



# LABORATORY UPDATE

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## Routine Testing

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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.

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

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

### New Test

| <b>Hemoglobin A1c with eAG w/Reflex to GlycoMark®</b> |  |                            |
|---|--|----------------------------|
| Clinical Significance:                                | Hemoglobin A1c monitors long term glucose control (2-3 months) in patients with diabetes mellitus. GlycoMark measures 1, 5-anhydroglucitol. The test is useful to assess glycemic excursions above the kidney renal threshold; therefore, it is a good indicator of postprandial blood glucose control over the prior 1-4 weeks. |                            |
| <b>Effective Date:</b>                                | <b>April 12, 2010</b>  |                            |
| Test Code:  | 16320  |                            |
| CPT Code:   | 83036  |                            |
| Specimen Requirements:                                | Submit two separate specimens:<br>1) whole blood (full lavender-top (EDTA) tube)<br>2) 1 ml serum  |                            |
| Transport Temperature:                                | Room temperature   |                            |
| Specimen Stability:                                   | Room temperature and Refrigerated: 7 days<br>Frozen: 6 months  |                            |
| Units of Measure:                                     | %  |                            |
| Reference Range:                                      | A1c value (% of total hemoglobin)      Interpretation  |                            |
|   | < 5.7  | Non-diabetic               |
|   | 5.7 – 6.4  | Increased risk of diabetes |
|   | > or = 6.5   | Consistent with diabetes   |
| Methodology:  | Immunoturbidimetry   |                            |
| Assay Category:                                       | FDA Approved/Cleared   |                            |
| Additional Information:                               | If the Hemoglobin A1c value is $\geq 6.5\%$ and $\leq 8.0\%$ a Glycomark® test code 19599 will be performed at an additional charge (CPT code(s): 84378).  |                            |

## Test Changes

### Change In Hemoglobin A<sub>1c</sub> Reference Intervals

In January 2010, the American Diabetes Association (ADA) recommended that hemoglobin A<sub>1c</sub> values be used as diagnostic tools in the identification of patients who have diabetes or who are at risk for development of diabetes<sup>1</sup>. To that end, DLO will adopt the ADA ranges used for the diagnosis of diabetes for all profiles containing hemoglobin A<sub>1c</sub> as a component, effective April 12, 2010.

<sup>1</sup> **Standards of Medical Care in Diabetes - 2010.** *Diabetes Care*, 33(Supp 1): S1-S61, 2010.

| <b>Hemoglobin A1c</b>   |   |                                   |
|-------------------------|---|-----------------------------------|
| Clinical Significance:  | This test is used for the routine diagnosis and monitoring of diabetes mellitus   |                                   |
| Effective Date:         | <b>April 12, 2010</b>   |                                   |
| Test Code:              | 496   |                                   |
| Reference Range:        | <b>A1c value (% of total hemoglobin)      Interpretation</b>  |                                   |
|                         | <b>&lt; 5.7</b>   | <b>Non-diabetic</b>               |
|                         | <b>5.7 – 6.4</b>  | <b>Increased risk of diabetes</b> |
|                         | <b>&gt; or = 6.5</b>  | <b>Consistent with diabetes</b>   |
| Additional Information: | Updated ADA table. This table also appears on the following test codes:<br>8181: Hemoglobin A1c with Calculated Mean Plasma Glucose<br>16802: Hemoglobin A1c with eAG<br>16715: Hemoglobin A1c with reflex to Glycomark<br>16320: Hemoglobin A1c with eAG, reflex to GlycoMark® |                                   |

