March 2014 - 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 #
91969	**PD-L1 Expression**	3/3/2014	2
92053	**ASCVD Risk Panel with Score**	3/10/2014	3
91234	**Respiratory Virus PCR Panel with 2009 H1N1**	4/21/2014	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 #
2692	2402	Herpes Simplex Virus Culture	4/7/2014	6
2649	2427	Herpes Simplex Virus Culture with Reflex to Typing	4/7/2014	6
17355	S51711	FISH, Locus-specific Probe (x1)	4/14/2014	7
19550		SureSwab, *Trichomonas vaginalis* RNA, Qualitative, TMA	4/14/2014	8
18873	S50959	**Aspergillus DNA, Qualitative Real-Time PCR**	4/21/2014	8
11274	S51498	**BK Virus DNA, Quantitative Real-Time PCR, Plasma**	4/21/2014	8
38482	RF342	**Black Olive (Rf342) IgE**	4/21/2014	9
17825	S51776	Bordetella pertussis IgG and IgA Antibodies, MAID	4/21/2014	9
10601	S49983	Cytomegalovirus DNA, Qualitative Real-Time PCR	4/21/2014	10
92029	RF307	**Hake (f307) IgE**	4/21/2014	10
35664	S51509	**Hepatitis D Virus (HDV) IgM Antibody, EIA**	4/21/2014	11
92032	RF318	**Jack Fruit (f318) IgE**	4/21/2014	11
92030	RF335	**Lupine Seed (f335) IgE**	4/21/2014	12
15564	S52516	Lyme Disease (Borrelia spp) DNA Qual Real-Time PCR, Synovial Fluid/CSF	4/21/2014	12
14767	K79	**Phthalic Anhydride (k79) IgE**	4/21/2014	12
11368	S51324	Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G	4/21/2014	13
2617	RE211	**Rabbit Urine (e211) IgE**	4/21/2014	13
15384	S52058	**Rheumatoid Factor Screen with Reflex to Titer, Synovial Fluid**	4/21/2014	13
4460	S49882	**Streptococcus Pneumoniae Ag Detection, LA**	4/21/2014	14
34451	S51519	Toxoplasma gondii DNA, Qualitative Real-Time PCR	4/21/2014	15
34052	S51742	**Varicella Zoster Virus (VZV) DNA, Qualitative Real-Time PCR**	4/21/2014	15
S49750		*Chlamydophila pneumoniae* Culture	4/28/2014	15

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 #
38267	S51888	**Catfish (f369) IgE**	4/21/2014	16
605	S50847	Lidocaine	4/21/2014	16
30760	S51909	**Lima Bean (f182) IgE**	4/21/2014	17

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 #
F45G	Allergen - Yeast (Bakers/Brewers) IgG	4/14/2014	18
9647	*Candida albicans* DNA DetectR™	4/14/2014	18
9646	*Gardnerella vaginalis* DNA DetectR™	4/14/2014	18
9648	*Trichomonas vaginalis* DNA DetectR™	4/14/2014	18
9645	Vaginitis DNA DetectR™	4/14/2014	18
S51838	CA 125, CSF	4/21/2014	19
S52496	Ganglioside GM-1 Antibodies (IgG & IgM)	4/21/2014	19
S52050	Respiratory Virus PCR Panel with 2009 H1N1	4/21/2014	19
S51035	Adenovirus Serotyping	4/28/2014	19
S52365	Enterovirus Serotyping	4/28/2014	19
S50642	Haemophilus Influenzae Serotyping (A-F), SA	4/28/2014	19
S50675	Neisseria Meningitidis Serotyping, SA	4/28/2014	19

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 #
S43005		**Drugs of Abuse Screen (11 Panel), Fluid**	4/7/2014	20
S46130		Methylphenidate and Metabolite, Urine	4/14/2014	20

New Test Offerings

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

PD-L1 Expression	
Message	***This test is not available for New York Patient testing****
Clinical Significance	**PD-L1, (also known as B7-H1/CD274) is a B7 family member expressed by hematopoietic and parenchymal cells that regulates self-tolerance in vivo by binding to programmed cell death-1 (PD-1) on T lymphocytes, causing both inhibition of T lymphocyte activation directly and through induction of T regulatory cells. Blockade or absence of the PD-L1:PD-1 interaction results in exacerbation of autoimmune diseases. During disease flares, patients with SLE fail to upregulate PD-L1 expression on circulating antigen presenting cells. In remission, SLE patients expressed PD-L1 at levels equal to or greater than controls.**
Effective Date	**3/3/2014**

