



LABORATORY UPDATE

www.dlolab.com

Routine Testing

Test Changes

- Creatine Kinase, Total - Update reference range 3
- Folate, Serum - Update transport temperature and stability 3
- Vitamin B12 - Update stability 4
- Vitamin B12/Folate, Serum Panel - Update stability 4

**Quest Diagnostics Nichols Institute (San Juan Capistrano and Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

- *Chlamydia trachomatis* RNA, TMA, Rectal 5
- *Chlamydia trachomatis/Neisseria gonorrhoeae* RNA, TMA, Rectal..... 5
- *Chlamydia trachomatis/Neisseria gonorrhoeae* RNA, TMA, Throat 6
- *Chlamydia trachomatis* RNA, TMA, Throat..... 6
- *Neisseria gonorrhoeae* RNA, TMA, Rectal 7
- *Neisseria gonorrhoeae* RNA, TMA, Throat..... 7
- FISH, HER-2/neu with Reflex to IHC 8
- Zinc, Random Urine w/ Creatinine..... 8
- P53 Mutation Analysis, Plasma-bases, Leumeta™ 9
- Antimicrobial Susceptibility, Campylobactor, MIC Panel 10



The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

Test Changes

- *Ehrlichia chaffeensis* DNA Real-Time PCR – Update transport temperature.....10
- Angioedema Panel – Update specimen requirements.....10
- C4 Activation Panel – Update specimen requirements.....10
- Complement Activation Panel – Update specimen requirements.....10
- Lyme Disease Antibody, Total, EIA with Reflex to CSF Ratio – Update assay category.11
- *Mycobacterium avium-intracellulare* DNA, Qualitative PCR - Update assay category and add always message.11
- Susceptibility, Aerobic Actinomycetes (*Nocardia* and *Rhodococcus*), MIC - Update report format and result name.11
- Susceptibility, MAI Complex MIC – Update report format.12
- Susceptibility, Yeast, Comprehensive Panel – Update report format and result name.....12
- Zinc - Update specimen requirements, stability, and methodology.....13
- Zinc, Random Urine - Update specimen requirements, stability, reference range, methodology, removing Creatinine component.....13

Redirects

- Leptospira Antibody Screen with Reflex to Titer.....14

Discontinued Tests

- Central Diabetes Insipidus (CDI) Mutations14
- Leptospira Antibody14
- Nephrogenic Di Mut (AQP2).....14
- Nephrogenic Di Mut (AVPR2).....15
- p53 Gene Mutation Analysis, Plasma-based, Leumeta™15
- p53 Gene Mutation Analysis, Cell-based15
- Resistance to Thyroid Hormone (RTH) Mutation Analysis15
- Tremor/Ataxia Syndrome (FXTAS).....15

DLO is pleased to inform you of the following new and updated laboratory testing information:

Test Changes

Creatine Kinase, Total			
Clinical Significance:	Total CK is a test for myocardial infarction and skeletal muscle damage. Elevated results may be due to: myocarditis, myocardial infarction (heart attack), muscular dystrophy, muscle trauma or excessive exercise.		
Effective Date:	November 10, 2008		
Test Code:	374		
Reference Range	Age	Male (U/L)	Female (U/L)
	0-3 days (newborn)	<1578	<1578
	4 days to 28 days	< 183	< 134
	1-11 months	< 136	< 143
	1-6 yrs	< 160	< 143
	7-9 yrs	< 177	< 143
	10-12 yrs	< 217	< 143
	13-18 yrs	< 245	< 143
	>18 yrs	44-196	29-143
Additional Information:	Update reference range. Please note this test is included in the following group codes: 4451 -Creatine Kinase Isoenzyme Panel		

Folate, Serum		
Clinical Significance:	Folic acid deficiency is common in pregnant women, alcoholics, in patients whose diets do not include raw fruits and vegetables, and in people with structural damage to the small intestine. The most reliable and direct method of diagnosing folate deficiency is the determination of folate levels in both erythrocytes and serum. Low folic acid levels, however, can also be the result of a primary Vitamin B12 deficiency that decreases the ability of cells to take up folic acid.	
Effective Date:	November 10, 2008	
Test Code:	466	
Transport Temperature	Refrigerated	
Specimen Stability	Room temperature	24 hours
	Refrigerated	7 days
	Frozen	21 days
Methodology:	Immunoassay	
Additional Information:	Update transport temperature and stability.	