## Test Changes

| <b>ANA IFA Screen with Reflex to Titer and Pattern, IFA</b> |   |
|---|---|
| Clinical Significance:                                      | ANA is useful as a screening assay for connective tissue diseases.  |
| <b>Effective Date:</b>                                      | <b>April 12, 2010</b>   |
| <i>Former Test Name:</i>                                    | <i>ANAchoice<sup>™</sup> Screen with Reflex to Titer, IFA</i>   |
| Test Code:  | <b>249</b>  |
| CPT Code(s):  | 86038   |
| Specimen Requirements:                                      | 1 mL serum (minimum 0.5 mL)   |
| Transport Temperature:                                      | Room temperature  |
| Specimen Stability:   | Room temperature: 4 days<br>Refrigerated: 7 days<br>Frozen: 30 days   |
| Reference Ranges:   | <b>Screen:</b> <b>Negative</b>  |
|   | <b>Titer:</b> <b>&lt;1:40 Negative</b><br><b>1:40 – 1:80 Low Antibody Level</b><br><b>&gt; 1:80 Elevated Antibody Level</b>   |
| Methodology:  | <b>Immunofluorescence Assay (IFA)</b>   |
| Assay Category:   | <b>FDA Approved</b>   |
| Additional Information:                                     | Update test title, reference ranges, and methodology.<br>If the ANA IFA Screen is positive then an ANA Titer and Pattern will be performed at an additional charge (CPT: 86039).<br>Please note, due to a change in tissue substrate, the unique SSA/Ro pattern previously provided will now generally be detected as a speckled pattern. |

| <b>Glucose, Plasma</b>   |   |
|--------------------------|---|
| Clinical Significance:   | Plasma glucose levels may be abnormally high (hyperglycemia) or abnormally low (hypoglycemia). Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolic disorders including diabetes mellitus, idiopathic hypoglycemia, and pancreatic islet cell neoplasm. |
| <b>Effective Date:</b>   | <b>April 12, 2010</b>   |
| <i>Former Test Name:</i> | <i>Glucose, Fasting (P)</i>   |
| Test Code:               | 484   |
| Reference Range:         | 65-99 mg/dL<br><b>Fasting Reference Interval</b>  |
| Additional Information:  | Update test name and reference range message.   |

| <b>HCV RNA, Quantitative Real Time PCR</b> |   |
|--|---|
| Clinical Significance:                     | Useful in monitoring therapy and disease progression.   |
| <b>Effective Date:</b>                     | <b>April 12, 2010</b>   |
| Test Code:                                 | 35645   |
| Specimen Requirements:                     | 3 mL plasma collected in two EDTA Lavender-top tubes. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature ( <b>minimum volume 2.5mL</b> ) |
| Additional Information:                    | Update specimen requirement for minimum volume  |

| <b>Hepatic Function Panel</b> |   |
|-------------------------------|---|
| Clinical Significance:        | The hepatic function panel is useful as a broad general assessment of hepatic (liver) function. |
| <b>Effective Date:</b>        | <b>April 12, 2010</b>   |
| Test Code:                    | <b>10256</b>  |
| Specimen Stability:           | Room Temperature: 24 hours<br><b>Refrigerated: 72 hours</b><br><b>Frozen: Unacceptable</b>      |
| Transport Temperature:        | <b>Room temperature</b>   |
| Additional Information:       | Update stability.   |

| <b>36559 - Hepatitis C Viral RNA, Qualitative Real-Time PCR, w/Reflex to Quantitative</b> |   |
|---|---|
| Clinical Significance:  | Useful in monitoring therapy and disease progression  |
| <b>Effective Date:</b>  | <b>April 12, 2010</b>   |
| Specimen Requirements:  | <b>5 mL</b> plasma collected in two EDTA Lavender-top tubes. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature ( <b>minimum volume 3.0 mL</b> ) |
| Additional Information  | Update specimen requirements.   |

### Discontinued Tests

| <b>ANA IFA Screen with Reflex to Titer, IFA</b> |  |
|---|--|
| Clinical Significance:                          | ANA is useful as a screening assay for connective tissue disease disorders.  |
| <b>Effective Date:</b>                          | <b>April 12, 2010</b>  |
| Test Code:                                      | <b>38318</b>   |
| Additional Information:                         | Orders for this test on or after April 12, 2010 will be pointed to test code 249 (see related 249 changes in this document). |

