



# 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.

**Test Changes**

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

**Test Changes**

**Detection of Carbapenemase in *Enterobacteriaceae* Using the Modified Hodge Test**

Recently, a new form of resistance to a class of antimicrobial agents known as the Carbapenem group, first detected in the northeastern United States, is now spreading to other regions. A new test, the “Modified Hodge Test” has been developed to detect carbapenemase production in isolates of *Enterobacteriaceae*. In the United States, the most common carbapenemase found in *Enterobacteriaceae* is associated with *Klebsiella pneumoniae* and *E. coli* bacteria.

To confirm resistance, this new test will be performed on *Enterobacteriaceae* isolates such as *K. pneumoniae* and *E. coli*, with any carbapenem (imipenem, meropenem, ertapenem, or doripenem) result of resistant or intermediate. If this form of resistance is confirmed, the organism name on the patient’s report will be followed by “This organism is a carbapenemase producer” and the following message will appear in the “Therapy Comments” section of the report:

“The carbapenemase enzyme which confers resistance against all beta-lactam antibiotics (including all the carbapenems such as imipenem, meropenem, ertapenem and doripenem) was detected and the confirmatory test was positive.”

While the incidence of this form of resistance is still low, there will be no charge for this service.

<b>Partial Thromboplastin Time, Activated (aPTT)</b>	
Clinical Significance:	A screening test for deficiencies of plasma coagulation factors other than Factor VII and XIII. The test is also used to monitor patients on heparin therapy.
<b>Effective Date:</b>	<b>October 6, 2008</b>
Test Code:	763
<b>Reference Ranges:</b>	<b>22-34 seconds</b>
Additional Information	Update reference range.
<b>T3, Free</b>	
Clinical Significance:	This test is used to diagnose hyperthyroidism and to clarify thyroid status in the presence of a possible protein binding abnormality.
<b>Effective Date:</b>	<b>October 6, 2008</b>
Test Code:	<b>34429</b>
Specimen Stability:	<b>Room temperature: 7 days</b> <b>Refrigerated: 7 days</b> <b>Frozen: 28 days</b>
Additional Information:	Update specimen stability.

<b>T-3 Uptake</b>	
Clinical Significance:	T3 Uptake is decreased in pregnancy, estrogen administration, hyperproteinemia, and acute intermittent porphyria. It is increased in androgen administration, stress, and acute liver disease.
Effective Date:	<b>October 6, 2008</b>
Test Code:	861
Specimen Stability:	Room temperature: 7 days <b>Refrigerated: 7 days</b> Frozen: 28 days
Additional Information:	Update specimen stability.

## QUEST DIAGNOSTICS NICHOLS INSTITUTE, San Juan Capistrano & Chantilly

### New Tests

<b>Chikungunya Antibodies w/Reflex(es) to Titer</b>	
Clinical Significance:	Chikungunya virus is a mosquito-borne alpha-virus associated with large outbreaks of a febrile illness in Africa, Indian Ocean Islands, India, and Southeast Asia. These infections are associated with severe arthralgia, rash, and headache. Cases acquired by US residents during international travel have been described.
Effective Date:	<b>September 15, 2008</b>
Test Code:	<b>70188</b>
CPT Code(s):	<b>86790 (x2)</b>
Specimen Requirements:	<b>0.5 mL serum</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature: 7 days</b> <b>Refrigerated: 14 days</b> <b>Frozen: 30 days</b>
Reference Ranges:	<b>Negative</b>
Methodology:	<b>Immunofluorescence Assay</b>
Assay Category:	<b>ASR Class 1</b>
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	If IgG and/or IgM is positive, then IgG and/or IgM Titer will be performed at an additional charge (CPT code 86790 for each titer).

