



LABORATORY UPDATE

www.dlolab.com

Routine Testing

New Test

- ANA IFA, with Reflex to Titer/Pattern/Cascade 3
- Hemoglobin A1c with eAG 4

Test Changes

- ANAchoice™ Specific Antibodies Cascading Reflex – Test name change 5
- ANAchoice™ Specific Antibodies with Reflex to ds DNA – Test name change 6
- Culture, Fungus, Blood - Update sample requirements 6
- Mycobacterium, Blood Culture - Update sample requirements..... 6
- Protein C Activity - Update specimen requirements and stability. 7
- Protein C Activity with Reflex to Protein C Antigen - Update specimen requirements and stability 7
- Protein C Antigen - Update specimen requirements..... 7
- Protein C and S Activity with Reflex to Protein C and/or S Antigen – Update specimen requirements and stability 8
- Protein S Activity - Update specimen requirements and stability 8
- Protein S Activity with Reflex to Protein S Antigen - Update specimen requirements..... 8
- Protein S, Total Antigen - Update specimen requirements..... 9
- Protein, Total, with Creatinine, 24-Hour Urine – Update test and result name and reject criteria..... 9
- Protein, Total, with Creatinine, Random Urine - Update test and result name, and methodology 10
- Protein, Total and Protein Electrophoresis w/refl IFE - Update method, reject criteria, specimen requirements, CPU interface mapping and collection instructions..... 10

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

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

New Tests

- Procollagen Type I Intact N Terminal Propeptide11
- Plavix® P450 Genotype 11
- Tamoxifen P450 Genotype12
- ER/PR/Ki-67/DNA Image Analysis/HER2 FISH with Interpretation..... 12
- ER/PR/Ki-67/DNA Image Analysis with Interpretation13
- ER/PR/DNA Image Analysis/Her2 IHC with Reflex to HER2 FISH 13
- ER/PR/Ki-67 /DNA Image Analysis/HER2 with Reflex to FISH.....14
- ER/PR/Ki-67/HER2 with Reflex HER2 FISH with Interpretation..... 14
- ER/PR/DNA Image Analysis/HER2 FISH with Interpretation15

Test Changes

- Cholinesterase, Plasma - Update specimen requirements, stability, [test name](#), [reference ranges](#), [methodology](#), and test and result codes 15
- Cholinesterase, RBC and Plasma - Update test and result codes [specimen requirements](#), [stability reference ranges](#), and [method](#)..... 16
- Cholinesterase, Serum - Update test and result code, [test name](#), [methodology](#), specimen requirements, stability and reference ranges.....17
- Cholinesterase, Serum, Plasma, RBC - Update test and result code, sample volume, and reference ranges17
- Cholinesterase, Serum, with Dibucaine Inhibition - Update [test name](#), [specimen volume](#), stability, test and result codes, and reference ranges18
- Macroamylase- Update test and result name and methodology.....18
- Protein Electrophoresis Panel 1 - Update test name, specimen requirements, reject criteria, and method.19
- Protein S Activity with Reflex to Protein S Antigen, Total and Free - Update specimen requirements and stability19
- Protein S, Free - Update specimen requirements and stability20

Discontinued Tests

- Protein Electrophoresis and Kappa/Lambda Light Chains, Serum with Tracing20

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

Routine Testing

New Tests

ANA IFA, with Reflex to Titer/Pattern/Cascade			
Clinical Significance:	Antinuclear Antibodies are present in Systemic Lupus Erythematosus, Sjögren's Syndrome, Mixed Connective Tissue Disease, Scleroderma, liver disease, Drug Induced Lupus, Rheumatoid Arthritis, and other autoimmune diseases.		
Effective Date:	August 3, 2009		
Test Code:	16814		
CPT Code(s):	86038		
Specimen Requirements	1 mL serum		
Transport Temperature	Room temperature		
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days		
Reference Ranges:	ANA, IFA	Negative	
	ANA, IFA Titer	< 1:40	
	ANA, IFA Pattern	Not Applicable	
	Cascade Stage 1	dsDNA Antibody (IU/mL)	< or = 4 Negative 5 – 9 Indeterminate > or = 10 Positive
		Sm Antibody	< 1.0 Negative
		Sm/RNP Antibody	< 1.0 Negative
		RNP Antibody	< 1.0 Negative
	Cascade Stage 2	Chromatin Antibody	< 1.0 Negative
		SSA Antibody	< 1.0 Negative
		SSB Antibody	< 1.0 Negative
		Scl-70 Antibody	< 1.0 Negative
Cascade Stage 3	Jo-1 Antibody	< 1.0 Negative	
	Ribosomal P Antibody	< 1.0 Negative	
Centromere B Antibody	< 1.0 Negative		
Methodology:	Immunoassay		
Assay Category:	FDA Approved/Cleared		