Vitamin B12		
Clinical Significance:	Vitamin B12 is decreased in pernicious anemia, total or partial gastrectomy, malabsorption and certain congenital biochemical disorders.	
Effective Date:	November 10, 2008	
Test Code:	927	
Transport Temperature	Refrigerated	
Specimen Stability	Room temperature	7 days
	Refrigerated	7 days
	Frozen	28 days
Methodology:	Immunoassay	
Additional Information:	Update stability.	

Vitamin B12/Folate, Serum Panel		
Clinical Significance:	Folic acid deficiency is common in pregnant women, alcoholics, patients with diets that do not include raw fruits and vegetables, and people with structural damage to the small intestine. The most reliable and direct method of diagnosing folate deficiency is the determination of folate levels in both erythrocytes and serum. Low folic acid levels however, can also be the result of a primary Vitamin B12 deficiency that decreases the ability of cells to take up folic acid. Vitamin B12 is decreased in pernicious anemia, total or partial gastrectomy, malabsorption and certain congenital biochemical disorders.	
Effective Date:	November 10, 2008	
Test Code:	7065	
Transport Temperature	Refrigerated	
Specimen Stability	Room temperature	24 hours
	Refrigerated	7 days
	Frozen	21 days
Methodology:	Immunoassay	
Additional Information:	Update stability.	

**Quest Diagnostics Nichols Institute (San Juan Capistrano and Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

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

<i>Chlamydia trachomatis</i> RNA, TMA, Rectal	
Clinical Significance:	<i>Chlamydia trachomatis</i> may infect the anal/rectal canal of sexually active individuals. Detection of this organism may be important for determining the risk for disease progression or transmission.
Effective Date:	September 23, 2008
Test Code:	16505
CPT Code(s):	87491
Specimen Requirements:	Rectal swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

<i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> RNA, TMA, Rectal	
Clinical Significance:	Both <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> may infect the anal/rectal canal of sexually active individuals. Detection of this organism may be important for determining the risk for disease progression or transmission.
Effective Date:	September 23, 2008
Test Code:	16506
CPT Code(s):	87491, 87591
Specimen Requirements:	Rectal swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

<i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> RNA, TMA, Throat	
Clinical Significance:	Both <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> may infect the oral/pharyngeal cavity of sexually active individuals. Detection of this organism may be important for determining the risk for disease progression or transmission.
Effective Date:	September 23, 2008
Test Code:	70051
CPT Code(s):	87491, 87591
Specimen Requirements:	Throat swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

<i>Chlamydia trachomatis</i> RNA, TMA, Throat	
Clinical Significance:	<i>Chlamydia trachomatis</i> may infect the oral/pharyngeal cavity of sexually active individuals. Detection of this organism may be important for determining the risk for disease progression or transmission.
Effective Date:	September 23, 2008
Test Code:	70048
CPT Code(s):	87491
Specimen Requirements:	Throat swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

<i>Neisseria gonorrhoeae</i> RNA, TMA, Rectal	
Clinical Significance:	Both <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> (GC) may infect the rectal of sexually active individuals. This test will detect the presence of both organisms from rectal sources.
Effective Date:	September 23, 2008
Test Code:	16504
CPT Code(s):	87591
Specimen Requirements:	Rectal swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

