



LABORATORY UPDATE

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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.

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

Routine Testing

New Test

HIV-1 RNA, Quantitative, Real-Time PCR <i>Reportable range: 48 to 10,000,000 HIV-1 RNA copies/mL (1.68 – 7.00 log copies/mL)</i>					
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. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.				
Effective Date:	May 5, 2008				
Test Code:	40085				
CPT Code(s):	87536				
Specimen Requirements:	3 mL (1.1 mL minimum) of separated plasma from EDTA (lavender-top) or from PPT Potassium EDTA (white-top) plasma separator tube. INSTRUCTIONS: Separate plasma from the cells by centrifugation within 6 hrs after collection, and transfer the plasma to a screw-cap vial and ship frozen. REJECT CRITERIA: Frozen plasma received in plasma preparation tube (PPT) (in situ).				
Transport Temperature:	Frozen				
Specimen Stability:	Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days				
Reference Range:	<table border="1"> <tr> <td>HIV-1 RNA: Copies/mL:</td> <td>< 48 copies/mL</td> </tr> <tr> <td>Log copies/mL:</td> <td>< 1.68 log copies/mL</td> </tr> </table> <p>Interpretation: a) Below the linear range, the assay reports results as: <ul style="list-style-type: none"> HIV-1 RNA <48 copies/mL Not Detected <p style="text-align: center;">-or-</p> <ul style="list-style-type: none"> HIV-1 RNA <48 copies/mL Detected <i>This patient had a HIV-1 RNA viral load below the lower Limit of Quantitation for this assay (48 copies/mL), but above the lower Limit of Detection for the test. Because of the low viral load, we were unable to accurately determine the actual level of the virus in this patient's sample. Repeat testing may be warranted, when clinically indicated.</i> b) Above the linear range, the assay reports results as: >10,000,000 copies/mL</p>	HIV-1 RNA: Copies/mL:	< 48 copies/mL	Log copies/mL:	< 1.68 log copies/mL
HIV-1 RNA: Copies/mL:	< 48 copies/mL				
Log copies/mL:	< 1.68 log copies/mL				
Methodology:	Real-Time Polymerase Chain Reaction				
Assay Category:	FDA Approved/Cleared				
Additional Information:	This test replaces: 34205 - HIV-1 RNA, QN, PCR; 34220 - HIV-1 RNA, QN, PCR Ultra; 14484 - HIV-1 RNA, QN, PCR, Expanded Range and 39453 - HIV-1 RNA, QN, PCR, Upper Expanded Range.				

Test Changes

BUN/Creatinine Ratio w/eGFR	
Clinical Significance:	The BUN/Creatinine ratio is useful in the differential diagnosis of acute or chronic renal disease. Reduced renal perfusion, e.g., congestive heart failure, or recent onset of urinary tract obstruction will result in an increase in BUN/Creatinine ratio.
Effective Date:	May 5, 2008
Test Code:	296
Reference Range:	Male and Female 6-22 (calculation)
Additional Information:	When the patient's BUN and Creatinine are both within normal limits, the BUN/Creatinine ratio will not be reported. Please note this change also affects the following test codes: 10165 – Basic Metabolic Panel w/eGFR; 10231 – Comprehensive Metabolic Panel w/eGFR; 10314 – Renal Function Panel w/eGFR.
Cytomegalovirus Antibody (IgG)	
Clinical Significance:	CMV infections are common and usually asymptomatic. In patients who are immunocompromised, CMV may cause disseminated, severe disease. CMV may cause birth defects in a minority of infected newborns. Antibody IgG may represent prior exposure or recent infection if there is a significant change in titer between acute and convalescent specimens.
Effective Date:	May 5, 2008
<i>Former Test Name:</i>	<i>Cytomegalovirus IgG Antibody</i>
Test Code:	403
Reference Range:	CMV IgG Ab: UOM: Index Value < OR = 0.90 Negative - No CMV IgG Antibody Detected 0.91 - 1.09 Equivocal > OR = 1.10 Positive - CMV IgG Antibody Detected
Additional Information:	Update test name and units of measure. Please note this change also affects the following test codes: 6732-Cytomegalovirus Antibodies (IgG, IgM), 37678-Cytomegalovirus Antibody (IgG) with Reflex to IgM; 6444-Torch Panel, Acute.
Cytomegalovirus Antibody (IgM)	
Clinical Significance:	CMV infections are common and usually asymptomatic. In patients who are immunocompromised, CMV may cause disseminated, severe disease. CMV may cause birth defects in a minority of infected newborns. An elevated titer of Antibody IgM represents recent CMV infection.
Effective Date:	May 5, 2008
<i>Former Test Name:</i>	<i>Cytomegalovirus IgM Antibody</i>
Test Code:	8503
Reference Range:	CMV IgM Ab: UOM: Index Value < 0.90 Negative - No CMV IgM Antibody Detected 0.90 - 1.10 Equivocal > OR = 1.11 Positive - CMV IgM Antibody Detected
Additional Information:	Update test name and units of measure. Please note this change also affects the following test codes: 6732-Cytomegalovirus Antibodies (IgG, IgM), 37678-Cytomegalovirus Antibody (IgG) with Reflex to IgM; 6444-Torch Panel, Acute.