<b>Enterovirus/Parechovirus RNA, Qualitative Real-Time PCR</b>	
Clinical Significance:	This broad spectrum assay detects the genomic RNA of members of the Enterovirus genus (including enteroviruses, echoviruses, coxsackieviruses and polioviruses) as well the genomic RNA of members of the Parechovirus genus. The use of this assay allows for rapid patient testing as an aid in the diagnosis of viral meningitis or sepsis-like syndromes.
Effective Date:	<b>September 15, 2008</b>
Test Code:	<b>70189</b>
CPT Code(s):	<b>87498; 87798</b>
Specimen Requirements:	<b>0.7 mL CSF, plasma (EDTA or ACD), or serum or 1 gram stool, or 1 throat or rectal swab</b>
Transport Temperature:	<b>Refrigerated: CSF, plasma (EDTA or ACD), serum or swabs Frozen: stool</b>
Specimen Stability:	<b>Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days</b>
Reference Ranges:	<b>Not detected</b>
Methodology:	<b>Real-Time RT-PCR</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Focus Diagnostics, Inc.
<b>Mumps Virus RNA, Qualitative Real-Time PCR</b>	
Clinical Significance:	This real-time PCR assay is able to rapidly detect mumps virus RNA in infected individuals. It can be used as a tool to help diagnose disease in vaccinated and unvaccinated individuals, particularly in the situations of disease outbreak.
Effective Date:	<b>September 15, 2008</b>
Test Code:	<b>70172</b>
CPT Code(s):	<b>87798</b>
Specimen Requirements:	<b>Oral/ buccal swab in sterile, leak proof container in 3 mL M4 media, V-C-M medium (green-cap) tube or equivalent (UTM)</b>
Transport Temperature:	<b>Refrigerated</b>
Specimen Stability:	<b>Room Temperature: 48 hours Refrigerated: 7 days Frozen: 30 days</b>
Reference Ranges:	<b>Not detected</b>
Methodology:	<b>Real-Time RT-PCR</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Focus Diagnostics, Inc.

<b>Factor XI Activity and Human Inhibitor</b>			
Clinical Significance:	Factor XI Inactivator assay is used to quantitate the inhibitor present in a patient sample. The Bethesda assay is the most common test for determination of circulating FXI inhibitor in plasma.		
<b>Effective Date:</b>	<b>October 6, 2008</b>		
Test Code:	<b>17854</b>		
CPT Code(s):	<b>85270, 85335</b>		
Specimen Requirements:	<b>2 mL(x2) 3.2% sodium citrate (lt. blue-top) plasma (minimum: 1 mL [x2])</b>		
Transport Temperature:	<b>Frozen</b>		
Specimen Stability:	<b>Room temperature and refrigerated: Frozen only Frozen: 14 days; -70 degrees: 1 year</b>		
Set-Up/Analytic Time:	<b>Set up: Tue AM; reports Wed E</b>		
Reference Ranges:	<b>Factor XI Activity:</b>	<b>65-150</b>	<b>% normal</b>
	<b>Factor XI Human Inhibitor:</b>	<b>Less than 0.4</b>	<b>Bethesda unit</b>
Methodology:	<b>Clot based, Bethesda Assay</b>		
Assay Category:	<b>Laboratory Developed Test</b>		
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano.		

#### **von Willebrand Comprehensive Panel 2**

*Includes: Interpretation \* Activated Partial Thromboplastin Time \* Factor VIII Activity, Clotting \* von Willebrand Factor Antigen \* Ristocetin Cofactor \* von Willebrand Factor Collagen Binding Assay \* von Willebrand Antigen, Multimeric Analysis*

Clinical Significance:	von Willebrand Disease is the most common inherited bleeding disorder, but acquired forms also exist. Clinical manifestations include excessive bruising, menorrhagia, other mucosal bleeding, and post-operative hemorrhage. Defects in the von Willebrand molecule may be quantitative or qualitative, thus requiring a panel of tests in order to make the diagnosis, identify the subtype, and ultimately determine the proper therapy.		
<b>Effective Date:</b>	<b>October 6, 2008</b>		
Test Code:	<b>15540</b>		
CPT Code(s):	<b>85730, 85240, 85246, 85245, 83520, 85247</b>		
Specimen Requirements:	<b>3 mL 3.2% sodium citrate (lt. blue-top) plasma [x3]</b>		
Transport Temperature:	<b>Frozen</b>		
Specimen Stability:	<b>Room temperature and refrigerated: Frozen Only Frozen: 14 days</b>		
Reference Ranges:	<b>See individual assays</b>		
Methodology:	<b>See individual assays</b>		
Assay Category:	<b>Laboratory Developed Test</b>		
Performing Site:	Quest Diagnostics Nichols Institute		

