL)** whole blood collected in an EDTA (lavender-top) tube
Reject Criteria	**Clotted**
Transport Temperature	**Room Temperature**
Units Of Measure	**mcg/L**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 4311SR / Cyclosporine A, Whole Blood [Immunoassay] with Serial Reporting

Fetal Fibronectin	
Clinical Significance	**Fetal fibronectin is a protein that performs two roles during pregnancy. It is produced by the placenta and acts as the glue that attaches the placenta to the uterine wall. In late pregnancy, it acts as a lubricant, aiding in the passage of the newborn through the vaginal canal. Amniotic fluid contains fetal fibronectin and when the membranes leak, fetal fibronectin can be detected in a cervicovaginal collection. This can be used as a predictor of pre-term delivery, defined as less than 37 weeks gestation.**
Effective Date	**2/26/2013**
Test Code	1440

Specimen Requirements	**Adeza Biomedical Specimen Collection Kit**
Instructions	**1. The specimen should be obtained from the posterior fornix of the vagina during a speculum examination. The polyester tipped swab provided in the collection kit should be inserted into the vagina and lightly rotated across the posterior fornix for approximately 10 seconds to absorb the cervical/vaginal secretions.** **2. Carefully remove the swab from the vagina and immerse the swab tip in the tube of buffer provided with the specimen collection kit.** **3. Break the shaft (at the score) even with the top of the tube. Align the shaft with the hole inside the tube cap and push down lightly over the shaft, sealing the tube.** **4. Label the tube with the patients name and any other identifying information required on the tube label. Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested for fetal fibronectin.**
Transport Temperature	Refrigerated
Specimen Stability	**Room Temperature: 8 hours** **Refrigerated: 72 hours** **Frozen: 3 months**
Set-up/Analytic Time	Set up: **Mon-Sun**; Report available: 1 day
Reference Range	**Negative**
Methodology	**Solid Phase Immunosorbent Colorimetric Assay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Additional Information	**Limitations:** **The Fetal Fibronectin test result should not be interpreted as absolute evidence for the presence or absence of a process that will result in delivery in < or = 7 days from specimen collection for symptomatic women or < or = 34 weeks, 6 days of gestation for asymptomatic women. A positive Fetal Fibronectin Enzyme Immunoassay or Rapid fFN result may be observed for patients who have experienced cervical disruption caused by, but not limited to, events such as sexual intercourse, digital cervical examination, or vaginal probe ultrasound. The test sensitivity is 86.4%, specificity is 82.3%, positive predictive value is 12.7%, and negative predictive value is 99.5% in symptomatic women.**

Glucose	
Effective Date	**2/26/2013**
Test Code	5301
Specimen Requirements	1 mL serum (minimum 0.5 mL) **Patient preparation: Fasting required. Fasting is defined as no consumption of food or beverage other than water for at least 8 hours before testing.**
Specimen Stability	**Whole blood (gray-top)**: **Room temperature: 24 hours** **Refrigerated: 72 hours** **Frozen: Unacceptable** **Note: Serum and plasma submissions must be separated from cells.**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Lead, Blood	
Message	**Removal of demographic "ask at order entry" questions in CPU mapping. Information for public health reporting is still required for applicable assays and should be included with order but will no longer be required in transmitted order. CPU mapping will include assay result codes only.**

Effective Date	**2/26/2013**
Test Code	4861W
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	

Test Codes:	**Name:**
4861X	LEAD, BLOOD (PRIORITY)
4861I	LEAD, BLOOD (OSHA)
4861IX	LEAD, BLOOD (OSHA PRIORITY)
4861CP	LEAD CAPILLARY
4080W	HEAVY METALS PANEL, BLOOD

Pneumocystis jiroveci (carinii), DFA	
Effective Date	**2/26/2013**
Former Test Name	***Pneumocystis jiroveci (carinii) Antigen Detection***
Test Code	7745
Specimen Requirements	**3 mL (2 mL) bronchial lavage/wash or sputum** **Alternatives:** **Bronchial brushing or Two acetone fixed slides from bronchial brushing/wash**
Instructions	**1. Source of specimen is required, please include on requisition.** **2. Respiratory specimens such as sputum, bronchial wash, bronchoalveolar lavage, or pleural fluid collected in sterile container are acceptable. Ship specimens on cold packs.** **3. Unacceptable specimens: specimen in fixatives, slides fixed with ethanol or formalin.**
Transport Temperature	Refrigerated
Specimen Stability	**Bronchial lavage/wash, sputum:** **Room temperature: Unacceptable** **Refrigerated: 7 days** **Frozen: Unacceptable** **Slides**: **Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 30 days**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

RPR (Monitor) with Reflex to Titer	
Effective Date	**2/26/2013**
Test Code	799
Reject Criteria	**Gross hemolysis; gross lipemia**
Instructions	**Remove current collection instructions**
Transport Temperature	**Room temperature**

Set-up/Analytic Time	**Set up: Tues-Sat; Report available: 1-5 days**
Always Message	**The RPR is a non-treponemal-specific test; therefore, a treponemal-specific confirmatory test should be performed unless prior syphilis infection has been documented for this patient.**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	**Result Name**
8600747	**RPR Screen**
***This is a true reflex. Please build the unit codes below separately. Non-Orderable Reflex* 799-2 Reflex RPR Titer**	
Result Code	**Result Name**
86007408	**RPR Titer**

