



LABORATORY UPDATE

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Routine Testing

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

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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

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

New Test

| Protein, Total w/Creat, 12 Hour Urine | | |
|--|---|---|
| Clinical Significance: | The determination of proteinuria is a well established laboratory procedure for the evaluation of renal disease (glomerular, tubular and overflow proteinuria), urinary tract inflammation, orthostatic proteinuria and preeclampsia (a potential complication of pregnancy). A more rapid clinical assessment of proteinuria using a 12 hour specimen enables a faster diagnosis with subsequent intervention in several of the clinical conditions cited above. | |
| Effective Date: | January 18, 2010 | |
| Test Code: | 16993 | |
| CPT Code(s): | 84156, 82570 | |
| Specimen Requirements: | 10 ml (2mL minimum) aliquot from a well-mixed, 12 hour collection. No preservatives. Record 12 hour urine volume on test request form and urine vial. | |
| Rejection Criteria: | <i>Acidified Urine</i> | |
| Transport Temperature: | <i>Room Temperature</i> | |
| Specimen Stability: | Room Temperature: 4 days Refrigerated: 5 days Frozen: 30 days | |
| Reference Ranges: | Creatinine, 12 Hour Urine | Males: 314-1773 mg/12hr Females: 160-1241 mg/12hr |
| | Protein, Total, 12 Hour Urine | 8-98 mg/12hr |
| | Volume, Total | 200-1700 mL/12hr |
| | TProtein/g Creat/12hr | Males: 22-83 mg/g creat/12hr Females: 15-127 mg/g creat/12hr |
| | Protein/Creat Ratio | Males: <0.084 Females: <0.128 |
| Methodology: | Spectrophotometry-Colorimetric | |
| Assay Category: | FDA Approved/Cleared | |

Test Changes

| Aluminum, 24 hr Urine | |
|------------------------------|---|
| Clinical Significance: | Individuals undergoing hemodialysis are at risk for aluminum toxicity. Prolonged accumulation may cause anemia, encephalopathy, and vitamin D-resistant osteomalacia. Also, workers exposed to high levels or to long-term low levels of aluminum dust are at increased risk of toxicity. |
| Effective Date: | January 11, 2010 |
| <i>Former Test Name:</i> | <i>Aluminum, 24 Hour Urine (w/o creatinine)</i> |
| Test Code: | 14451 |
| Specimen Requirements: | 7 mL 24 hr urine in a no preservative container (minimum 3 mL) Collect without preservative (preferred). Collect and transport in a plastic, acid-washed, metal-free, container. Record total volume on specimen container and on test requisition. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | <36 mcg/24 h |
| Methodology: | Atomic Spectroscopy |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, Chantilly |
| Additional Information: | Update test name, specimen requirements, transport temperature, stability, reference range, and method. |

| Aluminum | |
|--------------------------|---|
| Effective Date: | January 11, 2010 |
| <i>Former Test Name:</i> | <i>Aluminum, Serum</i> |
| Test Code: | 2958 |
| Specimen Requirements: | 2 mL serum in royal blue-top trace element tube (minimum 0.7 mL) Draw one vacutainer of blood and discard. Draw second vacutainer. Allow serum or plasma to clot in an upright position. Centrifuge and pour (do not pipette) the serum or plasma in a metal-free tube. Plasma is an acceptable specimen type. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 4 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | Serum/ Plasma: <7 mcg/L Dialysis: <40 mcg/L |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test name, specimen requirements, stability, reference range, and method. |

| Aluminum, Random Urine | |
|--------------------------------|--|
| Effective Date: | January 11, 2010 |
| <i>Former Test Name:</i> | <i>Aluminum, Random Urine (w/o creatinine)</i> |
| Test Code: | 6024 |
| Specimen Requirements: | 7 mL random urine in acid-washed, metal-free container (minimum 2 mL) |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute, Chantilly |
| Additional Information: | Update test name, specimen requirements, transport temperature, stability, and method. |

| Copper, 24-Hour Urine | |
|--------------------------------|---|
| Clinical Significance: | Copper is an essential element that is a cofactor of many enzymes. Copper metabolism is disturbed in Wilson's disease, Menkes disease, primary biliary cirrhosis, and Indian childhood cirrhosis. Urinary copper concentrations are useful to monitor patients who are on chelation therapy. Copper concentrations are also useful to monitor patients, especially preterm newborns, on nutritional supplementation. Results of copper are often interpreted together with ceruloplasmin. |
| Effective Date: | January 11, 2010 |
| Test Code: | 365 |
| Specimen Requirements: | 7 mL 24 hour urine in 24 hour container (acid washed) (minimum 3 mL) Random urine is not acceptable. Collect without preservative. Transport in a plastic, acid-washed, metal-free, container. Record total volume on specimen container and on test requisition. |
| Rejection Criteria: | Hemolysis and fecal contamination. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | 15-60 mcg/24 h |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test code, specimen requirements, transport temperature, stability, reference range, and method. |