Test Code	**91969**
CPT Codes	**88184, 88185 (x3)**
Specimen Requirements	**10 mL (5 mL minimum) whole blood collected in a sodium heparin (green-top) tube**
Reject Criteria	**Hemolysis, received refrigerated, received frozen, visible clots, samples >30 hours**
Instructions	**Fasting preferred to avoid lipemia.** *****CLIENTS-CONTACT THE LAB PRIOR TO ORDERING FOR SPECIAL LOGISTICS ARRANGEMENTS***** *****PSC-FOLLOW SHORT STABILITY SOP***** **Test available by prior arrangement only. Special sample collection and transportation arrangements must be made prior to ordering the test. Contact your local Customer Service Department and request to speak to someone in Referral Testing Department for specific instructions.** **10 mL (minimum of 5 mL) whole blood collected in sodium heparin-green-top. Aseptically collect whole blood into specimen collection tube containing sodium heparin.** **Whole blood must be transported at room temperature. Samples should be received within 30 hours from collection. An appropriate time should be selected for expeditious transport. Maintain and transport blood at room temperature. Avoid temperatures <15° C and >37° C. In hot weather, it may be necessary to pack the specimen in a container with insulating material around it and place this container inside another that contains a cold pack (ice pack) and absorbent material. This method will help retain the specimen at ambient temperature.** **For longitudinal studies, draw samples at the same time of day to minimize diurnal variation.** ***Samples received > 30 hours after collection will be rejected.***
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 30 hours** **Refrigerated and Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Tues-Fri; Report available: 2-6 days**
Reference Range	**PD-L1 Expression:** — **No reference range available** **Ratio:** — **> or = 5**
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	**Peripheral Blood Mononuclear Cells Culture, Flow Analysis**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86010363** / **PD-L1 Expression** / **%** **86010364** / **Ratio** / **Ratio**

ASCVD Risk Panel with Score	
Message	***Includes: Cholesterol, Total * HDL Cholesterol * Triglycerides * Non-HDL and Calculated Components * Cholesterol, Direct LDL * ASCVD Risk Scores***
Clinical Significance	**This panel provides the 10-year and lifetime risk of atherosclerotic cardiovascular disease (ASCVD) using lipid results with anthropomorphic data and family history.** **The ASCVD risk assessment is recommended in the 2013 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.**
Effective Date	**3/10/2014**
Test Code	**92053**

<table>
<tr><td>CPT Codes</td><td>82465, 83718, 84478 or 81599*
Coding may vary depending on health plan or government payer requirements. CMS does not currently recognize MAAA CPT codes for Medicare claims.</td></tr>
<tr><td>Specimen Requirements</td><td>2 mL (1 mL minimum) serum</td></tr>
<tr><td>Reject Criteria</td><td>Gross hemolysis; moderate to gross icterus; anticoagulants other than heparin</td></tr>
<tr><td>Instructions</td><td>The patient should fast 9-12 hours prior to collection.

For risk calculations to be performed, the following patient specific information have to be provided at time of order:
Age: Years
Gender M (for male) or F (for female)
Race - African American: Y (for yes) or N (for no)
Systolic Blood Pressure: mmHg
Treatment for High Blood Pressure: Y (for yes) or N (for no)
Diabetes Status: Y (for yes) or N (for no)
Smoking Status: Y (for Yes) or N (for no)</td></tr>
<tr><td>Transport Temperature</td><td>Refrigerated (EBUs)
Room Temperature (all other sites)</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature: 48 hours
Refrigerated: 5 days
Frozen: 15 days</td></tr>
<tr><td>Set-up/Analytic Time</td><td>Set up: Mon-Fri; Report available: 3-6 days</td></tr>
<tr><td>Reference Range</td><td>See individual assays</td></tr>
<tr><td>Methodology</td><td>Spectrophotometry, Enzymatic</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, San Juan Capistrano</td></tr>
<tr><td>CPU Mappings</td><td>
<table>
<tr><td colspan="3">92053-1-Cholesterol, Total</td></tr>
<tr><td>Result Code</td><td>Result Name</td><td>Unit of Measure</td></tr>
<tr><td>25003000</td><td>Cholesterol, Total</td><td>mg/dL</td></tr>
<tr><td colspan="3">92053-2-HDL Cholesterol</td></tr>
<tr><td>Result Code</td><td>Result Name</td><td>Unit of Measure</td></tr>
<tr><td>25015900</td><td>HDL Cholesterol</td><td>mg/dL</td></tr>
<tr><td colspan="3">92052-3-Triglycerides</td></tr>
<tr><td>Result Code</td><td>Result Name</td><td>Unit of Measure</td></tr>
<tr><td>25002900</td><td>Triglycerides</td><td>mg/dL</td></tr>
<tr><td colspan="3">92053-4-Non-HDL and Calculated Components</td></tr>
<tr><td>Result Code</td><td>Result Name</td><td>Unit of Measure</td></tr>
<tr><td>25016900</td><td>LDL Chol, Calculated</td><td>mg/dL</td></tr>
<tr><td>25017000</td><td>Cholesterol/HDL Ratio</td><td>calc</td></tr>
<tr><td>25017210</td><td>Non-HDL Cholesterol</td><td>mg/dL</td></tr>
<tr><td colspan="3">*TR 92053-6-Cholesterol, Direct LDL</td></tr>
<tr><td>Result Code</td><td>Result Name</td><td>Unit of Measure</td></tr>
<tr><td>25008600</td><td>Direct LDL</td><td>mg/dL</td></tr>
<tr><td colspan="3">92053-5-ASCVD Risk Scores</td></tr>
</table>
</td></tr>
</table>