Fecal Fat, Qualitative	
Clinical Significance:	Results may indicate malabsorption or maldigestion. False positive results can occur due to mineral oil or castor oil present in the specimen. Large number of neutral fat globules may indicate steatorrhea.
Effective Date:	May 5, 2008
Test Code:	3967
Transport temperature	Frozen
Specimen Stability:	Room Temperature: 1 hour Refrigerated: 5 days Frozen: 30 days
Additional Information:	Update transport temperature and stabilities. Many specimens for Fecal Fat analysis are rejected due to stability issues. In the interest of patient care, please submit all stool specimens for fecal fat as FROZEN specimens. This will ensure a reduction in specimens that have exceeded stability.

HIV-1 RNA, Quantitative PCR w/Reflex to Genotype	
Clinical Significance:	Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA, quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy.
Effective Date:	May 5, 2008
Test Code:	34471
Specimen Requirements:	7 mL (2.2 minimum) of separated plasma from EDTA (lavender-top) or from PPT Potassium EDTA (white-top) plasma separator tube. INSTRUCTIONS: Separate plasma from the cells by centrifugation within 6 hrs after collection, and transfer the plasma to a screw-cap vial and ship frozen. REJECT CRITERIA: Frozen plasma received in plasma preparation tube (PPT) (<i>in situ</i>). Please note: ACD collection containers are no longer acceptable.
Specimen Stability:	Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days
Reference Range:	HIV-1 RNA: Not Detected Copies/mL: < 48 copies/mL Log copies/mL: < 1.68 log copies/mL
Additional Information:	Update the specimen requirements, stability, reference range and reportable range. Please note: The HIV-1 RNA Quantitative PCR component of the group will be replaced with test code 40085, listed in the New Tests section.

HIV-1 RNA, Quantitative PCR with Reflex to VirtualPhenotype™	
Clinical Significance:	Measurement of HIV-1 plasma levels (viral load) provides a direct assessment of viremia and should be used in conjunction with CD4+ T-cell counts. HIV-1 RNA, quantitation is useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor the effectiveness of antiretroviral therapy.
Effective Date:	May 5, 2008
Test Code:	10435
Specimen Requirements:	7 mL (2.2 minimum) of separated plasma from EDTA (lavender-top) or from PPT Potassium EDTA (white-top plasma separator tube. INSTRUCTIONS: Separate plasma from the cells by centrifugation within 6 hrs after collection, and transfer the plasma to a screw-cap vial and ship frozen. REJECT CRITERIA: Frozen plasma received in plasma preparation tube (PPT) (in situ). Please note: ACD collection containers are no longer acceptable.
Specimen Stability:	Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days
Reference Range:	HIV-1 RNA: Not Detected Copies/mL: < 48 copies/mL Log copies/mL: < 1.68 log copies/mL
Additional Information:	Update the specimen requirements, stability, reference range and reportable range. Please note: The HIV-1 RNA Quantitative PCR component of the group will be replaced with test code 40085, listed in the New Tests section.