<i>Neisseria gonorrhoeae</i> RNA, TMA, Throat	
Clinical Significance:	<i>Neisseria gonorrhoeae</i> may infect the throat of sexually active individuals. This test will detect the presence of this organism from throat/pharyngeal sources.
Effective Date:	September 23, 2008
Test Code:	70049
CPT Code(s):	87591
Specimen Requirements:	Throat swab in Aptima® Combo 2 Transport Media Reject criteria: Transport tubes with 2 swabs; Transport tubes with non-GenProbe® swabs; Specimens in broken containers; Swab submitted in M4 transport media or Viral Culture Media (VCM).
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated and Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	Transcription-Mediated Amplification (TMA)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute

FISH, HER-2/neu with Reflex to IHC	
Clinical Significance:	According to ASCO/CAP guidelines (Wolff et al., Arch Pathol Lab Med 2007; 131:18-43), it is recommended that patients with invasive and metastatic breast cancer be tested for HER2 amplification by fluorescence in situ hybridization (FISH) and/or for HER2 overexpression by immunohistochemistry (IHC). The guidelines recommend a testing algorithm that defines positive, negative, and equivocal values for both the IHC and FISH. The HER2 test result is predictive and determines patient eligibility for targeted therapy of Trastuzumab, which is effective in patients with a positive HER2 result (ratio >2.2).
Effective Date:	October 6, 2008
Test Code:	19859
CPT Code:	88368 (x2)
Specimen Requirements:	Formalin-fixed, paraffin-embedded tissue (IHC specimen transport kit)
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and refrigerated: Indefinite; Frozen: Unacceptable
Reference Range:	Interpretive report
Methodology:	Fluorescence In Situ Hybridization
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Pathology report is required. If HER2 is equivocal, then Test Code 30316-HER2 [HercepTest®], IHC, with Interpretation will be performed at an additional charge (CPT: 88342). This test may be cancelled and replaced 416 - Cytogenetics Communication if no results are obtained.

Zinc, Random Urine with Creatinine				
Clinical Significance:	Zinc is an essential element involved in a myriad of enzyme systems including wound healing, immune function, and fetal development. Zinc measurements are used to detect and monitor industrial, dietary, and accidental exposure to zinc. Also, Zinc measurements may be used to evaluate health and monitor response to treatment.			
Effective Date:	November 24, 2008			
Test Code:	16502			
CPT Code(s):	84630, 82570			
Specimen Requirements:	7 mL random urine in acid washed container Collect in an acid washed container			
Transport Temperature:	Room temperature			
Specimen Stability:	Room temperature and refrigerated: 5 days; Frozen: 14 days			
Reference Ranges:	Zinc:	100 – 810	mcg/g creat	
	Creatinine, Random Urine:	0-6 months 7-11 months 1-2 years 3-8 years 9-12 years >12 years: Male: Female:	2-32 2-36 2-128 2-149 2-183 20-370 20-320	mg/dL mg/dL mg/dL mg/dL mg/dL mg/dL
Methodology:	Atomic Spectroscopy/ICP/MS and colorimetric, kinetic			
Assay Category:	Laboratory Developed Test			
Performing Site:	Quest Diagnostics Nichols Institute			