| Copper | | | | |
|-------------------------|---|--------------|---------------|--------|
| Effective Date: | January 11, 2010 | | | |
| Test Code: | 363 | | | |
| Specimen Requirements: | 2 mL serum in no additive (royal blue-top) trace element (minimum 0.7 mL) Draw vacutainer of blood. Allow serum or plasma to clot in an upright position. Centrifuge and pour (do not pipette) the serum or plasma into a metal-free tube. | | | |
| Transport Temperature: | Room Temperature | | | |
| Reference Ranges: | Adult: | | 70-175 | mcg/dL |
| | Pediatric: | 0-5 months: | 38-104 | mcg/dL |
| | | 6-11 months: | 24-152 | mcg/dL |
| | | 1 year: | 76-193 | mcg/dL |
| | | 2-3 years: | 87-187 | mcg/dL |
| | | 4-5 years: | 56-191 | mcg/dL |
| | | 6-9 years: | 117-181 | mcg/dL |
| | | 10-13 years: | 87-182 | mcg/dL |
| 14-17 years: | 75-187 | mcg/dL | | |
| Methodology: | Atomic Spectroscopy | | | |
| Performing Site: | Quest Diagnostics Nichols Institute | | | |
| Additional Information: | Update specimen requirements, reference range, and method. | | | |

| Rickettsia (RMSF) Antibodies (IgG, IgM) with Reflex to Titers | | |
|--|--|---------------------|
| Clinical Significance: | Antigen specific IgG and IgM titers allow rapid diagnosis of infection by any of the spotted fever group of rickettsial agents. This group of agents include <i>R. rickettsii</i> (Rocky Mountain Spotted Fever) and <i>R. akaria</i> (rickettsial pox), both seen in the continental United States. | |
| Effective Date: | January 11, 2010 | |
| <i>Former Test Name:</i> | <i>Rocky Mountain Spotted Fever Antibodies (IgG, IgM) with Reflex to Titers</i> | |
| Test Code: | 6419 | |
| CPT Code(s): | 86757 (x2) | |
| Specimen Requirements: | 1 mL serum (minimum 0.2 mL) | |
| Transport Temperature: | Room temperature | |
| Specimen Stability: | Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days | |
| Reference Ranges: | Screen: | Not Detected |
| | Titer: | <1:64 |
| Methodology: | Immunofluorescence Assay (IFA) | |
| Assay Category: | FDA Approved | |
| Additional Information: | If RMSF Antibody Screen, IgG is Detected, RMSF Antibody Titer, IgG will be performed at an additional charge (CPT code(s): 86757). If RMSF Antibody Screen, IgM is Detected, RMSF Antibody Titer, IgM will be performed at an additional charge (CPT code(s): 86757). Update test name, specimen volume, stability, reference range, methodology and assay category. | |

| Rickettsia (Typhus Fever) Antibodies (IgG, IgM) with Reflex to Titers | |
|--|---|
| Clinical Significance: | Antigen specific IgG and IgM titers allow rapid diagnosis of infection by one or more of the typhus fever group of rickettsial agents. This group includes <i>Rickettsia typhi</i> (endemic or murine typhus) <i>R. prowazeki</i> (epidemic typhus), and Brill-Zinsser disease caused by reactivation of latent <i>R. prowazeki</i> . |
| Effective Date: | January 11, 2010 |
| <i>Former Test Name:</i> | <i>Typhus (Murine) Antibody (IgG, IgM) w/ Reflex to Titers</i> |
| Test Code: | 37503 |
| CPT Code(s): | 86757 (x2) |
| Specimen Requirements: | 1 mL serum (minimum 0.2 mL) |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | Screen: Not Detected Titer: <1:64 |
| Methodology: | Immunofluorescence Assay (IFA) |
| Assay Category: | FDA Approved |
| Additional Information: | If Rickettsia (Typhus Fever) IgG and IgM Screens are Detected, titers will be performed at an additional charge (CPT code(s): 86757 for each titer performed). Update test name, specimen volume, stability, reference range, methodology and assay category. |