Discontinued Tests

HIV-1 RNA, Quantitative, PCR	
Effective Date:	May 5, 2008
Test Code:	34205
Additional Information:	The recommended test code for the HIV-1 RNA, Quantitative Assay by RT-PCR is 40085. See New Test Section .
HIV-1 RNA, Quantitative, PCR Ultrasensitive	
Effective Date:	May 5, 2008
Test Code:	34220
Additional Information:	The recommended test code for the HIV-1 RNA, Quantitative Assay by RT-PCR is 40085. See New Test Section .
HIV-1 RNA, Quantitative, PCR, Expanded Range	
Effective Date:	May 5, 2008
Test Code:	14484
Additional Information:	The recommended test code for the HIV-1 RNA, Quantitative Assay by RT-PCR is 40085. See New Test Section .

HIV-1 RNA, Quantitative, PCR, Upper Expanded Range	
Effective Date:	May 5, 2008
Test Code:	39453
Additional Information:	The recommended test code for the HIV-1 RNA, Quantitative Assay by RT-PCR is 40085. See New Test Section.
Testosterone, Free and Weakly Bound	
Effective Date:	May 5, 2008
Test Code:	30741
Additional Information:	This test will be discontinued. The recommended alternative is 14966 - Testosterone, Free, Bioavailable and Total, LC/MS/MS. Please note that gel barrier-tubes (SST) are not acceptable.

QUEST DIAGNOSTICS NICHOLS INSTITUTE, San Juan Capistrano & Chantilly

New Tests

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

RBC Fragility – Incubated	
Clinical Significance:	Osmotic (RBC) Fragility is used to assess disorders of the erythrocyte membrane. Increased osmotic fragility is found in hereditary spherocytosis, other RBC membrane disorders and in idiopathic acquired hemolytic anemias. Diminished fragility is seen-in conditions in which target cells are found.
Effective Date:	May 5, 2008
Test Code:	17364
CPT Code:	85557
Specimen Requirements:	5 mL Sodium heparin (green-top tube) whole blood Specimens must be received at laboratory within 24 hours of collection Monday through Thursday. Ship overnight express.
Transport Temperature:	Refrigerated
Specimen Stability:	Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	0.85% NaCl = 0% 0.65% NaCl = 0-19% 0.60% NaCl = 0-40% 0.55% NaCl = 5-70% 0.50% NaCl = 36-88% 0.45% NaCl = 54-96% 0.40% NaCl = 65-100% 0.35% NaCl = 72-100% 0.30% NaCl = 80-100%
Methodology:	Colorimetric, Kinetic
Assay Category:	Laboratory Developed Test
Additional Information:	Test performed at Quest Diagnostics Nichols Institute, Chantilly.

New Tests to Specialty Laboratories

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

Fentanyl and Norfentanyl, Urine			
Clinical Significance:	Fentanyl is an opioid analgesic, with an analgesic potency of about 80 times that of morphine.		
Effective Date:	May 5, 2008		
Test Code:	17607		
CPT Code(s):	83925		
Specimen Requirements:	4 mL random urine		
Transport Temperature:	Room temperature		
Specimen Stability:	Room temperature: 14 days Refrigerated: 14 days Frozen: 14 days		
Reference Ranges:	By report		
	Limit of quantitation:	Fentanyl: 0.05 ng/mL Norfentanyl: 0.05 ng/mL	
Methodology:	Mass Spectrometry		
Assay Category:	Laboratory Developed Test		
Additional Information:	This test will be performed at Specialty Laboratories.		
Influenza Virus Type A Antibody (IgG, IgM)			
Clinical Significance:	Aids in the diagnosis of Influenza, or the "flu", a highly contagious, febrile, acute infection of the nose, throat, bronchial airways and lungs caused by the influenza virus.		
Effective Date:	May 5, 2008		
Test Code:	17793		
CPT Code(s):	86710 x2		
Specimen Requirements:	1 mL serum or EDTA (lavender-top tube) plasma		
Transport Temperature:	Refrigerated		
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 56 days		
Set-Up/Analytic Time:	Set up once a week. Specimen must be received by Tuesday PM to be reported on Friday.		
Reference Ranges:	Influenza A IgG Abs	<0.80	Index
	Influenza A IgM Abs	<0.80	Index
	Reference range for Influenza A Abs: Less than 0.80 Index Negative 0.80-1.20 Index Equivocal Greater than 1.20 Index Positive		
Methodology:	Immunoassay		
Assay Category:	Research Use Only		