P53 Mutation Analysis, Plasma-based, Leumeta™	
Clinical Significance:	Somatic mutation of the p53 tumor suppressor gene is the most common genetic alteration seen in human cancers, with >50% of adult human tumors bearing inactivating mutations or insertions, deletions in the P53 gene. Wild type p53 prevents genetic instability and participates in the apoptotic response to radiotherapy and chemotherapy. Mutations in P53 gene usually correlate with poor outcome and early recurrence in cancer. This test provides important prognostic and predictive information for patients with B-CLL, breast cancer, cervical cancer, melanoma or other cancers.
Effective Date:	November 24, 2008
Test Code:	16515
CPT Code(s):	83891, 83898 (x6), 83892 (x6), 83909 (x12), 83904 (x12), 83912
Specimen Requirements:	6 mL EDTA preservative whole blood Submission of whole blood (preferred): Follow standard whole blood collection procedure. Collect 5-6 mL whole blood samples in an EDTA tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood. Record the draw time; also record sample type on the tube, or block ID on requisition form. Ship immediately to maintain sample stability.
Transport Temperature:	Refrigerated (cold packs)
Specimen Stability:	Room temperature: 72 hours; Refrigerated: 7 days; Frozen: Unacceptable
Reference Ranges:	<p>P53 Mutations, Leumeta: Negative</p> <p>Exon 4: No Reference Range available Exon 5: No Reference Range available Exon 6: No Reference Range available Exon 7: No Reference Range available Exon 8: No Reference Range available Exon 9: No Reference Range available</p> <p>Interpretation: Mutations in p53 tumor suppressor gene occur in greater than 50% adult human cancers. The p53 gene mutations usually correlate with poor outcome and early recurrence in cancer. Testing was performed on P53 exon 4-9 which accounts for >90% mutations in p53 gene. We cannot rule out the possibilities on mutation in other sites of the gene. The total nucleic acid was extracted from patient's plasma, PB/BM cells or paraffin embedded tissues. PCR reactions are performed to amplify exon 4-9 of p53 gene. The PCR products are then purified and sequenced in both forward and reverse directions. All mutations, deletions and insertions detected in the P53 exons 4-9 will be reported. This assay does not detect large deletions in the p53 gene. For (17p-) please refer to FISH assay. The sensitivity of this sequencing assay is 20% of mutant cell in the background of normal cells. 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.</p>
Methodology:	Polymerase Chain Reaction, Sequencing
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Antimicrobial Susceptibility, Campylobacter, MIC Panel	
Clinical Significance:	Enteric campylobacters most frequently include <i>C. jejuni</i> and <i>C. coli</i> . The organisms cause gastrointestinal infections that manifest most often as watery diarrhea. Early therapy eliminates the organism from stool and often decreases the duration of symptoms.
Effective Date:	November 17, 2008
Test Code:	16528
Report Format:	Organism Ciprofloxacin Clindamycin Erythromycin Gentamicin Tetracycline
Assay Category:	Research Use Only
Performing Site:	Focus Diagnostics, Inc.
Additional Information	Remove result codes for Ampicillin, Chloramphenicol, Imipenem and update assay category.

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

11353-Ehrlichia chaffeensis DNA RT PCR	
Effective Date:	November 17, 2008
Transport Temperature:	Refrigerated (cold packs)
Additional Information	Update transport temperature.

37541-Angioedema Panel	
35071-C4 Activation Panel	
7159-Complement Activation Panel	
Effective Date:	November 17, 2008
Specimen Requirements:	1 mL no additive (red-top) serum AND 1 mL EDTA (lavender-top) plasma
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements to include additional specimens required.

Lyme Disease Antibody, Total, EIA with Reflex to CSF Ratio	
Clinical Significance:	Detection of intrathecally-produced organism-specific antibodies in CSF indicate central nervous system infection.
Effective Date:	November 24, 2008
Test Code:	10534
Assay Category:	FDA Approved/ Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update assay category.

<i>Mycobacterium avium-intracellulare</i> DNA	
Clinical Significance:	This test is used to detect the presence of either <i>M. avium</i> or <i>M. intracellulare</i> in a patient's specimen. The use of real-time PCR to assay for the presence of <i>M. avium</i> and/or <i>M. intracellulare</i> DNA in clinical specimens allows for rapid patient testing (3 to 4 hours compared to several weeks or more for conventional culture and DNA hybridization) and for distinguishing infections caused by <i>M. tuberculosis</i> or other mycobacterial species.
Effective Date:	November 24, 2008
Test Code:	16064
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update assay category and add LDT always message.