Additional Information	**If the RPR Screen is Reactive, then the RPR Titer will be performed at an additional charge (CPT code 86593).**

Susceptibility, *Mycobacterium tuberculosis*, First-tier Drugs	
Clinical Significance	**Susceptibility reports can be used as a guide in the choice of first course therapy or in confirming antimicrobial resistance that leads to a further course of treatment. Also used to estimate the prevalence of primary and acquired antimicrobial resistance in a community.**
Effective Date	**2/26/2013**
Former Test Name	***AFB Susceptibility: M. tuberculosis Primary Drugs Susceptibility***
Test Code	5649
Specimen Requirements	**Pure culture of mycobacteria in Agar slant submitted in double walled container.**
Instructions	**Pure culture agar slant/plate or broth-based media must be safely contained in double-walled container. Transport at room temperature. Mixed or contaminated cultures are not acceptable.**
Specimen Stability	**Room Temperature: 30 days** **Refrigerated: 30 days** **Frozen: Unacceptable**
Always Message	**The units of measure, in mcg/mL, are the critical concentrations as they relate to the agar proportion method. The critical concentration is the lowest concentration that inhibits 95% of "wild type" strains of M. tuberculosis that have not been exposed to the drug, but that simultaneously does not inhibit strains of M. tuberculosis that are considered resistant when isolated from patients are not responding to therapy.** **This test was performed on the BACTEC MGIT 960 System.**
Methodology	**Broth Based Susceptibility (a variation of the Agar Proportion Method)**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

T3, Reverse	
Message	**Test is now approved for New York patients.**
Effective Date	**2/26/2013**
Former Test Name	***Triiodothyronine, Reverse (RT3)***
Test Code	3236
Assay Category	**FDA Exempt**

Performing Site	Quest Diagnostics Nichols Institute, Valencia

Tryptase	
Effective Date	**3/4/2013**
Test Code	3460
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 2 days** **Refrigerated: 7 days** **Frozen: 1 month**
Set-up/Analytic Time	**Set up: Tues,Thurs, Sat; Report available: 1-4 days**
Reference Range	**<11.0 ug/L**
Assay Category	**FDA Approved/Cleared**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

AFB Identification Mycobacterium spp. by HPLC	
Effective Date	**3/12/2013**
Former Test Name	***AFB Identification Mycobacterium spp. by HPLC reflex Suscept***
Test Code	5648
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Additional Information	**Add to Notes:** **6. If Mycobacterium tuberculosis is suspected please order test code 2939 AFB IDENTIFICATION BY DNA PROBE [GEN PROBE] W/REFLEX HPLC.**

***Chlamydia trachomatis* Antigen, DFA**	
Effective Date	**3/12/2013**
Former Test Name	***Chlamydia trachomatis Antigen Detection [DFA]***
Test Code	2440
Specimen Requirements	**Specimen 1: Smear/Slides 3.0 (2.0)** **Alternate:UTM/M4 Transport Media/Swab** **See COLLECTION INSTRUCTIONS** **Alternate: VCM Transport Media 3.0 mL (1.0mL)**
Instructions	**1. Specimens should be collected early in the acute phase of infection. The chance of microorganism recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many microorganisms** **2. Two prepared slides or smears can be submitted. Fix with methanol. Place in slide holder. Ship at ambient temperature** **3. Acceptable specimens:** **Urethral, cervical, rectal mucosal, eye, nasopharyngeal specimens.** **4. To maintain optimum viability, place swab or fluid into UTM or equivalent Chlamydia transport medium. Transport the specimen to the laboratory as soon as possible. Best recovery is obtained when the specimens are refrigerated at 2-8°C or kept on wet ice following collection and while in transit. If there will be a long delay before processing, specimens in UTM or equivalent should be frozen at -70°C or colder and transported on dry ice. Storage or transport at -20°C is not acceptable.** **5. Unacceptable specimens:** **Urine, wooden shaft or calcium alginate swabs, dry swabs. Swabs in bacterial gel-based transport**

	media, swabs in nucleic acid transport media, tissues in fixatives. Broken slides. **6. Specimen source is essential because processing and set up is dependent on it. Indicate on the requisition form where specimen was obtained.** **9. Universal transport media (UTM) and dacron-tipped swabs with plastic or fine-wire shafts available for use with UTM are provided. Please call Client Services, 800-421-4449 to request media.**
Specimen Stability	**Specimen 1: Smear/Slides** **Room temperature: 14 days** **Refrigerated: 14 days** **Frozen: 14 days** **Alternate:UTM/M4 Transport Media/Swab** **Room temperature: 24 hours** **Refrigerated: 72 hours** **Frozen: 7 days** **Alternate: VCM Transport Media** **Room temperature: 24 hours** **Refrigerated: 72 hours** **Frozen: 7 days**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