## Redirects

| <b>HTLV-I/II Antibody, w/Reflex to Western Blot</b> |   |
|---|---|
| Clinical Significance:                              | HTLV-I is associated with adult T-cell lymphoblastic leukemia and B-cell chronic lymphocytic leukemia. HTLV-II is less common and is associated with neoplasias of the CD8 T lymphocytes. Blood donor screening began in 1998. Western blot is used for confirmation of Antibody testing. |
| <b>Effective Date:</b>                              | <b>April 19, 2010</b>   |
| Test Code:  | <b>36175</b>  |
| Specimen Requirements:                              | 1 mL serum ( <b>0.7 mL minimum</b> )<br><b>Plasma collected in sodium heparin (green-top tube) is no longer acceptable.</b>   |
| Transport Temperature:                              | Refrigerated  |
| Set-Up/Analytic Time:                               | <b>Set up Mon - Fri AM; reports next day</b>  |
| Reference Ranges:                                   | <b>Nonreactive</b>  |
| Methodology:  | <b>Chemiluminescence, Immunoassay, Western Blot</b>   |
| Assay Category:                                     | <b>FDA Approved/Cleared (Western Blot: Research Use Only)</b>   |
| Performing Site:                                    | Quest Diagnostics Nichols Institute, <b>Chantilly</b> (previously also performed at Quest Diagnostics Nichols Institute, San Juan Capistrano)   |
| Additional Information:                             | Update specimen requirements, performing site and minimum volume. If the HTLV-I/II Antibody is reactive, then Test Code 8511 HTLV-I/II, Western Blot, will be performed at an additional charge (CPT: 86689).   |

| <b>HTLV-I/II, Western Blot</b> |   |
|--------------------------------|---|
| <b>Effective Date:</b>         | <b>April 19, 2010</b>   |
| Test Code:                     | <b>8511</b>   |
| Specimen Requirements:         | 1 mL serum  |
| Transport Temperature:         | Refrigerated  |
| Reference Ranges:              | <b>Negative</b>   |
| Performing Site:               | Quest Diagnostics Nichols Institute, <b>Chantilly</b> (previously also performed at Quest Diagnostics Nichols Institute, San Juan Capistrano) |
| Additional Information:        | Update reference range and performing site.   |

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & 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.

| <b>c-KIT Mutations with Reflex to PDGFRA Mutations for GIST</b>                   |   |
|---|---|
| <i>**Includes: c-KIT Mutation Analysis, Cell-based * PDGFRA Mutation Analysis</i> |   |
| Clinical Significance:  | Eighty percent of patients with gastrointestinal stromal tumor (GIST) have a c-KIT mutation in exon 9, 11, 13, or 17. The presence of a mutation usually predicts poor survival. Patients with C-KIT mutations other than D816V are likely to respond to imatinib (Gleevec) therapy. Mutations in the PDGFRA gene are found in about 7% of gastrointestinal stromal tumors (GISTs), especially in KIT wild type GISTs. PDGFRA mutations also have been described in synovial sarcomas (SSs) and malignant peripheral nerve sheath tumors (MPNST). GISTs with PDGFRA mutations (except D842V) are likely to respond to imatinib. |
| <b>Effective Date:</b>  | <b>April 19, 2010</b>   |
| Test Code:  | <b>16237</b>  |
| CPT Code(s):  | <b>83891, 83898 (x5), 83892 (x5), 83904 (x10), 83909(x10), 83912</b>  |
| Specimen Requirements:  | <b>Formalin fixed paraffin embedded tissue<br/>Collect 6 mL of whole blood or 3 mL bone marrow in lavender-top EDTA) tube. Whole blood or bone marrow is shipped refrigerated. Do not freeze whole blood or bone marrow. After collection of the sample, draw date and time, as well as sample type, must be written on the tube and included as requested information.</b>   |
| Rejection Criteria:   | <b>Grossly hemolyzed, clotted, or frozen whole blood or bone marrow</b>   |
| Transport Temperature:  | <b>Room temperature</b>   |
| Specimen Stability:   | <b>Room temperature and Refrigerated: Indefinite<br/>Frozen: Do Not Freeze</b>  |
| Reference Ranges:   | <b>C-KIT Mutation,Cell-based: Not Detected</b>  |
| Methodology:  | <b>Polymerase Chain Reaction, Sequencing</b>  |
| Assay Category:   | <b>Laboratory Developed Test</b>  |
| Performing Site:  | Quest Diagnostics Nichols Institute, San Juan Capistrano  |
| Additional Information:   | If C-KIT Mutation, Cell-based result is None detected, then PDGFRA Mutation Analysis will be performed at an additional charge (CPT code(s):83902, 83898, 83904)  |