Additional Comments:	<p>The ANA IFA with reflex to titer/pattern/Cascade begins with an ANA (Anti-Nuclear Antibody) IFA Screen.</p> <p>If the ANA IFA Screen is positive then an ANA Titer and Pattern will be performed at an additional charge (CPT: 86039). Additionally, five antibodies will be performed at an additional charge: dsDNA (CPT: 86225), Sm/RNP (CPT: 86235), RNP (CPT: 86235), Sm (CPT: 86235), and Chromatin (CPT: 86235).</p> <p>If any of those five antibodies are positive, the cascade stops and the results are reported.</p> <p>If all five of those antibodies are negative, four additional antibodies will be performed at an additional charge: SSA (CPT: 86235), SSB (CPT: 86235), Scl-70 (CPT: 86235), Jo-1 (CPT: 86235).</p> <p>If any of those four antibodies are positive, the cascade stops and the results are reported.</p> <p>If all four of those antibodies are negative, the following two additional antibodies will be performed at an additional charge: Ribosomal P (CPT: 83516) and Centromere B (CPT: 86038).</p> <p>Please note the cascade stops upon the first positive antibody result(s) found in a group and an interpretive message is applied based on this information. It is possible that antibodies in subsequent groups are also positive, but will not be added, billed, or reported. Please contact your local Quest Diagnostics Laboratory if you are interested in adding this additional testing.</p>
----------------------	---

Hemoglobin A1c with eAG	
Clinical Significance:	Monitors long term glucose control (2-3 months) in patients with diabetes mellitus utilizing Hemoglobin A1c and the estimated Average Glucose (eAG)
Effective Date:	Now available
Test Code:	16802
CPT Code:	83036
Specimen Requirements:	1 mL whole blood collected in a lavender-top (EDTA) tube
Transport Temperature:	Room Temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 7 days Frozen: 6 months
Units of Measure:	%
Reference Range:	Non-Diabetic: <6.0% % of total Hgb
Methodology:	Immunoturbidimetry
Assay Category:	FDA approved
Additional Information:	eAG in both mg/dL and mmol/L (calculated) will be reported with the Hemoglobin A1c result..

Test Changes

ANachoice™ Specific Antibodies Cascading Reflex	
Clinical Significance:	This test provides a cost-effective and medically justified approach to evaluating patients with suspected rheumatologic disease. Eleven antibodies associated with specific rheumatologic disease entities are analyzed and resulted in sequential tiers until positive findings are reported. The test is not intended for the work-up of autoimmune hepatitis or other non-rheumatologic diseases.
Effective Date:	August 3, 2009
Former TestName:	<i>ANachoice™ Cascading Reflex</i>
Test Code:	19946
Additional Comments:	<p>Update test name.</p> <p>The ANachoice™ Specific Antibodies Cascading Reflex begins with an ANA (Anti-Nuclear Antibody) Screen that tests for the 11 most common antibodies associated with Connective Tissue Disease.</p> <p>If the ANachoice™ is positive, five antibodies will be performed at an additional charge: dsDNA (CPT: 86225), Sm/RNP (CPT: 86235), RNP (CPT: 86235), Sm (CPT: 86235), and Chromatin (CPT: 86235).</p> <p>If any of those five antibodies are positive, the cascade stops and the results are reported.</p> <p>If all five of those antibodies are negative, four additional antibodies will be performed at an additional charge: SSA (CPT: 86235), SSB (CPT: 86235), Scl-70 (CPT: 86235), Jo-1 (CPT: 86235).</p> <p>If any of those four antibodies are positive, the cascade stops and the results are reported.</p> <p>If all four of those antibodies are negative, the following two additional antibodies will be performed at an additional charge: Ribosomal P (CPT: 83516) and Centromere B (CPT: 86038).</p> <p>Please note the cascade stops upon the first positive antibody result(s) found in a group and an interpretive message is applied based on this information. It is possible that antibodies in subsequent groups are also positive, but will not be added, billed, or reported. Please contact your DLO if you are interested in adding this additional testing.</p>

ANAchoice™ Specific Antibodies with Reflex to ds DNA	
Clinical Significance:	This assay may be useful in diagnosing and monitoring connective tissue diseases.
Effective Date:	August 3, 2009
Former TestName:	ANAchoice™ Screen with Reflex to ds DNA
Test Code:	10547
CPT Code(s):	86038
Additional Information:	If the ANAchoice™ Specific Antibody is positive, dsDNA (CPT: 86225) will be added at an additional charge.