| Selenium | | | | | | | | | | | | | | | | | |
|-------------------------|--|-------------------|-------|--|--|----------|-------|--|-------|-----------|--------|--|-------|------------|--------|--|-------|
| Clinical Significance: | Selenium is an element of parenteral nutrition. Monitoring the selenium concentration is useful in assessing parenteral nutrition, especially recent intake. Concentrations are also monitored in children with propionic acidemia who require special diets with supplements. | | | | | | | | | | | | | | | | |
| Effective Date: | January 11, 2010 | | | | | | | | | | | | | | | | |
| Test Code: | 5507 | | | | | | | | | | | | | | | | |
| CPT Code(s): | 84255 | | | | | | | | | | | | | | | | |
| Specimen Requirements: | 2 mL serum in EDTA (royal blue-top) trace element tube (minimum 0.7 mL) Centrifuge serum or plasma specimens within 1 hour of collection. Immediately separate serum or plasma specimens from the cells into trace element collection vials(s). | | | | | | | | | | | | | | | | |
| Transport Temperature: | Refrigerated | | | | | | | | | | | | | | | | |
| Specimen Stability: | Room temperature: 8 hours Refrigerated: 14 days Frozen: 30 days | | | | | | | | | | | | | | | | |
| Reference Ranges: | Adults: 63-160 mcg/L | | | | | | | | | | | | | | | | |
| | <table border="1"> <thead> <tr> <th>Pediatric:</th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td><2 years</td> <td>16-71</td> <td></td> <td>mcg/L</td> </tr> <tr> <td>2-3 years</td> <td>40-103</td> <td></td> <td>mcg/L</td> </tr> <tr> <td>4-16 years</td> <td>55-134</td> <td></td> <td>mcg/L</td> </tr> </tbody> </table> | Pediatric: | | | | <2 years | 16-71 | | mcg/L | 2-3 years | 40-103 | | mcg/L | 4-16 years | 55-134 | | mcg/L |
| Pediatric: | | | | | | | | | | | | | | | | | |
| <2 years | 16-71 | | mcg/L | | | | | | | | | | | | | | |
| 2-3 years | 40-103 | | mcg/L | | | | | | | | | | | | | | |
| 4-16 years | 55-134 | | mcg/L | | | | | | | | | | | | | | |
| Methodology: | Atomic Spectroscopy | | | | | | | | | | | | | | | | |
| Performing Site: | Quest Diagnostics Nichols Institute | | | | | | | | | | | | | | | | |
| Additional Information: | Update test code, method, specimen requirements, transport temperature, stability, reference range and method. | | | | | | | | | | | | | | | | |

| Varicella zoster Virus Antibody (IgG) | | | |
|--|---|---|--------------|
| Clinical Significance: | Varicella Zoster Virus (VZV) causes chickenpox and when reactivated, potentially decades later, causes shingles. Twenty percent of adults will develop shingles, a rash or blister of the skin that may cause severe pain. Varicella-zoster IgG, EIA reliably measures immunity due to previous infection, but is unsuitable for detection of post-vaccination immune status. | | |
| Effective Date: | January 11, 2010 | | |
| Test Code: | 4439 | | |
| Reference Ranges: | < or = 0.90 | Negative- No VZV IgG Antibody Detected | Index |
| | 0.91 - 1.09 | Equivocal | Index |
| | > or = 1.10 | Positive- VZV IgG Antibody Detected | Index |
| Additional Information: | Update reference range and units of measure. | | |

| Zinc, 24-Hour Urine | |
|----------------------------|--|
| Effective Date: | January 11, 2010 |
| Test Code: | 946 |
| Specimen Requirements: | 7 mL 24 hour urine in 24-hour urine container - acid washed (minimum 3 mL) 24 hour urine is the only acceptable specimen type. Collect without preservative. Collect and transport in a plastic, acid-washed, metal-free, container. Record total volume on specimen container and on test requisition. |
| Rejection Criteria: | Hemolysis and fecal contamination |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | 100-1200 mcg/24 h |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test code, specimen requirements, stability, reference range, units of measure, and method. |

| 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: | January 11, 2010 |
| Test Code: | 945 |
| Specimen Requirements: | 2 mL plasma in EDTA (royal blue-top) trace element tube (minimum 0.7 mL) Separate plasma or serum from cells within 2 hours. Transfer separated plasma to a plastic transfer vial from a Quest Diagnostics "Trace element and metal free" collection kit. Alternately, transfer separated plasma or serum to a second non-additive royal blue-top tube for transport. |
| Rejection Criteria: | Hemolysis; plasma not separated from cells within 2 hours; non-trace metal certified containers. |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test code, specimen requirements, and method . |

| Zinc with Creatinine, Random Urine | |
|---|---|
| Effective Date: | January 11, 2010 |
| Former Test Name: | <i>Zinc, Random Urine with Creatinine</i> |
| Test Code: | 16502 |
| Specimen Requirements: | 7 mL random urine in acid washed container (minimum 2 mL) Collect urine in an acid-washed plastic container. |
| Rejection Criteria: | Hemolysis |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test code, test name, specimen requirements, stability and method. |

| Zinc, Random Urine | |
|---------------------------|---|
| Effective Date: | January 11, 2010 |
| Test Code: | 6353 |
| Specimen Requirements: | 7 mL random urine in acid washed container (minimum 2 mL) Collect urine in an acid-washed plastic container. |
| Rejection Criteria: | Hemolysis and fecal contamination. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | Not established |
| Methodology: | Atomic Spectroscopy |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test code, specimen requirements, stability and method. |