Influenza Virus Type B Antibody (IgG, IgM)							
Clinical Significance:	Aids in the diagnosis of Influenza, or the "flu", a highly contagious, febrile, acute infection of the nose, throat, bronchial airways and lungs caused by the influenza virus						
Effective Date:	May 5, 2008						
Test Code:	15518						
CPT Code(s):	86710 x2						
Specimen Requirements:	1 mL serum or EDTA (lavender-top tube) plasma						
Transport Temperature:	Refrigerated						
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 56 days						
Set-Up/Analytic Time:	Set up once a week. Specimen must be received by Tuesday PM to be reported on Friday.						
Reference Ranges:	<table border="0"> <tr> <td>Influenza B IgG Abs</td> <td><0.80</td> <td>Index</td> </tr> <tr> <td>Influenza B IgM Abs</td> <td><0.80</td> <td>Index</td> </tr> </table> <p>Reference range for Influenza B Abs: Less than 0.80 Index Negative 0.80-1.20 Index Equivocal Greater than 1.20 Index Positive</p>	Influenza B IgG Abs	<0.80	Index	Influenza B IgM Abs	<0.80	Index
Influenza B IgG Abs	<0.80	Index					
Influenza B IgM Abs	<0.80	Index					
Methodology:	Immunoassay						
Assay Category:	Research Use Only						

Influenza Virus Type A Antibody (IgM)				
Clinical Significance:	Aids in the diagnosis of Influenza, or the "flu", a highly contagious, febrile, acute infection of the nose, throat, bronchial airways and lungs caused by the influenza virus			
Effective Date:	May 5, 2008			
Test Code:	40082			
CPT Code(s):	86710			
Specimen Requirements:	1 mL serum or EDTA (lavender-top tube) plasma			
Transport Temperature:	Refrigerated			
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 56 days			
Set-Up/Analytic Time:	Set up once a week. Specimen must be received by Tuesday PM to be reported on Friday.			
Reference Ranges:	<table border="0"> <tr> <td>Influenza A IgM Abs</td> <td><0.80</td> <td>Index</td> </tr> </table> <p>Reference range for Influenza A Abs: Less than 0.80 Index Negative 0.80-1.20 Index Equivocal Greater than 1.20 Index Positive</p>	Influenza A IgM Abs	<0.80	Index
Influenza A IgM Abs	<0.80	Index		
Methodology:	Immunoassay			
Assay Category:	Research Use Only			

Influenza Virus Type B Antibody (IgM)	
Clinical Significance:	Aids in the diagnosis of Influenza, or the "flu", a highly contagious, febrile, acute infection of the nose, throat, bronchial airways and lungs caused by the influenza virus
Effective Date:	May 5, 2008
Test Code:	40081
CPT Code(s):	86710
Specimen Requirements:	1 mL serum or EDTA (lavender-top tube) plasma
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 56 days
Set-Up/Analytic Time:	Set up once a week. Specimen must be received by Tuesday PM to be reported on Friday.
Reference Ranges:	Influenza B IgM Abs <0.80 Index Reference range for Influenza B Abs: Less than 0.80 Index Negative 0.80-1.20 Index Equivocal Greater than 1.20 Index Positive
Methodology:	Immunoassay
Assay Category:	Research Use Only

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.