***Chlamydia trachomatis* Culture**	
Effective Date	**3/12/2013**
Test Code	2400
Specimen Requirements	**Specimen 1: UTM/M4 Transport Media/Swab 3.0ml (1.0ml)** **See COLLECTION INSTRUCTIONS** **Alternate: VCM Transport Media 3.0 mL (1.0mL)**
Instructions	**1. Specimen source is essential because processing and set up is dependent on it. Indicate on the requisition form where specimen was obtained.** **2. Specimens should be collected early in the acute phase of infection. The chance of microorganism recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many microorganisms** **3. Acceptable specimens:** **Urethral, cervical, rectal mucosal, eye, nasopharyngeal (aspirate/wash/swab) specimens, body fluid, seminal fluid.** **4. To maintain optimum viability, place swab or fluid into UTM or equivalent Chlamydia transport medium and transport the specimen to the laboratory as soon as possible. Best recovery is obtained when the specimens are refrigerated at 2-8°C or kept on wet ice following collection and while in transit. If there will be a long delay before processing, specimens in UTM or equivalent should be frozen at -70°C or colder and transported on dry ice. Storage or transport at -20°C is not acceptable. Raw (unpreserved) samples should only be refrigerated and not frozen.** **5. Unacceptable specimens:** **Urine, wooden shaft or calcium alginate swabs, dry swabs. Swabs in bacterial gel-based transport media, swabs in nucleic acid transport media, tissues in fixatives** **6. Universal transport media (UTM) and dacron-tipped swabs with plastic or fine-wire shafts available for use with UTM are provided. Please call Client Services, 800-421-4449 to request media**
Specimen Stability	**Specimen 1: UTM/M4 Transport Media/Swab** **Room temperature: 24 hours** **Refrigerated: 72 hours** **Frozen: 7 days** **Alternate: VCM Transport Media** **Room temperature: 24 hours** **Refrigerated: 72 hours** **Frozen: 7 days**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

<table>
<tr><th colspan="2">Growth Hormone</th></tr>
<tr><td>Effective Date</td><td>3/12/2013</td></tr>
<tr><td>Test Code</td><td>3182</td></tr>
<tr><td>Specimen Requirements</td><td>1 mL (0.5 mL) Serum</td></tr>
<tr><td>Reference Range</td><td>< 20 years: < or = 13.0 ng/mL
> or = 20 years: < or = 10.0 ng/mL</td></tr>
<tr><td>Always Message</td><td>Because of a pulsatile secretion pattern, random (unstimulated) growth hormone (GH) levels are frequently undetectable in normal children and adults are not reliable for diagnosing GH deficiency. Regarding suppression tests, failure to suppress GH is diagnostic of acromegaly. Typical GH response in healthy subjects:
Using the glucose tolerance (GH suppression) test, acromegaly is ruled out if the patient's GH level is <4.0 ng/mL at any point in the timed sequence. Using GH stimulation testing, the following result at any point in the timed sequence makes GH deficiency unlikely:
Adults (> or = 20 years)
Insulin Hypoglycemia: > or = 5.1 ng/mL
Arginine/GHRH > or = 4.1 ng/mL
Children (< 20 years)
All Stimulation Tests > or = 10.0 ng/mL</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, Valencia</td></tr>
<tr><td>Tests Affected</td><td>
<table>
<tr><th>Test Codes:</th><th>Name:</th></tr>
<tr><td>3171</td><td>Growth Hormone (GH), 2 Specimens</td></tr>
<tr><td>3175</td><td>Growth Hormone (GH), 3 Specimens</td></tr>
<tr><td>3185</td><td>Growth Hormone (GH), 4 Specimens</td></tr>
<tr><td>3195</td><td>Growth Hormone (GH), 5 Specimens</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th colspan="2">Respiratory Virus Panel, DFA</th></tr>
<tr><td>Effective Date</td><td>3/12/2013</td></tr>
<tr><td>Former Test Name</td><td>Respiratory Infection Evaluation, Viral</td></tr>
<tr><td>Test Code</td><td>2425</td></tr>
<tr><td>Specimen Requirements</td><td>Specimen 1: Viral Transport Media or equivalent 3.0mL (1.0mL)

Alternates:
M4 / VCM Transport Media/Swab 3.0mL (1.0mL)
Sterile Container/Tube 3.0mL (1.0mL)
Smear/Slides 8.0 (4.0)</td></tr>
<tr><td>Instructions</td><td>Collection instructions
1. Source of specimen is required, please include on requisition.
2. 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.
3. Submit 8 acetone-fixed slides or specimens in viral transport media.
Acceptable specimens: Nasopharyngeal swab/washings/aspirate, bronchial lavage.
4. Unacceptable specimens:
Throat swabs on patients less than 2 years of age, non-respiratory sites, specimen in nucleic acid transport system, dry swabs, wooden or calcium alginate swabs, samples received ambient or frozen at -20 degrees C.
5. Specimens received more than 72 hours from time of draw must be frozen at -70C or on dry ice. Do not freeze at -20 C. Virus loses infectivity.
6. Ship specimens on cold pack or on dry ice.
7. Viral transport media and dacron-tipped swabs with plastic or fine-wire shafts available for use are provided. Please call Client Services, 800-421-4449 to request media.</td></tr>
</table>

Specimen Stability	**Specimen 1: Viral Transport Media or equivalent** **Room temperature: Unacceptable** **Refrigerated: 4 days** **Frozen: 30 days** **Alternate: M4 / VCM Transport Media/Swab** **Room temperature: Unacceptable** **Refrigerated: 4 days** **Frozen: 30 days** **Alternate: Sterile Container/Tube** **Room temperature: Unacceptable** **Refrigerated: 72 hours** **Frozen: Unacceptable** **Alternate: Smear/Slides** **Room temperature: 7 days** **Refrigerated: 7 days** **Frozen: 7 days**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	