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

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

| Genomic Alterations, Oncology, ClariSure™ CGH | |
|--|--|
| Clinical Significance: | To integrate CGH into the investigation of neoplasms to assess genomic alterations and overall genomic complexity of the abnormal clone. To be used in conjunction with other established clinical laboratory tests for the malignancy in question. |
| Effective Date: | December 14, 2009 |
| Test Code: | 16800 |
| CPT Code(s): | 88386, 83891, 83892, 83898 |
| Specimen Requirements: | 3 mL bone marrow in sodium heparin tube Bone marrow or whole blood in sodium heparin tube. Ship at room temperature. Other vacutainer tubes containing EDTA or ACD are acceptable. See Genetics Specimen Collection Section for detailed specimen instructions. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature and Refrigerated: See Instructions Frozen: Unacceptable |
| Reference Ranges: | Accompanies report |
| Methodology: | Comparative Genomic Hybridization |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| Genomic Alterations, POC, ClariSure™ CGH | |
|---|---|
| Clinical Significance: | This array-based comparative genomic hybridization (aCGH) products of conception assay is used to detect genomic alterations that may be associated with fetal miscarriage. Use in conjunction with prenatal conventional cytogenetics testing and clinical evaluation of the miscarriage. |
| Effective Date: | December 14, 2009 |
| Test Code: | 16884 |
| CPT Code(s): | 88386, 83891, 83892, 83898 |
| Specimen Requirements: | Product of conception tissue in transport media Fetal tissue sample minimum 2x3 mm sterile container in Hanks', Ringer's solution or culture medium with antibiotics. Refrigerate (DO NOT FREEZE) specimen until pickup. Ship refrigerated. Or cultured cells from tissue specimen. See Genetics Specimen Collection Section for detailed specimen instructions. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT. |
| Transport Temperature: | Refrigerated |
| Specimen Stability: | Room temperature and Refrigerated: See Instructions Frozen: Unacceptable |
| Reference Ranges: | Accompanies report |
| Methodology: | Comparative Genomic Hybridization |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| HIV-1 RNA, QL TMA, CSF | |
|-------------------------------|---|
| Clinical Significance: | This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. |
| Effective Date: | December 14, 2009 |
| Test Code: | 16879 |
| CPT Code(s): | 87535 |
| Specimen Requirements: | 1.6 mL CSF in sterile leak-proof container CSF: Collect at least 1.6 mL in a sterile screw-capped container (0.6 mL min). Do not use heparin tube for collection. Ship CSF frozen. |
| Transport Temperature: | Frozen |
| Specimen Stability: | Room temperature: 72 hours Refrigerated: 5 days Frozen: 35 days |
| Reference Ranges: | Not Detected |
| Methodology: | TMA |
| Assay Category: | FDA Approved/Cleared/Modified/Molecular assay |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| Interferon Beta 1a (IFNB-1a) AB | |
|--|--|
| Clinical Significance: | Highly elevated levels of neutralizing antibodies (NAb >1:100) to interferon-beta used as therapy in patients with Multiple Sclerosis have been reported to correlate with predictable loss of interferon-beta bioactivity. In patients with elevated NAb levels from >1:20 to <1:100, interferon-beta bioactivity may still be present, but does not necessarily correlate to the exact NAb titer, and continued patient monitoring may be warranted. There is no apparent loss of interferon-beta bioactivity in patients who test positive in the binding antibody assay, but negative for NAb; however, continued patient monitoring may also be warranted in this instance as well. |
| Effective Date: | January 11, 2010 |
| Test Code: | 16201 |
| CPT Code(s): | 86849 |
| Specimen Requirements: | 1 mL serum |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | <1:20 |
| Methodology: | Tissue Culture/Neutralization |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Focus Diagnostics, Inc. |

| Interferon Beta 1b (IFNB-1b) AB | |
|--|---|
| Effective Date: | January 11, 2010 |
| Test Code: | 16202 |
| CPT Code(s): | 86849 |
| Specimen Requirements: | 1 mL serum |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | <1:20 |
| Methodology: | Tissue Culture/Neutralization |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Focus Diagnostics, Inc. |