| <b>Hepatocellular Carcinoma Panel</b><br><i>**Includes: Alpha-Fetoprotein (AFP) and AFP-L3 * DCP (Des-Gamma-Carboxy-Prothrombin)</i> |  |
|--|--|
| Clinical Significance:   | HCC Risk Panel includes serum AFP-L3%, total AFP and DCP. The combined measurement helps discriminate benign and malignant conditions related to primary liver diseases [1-4]. Furthermore, the combination measurement of three HCC biomarkers can identify a greater number of patients at risk of developing HCC than with each marker alone. |
| Effective Date:  | <b>April 19, 2010</b>  |
| Test Code:   | <b>16222</b>   |
| CPT Code(s):   | <b>82107, 83951</b>  |
| Specimen Requirements:   | <b>2 ml no additive (red-top) serum</b>  |
| Rejection Criteria:  | <b>Lipemic specimens; Hemolysis; Heavy, visible particulate matter</b>   |
| Transport Temperature:   | <b>Frozen</b>  |
| Specimen Stability:  | <b>Room temperature: 48 hours<br/>Refrigerated: 5 days<br/>Frozen: 21 days</b>   |
| Reference Ranges:  | <b>AFP: 1.6-4.5 ng/mL</b>  |
|  | <b>AFP-L3: 0.5-9.9 %</b>   |
|  | <b>DCP: &lt; OR = 7.5 ng/mL</b>  |
| Methodology:   | <b>Liquid-phase Binding Assay System, Immunoassay</b>  |
| Assay Category:  | <b>FDA Approved/Cleared</b>  |
| Performing Site:   | <b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>  |

| <b>16224 -InScape™ Ki-67, Quantitative IHC with Interpretation</b><br><b>16223 -InScape™ Ki-67, Quantitative IHC without Interpretation</b> |  |
|---|--|
| Clinical Significance:  | Staining for Ki-67 can be used to aid in assessing the proliferative activity of normal and neoplastic tissue. Ki-67 is proliferation marker that correlates with flow cytometric S-phase. Various published studies have suggested that overexpression of Ki-67 in breast cancer may be an unfavorable prognostic indicator. For other types of tumors, definitive interpretive criteria for Ki-67 expression may vary. |
| Effective Date:   | <b>March 8, 2010</b>   |
| CPT Code(s):  | <b>88361</b>   |
| Specimen Requirements:  | <b>Formalin fixed paraffin embedded tissue in IHC specimen transport kit</b>   |
| Rejection Criteria:   | <b>Specimens other than paraffin block or slides</b>   |
| Transport Temperature:  | <b>Room temperature</b>  |
| Specimen Stability:   | <b>Room temperature and Refrigerated: Indefinite<br/>Frozen: Do Not Freeze</b>   |
| Reference Ranges:   | <b>Accompanies report</b>  |
| Methodology:  | <b>Immunohistochemistry</b>  |
| Assay Category:   | <b>Laboratory Developed Test</b>   |
| Performing Site:  | <b>Quest Diagnostics Nichols Institute</b>   |