<b>von Willebrand Disease (vWD) Type 2N (vWF: Factor VIII Binding Activity)</b>	
Clinical Significance:	To differentiate between hemophilia A, hemophilia A carrier state, and type 2N vWD. The Type IIN vWD is associated with mild to moderate FVIII deficiency and otherwise normal vonWillebrand Antigen and Ristocetin Cofactor.
<b>Effective Date:</b>	<b>October 6, 2008</b>
Test Code:	<b>70068</b>
CPT Code(s):	<b>83520</b>
Specimen Requirements:	<b>1 mL 3.2% Sodium Citrate (lt. blue-top) plasma</b>
Transport Temperature:	<b>Frozen (Do not thaw)</b>
Specimen Stability:	<b>Room temperature and refrigerated: Unacceptable</b> <b>Frozen: 21 days</b>
Reference Ranges:	<b>0.73-1.42 ratio</b>
Methodology:	<b>Immunoassay</b>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
<b>House Dust (<i>Blomia tropicalis</i>) (d201) IgE</b>	
Clinical Significance:	<i>Blomia tropicalis</i> , a storage mite found predominantly in agricultural environments, is an important contributor to the allergen content in house dust in tropical and subtropical regions. Allergens produced by <i>Blomia tropicalis</i> are an important cause of IgE-mediated sensitization among patients with asthma. The presence of allergen specific IgE antibodies in serum of a patient is highly predictive of the likelihood that the individual will exhibit immediate hypersensitivity upon exposure to the allergen.
<b>Effective Date:</b>	<b>October 13, 2008</b>
Test Code:	<b>3299</b>
CPT Code(s):	<b>86003</b>
Specimen Requirements:	<b>1 mL no additive serum separator tube serum</b>
Transport Temperature:	<b>Room temperature</b>
Specimen Stability:	<b>Room temperature and refrigerated: 14 days</b> <b>Frozen: 21 days</b>
Reference Ranges:	<b>&lt;0.35 kU/L</b>
Methodology:	<b>Immunoassay</b>
Assay Category:	<b>ASR Class 1</b>
Performing Site:	Quest Diagnostics Nichols Institute

<b>Methylmalonic Acid, Urine</b>																										
Clinical Significance:	Methylmalonic Acid (MMA) is useful to diagnose and monitor vitamin B12 (cobalamin) deficiency, and to diagnose and monitor patients with methylmalonic acidemia.																									
Effective Date:	<b>October 20, 2008</b>																									
Test Code:	<b>16508</b>																									
CPT Code(s):	<b>83921</b>																									
Specimen Requirements:	<b>1.7 mL urine with no preservative in sterile screw cap container</b>																									
Transport Temperature:	<b>Frozen</b>																									
Specimen Stability:	<b>Room temperature: Unacceptable Refrigerated: 12 days Frozen: 30 days -70 degrees: 90 days</b>																									
Reference Ranges:	<table border="1"> <thead> <tr> <th>Methylmalonic Acid, Urine:</th> <th>&lt; or = 2.7</th> <th colspan="2">mmol/molcreatinine</th> </tr> </thead> <tbody> <tr> <td rowspan="6">Creatinine, Random Urine:</td> <td>0-6 months</td> <td>0.18-2.86</td> <td>mmol/L</td> </tr> <tr> <td>7-11 months</td> <td>0.18-3.19</td> <td>mmol/L</td> </tr> <tr> <td>1-2 years</td> <td>0.18-11.33</td> <td>mmol/L</td> </tr> <tr> <td>3-8 years</td> <td>0.18-13.19</td> <td>mmol/L</td> </tr> <tr> <td>9-12 years</td> <td>0.18-16.19</td> <td>mmol/L</td> </tr> <tr> <td>Adults</td> <td>2.38-26.55</td> <td>mmol/L</td> </tr> </tbody> </table>			Methylmalonic Acid, Urine:	< or = 2.7	mmol/molcreatinine		Creatinine, Random Urine:	0-6 months	0.18-2.86	mmol/L	7-11 months	0.18-3.19	mmol/L	1-2 years	0.18-11.33	mmol/L	3-8 years	0.18-13.19	mmol/L	9-12 years	0.18-16.19	mmol/L	Adults	2.38-26.55	mmol/L
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	9-12 years	0.18-16.19	mmol/L																							
	Adults	2.38-26.55	mmol/L																							
Methodology:	<b>Liquid Chromatography/Tandem Mass Spectrometry (LCMSMS)</b>																									
Assay Category:	<b>Laboratory Developed Test</b>																									
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano																									