Test Codes:	Name:
2424	Parainfluenza Types 1-3 Antigen
2423	Influenza Virus, Types A & B Detection [DFA]
2523	Influenza Virus, Types A Detection [DFA]
2524	Influenza Virus, Types B Detection [DFA]
2509	Adenovirus Antigen Detection
2704	Respiratory Syncytial Virus Antigen Detection [DFA]

Group B Strep, PCR	
Effective Date	**3/18/2013**
Former Test Name	***Streptococcus Group B DNA DetectR™***
Test Code	9640
Always Message	**According to the College of American Pathologists (CAP), all patients testing negative for GBS by direct PCR should be cultured for GBS by the broth method.**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Ferritin	
Clinical Significance	**Useful in the diagnosis of hypochromic, microcytic anemias. Decreased in iron deficiency anemia and increased in iron overload.**
Effective Date	**3/19/2013**
Test Code	3170
Specimen Requirements	**1.0 mL (0.5 mL)** Serum
Reject Criteria	**Grossly hemolyzed**
Specimen Stability	**Applies to test code 3170 only:**

	Room temperature: 7 days **Refrigerated: 7 days** **Frozen: 28 days**
Reference Range	**Age (ng/mL) Female (ng/mL) Male (ng/mL) Age (ng/mL) Female (ng/mL) Male (ng/mL)** **< 1 month 25 – 200 25 – 200 20 – 39 years 10 – 154 20 – 345** **1 – 2 months 200 – 600 200 – 600 40 – 59 years 10 – 232 20 – 380** **3 – 5 months 50 – 200 50 – 200 > 59 years 20 - 288 20 - 380** **6 – 11 months 7 – 140 7 – 140** **1 – 19 years 10 – 143 10 – 105**
Always Message	**Remove existing message.**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 3535 / Iron Status MonitR

Redirects

Hemoglobin, Free, Plasma	
Effective Date	**2/11/2013**
Former Test Name	*Hemoglobin Plasma [514]*
Former Test Code	*S51309*
Test Code	514
Instructions	**Centrifuge plasma within 1 hour of collection, transfer the plasma to a sterile, plastic, screw-cap vial(s), and send refrigerated (cold packs).**
Set-up/Analytic Time	**Mon-Fri; Report available 2-3 days**
Performing Site	**Quest Diagnostics Nichols Institute, Chantilly**
CPU Mappings	**Result Code** / **Result Name** **85988650** / **Hemoglobin, Free, Plasma**

Testosterone, Free and Total, LC/MS/MS	
Effective Date	**2/19/2013**
Former Test Name	*Testosterone, Free and Total LC/MS/MS [36170][NY]*
Former Test Code	*S51829N*
Test Code	**36170**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name**

85996653	Testosterone Total
86000542	Testosterone Free

Biotin (Vitamin B7)	
Effective Date	**2/26/2013**
Former Test Name	*Biotin 1493*
Former Test Code	*S41147*
Test Code	391
CPT Codes	84591
Specimen Requirements	2 mL (1 mL) frozen serum - **protect from light**
Reject Criteria	Gross hemolysis, Lipemia, Received room temperature, Received refrigerated, Samples not protected from light, Samples other than serum
Instructions	Allow sample to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes and transfer serum to plastic, amber vial. If amber vial is not available. wrap tube in aluminum foil to protect from light. **Freeze within 30 minutes and send frozen.**
Transport Temperature	Frozen
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days
Set-up/Analytic Time	Set up: Tue; Report Available: 19 days
Reference Range	Pediatric (<12 years): 57.0-2460.2 pg/mL Adult (> or =12 years): 221.0-3004.0 pg/mL
Units Of Measure	pg/mL
Always Message	The performance characteristics of the listed assay was validated by Cambridge Biomedical Inc. The US FDA has not approved or cleared this test. The results of this assay can be used for clinical diagnosis without FDA approval. Cambridge Biomedical Inc. is a CLIA certified, CAP accredited laboratory for performing high complexity assays such as this one.
Methodology	Bioassay
Assay Category	Laboratory Developed Test
Performing Site	Cambridge Biomed Research Group
CPU Mappings	**Result Code**: 85997128 — **Result Name**: Vitamin B7 (Biotin)

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	**2/26/2013**

Former Test Name	*Pantothenic Acid*
Former Test Code	*S44445*
Test Code	**91030**
CPT Codes	**84591**
Specimen Requirements	**1.2 mL (0.6 mL) Serum** **Alternate: 1.2 mL (0.6 mL) Plasma collected in an EDTA (lavender-top) or Sodium heparin (green-top)**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 6 hours** **Refrigerated: 4 days** **Frozen: 30 days**
Set-up/Analytic Time	**Mon,Wed, Fri; 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**