Susceptibility Aerobic Actinomycetes	
Clinical Significance:	To aid physician in determining selection of antimicrobial agents for treatment of disease caused by organisms included in the Aerobic Actinomycetes group.
Effective Date:	November 24, 2008
Test Code:	14908
Report Format:	Organism Identification Amikacin Amoxicillin/Clavulanic Ac Ceftriaxone Ciprofloxacin Clarithromycin Imipenem Linezolid Minocycline Tobramycin Trimethoprim/Sulfamethoxa Comment:
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update Report Format and result name. Remove Cefepime and Cefotaxime and add Linezolid.

Susceptibility, MAI Complex MIC	
Clinical Significance:	To aid physician in determining selection of anti-mycobacterial agents for treatment of disease caused by organisms included in the MAC group.
Effective Date:	November 24, 2008
Test Code:	10591
Report Format:	Organism Identification: Amikacin: Ciprofloxacin: Clarithromycin: Ethambutol: Linezolid: Moxifloxacin: Rifabutin (Ansamycin): Rifampin: Streptomycin:
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update report format by adding Linezolid and Moxifloxacin.

Susceptibility, Yeast, Comprehensive Panel	
Clinical Significance:	This test is used to determine the susceptibility of a pure culture yeast isolate to the most common antifungal drugs. Results are useful in selecting optimal therapy.
Effective Date:	November 24, 2008
Test Code:	17823
Report Format:	Organism Identification: Amphotericin B: 5-Flucytosine: Anidulafungin: Caspofungin: Micafungin: Fluconazole: Itraconazole: Posaconazole: Voriconazole: Comment:
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update report format and result name. Removed: Ketoconazole and Flucytosine. Added: 5-Flucytosine, Micafungin, and Anidulafungin.

Zinc					
Clinical Significance:	Zinc is an essential element involved in a myriad of enzyme systems including wound healing, immune function, and fetal development. Zinc measurements are used to detect and monitor industrial, dietary, and accidental exposure to zinc. Also, zinc measurements may be used to evaluate health and monitor response to treatment.				
Effective Date:	November 24, 2008				
Test Code:	945				
CPT Code(s):	84630				
Specimen Requirements:	<p>2 mL EDTA (royal blue-top) Trace Element Collection plasma (minimum: 0.7 mL)</p> <p>Be sure to gently mix the specimen promptly after phlebotomy. Centrifuge the tube at 1000G for 10 minutes, separate plasma from cells immediately, pour the plasma into a plastic trace element shipping container. Hemolysis is unacceptable.</p> <p>Use powder-less gloves. Firmly replace the cap on the vial and ship the specimen room temperature. Do not use royal-blue top tube tubes containing heparin since the specimen frequently will gel or develop microclots overtime. Separate plasma from cells within 2 hours.</p> <p>Transfer separated plasma to a plastic transfer vial from Quest Diagnostics "trace element and metal free" collection kit.</p>				
Transport Temperature:	Room temperature				
Specimen Stability:	Room temperature: 5 days; Refrigerated: 10 days; Frozen: 30 days				
Reference Ranges:	<table> <tr> <td>Adults:</td><td>60-130 mcg/dL</td></tr> <tr> <td>Pediatric:</td><td> 0-5 months: 26-141 mcg/dL 6-11 months: 29-131 mcg/dL 1 year: 31-120 mcg/dL 2-3 years: 29-115 mcg/dL 4-5 years: 48-119 mcg/dL 6-9 years: 48-129 mcg/dL 10-13 years: 25-148 mcg/dL 14-17 years: 46-130 mcg/dL </td></tr> </table>	Adults:	60-130 mcg/dL	Pediatric:	0-5 months: 26-141 mcg/dL 6-11 months: 29-131 mcg/dL 1 year: 31-120 mcg/dL 2-3 years: 29-115 mcg/dL 4-5 years: 48-119 mcg/dL 6-9 years: 48-129 mcg/dL 10-13 years: 25-148 mcg/dL 14-17 years: 46-130 mcg/dL
Adults:	60-130 mcg/dL				
Pediatric:	0-5 months: 26-141 mcg/dL 6-11 months: 29-131 mcg/dL 1 year: 31-120 mcg/dL 2-3 years: 29-115 mcg/dL 4-5 years: 48-119 mcg/dL 6-9 years: 48-129 mcg/dL 10-13 years: 25-148 mcg/dL 14-17 years: 46-130 mcg/dL				
Methodology:	Atomic Spectroscopy/ICP/MS				
Assay Category:	Laboratory Developed Test				
Performing Site:	Quest Diagnostics Nichols Institute				
Additional Information:	Update specimen requirements, stability, and methodology.				