<b>PML/RARA t(15;17), Quantitative Real-Time PCR, Plasma-based, Leumeta™</b>			
Clinical Significance:	PML-RARa fusion oncogene is present in >99% of cases of acute promyelocytic leukemia (APL). This real-time RT-PCR assay can be used to detect the presence of two gene fusion patterns: short and long. It can be used to monitor minimal residual disease in APL. Ideally current patient samples should be tested side by side with the previous sample to determine if there is any change in the disease course.		
Effective Date:	<b>October 20, 2008</b>		
Test Code:	<b>70182</b>		
CPT Code(s):	<b>83891, 83898, 83900, 83896 (x2), 83902 (x2), 83912</b>		
Specimen Requirements:	<b>6 mL EDTA (lavender-top) whole blood</b>		
Transport Temperature:	<b>Refrigerated</b>		
Specimen Stability:	<b>Room temperature: 72 hours Refrigerated: 7 days Frozen: Unacceptable</b>		
Reference Ranges:	<b>Negative pg/uL and ratio</b>		
Methodology:	<b>Real-Time Reverse Transcriptase-Polymerase Chain Reaction</b>		
Assay Category:	<b>ASR Class 1</b>		
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano		

### 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>Brucella Antibodies (IgG, IgM), Serum</b>	
<b>Effective Date:</b>	<b>October 6, 2008</b>
Test Code:	10566
Reference Ranges:	<b>&lt;0.80</b>
	<b>Interpretive Criteria:</b> <b>&lt;0.80 Antibody not detected</b> <b>0.80 - 1.09 Equivocal</b> <b>&gt; or = 1.10 Antibody detected</b>
Assay Category	<b>FDA Approved/Cleared</b>
Performing Site:	Focus Diagnostics, Inc.
Additional Information	Update reference range, interpretive criteria, and assay category. Remove ASR always message. Please note this code is included in the following group codes available 8/18/2008: 70141-Febrile Antibodies Panel; 70142-Febrile Antibodies and Francisella Panel; 70140- Salmonella and Brucella Panel
<b>Factor VIII Inhibitor Panel</b>	
Clinical Significance:	The presence of alloantibodies against factor VIII activity is a complication of treatment in hemophilia A, while the presence of autoantibodies may develop spontaneously in patients with acquired Factor VIII-C deficiency. The presence of Factor VIII inhibitor may lead to the neutralization (inactivation) of transfused or endogenous Factor VIII activity. The detection and magnitude of Factor VIII inhibitor is of great importance in the care of these patients. Factor VIII inhibitor EIA assay provides a quick method for the detection of Factor VIII inhibitor with less sample volume.
<b>Effective Date:</b>	<b>October 13, 2008</b>
Test Code:	40083
Reference Range:	<i>%19565RQEZ - Factor VIII Inhibitor, EIA Screen- No change</i> <i>%347ARQEZ - Factor VIII Activity, Clotting</i> <b>Factor VIII Activity:   50-180   % normal</b> <i>%5062BRQEZ - Factor VIII Human Inhibitor- No change</i> <i>%10492BRQEZ - Nijmegen Assay- No change</i>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update reference range.