Amino Acid Analysis, LC/MS, CSF											
Clinical Significance:	Amino Acid analysis is necessary for the diagnosis of a variety of inborn errors of metabolism. These include, but are not limited to, phenylketonuria, tyrosinemia, citrullinemia, non-ketotic hyperglycinemia, maple syrup urine disease, and homocystinuria. The assay is also key for the continued monitoring of treatment plans for these disorders and useful for assessing nutritional status of patients. Our methodology is highly accurate at very low levels as well as at elevated levels.										
Effective Date:	May 12, 2008										
Test Code:	29881										
Reference Ranges:	Beta-Amino Isobutyric Acid < or = 2 umol/L										
Additional Information:	Update reference range for Beta-Amino Isobutyric Acid only. No change to other amino acids in this code.										
767- Amino Acid Analysis, LC/MS, Plasma											
Effective Date:	May 12, 2008										
Reference Ranges:	<table border="1"> <thead> <tr> <th>Beta-Amino Isobutyric Acid</th> <th>Units of Measure</th> </tr> </thead> <tbody> <tr> <td><1 month: < or = 9</td> <td>umol/L</td> </tr> <tr> <td>1 month-23 months: < or = 8</td> <td>umol/L</td> </tr> <tr> <td>2 years-17 years: < or = 6</td> <td>umol/L</td> </tr> <tr> <td>>=18 years: < or = 3</td> <td>umol/L</td> </tr> </tbody> </table>	Beta-Amino Isobutyric Acid	Units of Measure	<1 month: < or = 9	umol/L	1 month-23 months: < or = 8	umol/L	2 years-17 years: < or = 6	umol/L	>=18 years: < or = 3	umol/L
Beta-Amino Isobutyric Acid	Units of Measure										
<1 month: < or = 9	umol/L										
1 month-23 months: < or = 8	umol/L										
2 years-17 years: < or = 6	umol/L										
>=18 years: < or = 3	umol/L										
Additional Information:	Update reference range for Beta-Amino Isobutyric Acid only. No change to other amino acids in this code.										
DNA (ds) Antibody, Crithidia IFA w/Reflex to Titer											
Clinical Significance:	dsDNA Antibody is detected in patients with active systemic lupus erythematosus (SLE) and approximately 20% of patients with mixed connective tissue disease.										
Effective Date:	May 12, 2008										
<i>Former Test Name:</i>	<i>DNA (DS) Antibody, Crithidia IFA w/Reflex to Titer</i>										
Test Code:	37092										
Reference Range:	<table border="1"> <tbody> <tr> <td>DNA Ab (ds) Crithidia, IFA:</td> <td>NEGATIVE</td> </tr> <tr> <td>DNA Ab(ds) Crithidia Titer:</td> <td><1:10 titer</td> </tr> </tbody> </table>	DNA Ab (ds) Crithidia, IFA:	NEGATIVE	DNA Ab(ds) Crithidia Titer:	<1:10 titer						
DNA Ab (ds) Crithidia, IFA:	NEGATIVE										
DNA Ab(ds) Crithidia Titer:	<1:10 titer										
Additional Information:	Update reference range and test name. Please note this change also affects TC 37521-ANaChoice(TM) Panel 1 with Reflexes and is included in the following group codes: 37491-Lupus (SLE) Panel.										
Industrial Cadmium Screen (PT-Demo)											
Clinical Significance:	This panel is used for monitoring workers for potential exposure to cadmium in the workplace. The beta-2-microglobulin, blood and urine cadmium are integrated to specify the exposure category.										
Effective Date:	May 12, 2008										
Test Code:	8887										