| PIK3CA Mutation Analysis | |
|---------------------------------|--|
| Clinical Significance: | PIK3CA mutation has been associated with poor prognosis in endometrial, breast, and colorectal cancers. Mutations in exons 9 and 20 of PIK3CA have also been associated with resistance to cetuximab therapy in patients with colorectal cancer. |
| Effective Date: | December 14, 2009 |
| Test Code: | 16897 |
| CPT Code(s): | 83891, 83907, 83898 (x3), 83894, 83904 (x6), 83912 |
| Specimen Requirements: | Formalin fixed paraffin embedded tissue |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze |
| Reference Ranges: | Accompanies report |
| Methodology: | Polymerase Chain Reaction, Sequencing |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| MLH1 Gene Sequencing, HNPCC | |
|------------------------------------|---|
| Clinical Significance: | This test should be offered to patients with colorectal cancer who meet the Bethesda criteria established by National Cancer Institute (NCI), especially those whose tumors display loss of staining for the MLH1 protein by immunohistochemistry and/or microsatellite instability (MSI). This test is often ordered along with testing of the other mismatch repair genes MSH2 and Detection of a germline mutation in one of the mismatch repair genes establishes a clinical diagnosis of HNPCC. Mutation detection in at risk family members allows predictive diagnosis of the disease and thus intensive screening and early intervention or prevention of cancer. |
| Effective Date: | January 11, 2010 |
| Test Code: | 16926 |
| CPT Code(s): | 83891, 83898 x19, 83894, 83892 x19, 83904 x19, 83912 |
| Specimen Requirements: | 5 mL EDTA (lavender-top) whole blood Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature & Refrigerated: 8 days Frozen: Do Not Freeze |
| Reference Ranges: | Accompanies Report |
| Methodology: | PCR and Dye-Terminator Sequencing Reaction |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| MSH2 Gene Sequencing, HNPCC | |
|------------------------------------|---|
| Clinical Significance: | This test should be offered to patients with colorectal cancer who meet the Bethesda criteria established by the National Cancer Institute (NCI), especially those whose tumors display loss of staining for the MSH2 protein by immunohistochemistry and/or microsatellite instability (MSI). This test is often ordered along with testing of the other mismatch repair genes MLH1 and MSH6. Detection of a germline mutation in one of the mismatch repair genes establishes a clinical diagnosis of HNPCC. Mutation detection in at risk family members allows predictive diagnosis of the disease and thus intensive screening and early intervention or prevention of cancer. |
| Effective Date: | January 11, 2010 |
| Test Code: | 16928 |
| CPT Code(s): | 83891, 83898 (x17), 83894, 83892 (x17) 83904(x17), 83912 |
| Specimen Requirements: | 5 mL whole blood collected in EDTA (lavender-top) Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze. |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature and Refrigerated: 8 days Frozen: Do Not Freeze |
| Reference Ranges: | Accompanies report |
| Methodology: | PCR and Dye-Terminator Sequencing Reaction |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| Antimicrobial Level, Rifabutin, HPLC | |
|---|--|
| Clinical Significance: | Rifabutin is the active antimycobacterial agent of the medication Mycobutin and is particularly effective in treating Mycobacterium tuberculosis and <i>M. avium</i> complex (MAC), whose components include <i>M. avium</i> and <i>M. intracellulare</i> . The bloodstream level of rifabutin should be monitored to ensure that adequate levels of the drug are administered, absorbed and subsequently excreted from the body to prevent drug build-up that might lead to toxic side effects and to ensure proper dosing and other medications. |
| Effective Date: | January 18, 2010 |
| Test Code: | 16208 (Focus 51949) |
| CPT Code(s): | 82492 |
| Specimen Requirements: | 2 mL serum collected in a no additive (red-top) container |
| Transport Temperature: | Frozen |
| Specimen Stability: | Room temperature and Refrigerated: Unacceptable Frozen: 14 days |
| Reference Ranges: | <0.01 mcg/mL |
| Methodology: | High Performance Liquid Chromatography |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Focus Diagnostics, Inc. |

| Bacterial Identification, Phenotypic and Sequencing | |
|--|--|
| Clinical Significance: | This test uses genotypic methods for identification of esoteric clinical isolates. Organisms requiring extensive identification beyond simple routine methods are sequenced. DNA sequencing involves the sequencing and analysis of the 16S ribosomal RNA gene to identify bacteria to the genus level or below. |
| Effective Date: | January 18, 2010 |
| Test Code: | 16860 |
| CPT Code(s): | 87153 |
| Specimen Requirements: | Preferred specimen is culture isolate in an agar slant in a double walled container. Mixed cultures will not be accepted. Subculture isolate to the appropriate slant and submit in double walled container |
| Rejection Criteria: | Mixed cultures; Cultures shipped frozen |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature and Refrigerated: Determined by viability Frozen: Unacceptable |
| Reference Ranges: | Not applicable |
| Methodology: | 16S Sequencing |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute |

| Bacterial Vaginosis DNA, Quantitative Real-Time PCR <i>Includes organisms: Lactobacillus spp., Atopobium vaginae, Megasphaera spp., and Gardnerella vaginalis.</i> | |
|--|--|
| Clinical Significance: | Concentrations of Lactobacilli are collectively reported under the term " <i>Lactobacillus spp.</i> ", as these species are among the peroxide producing Lactobacilli thought to be protective against bacterial vaginosis. In the absence of peroxide producing Lactobacilli, <i>Atopobium vaginae</i> , <i>Megasphaera spp.</i> , and Gardnerella (> 6.0 log (cells/ mL) have been associated with vaginosis. |
| Effective Date: | January 18, 2009 |
| Test Code: | 16898 |
| CPT Code(s): | 87799 (x3), 87512 |
| Specimen Requirements: | Vaginal swab in 0.7 mL Aptima Vaginal Swab Collection Kit Follow the instructions provided in the Aptima Vaginal Swab Collection Kit. Remove the swab from the packaging and insert the swab into the vagina about two inches inside the opening. Gently rotate for 10 to 30 seconds, making sure that the swab touches the wall of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label. Carefully break the swab shaft at the score line against the side of the tube and discard the top portion of the swab shaft. Tightly screw the cap onto the tube. |
| Rejection Criteria: | Specimens containing heparin; Samples from leaking, uncapped or broken container |
| Transport Temperature: | Refrigerated |
| Specimen Stability: | Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days |
| Reference Ranges: | Accompanies report |
| Methodology: | Real Time PCR |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| Dengue Virus IgG Avidity | |
|---------------------------------|--|
| Clinical Significance: | Primary infection with a given (Dengue virus) DV serotype induces an immune response that protects against re-infection by that serotype. However, later infection of the same individual by another DV serotype, referred to as secondary infection, is associated with an increased risk for dengue hemorrhagic fever. Thus, discrimination of acute primary from acute secondary DV infection can play a role in guiding clinical care. |
| Effective Date: | January 18, 2009 |
| Test Code: | 16987 |
| CPT Code(s): | 86790 (x2) |
| Specimen Requirements: | 0.5 mL serum |
| Transport Temperature: | Room temperature |
| Specimen Stability: | Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days |
| Reference Ranges: | >0.35 |
| Methodology: | Immunoassay |
| Assay Category: | ASR1 |
| Performing Site: | Focus Diagnostics, Inc. |