<b><i>Legionella pneumophila</i> Antibody (IgM), IFA</b>	
Clinical Significance:	Legionnaire's disease is associated with pneumonia and other illnesses. Seroconversion may be delayed and cross-reactivity with other organisms limits the application of serology in clinical care.
<b>Effective Date:</b>	<b>October 13, 2008</b>
Test Code:	30268
Reference Range:	<p>&lt; or = 256 titer</p> <p><b>This indirect immunofluorescent assay detects serum IgM antibodies to <i>Legionella pneumophila</i> serogroups 1-6. A single titer of greater than 256 is presumptive evidence of infection at an undetermined time. The best serologic evidence of current or recent infection with <i>Legionella</i> is IgG seroconversion or a fourfold rise in IgG titers between acute and convalescent sera.</b></p> <p><b>Most seroconversions occur within 3 weeks, but patients should be monitored for 6 weeks, and some patients never seroconvert. IgM antibody can persist for considerable lengths of time, making separation of new from old disease by the assessment of IgM antibody levels unfeasible.</b></p> <p><b>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.</b></p>
Assay Category:	<b>Laboratory Developed Test</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update reference range format, always message, and assay category.
<b>Aspirin Resistance (11-Dehydrothromboxane B2)</b>	
Clinical Significance:	Aspirin (which inhibits platelet cyclo-oxygenase) reduces the risk of thrombosis in cardiovascular disease by impairing platelet function. Patients who do not respond to the platelet inhibitory effects of aspirin are designated as "Aspirin Resistant". The measurement of 11-dehydrothromboxane B-2 in urine (the principal metabolite of platelet cyclo-oxygenase derived thromboxane B-2) indicates lack of aspirin responsiveness.
<b>Effective Date:</b>	<b>October 20, 2008</b>
<i>Former Test Name:</i>	<i>Aspirin Resistance (11-Dehydro Thromboxane B2)</i>
Test Code:	16174
Specimen Requirements:	<p><b>4 mL preserved urine in BD C&amp;S Urine Vacutainer Tube (minimum: 3 mL)</b></p> <p>Recommend using BD C&amp;S Vacutainer tube for collection (Quest Stock Clerk # 131521).</p>
Specimen Stability:	<p>Room temperature: 7 days</p> <p><b>Refrigerated: 14 days</b></p> <p>Frozen: 90 days</p>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update test and result name, specimen requirements, and sample stability.

<b>Gastric Parietal Cell Antibody, ELISA</b>	
Clinical Significance:	Gastric Parietal Cell Antibodies are found in 90% of patients with pernicious anemia. They are also found in autoimmune chronic atrophic gastritis preceding pernicious anemia. The antigenic target is the H+/K+ ATPase gastric proton pump responsible for parietal cell acid generation in the stomach.
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	15114
Specimen Requirements:	<b>1 mL serum (minimum: 0.3 mL)</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update sample volume.
<b>HTLV-I/II Antibody, EIA with Positives Reflexed to Western Blot</b>	
Clinical Significance:	HTLV-1 is associated with adult T-cell leukemia (ATL) and HTLV-1 associated myelopathy/ tropical spasticparaparesis (HAM/TSP). HTLV-2 is associated with a disease resembling HAM/TSP and ataxia.
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	36175
Specimen Requirements:	1 mL serum ( <b>minimum: 0.6 mL</b> )
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update minimum sample volume.
<b>Protein S Panel</b>	
Clinical Significance:	Provides for distinguishing Type I, II, and III Protein S deficiency which may help in appropriate diagnosis, treatment and genetic counseling.
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	11343
Specimen Requirements:	<b>2 mL 3.2% sodium citrate (lt. blue-top) [x2] plasma (minimum: 1 mL)</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update sample volume.
<b>Pyridinium Collagen Cross-Links, 2-Hour Urine</b>	
Clinical Significance:	Pyridinium Collagen Cross-Links reflects bone resorption (breakdown).
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	36097
Specimen Requirements:	5 mL 2-hour urine in 24-hour urine container ( <b>minimum: 1 mL</b> ) OK to add preservative after collection
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update minimum sample volume.
<b>T and B Cells, Total</b>	
Clinical Significance:	This test is used to measure total T (CD3+) and total B (CD19+) lymphocytes in peripheral blood.
<b>Effective Date:</b>	<b>October 20, 2008</b>
<i>Former Test Name:</i>	<i>T &amp; B Cells, Total</i>
Test Code:	39588
Specimen Requirements:	5 mL EDTA (lavender-top) whole blood ( <b>minimum: 0.5 mL</b> ) Do not transfer whole blood to M4 preservative. <b>Whole blood collected in ACD or sodium heparin (green-top) tube is not acceptable.</b> <b>Submit the preferred EDTA tubes at room temperature. Volumes less than 1 mL should be submitted in a pediatric EDTA tube.</b>
Specimen Stability:	<b>Room temperature: 72 hours</b> Refrigerated and frozen: Room temperature only
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test name, specimen requirements, and stability.