Specimen Requirements:	<p>10 mL random urine, no preservative in acid washed container and 10 mL random urine, no preservative in a sterile screw-cap container and 4 mL EDTA (royal blue-top) whole blood One aliquot of blood, and 2 separate aliquots of urine (prepared as below) are required. For blood Cadmium, collect blood in royal blue top (EDTA) tubes. Ship blood refrigerated. Frozen whole blood is unacceptable. For urine Cadmium and Beta-2-Microglobulin, patient should void bladder, then drink at least 500 mL of water. A urine sample should be collected within 1 hour in an acid-washed container and poured into two different aliquots. One aliquot is to be poured into an acid-washed shipping vial and the other poured into a sterile screw cap container. Use powder-less gloves. Each vial is properly labeled as to patient ID, draw date, and accession number. Furthermore, the sterile screw cap container is to be labeled as "For Beta-2-Microglobulin" and pH 8 with 1M aqueous NaOH at the draw site. Beta-2-Microglobulin is unstable in acidic urine (less than pH6). Ship refrigerated. The acid-washed vial is to be labeled as "For Cadmium". Ship refrigerated. Do not adjust the pH. Restrict patient from eating shellfish for at least 3 days prior to specimen collection.</p>	
Specimen Stability:	Random urine	Blood
	Room temperature: 8 hours Refrigerated: 7 days Frozen: 14 days	Room temperature: 2 days Refrigerated: 5 days Frozen: Unacceptable
Additional Information:	Update specimen requirements and stability.	

Discontinued Tests

Osmotic Fragility, Erythrocytes	
Effective Date:	May 5, 2008
Test Code:	37370
Additional Information:	This test is being discontinued. The recommended alternative is Test Code 17364- RBC Fragility – Incubated in the new test section.

Focus Diagnostics Redirects

Brucella Antibodies (IgG,IgM), Serum	
Clinical Significance:	Brucellosis is caused by transmission from animal to human. Brucella abortus is transmitted from cows. A high titer of IgM suggests recent exposure. A high titer of IgG suggests active infection. A lower titer of IgG may indicate past exposure or treated infection.
Effective Date:	May 19, 2008
<i>Former Test Name:</i>	<i>Brucella Antibody (IgG, IgM), EIA</i>
Test Code:	10566
CPT Code(s):	86622 (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:	<p>Brucella IgG: <9 U Brucella IgM: <9 U</p> <p>Interpretive criteria: <9 U Antibody not detected 9-11 U Equivocal >11 U Antibody detected</p> <p>Acute brucellosis is characterized by the appearance of Brucella-specific IgM within the first week of infection, followed by the appearance of Brucella-specific IgG after the second week. Levels of both IgM and IgG decline slowly over several months in conjunction with recovery. Persistence of high IgG levels with declining or absent IgM suggests chronic infection or relapse. If acute infection is suspected, Brucella culture and/or antibody testing of another serum specimen (collected 1-2 weeks after this specimen) may be warranted.</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.</p>
Methodology:	Immunoassay
Assay Category:	ASR Class 1
Additional Information:	<p>This test, previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano and Chantilly, will now be performed at Focus Diagnostics.</p>