Result Code	Type	Result Name	Unit of Measure
86010626		10 Year ASCVD Risk	%
86010627		10 Year ASCVD Risk Goal	%
86010628		Lifetime ASCVD Risk	%
86010629	Prompt-Result	African American	
86006867	Prompt-Result	Systolic Blood Pressure	mmHg
86010497	Prompt-Result	Treatment for High B.P.	
86006870	Prompt-Result	Diabetes	
86006866	Prompt-Result	Current Smoker	

TR (True Reflexing Flag)
CPU interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.

Additional Information	**If Triglyceride is >400 mg/dL, then Cholesterol, Direct LDL will be performed at an additional charge (CPT code(s) 83721).**

Respiratory Virus PCR Panel with 2009 H1N1	
Message	***** This test is not available for New York patient testing.*****
Effective Date	**4/21/2014**
Test Code	**91234**
CPT Codes	**87632**
Specimen Requirements	**3 mL (1 mL minimum) Throat swab or Nasopharyngeal swab collected in a Multi Microbe Media (M4) or V-C-M medium (green-cap) tube or equivalent (UTM)**
Reject Criteria	**Calcium alginate swabs**
Instructions	**Samples in M4 media (includes nasopharyngeal, throat swab): Use sterile vials containing 3 mL of sterile M4 media. Do not use calcium alginate swabs, as they may contain substances that inhibit PCR testing. Nasopharyngeal aspirate: Submit in a sterile container with leak-proof cap**.
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Daily; Report available: 1 day**
Reference Range	**Not detected**
Methodology	**See individual assays**
Performing Site	**Focus Diagnostics, Inc.**

CPU Mappings

Result Code	Type	Result Name
86002425	Prompt-Result	Source
86002433		Adenovirus DNA, QL PCR
70043807	Prompt-Result	Source

70043808		**Influenza A RNA**
70043809		**2009 H1N1 Influenza RNA**
85866400	**Prompt-Result**	**Source**
86002422		**Parainfluenza 1 RNA**
86002423		**Parainfluenza 2 RNA**
86002424		**Parainfluenza 3 RNA**
86008783		**Parainfluenza 4 RNA**
86002575	**Prompt-Result**	**Source**
86002421		**RSV RNA, Qualitative PCR**

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.*

Herpes Simplex Virus Culture	
Effective Date	**4/7/2014**
Former Test Code	*2402*
Test Code	**2692**
Specimen Requirements	**Preferred:** **Nasal/nasopharyngeal swab, endocervical swab, eye swab or lesion (vesicle) aspirate swab, urethral swab, vaginal swab, rectal mucosa swab (without feces) or throat swab collected in VCM (green-cap) tube or equivalent** **Acceptable:** **3 mL (1 mL fluid or 1 g tissue minimum) Bronchial lavage/wash or Nasopharyngeal lavage/wash or fresh (unfixed) tissue collected in VCM (green-cap) tube or equivalent or sterile screw capped container**
Reject Criteria	**CSF; Sputum; Raw (unpreserved) stool; dry swabs; Molecular transport systems; Bacterial transport systems; tissue or biopsies in formalin or other fixatives; calcium alginate swabs; wooden shaft swabs; non gel-based bacterial transports**
Instructions	**To maintain optimum viability, place swab into VCM (equal volumes of fluid/tissue and VCM) or equivalent 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 VCM 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.** **Note: PCR is the preferred test for CSF (preferred specimen: 1 mL CSF submitted in a sterile, leak-proof container without transport media).**
Specimen Stability	**VCM or equivalent:** — **Room temperature: Unacceptable; Refrigerated: 4 days; Frozen -20°C: Unacceptable; Frozen -70°C: 30 days** **Raw (unpreserved) specimen:** — **Room temperature: Unacceptable; Refrigerated: 72 hours; Frozen: Unacceptable**
Methodology	**Centrifuge Enhanced Culture, Histochemical Stain**

Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Type	Result Name
86007404	Prompt-Result	Specimen Source:
70000100		HSV Culture

Herpes Simplex Virus Culture with Reflex to Typing	
Effective Date	**4/7/2014**
Former Test Code	*2427*
Test Code	**2649**
Specimen Requirements	**Preferred:** **Nasal/nasopharyngeal swab, endocervical swab, eye swab or lesion (vesicle) aspirate swab, urethral swab, vaginal swab, rectal mucosa swab (without feces) or throat swab collected in VCM (green-cap) tube or equivalent** **Acceptable:** **3 mL (1 mL fluid or 1 g tissue minimum) Bronchial lavage/wash or Nasopharyngeal lavage/wash or fresh (unfixed) tissue collected in VCM (green-cap) or equivalent or sterile screw capped container**
Reject Criteria	**CSF; Sputum; Raw (unpreserved) stool; dry swabs; Molecular transport systems; Bacterial transport systems; tissue or biopsies in formalin or other fixatives; calcium alginate swabs; wooden shaft swabs; non gel-based bacterial transports**
Instructions	**To maintain optimum viability, place swab into VCM (equal volumes of fluid/tissue and VCM) or equivalent 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 VCM 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.** **Note: PCR is the preferred test for CSF (preferred specimen: 1 mL CSF submitted in a sterile, leak-proof container without transport media).**
Specimen Stability	

VCM or equivalent:	**Room temperature: Unacceptable** **Refrigerated: 4 days** **Frozen -20°C: Unacceptable** **Frozen -70°C: 30 days**
Raw (unpreserved) specimen:	**Room temperature: Unacceptable** **Refrigerated: 72 hours** **Frozen: Unacceptable**

Methodology	**Centrifuge Enhanced Culture, Histochemical Stain, Monoclonal Fluorescent Antibody Typing**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Type	Result Name
86007404	Prompt-Result	Specimen Source:
70000100		HSV Culture
This is true a reflex. Please build the unit code below separately. ***Non-orderable Reflex RRP-Type 1, Herpes simplex Virus***		
Result Code	**Result Name**	
70000175	HSV Type 1	

	This is a true reflex. Please build the unit code below separately. ***Non-orderable reflex RRQ-Type 2, Herpes simplex Virus*** **Result Code** / **Result Name** **70000150** / **HSV Type 2**
Additional Information	If Herpes Simplex Virus Culture, Rapid Method is "Isolated", then RRQ-Type 2, Herpes Simplex Virus will be performed at an additional charge (CPT code(s) 87140). If Type 2 Herpes Simplex Virus is "Not Isolated" then RRP-Type 1 Herpes Simplex Virus will be performed at an additional charge (CPT code(s) 87140).

FISH, Locus-specific Probe (x1)	
Effective Date	**4/14/2014**
Former Test Code	*S51711*
Test Code	**17355**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
CPU Mappings	**Result Code** / **Type** / **Result Name** **86005175** / / FISH,LocusSpecific(1) **85997860** / **Prompt-Result (no return)** / **Specimen Type/Source/Vol:** **86007537** / **Prompt-Result (no return)** / **Clinical Indication:** **86007538** / **Prompt-Result (no return)** / **Referring Physician:** **85997863** / **Prompt-Result (no return)** / **Referring Physician Phone:** **85997864** / **Prompt-Result (no return)** / **Client/Phone #:** **86007469** / **Prompt-Result (no return)** / **Client Accession #:** **86007539** / **Prompt-Result (no return)** / **Patient ID:**
Additional Information	**Update report format**

SureSwab, *Trichomonas vaginalis* RNA, Qualitative, TMA	
Effective Date	**4/14/2014**
Test Code	19550
Specimen Requirements	**ThinPrep is no longer acceptable**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

Aspergillus DNA, Qualitative Real-Time PCR	
Message	***** This test is not available for New York patient testing *****
Effective Date	**4/21/2014**
Former Test Name	*Aspergillus DNA, PCR*
Former Test Code	*S50959*
Test Code	**18873**

Set-up/Analytic Time	Set up: Daily; **Report available: 1-2 days**
Methodology	**Real-Time Polymerase Chain Reaction**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	