Cobalt, Serum/Plasma [345]	
Clinical Significance	**Purpose: Occupational exposure monitoring, evaluation of orthopedic implants**
Effective Date	**3/5/2013**
Former Test Name	*Cobalt [3480]*
Former Test Code	*S50818*
Test Code	**345**
CPT Codes	83018
Specimen Requirements	**0.5 mL (0.2 mL) serum collected in no additive (royal blue-top) tube** **Alternate: 0.5 mL (0.2 mL) plasma collected in an EDTA (royal blue-top) tube**
Instructions	**All venipunctures should be performed using trace metal-free, dark/royal blue top tubes. Promptly centrifuge and separate serum or plasma specimens into acid-washed, plastic, screw-capped vial(s), using approved guidelines.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 10 days** **Refrigerated: 10 days** **Frozen: 10 days**
Set-up/Analytic Time	**Set-up: Mon-Fri; Report available 3-4 days**
Reference Range	**0.1-0.4 mcg/L**

Units Of Measure	mcg/L
Methodology	Inductively-Coupled Plasma/Mass Spectrometry
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, Chantilly**
CPU Mappings	**Result Code**: **86008383** — **Result Name**: **Cobalt, Serum/Plasma**

Discontinued Tests

Comprehensive Drug Screen Stool [1864ST]	
Effective Date	**1/7/2013**
Test Code	S50604
Additional Information	The recommended alternative is 4129U Drugs Of Abuse Screen Urine W/reflex Confirmation performed at Quest Diagnostics Nichols Institute, Valencia

Bartonella DNA PCR, Tissue [47000]	
Effective Date	**1/22/2013**
Test Code	S49602
Additional Information	The replacement test is S51531 Bartonella DNA PCR [47000] performed at Focus Diagnostics

Deoxycorticosterone [6559X]	
Effective Date	**1/22/2013**
Test Code	S51354
Additional Information	The recommended alternative is: 90973 Deoxycorticosterone, LC/MS/MS, in the New Test Offerings Section

Treponema pallidum Total Antibodies, FTA-Antibodies Quant	
Effective Date	**1/22/2013**
Test Code	7560
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Additional Information	**Suggested alternative test 2104 Treponema pallidum Total Antibodies [IFA]**

Vitamin B3 (Whole Blood Niacin)	
Effective Date	**2/25/2013**
Test Code	S44505

Additional Information	The recommended alternative is: 91029 Vitamin B3 performed at Quest Diagnostics Nichols Institute, Valencia

Zolpidem Screen Urine [9498]	
Effective Date	**2/26/2013**
Test Code	S49644
Additional Information	The recommended alternative is: • 91258 Zolpidem Quantitation, Urine performed at Quest Diagnostics Nichols Institute, Chantilly

New York Update

SureSwab™ Herpes Simplex Virus, Type 1/2 DNA, Real-Time PCR	
Message	**Test is now approved for New York patients.**
Effective Date	**12/12/2012**
Test Code	90570
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Vitamin B2 [36399]	
Message	*** This test is not available for New York patient testing. ***
Effective Date	**1/29/2013**
Test Code	S49825
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Testosterone, Free, Total, and Sex Hormone Binding Globulin	
Message	**Test is now approved for New York patients.**
Effective Date	**1/30/2013**
Test Code	3231
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 37073 / Testosterone,Total and Free and Sex Hormone Binding Globulin

Testosterone, Total, LC/MS/MS	
Message	**Test is now approved for New York patients.**
Effective Date	**1/30/2013**

Test Code	3922
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Tests Affected	**Test Codes:** / **Name:** 36170 / Testosterone, Free and Total. LC/MS/MS

Send Outs

Lyme Disease Antibody Index for CNS Infection	
Effective Date	**1/22/2013**
Test Code	S52388
Specimen Requirements	**2 mL serum (1.0 mL) AND 2 mL CSF (1.0 mL)**
Performing Site	Focus Diagnostics

***Sporothrix* Antibody [9673]**	
Clinical Significance	**Aiding in the diagnosis of extracutaneous sporotrichosis.**
Effective Date	**1/22/2013**
Test Code	S49883
Reject Criteria	**Gross hemolysis; Gross lipemia**
Set-up/Analytic Time	**Mon,Wed,Fri; Report available: 1-4 days**
Performing Site	Mayo Medical Laboratories

Acetone Blood [205]	
Effective Date	**1/29/2013**
Test Code	S41710
Specimen Requirements	**1 mL (0.5 mL) whole blood collected in a fluoride oxalate (gray-top) tube** **Alternative:** **1 mL (0.5 mL) whole blood (EDTA or heparin)**
Instructions	**Do not use alcohol solutions** as skin preparation for drawing specimens. Use non-alcohol solutions such as Betadine(R) or Zephiran (R). Keep transport container tightly sealed.
Set-up/Analytic Time	**Set-up: Tue-Sat; Report available: 72 hours**
Reference Range	**None detected**
Always Message	**Reportable Limit: 5 mg/dL**
Performing Site	Quest Diagnostics, West Hills