Culture, Fungus, Blood	
Effective Date:	September 14, 2009
Test Code:	4606
Specimen Requirements	5 ml blood or bone marrow drawn into a Bactec® Myco/F Lytic aerobic blood bottle.
Container Type	Bactec® Myco/F Lytic aerobic blood bottle
Specimen Stability	Room temperature: 48 hours Refrigerated and Frozen: Unacceptable
Rejection Criteria	Received frozen Specimens in EDTA (lavender top tube) Specimens in Heparin (green top tube) Specimens in citrate, ACD or SPS (yellow-top tubes) Bactec® plus aerobic/f (silver label with gray-top) bottles Bactec® lytic/10 anaerobic/f (purple label and cap) bottles Bactec® peds bottle
Additional Information	Update sample requirements.

Mycobacterium, Blood Culture	
Effective Date:	September 14, 2009
Test Code:	10526
Specimen Requirements	5 ml blood or bone marrow drawn into a Bactec® Myco/F Lytic aerobic blood bottle.
Container Type	Bactec® Myco/F Lytic aerobic blood bottle
Rejection Criteria	Received frozen Specimens in EDTA (lavender top tube) Specimens in Heparin (green top tube) Specimens in citrate, ACD or SPS (yellow-top tubes) Bactec® plus aerobic/f (silver label with gray-top) bottles Bactec® lytic/10 anaerobic/f (purple label and cap) bottles Bactec® peds bottle
Additional Information	Update sample requirements.

Protein C Activity	
Effective Date:	August 3, 2009
Test Code:	1777
Specimen Requirements:	1 mL 3.2% Sodium Citrate (lt. blue-top) plasma Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 14 days -70 degrees: 1 year
Additional Information:	Update specimen requirements and stability. Please note this test is included in the following group codes: 39457-Protein C and Protein S, Functional; 11051-Thrombosis Panel; 11327-Thrombophilia Screen II, Inherited; 8757-Protein C Activity and Antigen

Protein C Activity with Reflex to Protein C Antigen	
Effective Date:	August 3, 2009
Test Code:	8754
Specimen Requirements:	3 mL 3.2% Sodium Citrate (lt. blue-top) plasma [1.5 mL x2] Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 14 days -70 degrees: 1 year
Additional Information:	Update specimen requirements and stability.

Protein C Antigen	
Clinical Significance:	Protein C Antigen levels may be decreased with congenital deficiency, treatment with oral anticoagulants, liver disease, DIC, and post-surgery.
Effective Date:	August 3, 2009
Test Code:	4948
Specimen Requirements:	1 mL 3.2% Sodium Citrate (lt. blue-top) plasma (minimum: 0.5 mL) 3.8% Sodium Citrate (lt. blue-top) is unacceptable Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Additional Information:	Update specimen requirements. Please note this test is included in the following test codes: 8757 -Protein C Activity and Antigen

Protein C and S Activity with Reflex to Protein C and/or S Antigen	
Effective Date:	August 3, 2009
Test Code:	7942
Specimen Requirements:	6 mL 3.2% Sodium Citrate (lt. blue-top) [3 mL x2] Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 14 days -70 degrees: 1 year
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements and stability.

Protein S Activity	
Clinical Significance:	Protein S Activity is used to diagnose acquired and hereditary deficiencies of Protein S. Protein S deficiency is associated with increased risk of thrombosis.
Effective Date:	August 3, 2009
Test Code:	1779
Specimen Requirements:	1 mL 3.2% Sodium Citrate (lt. blue-top) plasma (minimum: 0.5 mL) 3.8% Sodium Citrate (lt. blue-top) is unacceptable. Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 30 days; -70 degrees: 1 year
Additional Information:	Update specimen requirements and stability. Please note this test is included un the following group codes: 7039-Protein S, Antigenic and Functional; 39457-Protein C and Protein S, Functional; 11051-Thrombosis Panel; 11343X-Protein S Panel

Protein S Activity with Reflex to Protein S Antigen	
Effective Date:	August 3, 2009
Test Code:	8838
Specimen Requirements:	3 mL 3.2% Sodium Citrate (lt. blue-top) plasma (minimum: 0.5 mL) [1.5 mL x2] 3.8% Sodium Citrate (lt. blue-top) is unacceptable Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Additional Information:	Update specimen requirements.