Result Code	Type	Result Name
86007514	**Prompt-Result**	**Source**
86006676		**Aspergillus spp**
86006668		**A fumigatus**
86006674		**A terreus**

BK Virus DNA, Quantitative Real-Time PCR, Plasma	
Effective Date	**4/21/2014**
Former Test Name	*BK Virus DNA, Quant (47900)*
Former Test Code	*S51498*
Test Code	**11274**
Specimen Requirements	**0.7 mL (0.3 mL minimum) plasma collected in an EDTA (lavender-top), or ACD solution A or B tube**
Set-up/Analytic Time	**Set up: Daily; Report available: 1-3 days**
Always Message	**Reference Range: <500 copies/mL** **This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	

Result Code	Type	Result Name	Unit of Measure
85997450	**Prompt-Result**	**Source**	
85996501		**BK Virus DNA, QN PCR**	**copies/mL**

Black Olive (Rf342) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Olive, Black-Fresh IgE*
Former Test Code	*RF342*
Test Code	**38482**
Transport Temperature	**Room temperature**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Result Name	Unit of Measure

86003191	**Olive (Rf342) IgE**	**kU/L**
86003192	**Class**	

Bordetella pertussis IgG and IgA Antibodies, MAID	
Effective Date	**4/21/2014**
Former Test Code	*S51776*
Test Code	**17825**
Set-up/Analytic Time	Set up: Mon-Fri; **Report available: 1-4 days**
Units Of Measure	**IU/mL**
Always Message	Reference Ranges: PT IgG <45 **IU/mL** PT IgA <10 **IU/mL** FHA IgG <90 **IU/mL** FHA IgA <50 **IU/mL** **Levels of antibodies recognizing pertussis toxin (PT) and filamentous hemagglutinin (FHA) are typically increased following vaccination or natural exposure to Bordetella pertussis. This assay is not appropriate for assessing immunity to pertussis because the specific antibodies and have not been well defined. Detection of IgG antibodies is more sensitive than detection of IgA antibodies, since not all vaccinated or exposed individuals mount a detectable IgA response. The indicated reference range values reflect the 95th percentile of antibody levels from blood donors; thus, antibody levels above the reference range are highly suggestive of recent infection or vaccination. Increased levels of FHA antibodies alone may represent cross-reactive antibodies induced by infection with other Bordetella species, Mycoplasma pneumoniae, Chlamydophila pneumoniae or nonencapsulated Haemophilus influenzae.** **This assay was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	

Result Code	Result Name	Unit of Measure
86002313	PT IgG	**IU/mL**
86002315	PT IgA	**IU/mL**
86002314	FHA IgG	**IU/mL**
86002316	FHA IgA	**IU/mL**

Cytomegalovirus DNA, Qualitative Real-Time PCR	
Clinical Significance	**CMV infections are common and usually asymptomatic. In patients who are immunocompromised, CMV may cause disseminated, severe disease. CMV may cause birth defects in a minotiry of infected newborns. DNA methods provide the highest sensitivity and specificity of any method.**
Effective Date	**4/21/2014**
Former Test Code	*S49983*
Test Code	**10601**
Reject Criteria	**Heparinized specimens; Unspun PPT tube**
Set-up/Analytic Time	**Set up: Daily: Report available: 1 day**

Always Message	**Reference Range: Not detected** **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, Inc.
CPU Mappings	

Result Code	Type	Result Name
86007404	**Prompt-Result**	**Source**
86004959		**CMV DNA, QL PCR**

Hake (f307) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen-Hake IgE*
Former Test Code	*RF307*
Test Code	**92029**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 14 days** Frozen: 30 days
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Result Name	Unit of Measure
86010506	**Hake (f307) IgE**	**kU/L**
86010507	**Class**	

Hepatitis D Virus (HDV) IgM Antibody, EIA	
Clinical Significance	**Hepatitis D virus (HDV) infection occurs in association withHBV infection. A positive result for HDV IgM indicatesrecent HDV infection.**
Effective Date	**4/21/2014**
Former Test Name	*Hepatitis D Virus (HDV) IgM AB, EIA*
Former Test Code	*S51509*
Test Code	**35664**
Specimen Stability	**Room temperature: 7 days** Refrigerated: 14 days Frozen: 30 days
Always Message	**Reference Range: Negative** **Interpretive Criteria:** **Negative: Antibody not detected** **Positive: Antibody detected**