<table>
<tr><th colspan="2">Acylglycines Quant [81249]</th></tr>
<tr><td>Effective Date</td><td>1/29/2013</td></tr>
<tr><td>Test Code</td><td>S47310</td></tr>
<tr><td>Specimen Requirements</td><td>10 mL (4 mL minimum) random urine collected in a 10-mL urine tube</td></tr>
<tr><td>Reject Criteria</td><td>Specimens other than urine
Received room temperature</td></tr>
<tr><td>Instructions</td><td>Collect a random urine specimen (no preservative). Patient age is required. Include family history, clinical condition (asymptomatic or acute episode), diet and drug therapy information.</td></tr>
<tr><td>Specimen Stability</td><td>Refrigerated: 24 hours
Frozen: 1 year</td></tr>
<tr><td>Performing Site</td><td>Mayo Medical Laboratories</td></tr>
<tr><td>CPU Mappings</td><td>
<table>
<tr><th>VAL
Result Code:</th><th>Result Name:</th></tr>
<tr><td>100509</td><td>Ethylmalonic Acid</td></tr>
<tr><td>100510</td><td>2-Methylsuccinic Acid</td></tr>
<tr><td>100511</td><td>Glutaric Acid</td></tr>
<tr><td>100512</td><td>Isobutyrylglycine</td></tr>
<tr><td>47310</td><td>n-Butyrylglycine</td></tr>
<tr><td>100513</td><td>2-Methylbutyrylglycine</td></tr>
<tr><td>100514</td><td>Isovalerylglycine</td></tr>
<tr><td>47311</td><td>n-Hexanoylglycine</td></tr>
<tr><td>100515</td><td>n-Octanoylglycine</td></tr>
<tr><td>47312</td><td>3-Phenylpropionylglycine</td></tr>
<tr><td>100516</td><td>Suberylglycine</td></tr>
<tr><td>101781</td><td>trans-Cinnamoylglycine</td></tr>
<tr><td>100587</td><td>Dodecanedioic Acid</td></tr>
<tr><td>100588</td><td>Tetradecanedioic Acid</td></tr>
<tr><td>100589</td><td>Hexadecanedioic Acid</td></tr>
<tr><td>110833</td><td>Interpretation</td></tr>
<tr><td>86004979</td><td>Reviewed By</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th colspan="2">IBD sgi Diagnostic (1800)</th></tr>
<tr><td>Effective Date</td><td>1/29/2013</td></tr>
<tr><td>Test Code</td><td>S52567</td></tr>
<tr><td>Always Message</td><td>General Test Information
Patient test results are based on the Smart Diagnostic Algorithm which interprets complex patterns among assay values from a combination of serologic, genetic, and inflammatory markers.
The test was developed using 1,520 samples from well-characterized IBD patients and non-IBD disease and healthy controls.</td></tr>
</table>

Overall performance of PROMETHEUS IBD sgi Diagnostic: Sensitivity IBD 74%, CD 89%, UC 98%; Specificity IBD 90%, CD 81%, UC 83%. Smart Diagnostic Algorithm technology was trained (n=1083; 39% CD, 21% UC, 29% disease controls, and 11% healthy controls) and validated (n=437; 35% CD, 23% UC, 28% disease controls, and 14% healthy controls) from results of serology, genetic, and inflammation assays. A test result is the product of a collective evaluation of all individual assays by a complex algorithm. From this, it is possible to produce a result of "Pattern Not Consistent with IBD" when one or more assay values are above the specified reference value. It is also possible to produce a result of "Pattern Consistent with IBD" when all individual assay values are below the specified reference value. Reference values have been calculated based on a population of non-IBD controls.

Patient samples exhibiting a pattern consistent with IBD but not conclusive for a Crohn's Disease or Ulcerative Colitis pattern determination.

References available on request.

Prometheus diagnostic services provide important information to aid in the diagnosis and management of certain diseases. Test results should be used with other clinical and diagnostic findings to make a diagnosis. This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This this test may be covered by one or more US pending or issued patents - see prometheuslabs.com for details

Performing Site: Promethesus

CPU Mappings

Result Code	Result Name
113781	Patient Test Result
113763	ASCA IgA ELISA
113764	ASCA IgG ELISA
113765	Anti-OmpC IgA ELISA
113766	**Anti-CBir1 IgG ELISA**
113767	Anti-A4-Fla2 IgG ELISA
113768	Anti-FlaX IgG ELISA
113769	AutoAntibody ELISA
113770	IFA Perinuclear Pattern
113771	DNAse Sensitivity
113772	ATG16L1 SNP (rs2241880)
113773	ECM1 SNP (rs3737240)
113774	**NKX2-3 SNP (rs10883365)**
113775	STAT3 SNP (rs744166)
113776	ICAM-1
113777	VCAM-1
113778	VEGF
113779	CRP
113780	SAA

Monogenic Diabetes (MODY) Eval [885]	
Effective Date	**1/29/2013**
Former Test Name	*Monogenic Diabetes (MODY) Eval [850]*
Test Code	S51162
CPT Codes	**81406+AT (X2) and 81479+AT (X8)**
Instructions	**Hemolysis may compromise DNA recovery and integrity after 48 hrs**
Methodology	**DNA sequencing, Multiplex Ligation-dependent Probe Amplification**
Performing Site	Athena Diagnostics
Additional Information	**Indications for Testing: Non-ketotic insulin-sensitive hyperglycemia in individuals of any age; Family history of diabetes** **Profile Includes:** **GCK (MODY2) DNA Sequencing and DeletionTest, HNF4A (MODY1) DNA Sequencing and Deletion Test, IPF1 (MODY4) DNA Sequencing Test, TCF1 (MODY3) DNA Sequencing and Deletion Test, TCF2 (MODY5) DNA Sequencing and Deletion Test**