| Cytomegalovirus DNA UltraQuant® | |
|--|---|
| Clinical Significance: | Quantitates down to 100 copies/mL to provide ultrasensitive monitoring of CMV viral load. In patients receiving antiviral therapy, an increase in CMV viral load is indicative of reactivation of CMV infection or associated with the emergence of virus variants with reduced susceptibility to ganciclovir, foscarnet, and/or cidofovir. |
| Effective Date: | January 18, 2010 |
| Test Code: | 16982 |
| CPT Code(s): | 87497 |
| Specimen Requirements: | 10 mL whole blood EDTA --or-- 10 mL whole blood ACD 2 mL amniotic fluid Ship whole blood ambient or refrigerated. Amniotic fluid should be submitted frozen: Ship within 24 hours of collection. Amniotic fluid is not an approved specimen type for New York State patients. |
| Transport Temperature: | Room temperature: Whole Blood Frozen temperature: Amniotic Fluid |
| Specimen Stability: | Whole Blood: Room temperature: 4 days Refrigerated: 4 days Frozen: Unacceptable Amniotic Fluid: Room temperature: 4 days Refrigerated: 7 days Frozen: 60 days |
| Reference Ranges: | <100 copies/mL |
| Methodology: | Polymerase Chain Reaction |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Specialty Laboratories |

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.

| Angiotensin II | |
|-------------------------|---|
| Clinical Significance: | Angiotensin Converting Enzyme (ACE) converts Angiotensin I to Angiotensin II. Angiotensin II exerts a negative feedback control of renin release. Angiotensin II is useful in the classification of patients with hypertension. |
| Effective Date: | January 18, 2010 |
| Test Code: | 36718 |
| Reference Range: | < or = 86 ng/L |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information: | Update reference range. |

| Alpha-Fetoprotein, Amniotic Fluid with Reflex to AchE and Fetal Hgb | |
|--|---|
| Clinical Significance: | To diagnose neural tube and ventral wall defects. |
| Effective Date: | January 18, 2010 |
| Test Code: | 232 |
| Methodology: | Gel Electrophoresis, Radial Immunodiffusion, AFP: Chemiluminescent |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update methodology. |

| Chromosome Analysis and AFP with Reflex to AchE, Fetal Hgb, Amniotic Fluid | |
|---|---|
| Effective Date: | January 18, 2010 |
| <i>Former Test Name:</i> | <i>Chromosome Analysis & AFP w/Reflex to AchE & Fetal Hgb, Amniotic Fluid</i> |
| Test Code: | 14591 |
| Methodology: | Culture, Microscopy, Karyotype, Gel Electrophoresis, Radial Immunodiffusion, AFP: Chemiluminescent |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update test name and methodology. |

| <i>Clostridium difficile</i> Culture with Reflex to Toxin | | | |
|--|---|--|--|
| Clinical Significance: | <i>Clostridium difficile</i> is a spore-forming bacteria that is part of the normal intestinal flora. With intestinal overgrowth, <i>C. difficile</i> is the major cause of antibiotic-associated diarrhea and colitis. <i>C. difficile</i> is the primary cause of pseudomembranous colitis. Diagnosis by culture alone is insufficient. | | |
| Effective Date: | January 18, 2010 | | |
| <i>Former Test Name:</i> | <i>Clostridium difficile Culture with Reflex to Toxin Assay</i> | | |
| Test Code: | 15386 | | |
| Specimen Requirements: | 5 g stool in sterile screw cap container Stool swab in anaerobic transport tube is acceptable If specimens will be shipped ambient, they must be collected in an anaerobic transport. Raw stools collected in sterile containers must be shipped frozen at -70 degrees C. | | |
| Transport Temperature: | Frozen (Swab: ship Room temp) | | |
| Specimen Stability: | <table border="1"> <tr> <td>Stool: Room temperature: Unacceptable Refrigerated: 48 hours Frozen -70 degrees: 7 days</td> <td>Swab: Room temperature: 48 hours Refrigerated: Unacceptable Frozen Unacceptable</td> </tr> </table> | Stool: Room temperature: Unacceptable Refrigerated: 48 hours Frozen -70 degrees: 7 days | Swab: Room temperature: 48 hours Refrigerated: Unacceptable Frozen Unacceptable |
| Stool: Room temperature: Unacceptable Refrigerated: 48 hours Frozen -70 degrees: 7 days | Swab: Room temperature: 48 hours Refrigerated: Unacceptable Frozen Unacceptable | | |
| Performing Site: | Quest Diagnostics Nichols Institute | | |
| Additional Information: | Update test name and test code, specimen requirements, transport temperature and stability. | | |