	HDV infection occurs only in association with HBV infection. Detection of HDV IgM indicates active HDV replication due to either acute infection or reactivation of chronic infection. **This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	**Result Code** / **Result Name** **85982310** / **Hepatitis D Virus (HDV)IgM**

Jack Fruit (f318) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen-Jack Fruit IgE*
Former Test Code	*RF318*
Test Code	**92032**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86010510** / **Jack Fruit (f318) IgE** / **kU/L** **86010511** / **Class** /

Lupine Seed (f335) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Lupine Seed IgE*
Former Test Code	*RF335*
Test Code	**92030**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **86010508** / **Lupine Seed (f335) IgE** / **kU/L** **86010509** / **Class** /

Lyme Disease (Borrelia spp) DNA Qual Real-Time PCR, Synovial Fluid/CSF	
Effective Date	**4/21/2014**

Former Test Code	*S52516*
Test Code	**15564**
Set-up/Analytic Time	Set up: Daily; **Report available: 1-2 days**
Always Message	**Reference Range: Not detected** **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, Inc.
CPU Mappings	**Result Code** / **Type** / **Result Name** **86007518** / **Prompt-Result** / **Source** **86007022** / **Lyme Disease DNA**

Phthalic Anhydride (k79) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Phthalic Anhydride IgE*
Former Test Code	*K79*
Test Code	**14767**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **85997702** / **Phthalic Anhydride(k79)IgE** / **kU/L** **85997703** / **Class** /

Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G	
Message	*****This test is not available for New York patient testing.*****
Effective Date	**4/21/2014**
Former Test Code	*S51324*
Test Code	**11368**
Specimen Requirements	Preferred: 5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube **Acceptable:** **Remove volumes associated with Extracted DNA and bone marrow and fresh (unfixed) tissue and tissue biopsy**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Rabbit Urine (e211) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Rabbit Urine Proteins IgE*
Former Test Code	*RE211*
Test Code	**2617**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 14 days** Frozen: 30 days
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Methodology	**Immunoassay**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	

Result Code	Result Name	Unit of Measure
55151305	**Rabbit Urine (e211) IgE**	**kU/L**
55151310	**Class**	

Rheumatoid Factor Screen with Reflex to Titer, Synovial Fluid	
Message	***** This test is not available for New York patient testing. *****
Effective Date	**4/21/2014**
Former Test Name	*Rheumatoid Factor, LA Synovial Fluid*
Former Test Code	*S52058*
Test Code	**15384**
CPT Codes	**86430**
Specimen Requirements	1 mL **(0.3 mL minimum) Synovial fluid collected in a sterile screw cap container**
Reject Criteria	**Gross hemolysis; visible particulate matter**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 24 hours** **Refrigerated: 7 days** **Frozen: 21 days**
Set-up/Analytic Time	**Set up: Tues, Fri; Report available: 2-6 days**
Reference Range	**Negative**
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.**
CPU Mappings	

Result Code	Result Name
85999014	**Rheumatoid Factor, LA Scr**
This test is a true reflex. Please build the unit code below separately. **Non-orderable Reflex: 3834-2 Rheumatoid Factor, LA Titer**	
Result Code	**Result Name**

85999015	**Rheumatoid Factor,LA Titer**

Streptococcus Pneumoniae Ag Detection, LA	
Effective Date	**4/21/2014**
Former Test Name	*Streptococcus Pneumoniae Ag Detection*
Former Test Code	*S49882*
Test Code	**4460**
Specimen Requirements	Preferred: 1 mL (0.3 mL minimum) serum collected in red-top (no gel) tube **Acceptable:** **1 mL (0.3 mL minimum)** CSF **or random urine** collected in a sterile screw cap container
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: 7 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-2 days**
Reference Range	**Not detected**
Always Message	**Reference Range: Not detected** **This test should not be used as a substitute for gram stain and bacteriologic cultures in the diagnosis of septicemia and/or meningitis. Positive or negative test results should be considered presumptive and confirmed by culture.**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	**Result Code** / **Type** / **Result Name** **86007404** / **Prompt-Result** / **Source** **45068300** / **S.Pneumoniae Ag Detection, LA**

Toxoplasma gondii DNA, Qualitative Real-Time PCR	
Clinical Significance	**Toxoplasma gondii, an obligate intracellular parasite, is an important opportunistic pathogen of immunosuppressed patients. In AIDS patients and transplant patients, this infection may result in a life-threatening encephalitis. T. gondii can also cause a fatal infection of the fetus if an infection is acquired during pregnancy. Fetal death or major abnormalities such as blindness and mental retardation may occur when infection is acquired during the first trimester. PCR methods may be useful in identifying T. gondii in CSF of immunosuppressed patients or in the amniotic fluid of mothers thought to be recently infected.**
Effective Date	**4/21/2014**
Former Test Code	*S51519*
Test Code	**34451**
Set-up/Analytic Time	Set up: Daily; **Report available: 1-2 days**
Methodology	**Real-Time Polymerase Chain Reaction**
Performing Site	Focus Diagnostics, Inc.