Phospholipids [717]	
Effective Date	**1/29/2013**
Test Code	S51301
Reject Criteria	**Plasma; lipemia**
Instructions	**Centrifuge within 1 hour of collection. Immediately separate serum specimens from the cells into clean, plastic, screw-capped vial(s).**
Transport Temperature	**Refrigerated**
Specimen Stability	**Frozen: 60 days**
Set-up/Analytic Time	**Set up: Mon, Thurs; Report available: 1-4 days**
Performing Site	**This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano, will now be performed at Quest Diagnostics Nichols Institute, Chantilly.**

Cimetidine [1262]	
Effective Date	**2/4/2013**
Test Code	S43665
Specimen Requirements	3 mL serum **collected in a red-top tube (no gel)** --or-- 3 mL plasma collected in an **EDTA (lavender-top) or EDTA (pink-top) tube**
Reject Criteria	Polymer gel separation tube (SST or **PST**)
Specimen Stability	**Room temperature, Refrigerated and Frozen: 30 days**
Set-up/Analytic Time	**Set up: Thurs; Report available: 2 days**
Performing Site	National Medical Services

Metoclopramide, Serum/Plasma [3041SP]	
Effective Date	**2/4/2013**

Test Code	S52175
Specimen Requirements	**3 mL (1.2 mL minimum)** serum collected in a red-top tube (no gel) --or-- 3 mL plasma collected in an **EDTA (lavender-top) or EDTA (pink-top) tube**
Specimen Stability	Room temperature: 14 days **Refrigerated and Frozen: 30 days**
Set-up/Analytic Time	**Set up: Thurs; Report available: 2 days**
Performing Site	National Medical Services

Prostaglandins PG-D2	
Effective Date	**2/4/2013**
Test Code	S47815
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 24 Hours** **Frozen: 6 Months**
Performing Site	Interscience

CD57, CD3, CD8, Flow Cytometry	
Effective Date	**2/11/2013**
Test Code	S52011
Reference Range	

CD57+/CD3- of % Lymphs	**1 - 10 % Lymphocytes**
CD57+/CD3- of % WBC	**1 - 4 % WBC**
CD57+/CD3- Cells/uL	**20 - 258 Cells/uL**
CD57+/CD3-/CD8- of % Lymph	**1 - 5 % Lymphocytes**
CD57+/CD3-/CD8- of % WBC	**1 - 3 % WBC**
CD57+/CD3-/CD8- Cells/uL	**20 - 114 Cells/uL**
CD57+/CD8- of % Lymphs	**1 - 15 % Lymphocytes**
CD57+/CD8- of % WBC	**1 - 4 % WBC**
CD57+/CD8- Cells/uL	**20 - 248 Cells/uL**

Always Message	**It has been reported that lower frequencies of circulating CD57+ NK cells can be associated with chronic Lyme Disease. Increasing levels of CD57+CD3- lymphocytes over time for patients on antibiotic therapy appeared to correlate with clinical improvement (Stricker, RA and E.E. Winger, Immunology Letters 76 (2001) pp 43-48) .** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute. Performance characteristics refer to the analytical performance of the test.**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	**Result Name**
86002787	**CD57+/CD3- of % Lymphs**
86002788	**CD57+/CD3- of % WBC**

86002789	**CD57+/CD3- Cells/uL**
86002793	**CD57+/CD3-/CD8- of % Lymph**
86002794	**CD57+/CD3-/CD8- of % WBC**
86002795	**CD57+/CD3-/CD8- Cells/uL**
86002790	**CD57+/CD8- of % Lymphs**
86002791	**CD57+/CD8- of % WBC**
86002792	**CD57+/CD8- Cells/uL**

D-Xylose Absorption Blood Fasting [1198X]	
Effective Date	**2/11/2013**
Test Code	S49112
Specimen Requirements	**4 mL (1 mL minimum) whole blood collected in a sodium fluoride (gray-top) tube**
Instructions	**For fasting test, patient should fast overnight before blood collection.** **4 mL blood, drawn 1 hour post oral ingestion of d-Xylose. Label sample vial with patient's name and the time of collection postdose (e.g., 1 hour, etc.).** **4 mL blood, drawn 2 hours post oral ingestion of d-Xylose. Label sample vial with patient's name and the time of collection postdose (e.g., 2 hour, etc.).**
Set-up/Analytic Time	**Set up: Mon, Thurs; Report available: Next day**
Reference Range	**d-Xylose Absortion Test, Blood, Fasting** **Accompanies report** **d-Xylose Absortion Test, Blood, 1 Hour** **Age:** — **ReferenceRange:** **< 6 years** — **>14.9 mg/dL** **> or = 6 years** — **>19.9 mg/dL** **d-Xylose Absortion Test, Blood, 2 hour** **Age:** — **ReferenceRange:** **< 6 years** — **>14.9 mg/dL** **> or = 6 years** — **>19.9 mg/dL** **d-Xylose Absortion Test, Urine** — **ReferenceRange:** **25 g dose** — **4.1-8.2 g in 5hr urine** **5 g dose** — **1.2-2.4 g in 5-hr urine**

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	

Test code: S49112	
Result Code:	**Result Name:**
85990790	**d-Xylose, Blood, Fasting**
Test code: S49113	
85990784	**d-Xylose, Blood, 1 hr**
Test code: S49114	
85990785	**d-Xylose, Blood, 2hr**
Test code: S49104	
86002858	**d-Xylose, Urine, 5hr**
86002859	**Urine Total Volume**