| Phosphatidylinositol Ab (IgA) | |
|--------------------------------------|---|
| Clinical Significance: | Phospholipid autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyeline are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases. |
| Effective Date: | January 18, 2010 |
| Test Code : | 16686 |
| Reference Ranges: | Phosphatidylinositol IgA < 10 U/mL |
| Assay Category: | Research Use Only |
| Performing Site: | Specialty Laboratories |
| Additional Information: | Update reference range and assay category. Please note this test is included in the following group code: 10480 -Phosphatidylinositol Ab (IgG, IgA, IgM) |

| Phosphatidylethanolamine Ab (IgA) | |
|--|---|
| Clinical Significance: | Phospholipid autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyeline are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases. |
| Effective Date: | January 18, 2010 |
| Test Code: | 16682 |
| Reference Ranges: | Phosphatidylethanolamine IgA < 10 U/mL |
| Assay Category: | Research Use Only |
| Performing Site: | Specialty Laboratories |
| Additional Information: | Update reference range, units of measure and assay category. Please note this test is included in the following group code: 16619-Phosphatidylethanolamine Ab (IgG, IgA, IgM) |

| Phosphatidylcholine Ab (IgA) | |
|-------------------------------------|---|
| Clinical Significance: | Phospholipid autoantibodies specific to phosphatidylinositol (PI), phosphatidylglycerol (PG), phosphatidylserine (PS), phosphatidylethanolamine (PE), phosphatidylcholine (PC), phosphatidic acid (PA), cardiolipin (CL) and sphingomyeline are found in hematologic autoimmune diseases, especially anti-phospholipid syndrome (APS) and lupus erythematosus (SLE). APS is characterized by arterial and venous thrombosis, thrombocytopenia, and recurrent fetal loss; thrombosis, thrombocytopenia and hemolytic anemia also occur in SLE and are associated with the presence of phospholipids autoantibodies. Women with infertility showing spontaneous abortion or in vitro fertilization failure demonstrate PI autoantibodies in 25% of cases. |
| Effective Date: | January 18, 2010 |
| Test Code: | 16679 |
| Reference Ranges: | Phosphatidylcholine IgA < 10 U/mL |
| Assay Category: | Research Use Only |
| Performing Site: | Specialty Laboratories |
| Additional Information: | Update reference range, units of measure and assay category. Please note this test is included in the following group code: 30037-Phosphatidylcholine Ab (IgG, IgA, IgM) |

| Factor VIII Activity, Clotting w/Refl | |
|--|--|
| Clinical Significance: | In the presence of a suspected lupus anticoagulant, the one-stage APTT based assay may yield false low FVIII values consistent with "haemophilia" whereas the chromogenic assay avoids lupus anticoagulant interference and yields accurate FVIII results. |
| Effective Date: | January 25, 2010 |
| Test Code: | 70050 |
| Reference Ranges: | Coag Factor VIII Activity: 50-180 % normal Factor VIII, Chromogenic: 50-160 % normal |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information: | Update reference range and units of measure. |

| Factor VIII, Chromogenic | |
|---------------------------------|--|
| Effective Date: | January 25, 2010 |
| Test Code: | 16049 |
| Reference Ranges: | 50-160 % normal |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information: | Update reference range and units of measure. |

| Hepatitis B Virus DNA Qualitative, Real-Time PCR | |
|---|---|
| Clinical Significance: | Determine need to treat chronic HBV infection; indicator of chronic hepatitis when still positive 6 months after diagnosis of acute HBV infection; monitor response to therapy; demonstrate viral replication in patients with mutant HBV (eg, in HbeAg- and HbeAb+ individuals). |
| Effective Date: | January 25, 2010 |
| Test Code: | 34181 |
| Performing Site: | Quest Diagnostics Nichols Institute |
| Additional Information: | Update remove source result code. |