Zinc, Random Urine		
Effective Date:	November 24, 2008	
Test Code:	6353	
CPT Code(s):	84630	
Specimen Requirements:	7 mL random urine in acid washed container Collect urine in an acid washed container	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature and refrigerated: 5 days; Frozen: 14 days	
Reference Ranges:	Not applicable	
Methodology:	Atomic Spectroscopy/ICP/MS	
Assay Category:	Laboratory Developed Test	
Performing Site:	Quest Diagnostics Nichols Institute	
Additional Information:	Update specimen requirements, stability, reference range, methodology, removing Creatinine component.	
DLO	Page 13 of 15	October 2008

Redirects

Leptospira Antibody Screen with Reflex to Titer	
Clinical Significance:	Leptospirosis results from the direct or indirect exposure to urine from animals infected with Leptospira. Illness ranges from self-limiting disease, to meningitis, to hepatorenal failure. The IHA procedure uses a genus-specific antigen to identify antibodies recognizing Leptospira serotypes associated with disease in the United States.
Effective Date:	November 24, 2008
Test Code:	16529
CPT Code(s):	86720
Specimen Requirements:	0.5 mL serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	Screen: Negative
	Titer: Negative: <1:50 Borderline: 1:50 Positive: > or = 1:100
Assay Category:	FDA Approved/Cleared
Performing Site:	Focus Diagnostics, Inc
Additional Information	If screen result is positive, then Leptospira Antibody Titration, IHA (Serum) will be performed at an additional charge (CPT code(s): 86720). This test formerly performed at Nichols Institute, San Juan Capistrano and Chantilly will now be performed at Focus Diagnostics.

Discontinued Tests

Central Diabetes Insipidus (CDI) Mutations	
Effective Date:	November 24, 2008
Test Code:	15035
Additional Information:	This test will be discontinued due to low volume.

Leptospira Antibody	
Effective Date:	November 24, 2008
Test Code:	983
Additional Information:	This test will be discontinued. The recommended alternative is 16529 - Leptospira Antibody Screen with Reflex to Titer in the Redirects section.

Nephrogenic Di Mut (AQP2)	
Effective Date:	November 24, 2008
Test Code:	15028
Additional Information:	This test will be discontinued due to low volume.

Nephrogenic Di Mut (AVPR2)	
Effective Date:	
Test Code:	15034
Additional Information:	This test will be discontinued due to low volume.

p53 Gene Mutation Analysis, Leumeta™	
Effective Date:	November 24, 2008
Test Code:	19800
Additional Information:	This test will be discontinued. The recommended alternative is -P53 Mutation Analysis, Plasma-based, Leumeta in the New test section.

p53 Gene Mutation Analysis, Cell-based	
Effective Date:	November 24, 2008
Test Code:	19801
Additional Information:	This test will be discontinued. The recommended alternative is -P53 Mutation Analysis, Plasma-based, Leumeta in the New test section.

RTH Mutation Analysis	
Effective Date:	November 24, 2008
Test Code:	16053
Additional Information:	This test will be discontinued due to low volume.

Tremor/Ataxia Syndrome (FXTAS)	
Effective Date:	November 24, 2008
Test Code:	15668
Additional Information:	This test will be discontinued due to low volume.

AM=6am-12pm, PM=12pm-6pm, E=6pm-12am, Next Day=12am-6am Pacific Time