Tests Affected

Test Codes:	**Name:**
S49113	D-Xylose Absorption Blood 1 Hour [104521P]
S49114	D-Xylose Absorption Blood 2 Hours [104547P]]
S49104	D-Xylose Absorption Urine 5Hr [16469P]

HIV-1 Integrase Genotype [16868]	
Effective Date	**2/11/2013**
Test Code	S52113
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.** **The method used in this test is RT-PCR and sequencing of the HIV-1 integrase gene. The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies.** **The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings.**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	

Result Code	**Result Name**
112691	Value of Last Viral Load

	112692 — Date Viral Load Collected 112251 — Raltegravir Resistance **86008936 — Elvitegravir Resistance**
Additional Information	Report format change

Prekallikrein (Fletcher Factor) Activity [10334X]	
Effective Date	**2/11/2013**
Test Code	S51368
Additional Information	There is no recommended alternative for this test

Serotonin, Blood	
Effective Date	**2/12/2013**
Test Code	S51656
Reference Range	**56-244 ng/mL**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Hexosaminidase A and Total, S	
Message	**This test is now available for New York patient testing.*
Effective Date	**2/21/2013**
Former Test Name	*Hexosaminidase A and Total Hexosaminidase, Serum*
Test Code	S52578
Instructions	**Forms: New York State Clients-Informed consent is required. Please document on the request form or electronic order that a copy is on file.**
Transport Temperature	**Frozen**
Reference Range	**Hexosaminidase Total, S** **< or =15 yrs** — **> or =20 nmol/min/mL** **> or =16 yrs** — **10.4-23.8 nmol/min/mL** **Hexosaminidase Percent A,S** **< or =15 yrs** — **20-90%** **> or =16 yrs** — **56-80%**
Units Of Measure	**nmol/min/mL**
Performing Site	Mayo Medical Laboratories
CPU Mappings	**VAL Result Code:** — **Result Name:**

113795	**Hexosaminidase Total, S**
113796	**Hexosaminidase Percent A, S**
113797	**Interpretation (NAGS)**
86004126	Reviewed By

Additional Information	**The following result code will be removed from the VAL unit code: 113794**

Hexosaminidase A and Total, WBC	
Effective Date	**2/21/2013**
Former Test Name	*Hexosaminidase Blood [8775]*
Test Code	S49273
Reference Range	**Hexosaminidase Total** **< or =15 yrs** — **> or =20 nmol/min/mg** **> or =16 yrs** — **16.4-36.2 nmol/min/mg** **Hexosaminidase Percent A** **< or =15 yrs** — **20-80% of total** **> or =16 yrs** — **63-75% of total**
Units Of Measure	**nmol/min/mg**
Performing Site	Mayo Medical Laboratories
CPU Mappings	**VAL Result Code:** / **Result Name:** 35380 — **Hexosaminidase Total, WBC** 35381 — **Hexosaminidase Percent A, WBC** 35382 — **Interpretation (NAGW)** **86009305** — **Reviewed By**

Toxocara Antibody, ELISA (Fluid) [60945]	
Message	**This test is not available for NY patient testing**
Effective Date	**2/25/2013**
Former Test Name	*Toxocara Antibody, Fluid [60945]*
Test Code	S50740
Reference Range	**Negative**
Always Message	**Reference Range: Negative** **As with many parasitic serology assays, antibodies induced by other parasitic infections may crossreact in this assay.**
Performing Site	Focus Diagnostics, Inc.

Toxocara Antibody, ELISA (Serum) [40945]	
Effective Date	**2/25/2013**
Former Test Name	*Toxocara Abs [40945]*
Test Code	S50345
Reference Range	**Negative**
Always Message	**Reference Range: Negative** **Results of this assay must be interpreted with caution, as broad variations in antibody response occur, and levels may remain elevated for years after infection. Further, as with many parasitic serology assays, antibodies induced by other parasitic infections may crossreact in this assay. Although a negative result usually rules out infection with Toxocara spp., parallel testing of serial samples may prove useful in following patients with suspected Toxocara infection.**
Performing Site	Focus Diagnostics, Inc.

Legionella pneumophilia Antibodies (IgM)	
Effective Date	**2/26/2013**
Former Test Name	*Legionella Ab IgM [40605]*
Test Code	S41360
CPT Codes	86713 (x2)
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**
Reference Range	**Reference Range: <1:16** **IgM antibodies to Legionella pneumophila serogroup 1 and 6 additional L. pneumophila serogroups (2, 3, 4, 5, 6, 8) are measured using an IgM specific conjugate. We recommend that the IgM test always be performed in conjunction with the polyvalent antibody test.** **The IgM response to Legionella tends to develop concurrently with the IgG response and may remain elevated as long as the IgG response remains elevated. Cross reactions have been described with several species of bacteria and mycoplasma.** **This test was developed and its performance characteristics have been determined by Focus Diagnostics. 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.**
Performing Site	Focus Diagnostics
CPU Mappings	**Result Code** / **Result Name** **41360** / **L pneumophila (Sero 1)** **103045** / **L pneumophila(Sero 2-6,8)**