**16235 -InScape(TM) p53 Oncoprotein, Quantitative IHC with Interpretation**  
**16236 -InScape(TM) p53 Oncoprotein, Quantitative IHC without Interpretation**

|                        |   |
|------------------------|---|
| Clinical Significance: | The result of this immunohistochemical study is reported as a percent of tumor nuclei that demonstrate moderate or strong immunoreactivity. Various published studies have suggested that overexpression of p53 protein in breast cancer may be an unfavorable prognostic indicator. For other types of tumors, definitive interpretive criteria for p53 expression may vary. |
| <b>Effective Date:</b> | <b>March 8, 2010</b>  |
| CPT Code(s):           | <b>88361</b>  |
| Specimen Requirements: | <b>Formalin fixed paraffin embedded tissue in IHC specimen transport kit</b>  |
| Rejection Criteria:    | <b>Specimen other than paraffin block or slides</b>   |
| Transport Temperature: | <b>Room temperature</b>   |
| Specimen Stability:    | <b>Room temperature and Refrigerated: Indefinite<br/>Frozen: Do Not Freeze</b>  |
| Reference Ranges:      | <b>Accompanies report</b>   |
| Methodology:           | <b>Immunohistochemistry</b>   |
| Assay Category:        | <b>Laboratory Developed Test</b>  |
| Performing Site:       | Quest Diagnostics Nichols Institute   |

**16282 -Phospho-histone H3, IHC with Interpretation**  
**16257 -Phospho-histone H3, IHC without Interpretation**

|                        |   |
|------------------------|---|
| Clinical Significance: | <p>Modulation of chromatin structure plays an important role in the regulation of transcription in eukaryotes. The nucleosome, made up of four core histone proteins (H2A, H2B, H3 and H4), is the primary building block of chromatin (9). The amino-terminal tails of core histones undergo various post-translational modifications, including acetylation, phosphorylation, methylation and ubiquitination. These modifications occur in response to various stimuli and have a direct effect on the accessibility of chromatin to transcription factors and, therefore, on gene expression. In most species, histone H2B is primarily acetylated at Lys5, 12, 15 and 20. Histone H3 is primarily acetylated at Lys9, 14, 18 and 23. Acetylation at Lys9 appears to have a dominant role in histone deposition and chromatin assembly in some organisms. Phosphorylation at Ser10, Ser28 and Thr11 of histone H3 is tightly correlated with chromosome condensation during both mitosis and meiosis. Phosphorylation of Thr3 of histone H3 is highly conserved among any species and is catalyzed by the kinase haspin. Immunostaining with phospho-specific antibodies in mammalian cells reveals mitotic phosphorylation of H3 Thr3 in prophase and its dephosphorylation during anaphase.</p> <p>Phospho-histone H3 staining provides a simple and reliable method for quantifying proliferative potential. Phospho-histone H3 staining may be a useful method in other neoplasms in which accurate determination of proliferation potential is relevant to tumor grading or clinical treatment decision-making.</p> |
| Effective Date:        | <b>March 8, 2010</b>  |
| CPT Code(s):           | <b>88342</b>  |
| Specimen Requirements: | <b>Formalin fixed paraffin embedded tissue in IHC specimen transport kit</b>  |
| Transport Temperature: | <b>Room temperature</b>   |
| Specimen Stability:    | <b>Room temperature and Refrigerated: Indefinite<br/>Frozen: Do Not Freeze</b>  |
| Reference Ranges:      | <b>Accompanies report</b>   |
| Methodology:           | <b>Immunohistochemistry</b>   |
| Assay Category:        | <b>Laboratory Developed Test</b>  |
| Performing Site:       | Quest Diagnostics Nichols Institute, San Juan Capistrano  |