| Interferon Beta IgG, MAID w/Refl Neutralization | |
|--|---|
| Clinical Significance: | Some multiple sclerosis patients receiving recombinant interferon-beta (IFN β) develop FN β -specific antibodies that may block the therapeutic effect of the treatment. |
| Effective Date: | January 11, 2010 |
| Test Code: | 19509 |
| Performing Site: | Focus Diagnostics, Inc. |
| Reflex Criteria: | If the Interferon-Beta IgG is ≥ 4.0, this test will reflex to %19510 Interferon Beta (IFNB) Antibody Neutralization Assay (29558 should not be ordered alone). |
| Additional Information: | Update reflex criteria. |

| Mycophenolic Acid | | | |
|--------------------------|--|--|-------------------------|
| Clinical Significance: | Mycophenolic acid is an immunosuppressant used in tissue transplants. It prevents graft rejection by the host's immune system. It is very important to monitor its level. Too little of this drug will cause graft rejection, while too much will lead to infection. Monitoring its level is essential to optimize therapeutic effects, avoid toxicity, and assure compliance. | | |
| Effective Date: | January 25, 2010 | | |
| Test Code: | 10662 | | |
| Reference Range: | Mycophenolic Acid: MPA Glucuronide | (TROUGH) 1.0-3.5 (TROUGH) 35.0-100.0 | mcg/mL mcg/mL |
| Performing Site: | Quest Diagnostics Nichols Institute | | |
| Additional Information: | Update CPU interface mapping (add MPAG result code). | | |

| Tissue Plasminogen Activator (TPA), EIA | |
|--|--|
| Clinical Significance: | The Tissue Plasminogen Activator assay is used to detect disorders of the fibrinolytic system. |
| Effective Date: | January 25, 2010 |
| Test Code: | 29816 |
| Reference Ranges: | < OR =12.8 ng/mL |
| Additional Information: | Update reference range. Please note this test is included in the following group codes: 11340-Fibrinolysis Comprehensive Panel, 15108-tPA/PAI-1 Panel. |

| Bacterial 16S rDNA Sequencing | |
|--------------------------------------|--|
| Clinical Significance: | This test uses DNA sequencing and analysis of the 16S ribosomal RNA gene to identify bacteria at the genus and/ or species level. Genus and species information can be used to select appropriate therapeutic and management strategies. |
| Effective Date: | January 18, 2010 |
| Test Code: | 17221 |
| Specimen Requirements: | Culture isolate in Agar slant double walled container Preferred specimen is culture isolate in an agar slant in a double walled container. Mixed cultures will not be accepted. Subculture isolate to the appropriate slant and submit in double walled container. |
| Methodology: | 16S Sequencing |
| Assay Category: | Laboratory Developed Test |
| Performing Site: | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information | Update test code, specimen collection instruction, TAT, method, assay category and remove RUO always message. |

Discontinued Tests

| Aluminum, Plasma | |
|-------------------------|--|
| Effective Date: | January 11, 2010 |
| Test Code: | 4695 |
| Additional Information: | All versions of this test will be discontinued; the recommended alternative is 2958- Aluminum. |

| Interferon Beta (IFNB) Antibody Neutralization Assay | |
|---|---|
| Effective Date: | January 11, 2010 |
| Test Code: | 19510 |
| Additional Information: | This test will be discontinued. The recommended alternatives are 16201- Interferon Beta 1a (IFNB-1a) AB and/or 16202 - Interferon Beta 1b (IFNB-1b) AB. |

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

CPT 2010 AMA Changes

The American Medical Association (AMA) has made CPT code changes in the 2010 edition of the AMA Current Procedural Terminology (CPT) coding manual. Quest Diagnostics will be implementing the below CPT changes effective January 1, 2010.

| Quest Diagnostics Test Name | Quest Diagnostics Order Code | 2009 CPT Codes | NEW CPT Codes Effective 1/1/2010 |
|--|------------------------------|---|---|
| Procalcitonin, S | 19825 | 0194T | 84145 |
| Aspirin Resistance (11 Dehydrothromboxane B2) | 16174 | 83520, 82570 | 84431, 82570 |
| HE4, Ovarian Cancer Monitoring | 16500 | 86316 | 86305 |
| Cell Function Assay Cylex | 59644 | 86353 | 86352 |
| <i>Treponema pallidum</i> Ab, Particle Agglutination | 653 | 86781 | 86780 |
| FTA-Abs | 4112 | 86781 | 86780 |
| <i>Treponema pallidum</i> , IgG, IgM Ab Panel, IFA | 34323 | 86781 x2 | 86780 x2 |
| Donor Rapid Plasma Reagin w/Reflex Syph IgG | 19119 | 86592 If reflex performed 86781 | 86592 If reflex performed 86780 |
| Bacterial 16S rDNA Sequencing | 17221 | 87158 | 87153 |
| Mycobacteria Identification, DNA-Probes and HPLC-FL | 11137 | 87149 per probe Other CPT codes may be added dependent on the method of identification (87143 or 87118 or 87158) | 87149 per probe Other CPT codes may be added dependent on the method of identification (87143 or 87118 or 87153) |
| Clostridium difficile DNA and Toxin B Gene, QL Real Time PCR | 16739 | 87798, 83891, 83896, 83898, 83912 | 87798, 87493 |