<b>ABL Kinase Domain Mutation in CML, Cell-based</b>	
Clinical Significance:	Imatinib mesylate (ST1571;Gleevec) is a selective BCR-ABL kinase inhibitor, effective in the treatment of chronic myelogenous leukemia (CML). Most patients in chronic phase maintain durable responses; however, many in blast crisis fail to respond, or relapse quickly. ABL kinase domain mutations are the most commonly identified mechanism associated with relapse. The molecular monitoring in the first few months of therapy may play a crucial role in detecting patients at high risk of Imatinib resistance. This ABL kinase mutation assay may detect drug-resistant mutations before clinical relapse and identify candidate suitable for alternative therapy.
Effective Date:	<b>October 27, 2008</b>
Test Code:	16029
Specimen Requirements:	2.1 mL bone marrow or <b>6 mL EDTA (lavender-top) whole blood (minimum: 4 mL)</b> <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements.
<b>ABL Kinase Domain Mutation in CML, Plasma-based, Leumeta™</b>	
Clinical Significance:	The plasma based molecular assay is based on the new concept that in hematological diseases, tumor cell pour into their circulation their DNA and RNA, these components can be detected in plasma. Imatinib mesylate (ST1571;Gleevec) is a selective BCR-ABL kinase inhibitor, effective in the treatment of chronic myelogenous leukemia (CML). Most patients in chronic phase maintain durable responses; however, many in blast crisis fail to respond, or relapse quickly. ABL kinase domain mutations are the most commonly identified mechanism associated with relapse. The molecular monitoring in the first few months of therapy may play a crucial role in detecting patients at high risk of Imatinib resistance. This ABL kinase mutation assay may detect drug-resistant mutations before clinical relapse and identify candidate suitable for alternative therapy.
Effective Date:	<b>October 27, 2008</b>
Test Code:	16031
Specimen Requirements:	<b>6 mL EDTA (lavender-top) whole blood (minimum: 4 mL)</b> NOTE: Information regarding draw time and date is required to ensure stability of the sample be maintained. INSTRUCTION: Submission of whole blood is preferred. To avoid contamination, the laboratory will separate the plasma upon arrival. Follow standard whole blood collection procedure. Collect Whole blood samples in an EDTA tube. <b>Blood samples are shipped refrigerated.</b> Do not freeze whole blood. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b> Submission of Plasma is acceptable. Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top). Separate plasma from the cells by centrifugation, transfer the plasma to a separate plastic screw-cap vial, and ship frozen.
Transport Temperature:	<b>Whole blood: Refrigerated</b>   Plasma: Frozen
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update specimen requirements and transport temperature.