CPU Mappings	

Result Code	Type	Result Name
85997450	Prompt-Result	Source
86004705		Toxoplasma gondii DNA, PCR

Varicella Zoster Virus (VZV) DNA, Qualitative Real-Time PCR	
Message	***** This test is not available for New York Patient testing.*****
Clinical Significance	**This assay detect varicella zoster virus (VZV) DNA in skin lesions, cerebrospinal fluid (CSF) and whole blood. Detection of VZV DNA in CSF usually indicates active, not latent, infection. Detection of VZV DNA in appropriate clinical specimens permits rapid and sensitive patient testing.**
Effective Date	**4/21/2014**
Former Test Name	*Varicella Zoster (VZV) DNA, Qual Real-Time PCR*
Former Test Code	*S51742*
Test Code	**34052**
Set-up/Analytic Time	**Set up: Daily; Report available: 1 day**
Reference Range	**Not detected**
Assay Category	**Laboratory Developed Test**
Performing Site	Focus Diagnostics, Inc.
CPU Mappings	

Result Code	Type	Result Name
86007404	Prompt-Result	Source
85981700		Varicella-Zoster Virus (VZV) DNA, QL RT PCR

***Chlamydophila pneumoniae* Culture**	
Effective Date	**4/28/2014**
Test Code	S49750
Specimen Requirements	**Preferred:** **5 mL (2 mL minimum) lower respiratory secretions/washes, nasopharyngeal aspirate or lung tissue, submitted in VCM or equivalent** **Acceptable:** **Throat/nasopharyngeal swab, eye-conjunctiva, ear drainage/aspirate, arterial tissue, cardiac tissue, pericardial tissue or synovium tissue, submitted in VCM or equivalent.**
Reject Criteria	**Sputum; whole blood; specimen not received in VCM; specimen received room temperature**
Transport Temperature	**Frozen -70° C**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen -20° C: Unacceptable** **Frozen -70° C: 7 days**
Performing Site	Focus Diagnostics, Inc.

Redirects

Catfish (f369) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Catfish IgE [43210S]*
Former Test Code	*S51888*
Test Code	**38267**
Specimen Requirements	**0.3 mL (0.15 mL minimum) serum**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Reference Range	**<0.35 kU/L**
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. 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	**Immunoassay**
Performing Site	**This test previously performed at Viracor IBT will now be performed at Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
55084930	**Catfish (f369) IgE**	**kU/L**
55084940	**Class**	

Lidocaine	
Effective Date	**4/21/2014**
Former Test Code	*S50847*
Test Code	**605**
Specimen Requirements	**1 mL (0.2 mL minimum) serum collected in red-top (no gel) tube**
Reject Criteria	**Serum separator tubes**
Instructions	Centrifuge and immediately separate plasma or serum specimens from the cells into clean, plastic, screw-capped vial (s). **Collect as trough prior to next dose.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 2 days**
Reference Range	**1.5-5.0 mcg/mL**

Methodology	**Immunoassay**
Performing Site	**This test previously performed at PacTox will now be performed at Quest Diagnostics Nichols Institute, Chantilly.**
CPU Mappings	

Result Code	Result Name	Unit of Measure
80015200	Lidocaine	mcg/mL

Lima Bean (f182) IgE	
Effective Date	**4/21/2014**
Former Test Name	*Allergen - Bean Lima IgE [43510E]*
Former Test Code	*S51909*
Test Code	**30760**
Specimen Requirements	**0.3 mL (0.15 mL minimum) serum**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: as needed; Report available: 1-2 days**
Reference Range	**<0.35 kU/L**
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. 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	**Immunoassay**
Performing Site	**This test previously performed at Viracor IBT will now be performed at Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name	Unit of Measure
86010460	Lima Bean (f182) IgE	kU/L
86010461	Class	

Discontinued Tests

Allergen - Yeast (Bakers/Brewers) IgG	
Effective Date	**4/14/2014**
Test Code	F45G
Additional Information	The recommended alternative is 39545-Yeast (Bakers/Brewers) (f45G) IgG