Focus Diagnostics Test Changes

Adenovirus DNA, Qualitative Real-Time PCR	
Clinical Significance:	This test is used to determine the presence of Adenovirus in a patient's specimen. Organisms may be detected by PCR prior to diagnosis by immunological methods. PCR provides more rapid results than other methods, including culture.
Effective Date:	May 19, 2008
Test Code:	16046
Specimen Requirements:	<p>Throat or Nasopharyngeal swabs in M4 or V-C-M medium (green-cap) tube or equivalent (UTM) or 0.85 mL Plasma (in EDTA, ACD A or B or PPT)</p> <p>Acceptable specimen types include whole blood in ACD or EDTA, CSF in sterile screw cap container, Serum in SST and Tracheal lavage/ wash, and random urine.</p> <p>Samples in M4 media: (includes nasopharyngeal, throat, or conjunctiva swabs, BAL, or other body fluids in M4): Use sterile vials containing 3 mL of sterile M4 media. Do not use calcium alginate swabs, as they may contain substances that inhibit PCR testing.</p> <p>Plasma: Collect blood in sterile tubes containing EDTA or ACD as anticoagulant, or in Plasma Preparation Tube (PPT) tubes (preferred). Store collected whole blood at room temperature and separate plasma from cells within 2 hours of collection. Transfer plasma to sterile, plastic, screw-capped, aliquot tubes. Do not clarify plasma by filtration or further centrifugation. Avoid repeated freezing and thawing of specimen. NOTE: If blood is collected in a PPT tube, centrifuge within 2 hours of collection; the plasma is not required to be transferred to an aliquot tube.</p> <p>Bronchial Alveolar Lavage (BAL): Submit in a sterile container.</p> <p>Sputum: Collect in a sputum collection kit or a sterile, plastic container with a leak-proof cap.</p> <p>Urine or CSF: Collect in a sterile container with a leak-proof cap.</p> <p>Whole blood: Collect whole blood in sterile tubes containing EDTA or ACD as anticoagulant.</p> <p>Serum: Collect blood in sterile tubes with no anticoagulants; plastic serum separator tubes (SST's) are recommended. Allow blood to clot at room temperature and separate serum from cells within 2 hours of collection. Transfer serum to sterile, plastic screw-capped, tubes.</p>
Specimen Stability:	<p>Room temperature: 48 hours</p> <p>Refrigerated: 7 days</p> <p>Frozen: 30 days (Do not freeze whole blood)</p>
Additional Information:	Update specimen requirements and stability.

Atypical Pneumonia DNA Panel, Qualitative Real-Time PCR

Clinical Significance:	Atypical pneumonias share two features, which often makes it difficult to distinguish or diagnose the symptoms based on clinical presentation alone. The presentation is often a nonlobar, patchy, or interstitial pattern on chest x-ray. Routine culture and Gram stain fails to identify a causative agent.
Effective Date:	May 19, 2008
Test Code:	17610
Specimen Requirements:	1 mL Bronchial lavage/wash or Sputum (minimum 0.3 mL) or – Throat or Nasopharyngeal swab in 3.0 mL M4 or V-C-M medium (green-cap) tube or equivalent (UTM) Bronchial Alveolar Lavage (BAL)/wash: Wedge bronchoscope into sub-segmental bronchus; insert four 50 mL boluses of sterile saline into the suction port with immediate return suction after the insertion of each sample. Submit specimen in a sterile container. Sputum: Collect in a sputum collection kit or a sterile, plastic container with a leak-proof cap.
Specimen Stability:	Room temperature: 48 hours Refrigerated: 14 days Frozen: 30 days
Additional Information:	Update specimen requirements and stability.

Babesia microti DNA Real-Time PCR

Clinical Significance:	<i>Babesia microti</i> DNA PCR is a highly specific and sensitive method to detect the presence of <i>B. microti</i> DNA in clinical specimens; DNA sequences from the closely related canine pathogen <i>B. gibsoni</i> are not detected by this assay.
Effective Date:	May 19, 2008
Former Test Name:	<i>Babesia microti</i> DNA, PCR
Test Code:	37314
Specimen Requirements:	0.7 mL (0.3 mL min) whole blood (EDTA or ACD) or 1 tick (in ethanol or live)
Transport Temperature:	<i>Refrigerated</i>
Specimen Stability:	Room Temperature: 48 hours Refrigerated: 7 days Frozen: 30 days (DO NOT FREEZE WHOLE BLOOD)
Additional Information	Update test name, specimen requirements, and specimen stability.

Chlamydia pneumoniae DNA, Qualitative Real-Time PCR

Clinical Significance:	This test is used to determine the presence of <i>Chlamydia pneumoniae</i> in a patient's specimen. Organisms may be detected by PCR prior to detection by immunological methods. PCR provides more rapid results than other methods, including culture.
Effective Date:	May 19, 2008
Test Code:	16003
Specimen Requirements:	Throat or Nasopharyngeal swab in 3 mL M4 or V-C-M medium (green-cap) tube or equivalent (UTM) or 1 mL bronchial lavage/wash Nasopharyngeal lavage/wash is not acceptable
Specimen Stability:	Room temperature: 48 hours Refrigerated: 14 days Frozen: 30 days
Additional Information:	Update acceptable specimen types and stability.