| <b>PMS2, IHC without Interpretation</b> |  |
|---|--|
| Clinical Significance:                  | Defects in mismatch repair systems cause elevated spontaneous mutation rates and increased instability of DNA microsatellite repetitive sequences expressed. |
| <b>Effective Date:</b>                  | <b>March 8, 2010</b>   |
| Test Code:                              | <b>16254</b>   |
| CPT Code(s):                            | <b>88342</b>   |
| Specimen Requirements:                  | <b>Formalin fixed paraffin embedded tissue in IHC specimen transport kit</b>   |
| Rejection Criteria:                     | <b>Specimens other than paraffin block or slides</b>   |
| Transport Temperature:                  | <b>Room temperature</b>  |
| Specimen Stability:                     | <b>Room temperature and Refrigerated: Indefinite<br/>Frozen: Do Not Freeze</b>   |
| Reference Ranges:                       | <b>Accompanies report</b>  |
| Methodology:                            | <b>Immunohistochemistry</b>  |
| Assay Category:                         | <b>FDA Approved/Cleared</b>  |
| Performing Site:                        | Quest Diagnostics Nichols Institute  |

### **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.

| <b>16845 -Aldosterone/Plasma Renin Activity Ratio, LC/MS/MS<br/>16846 -Plasma Renin Activity, LC/MS/MS</b> |  |
|--|--|
| Clinical Significance:   | The Aldosterone-renin ratio is used to screen for primary aldosteronism. |
| <b>Effective Date:</b>   | <b>April 12, 2010</b>  |
| Rejection Criteria:  | <b>Plasma collected in Plasma separator tube is unacceptable.</b>        |
| Performing Site:   | Quest Diagnostics Nichols Institute, San Juan Capistrano                 |
| Additional Information:  | Update rejection criteria.   |

| <b><i>Chlamydophila pneumoniae</i> Culture</b> |   |
|--|---|
| Clinical Significance:                         | <i>Chlamydophila pneumoniae</i> , formerly called <i>Chlamydia pneumoniae</i> , is recognized as a common cause of atypical pneumonia and other acute respiratory diseases. Culture offers presumptive diagnosis and guidance for antibiotic selection. |
| <b>Effective Date:</b>                         | <b>April 19, 2010</b>   |
| Former Test Name:                              | <i>Chlamydia Pneumoniae Culture</i>   |
| Test Code:                                     | <b>34299</b>  |
| Specimen Requirements:                         | Bronchoalveolar lavage, throat swab, nasopharyngeal aspirate or wash, tracheal aspirate, lung tissue, or other respiratory secretions.<br>Use viral-chlamydial or chlamydial transport media.<br><b>Whole blood acceptable.</b>                         |
| Rejection Criteria:                            | <b>Reject specimen received in non-chlamydia approved viral transport media (VTM), or Gen Probe tubes.</b>  |
| Transport Temperature:                         | <b>All specimen types except whole blood: Frozen</b><br><b>Whole blood: Room temperature up to 48 hours</b>   |
| Specimen Stability                             | <b>Room temperature: unacceptable (whole blood 48 hours)</b><br><b>Refrigerated: 48 hours</b><br><b>Frozen: 14 days (do not freeze whole blood)</b>   |
| Reference Range:                               | <b>Not Isolated</b>   |
| Assay Category:                                | <b>Laboratory Developed Test</b>  |
| Performing Site:                               | Focus Diagnostics, Inc.   |
| Additional Information:                        | Update reporting title, reference range, specimen requirements, rejection criteria, transport temperature, specimen stability, assay category and result name.  |