***Candida albicans* DNA DetectR™**	
Effective Date	**4/14/2014**

Test Code	9647
Additional Information	There is no recommended alternative.
Tests Affected	**Test Codes:** / **Name:** P48613B — Custom Ameripath Cand and Trich P48613C — Custom Ameripath Gard and Cand

***Gardnerella vaginalis* DNA DetectR™**	
Effective Date	**4/14/2014**
Test Code	9646
Additional Information	There is no recommended alternative.
Tests Affected	**Test Codes:** / **Name:** P48613A — Custom Ameripath Gard and Trich P48613C — Custom Ameripath Gard and Cand

***Trichomonas vaginalis* DNA DetectR™**	
Effective Date	**4/14/2014**
Test Code	9648
Additional Information	The recommended alternative is 90521- Trichomonas vaginalis RNA, Qualitative TMA, PAP Vial
Tests Affected	**Test Codes:** / **Name:** P48613B — Custom Ameripath Gard and Trich P48613A — Custom Ameripath Gard and Trich

Vaginitis DNA DetectR™	
Effective Date	**4/14/2014**
Test Code	9645
Additional Information	There is no recommended alternative
Tests Affected	**Test Codes:** / **Name:** P48613A — Custom Ameripath Gard and Trich P48613B — Custom Ameripath Cand and Trich P48613C — Custom Ameripath Gard and Cand

CA 125, CSF

Effective Date	**4/21/2014**
Test Code	S51838
Additional Information	There is no recommended alternative.

Ganglioside GM-1 Antibodies (IgG & IgM)	
Effective Date	**4/21/2014**
Test Code	S52496
Additional Information	The recommended alternative is test code 37093- Ganglioside GM-1 Antibodies (IgG and IgM), EIA performed at Quest Diagnostics, San Juan Capistrano.

Respiratory Virus PCR Panel with 2009 H1N1	
Effective Date	**4/21/2014**
Test Code	S52050
Additional Information	The recommended alternative is test code 91234-Respiratory Virus PCR Panel with 2009 H1N1 in New Test Offering section.

Adenovirus Serotyping	
Effective Date	**4/28/2014**
Test Code	S51035
Additional Information	There is no recommended alternative.

Enterovirus Serotyping	
Effective Date	**4/28/2014**
Test Code	S52365
Additional Information	There is no recommended alternative.

Haemophilus Influenzae Serotyping (A-F), SA	
Effective Date	**4/28/2014**
Test Code	S50642
Additional Information	There is no recommended alternative.

Neisseria Meningitidis Serotyping, SA	
Effective Date	**4/28/2014**
Test Code	S50675
Additional Information	There is no recommended alternative.

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.**

<table>
<tr><th colspan="2">Drugs of Abuse Screen (11 Panel), Fluid</th></tr>
<tr><td>Effective Date</td><td>4/7/2014</td></tr>
<tr><td>Former Test Name</td><td>Drug Screen Fluid [1864FL]</td></tr>
<tr><td>Test Code</td><td>S43005</td></tr>
<tr><td>Specimen Requirements</td><td>7 mL (3.2 mL minimum) fluid</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature, Refrigerated and Frozen: Undetermined</td></tr>
<tr><td>CPU Mappings</td><td>
<table>
<tr><th>Result Code</th><th>Result Name</th><th>Unit of Measure</th></tr>
<tr><td>43005F</td><td>Opiates</td><td>ng/mL</td></tr>
<tr><td>43006F</td><td>Cocaine/Metabolites</td><td>ng/mL</td></tr>
<tr><td>43007F</td><td>Benzodiazepines</td><td>ng/mL</td></tr>
<tr><td>43008F</td><td>Cannabinoids</td><td>ng/mL</td></tr>
<tr><td>43009F</td><td>Amphetamines</td><td>ng/mL</td></tr>
<tr><td>43010F</td><td>Barbiturates</td><td>mcg/mL</td></tr>
<tr><td>43011F</td><td>Methadone</td><td>ng/mL</td></tr>
<tr><td>43013F</td><td>Phencyclidine</td><td>ng/mL</td></tr>
<tr><td>43014F</td><td>Propoxyphene</td><td>ng/mL</td></tr>
<tr><td>86010663</td><td>Methamphetamine</td><td>ng/mL</td></tr>
<tr><td>86010664</td><td>Oxycodone</td><td>ng/mL</td></tr>
</table>
</td></tr>
</table>

Methylphenidate and Metabolite, Urine	
Effective Date	**4/14/2014**
Test Code	S46130
Additional Information	This test will be discontinued. The recommended alternative is test code 91923- Methylphenidate Metabolite, Quantitative, Urine.