<b>ABL T315I Mutation in CML, Cell-based</b>	
Clinical Significance:	Mutations in the kinase domain of Bcr-abl are the leading cause of acquired imatinib resistance. Although mutations have been identified in more than 30 different amino acids, the highest degree of resistance was associated with single-point mutation T315I of the abl gene in the Bcr-abl fusion transcript. Early detection of T315I mutation of CML patient in therapy or pre-therapy could allow alternative treatment before resistance is detected cytogenetically or before disease progression becomes evident.
<b>Effective Date:</b>	<b>October 27, 2008</b>
Test Code:	19783
Specimen Requirements:	<b>6 mL EDTA (lavender-top) whole blood (minimum: 4 mL)</b> <b>Preferred sample type is whole blood. Bone marrow is acceptable.</b> <b>INSTRUCTION: Collect 6 mL of whole blood or 3 mL bone marrow in lavender-top (EDTA) tube. Whole blood or bone marrow is shipped refrigerated.</b> Do not freeze whole blood or bone marrow. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b>
Transport Temperature:	<b>Refrigerated</b>
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update test name, specimen requirements, and stability.

<b>ABL T315I Mutation in CML, Plasma-based, Leumeta™</b>	
Clinical Significance:	Mutations in the kinase domain of Bcr-abl are the leading cause of acquired imatinib resistance. Although mutations have been identified in more than 30 different amino acids, the highest degree of resistance was associated with single-point mutation T315I of the abl gene in the Bcr-abl fusion transcript. Early detection of T315I mutation of CML patient in therapy or pre-therapy could allow alternative treatment before resistance is detected cytogenetically or before disease progression becomes evident.
<b>Effective Date:</b>	<b>October 27, 2008</b>
Test Code:	19782
Specimen Requirements:	<b>6 mL EDTA (lavender-top) whole blood (minimum: 4 mL) (preferred)</b> <b>Or 3 mL EDTA (lavender-top) plasma (minimum: 2 mL)</b> Submission of whole blood (preferred): Follow standard whole blood collection procedure. <b>Collect 6 mL whole blood samples in EDTA tube. Blood samples are shipped refrigerated.</b> Do not freeze whole blood. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b> Submission of plasma (acceptable): Collect blood in sterile tubes containing EDTA anticoagulant (Lavender-top). Separate plasma from the cells by centrifugation within 2 hours after collection. Transfer the plasma to a separate plastic screw-cap vial, and ship frozen.
Specimen Stability:	<b>Whole blood</b>
	Room temperature and Refrigerated: 72 hours Frozen: Do Not Freeze
	<b>Plasma</b>
	<b>Room temperature and Refrigerated: Unacceptable</b> Frozen: 2 years
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update test name, specimen requirements, and stability.

**15052-bcr/abl Gene Rearrangement, Quantitative PCR, Cell-based  
15480-Chronic Lymphocytic Leukemia, IgVH Mutation Status, Cell-based**

<b>Effective Date:</b>	<b>October 27, 2008</b>
Specimen Requirements:	<b>6 mL</b> EDTA (lavender-top) whole blood ( <b>minimum: 4 mL</b> ) Preferred sample type is whole blood. Bone marrow is acceptable. <b>INSTRUCTION: Collect 6 mL of whole blood or 3 mL bone marrow in lavender-top (EDTA) tube. Whole blood or bone marrow is shipped at refrigerated.</b> Do not freeze whole blood or bone marrow. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b> Alternative samples: frozen cells must be approved by the medical director prior to sending. Do not thaw. Must remain frozen until testing.
Transport Temperature:	<b>Refrigerated</b>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements and transport temperature. Please note this change applies to the following group code: 15101X [3576]-bcr/abl Gene Rearrangement, Quantitative PCR with Reflex to Subtype.