| <b>C-KIT Mutation Analysis, Cell-based</b> |   |
|--|---|
| Clinical Significance:                     | Activating c-kit mutations have been indentified in various human cancers. C-kit exon 8 and 17 mutations have been described in patients with CBF-AMLs and usually confer a poor prognosis with increased relapse rate. C-kit exon 9, 11, 13, 17 mutations have been reported in nearly 90% GIST patients. The presence mutation usually predicts poor survival. C-kit exon 17 mutation has been reported in patients with systemic mastocytosis. |
| <b>Effective Date:</b>                     | <b>April 19, 2010</b>   |
| Test Code:                                 | <b>19961</b>  |
| Specimen Requirements:                     | 3 mL EDTA (lavender-top) whole blood <b>or Formalin fixed paraffin embedded tissue</b>  |
| Specimen Stability:                        | <b>Whole blood:</b>   |
|  | Room temperature: 7 days<br>Refrigerated: 14 days<br>Frozen: Unacceptable   |
| Specimen Stability:                        | <b>Tissue:</b>  |
|  | <b>Room temperature: Indefinite</b><br><b>Refrigerated: Indefinite</b><br><b>Frozen: Do Not Freeze</b>  |
| Reference Ranges:                          | <b>Not Detected</b>   |
| Performing Site:                           | Quest Diagnostics Nichols Institute, San Juan Capistrano  |
| Additional Information:                    | Update reference range, specimen requirements, test code, result codes, adding new prompted result codes Specimen Source and Paraffin Block #:  |

| <b>PDGFRA Mutation Analysis</b> |  |
|---------------------------------|--|
| <b>Effective Date:</b>          | <b>April 19, 2010</b>                                    |
| Test Code:                      | <b>16859</b>   |
| Reference Range:                | <b>Not Detected</b>                                      |
| Performing Site:                | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information:         | Update reference range.                                  |

| <b>Q Fever (<i>Coxiella burnetii</i>) Antibodies (IgG, IgM) with Reflex to Titers</b> |   |
|---|---|
| Clinical Significance:  | Caused by infection with rickettsiae <i>Coxiella burnetii</i> , Q Fever is characterized by fever with interstitial pneumonitis. Sixty percent of infected individuals are asymptomatic while some other infected individuals die from complications. |
| <b>Effective Date:</b>  | <b>April 19, 2010</b>   |
| Test Code:  | <b>37071</b>  |
| Reference Range:  | <b>Screen: Negative</b><br><b>Titer: &lt;1:16</b>   |
| Specimen Requirements:  | <b>1 mL (0.2 mL min.) serum</b>   |
| Specimen Stability:   | <b>Room temperature: 4 days</b><br><b>Refrigerated: 7 days</b><br><b>Frozen: 30 days</b>  |
| Performing Site:  | Quest Diagnostics Nichols Institute, San Juan Capistrano  |
| Additional Information:   | Update reference range, specimen requirements and stability.<br>If screens are positive, titers will be performed at an additional charge (CPT code(s): 86638 per titer performed).   |

| <b>Plasminogen Activator Inhibitor (PAI-1) Act.</b> |  |                       |       |
|---|--|-----------------------|-------|
| Clinical Significance:                              | Chromolize™ PAI-1 Activity is intended for the quantitative determination of Plasminogen Activator Inhibitor (PAI-1) activity in plasma to evaluate deep vein thrombosis, myocardial infarction, and risk of postoperative thrombosis. |                       |       |
| <b>Effective Date:</b>                              | <b>April 26, 2010</b>  |                       |       |
| Test Code:  | <b>10491</b>   |                       |       |
| Reference Ranges:                                   | <b>Males:</b>  | <b>&lt; or = 47.1</b> | IU/mL |
|   | <b>Females:</b>  | <b>&lt; or = 40.7</b> | IU/mL |
| Performing Site:                                    | Quest Diagnostics Nichols Institute, San Juan Capistrano   |                       |       |
| Additional Information:                             | Update reference range and always message.<br>Please note TC 10491 is included in the following group codes: 15108 - tPA/PAI-1 Panel; 11340-Fibrinolysis Comprehensive Panel.  |                       |       |

## Discontinued Tests

| <b>HTLV I &amp; II AB, Western Blot (CSF)</b> |  |
|---|--|
| <b>Effective Date:</b>                        | <b>April 19, 2010</b>  |
| Test Code:                                    | 34970  |
| Additional Information:                       | This test will be discontinued. The recommended alternative is 8511 HTLV-I/-II, Western Blot, performed at Quest Diagnostics Nichols Institute, Chantilly. |