<i>Ehrlichia chaffeensis</i> DNA Real-Time PCR	
Clinical Significance:	<i>Ehrlichia chaffeensis</i> DNA PCR is a highly sensitive method to detect the presence of <i>Ehrlichia chaffeensis</i> DNA in clinical specimens.
Effective Date:	May 19, 2008
<i>Former Test Name:</i>	<i>Ehrlichia chaffeensis</i> DNA, PCR
Test Code:	11353
Specimen Requirements:	0.7 mL (0.3 mL min) whole blood (EDTA or ACD) or 1 tick (in ethanol or live)
Transport Temperature:	Room temperature
Specimen Stability:	Room Temperature: 48 hours Refrigerated: 7 days Frozen: 30 days (DO NOT FREEZE WHOLE BLOOD)
Additional Information:	Update test name, specimen requirements, and specimen stability.

Influenza Type A and B RNA, Qualitative Real-time RT-PCR	
Clinical Significance:	This test is used to determine the presence of Influenza A or B in a patient's specimen. Organisms may be detected by PCR prior to diagnosis by immunological methods. PCR provides more rapid results than other methods, including culture.
Effective Date:	May 19, 2008
Test Code:	16086
Specimen Requirements:	Throat swab or Nasal/nasopharyngeal swab in 3 mL M4 or V-C-M medium (green-cap) tube or equivalent (UTM) or 0.85 mL Nasopharyngeal, Bronchial, or Tracheal lavage/wash or sputum Respiratory Samples in M4 Media: Use sterile vials containing 3 mL of sterile M4 media. If using swabs, use only sterile Dacron or rayon swabs with plastic or wire shafts. Do NOT use calcium alginate swabs, as they may contain substances that inhibit PCR testing. Break applicator sticks off near the tip to permit tightening of the cap. Bronchial Lavage: Collect in a sterile container with a leak-proof cap. Sputum: Collect in a sputum collection kit or a sterile, plastic container with a leak-proof cap.
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Additional Information:	Update specimen requirements and stability.

Interferon Beta (IFNB) Antibody Neutralization Assay		
Clinical Significance:	Highly elevated levels of neutralizing antibodies (NABs >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 NABs; however, continued patient monitoring may also be warranted in this instance as well.	
Effective Date:	May 19, 2008	
Test Code:	19510	
Specimen Stability:	Room temperature: 5 days Refrigerated: 14 days Frozen: 30 days	
Reference Range:	IFNB Neutralizing Ab Titer Interpretation Interferon Tested Prior Binding or Neutralizing AB Result	<1:20 Not applicable Not applicable Not applicable
Additional Information:	Update specimen stability and add result prompt The Interferon drug used for therapy and a previous positive Binding Antibody or Neutralizing Antibody test result must both be specified. Lack of this information will result in testing delays.	
16087-Parainfluenza Virus (Types 1, 2, and 3) RNA, Qualitative Real-Time PCR		
16094-Respiratory Virus Panel, Qualitative Real-Time PCR		
16047-RSV (Respiratory Syncytial Virus)RNA, Qualitative Real-Time PCR		
Effective Date:	May 19, 2008	
Specimen Requirements:	Throat swab or Nasal/nasopharyngeal swab in 3 mL M4 or V-C-M medium (green-cap) tube or equivalent (UTM) Respiratory Samples in M4 Media: Use sterile vials containing 3 mL of sterile M4 media. If using swabs, use only sterile Dacron or rayon swabs with plastic or wire shafts. Do NOT use calcium alginate swabs, as they may contain substances that inhibit PCR testing. Break applicator sticks off near the tip to permit tightening of the cap. Bronchial Lavage: Collect in a sterile container with a leak-proof cap. Sputum: Collect in a sputum collection kit or a sterile, plastic container with a leak-proof cap.	
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days	
Additional Information:	Update specimen requirements and stability.	

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