**bcr/abl Gene Rearrangement, Quantitative PCR, Plasma-based, Leumeta™**

Clinical Significance:	The plasma based molecular assay is based on the new concept that in hematological diseases, tumor cell pour into their circulation their DNA and RNA, these components can be detected in plasma. This assay is intended to quantitatively monitor the reduction or elimination of Bcr-Abl fusion transcript in CML patient's plasma, which measure the disease in the entire body rather than in the limited number cells in the collected sample.
<b>Effective Date:</b>	<b>October 27, 2008</b>
Test Code:	17853
Specimen Requirements:	<b>6 mL</b> EDTA (lavender-top) whole blood ( <b>minimum: 4 mL</b> ) <b>Bone marrow is not acceptable.</b> Preferred sample type is whole blood: Follow standard whole blood collection procedure. Collect whole blood samples in an EDTA tube. <b>Blood samples are shipped refrigerated.</b> Do not freeze whole blood. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b> Acceptable sample type is plasma: Collect blood in sterile tube containing EDTA anticoagulant (Lavender-top). Separate plasma from cells by centrifugation within 2 hours after collection. Transfer the plasma to a separate plastic screw-cap vial, and ship frozen.
Transport Temperature:	<b>Whole blood: Refrigerated</b> Plasma: Frozen
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements and transport temperature.

<b>Chronic Lymphocytic Leukemia, IgVH Mutation Status, Leumeta™</b>	
Clinical Significance:	The plasma based molecular assay is based on the concept that in hematological diseases, tumor cells pour into their circulation their DNA and RNA, these components can be detected in plasma. B cell chronic lymphocytic leukemia (B-CLL) is the most common leukemia in the Western world. Patients with B-CLL follow heterogeneous clinical courses. Some survive for prolonged periods without requiring definitive therapy, while others die rapidly despite aggressive treatment. Recent studies observed that patients might be divided into two groups based on the V gene mutation status. Patients with mutated V gene required minimal or no chemotherapy and had prolonged survival. Patients with unmutated V gene responded poorly to continuous multi-regimen chemotherapy and shorter survival. The delineation of mutation status is based on the degree of homology to the germline sequence. A 97% homology cut-off was found to provide a good discrimination.
Effective Date:	<b>October 27, 2008</b>
Test Code:	17702
Specimen Requirements:	<b>6 mL</b> EDTA (lavender-top) whole blood ( <b>minimum: 4 mL</b> ) NOTE: Information regarding draw time and date is required to ensure stability of the sample be maintained. INSTRUCTION: Submission of whole blood is preferred. To avoid contamination, the laboratory will separate the plasma upon arrival. Follow standard whole blood collection procedure. <b>Collect 6 mL Whole blood samples in an EDTA tube. Blood samples are shipped refrigerated.</b> Do not freeze whole blood. <b>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. Ship sample immediately due to short sample stability of 72 hours. If the stability of the sample can not be determined, delay in result or cancellation of test may occur.</b> Submission of Plasma is acceptable. Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top). Separate plasma from the cells by centrifugation, transfer the plasma to a separate plastic screw-cap vial, and ship frozen.
Transport Temperature:	<b>Whole blood and bone marrow: Refrigerated</b> Plasma: Frozen
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test name, specimen requirements, and stability.

## Discontinued Tests

<b>Factor XI Inhibitor Panel</b>	
<b>Effective Date:</b>	<b>October 6, 2008</b>
Test Code:	10097
Additional Information:	This test performed at ITxM Diagnostics will be discontinued. The recommended alternative is 17854-Factor XI Activity and Human Inhibitor
<b>Factor VIII Activity and Human Inhibitor with Reflex to Nijmegen Assay</b>	
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	17500
Additional Information:	This test will be discontinued. The recommended alternative is 40083 - Factor VIII Inhibitor Panel.
<b>Methylmalonic Acid, Urine</b>	
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	34877
Additional Information:	This test will be discontinued. The recommended alternative is 16508 - Methylmalonic Acid, Urine in the New tests section.
<b>von Willebrand Disease (vWD) Type 2N Panel</b>	
<b>Effective Date:</b>	<b>October 20, 2008</b>
Test Code:	19735
Additional Information:	This test will be discontinued. The recommended alternative is 70068-von Willebrand Disease (vWD) Type 2N (vWF: Factor VIII Binding Activity) in the New Tests section.

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