Protein S, Total Antigen	
Effective Date:	August 3, 2009
Test Code:	5165
Specimen Requirements:	1 mL 3.2% Sodium Citrate (lt. blue-top) plasma (minimum: 0.5mL) 3.8% Sodium Citrate (lt. blue-top) is unacceptable Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Additional Information:	Update specimen requirements. Please note this code is included in the following group codes: 7039-Protein S, Antigenic and Functional, 36457-Protein S Antigen and Protein S, Free, 11343-Protein S Panel

Protein, Total, with Creatinine, 24-Hour Urine			
Clinical Significance:	Urinary Total Proteins are negligible in healthy individuals. Concentrations are increased in patients with a wide variety of diseases that impair renal function including diabetes, hypertension, nephrotic syndrome, and drug nephrotoxicity.		
Effective Date:	August 3, 2009		
<i>Former Test Name:</i>	<i>Protein, Total, 24-Hour Urine</i>		
Test Code:	757		
Reference Ranges:	Protein, Total, 24 Hr Ur:	< 150	mg/24 h
	Protein/ Creatinine Ratio:	< or = 84	mg/g creat
	Creatinine, 24-Hour Urine:		
	< 3 years: Reference Range not established		
	3-8 years	0.11-0.68	g/24 hours
	9-12 years	0.17-1.41	g/24 hours
	13-17 years	0.29-1.87	g/24 hours
	Adults	0.63-2.50	g/24 hours
Methodology:	Spectrophotometry		
Additional Information:	Update test and result name, and methodology. Please note this test is included in the following group codes: 750 - Protein Electrophoresis, Total Protein, and Creatinine, 24-Hour Urine		

Protein, Total, with Creatinine, Random Urine			
Effective Date:	August 3, 2009		
<i>Former Test Name:</i>	<i>Protein, Total, Random Urine (with Creatinine)</i>		
Test Code:	1715		
Reference Ranges:	Protein/Creatinine Ratio	Male: 22-128	mg/g Creat
		Female: 21-161	
	Protein, Total, Random Ur	Male: 5-25	mg/dL
		Female: 5-24	
Methodology:	Spectrophotometry		
Additional Information:	Update test and result name, and methodology. Please note this test is included in the following group codes: 8525- Protein, Total and Protein Electrophoresis, Random Urine		

Protein, Total and Protein Electrophoresis w/refl IFE	
Clinical Significance:	Protein electrophoresis evaluates the major protein fractions (I.e., albumin, alpha1, alpha2, beta, and gamma proteins) to determine if there are deficiencies or excesses as seen with macroglobulinemia and multiple myeloma. Immunofixation is useful in characterizing M-components observed in the protein electrophoresis.
Effective Date:	August 3, 2009
Test Code:	10269
Specimen Requirements:	3 mL serum (minimum volume 1.5 mL) Overnight fasting is preferred. Plasma is not acceptable.
Reject Criteria:	Hemolysis
Methodology:	Electrophoresis, Spectrophotometry, Immunofixation
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update method, reject criteria, specimen requirements, CPU interface mapping and collection instructions.

New Tests

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

Procollagen Type I Intact N Terminal Propeptide																						
Clinical Significance:	Intact N-terminal propeptide of type I Procollagen is useful in the management of osteoporosis and monitoring bone formation therapies and antiresorptive therapies.																					
Effective Date:	June 1, 2009																					
Test Code:	16609																					
CPT Code:	83519																					
Specimen Requirements:	1 mL serum Gross hemolysis and gross lipemia are unacceptable.																					
Transport Temperature:	Refrigerated																					
Specimen Stability:	Room temperature: Unacceptable Refrigerated and Frozen: 60 days																					
Reference Ranges:	<table border="1"> <tbody> <tr> <td>Male:</td> <td>< 23 years:</td> <td>Not established</td> </tr> <tr> <td></td> <td>23-60 years:</td> <td>30 - 110 mcg/L</td> </tr> <tr> <td></td> <td>>60 years:</td> <td>Not established</td> </tr> <tr> <td>Female:</td> <td>< 20 years:</td> <td>Not established</td> </tr> <tr> <td></td> <td>20-45 years:</td> <td>22 - 104 mcg/L</td> </tr> <tr> <td></td> <td>46-60 years:</td> <td>20 - 108 mcg/L</td> </tr> <tr> <td></td> <td>>60 years:</td> <td>Not established</td> </tr> </tbody> </table>	Male:	< 23 years:	Not established		23-60 years:	30 - 110 mcg/L		>60 years:	Not established	Female:	< 20 years:	Not established		20-45 years:	22 - 104 mcg/L		46-60 years:	20 - 108 mcg/L		>60 years:	Not established
Male:	< 23 years:	Not established																				
	23-60 years:	30 - 110 mcg/L																				
	>60 years:	Not established																				
Female:	< 20 years:	Not established																				
	20-45 years:	22 - 104 mcg/L																				
	46-60 years:	20 - 108 mcg/L																				
	>60 years:	Not established																				
Methodology:	Immunoassay																					
Assay Category:	FDA Approved/Cleared																					
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly																					

Plavix® P450 Genotype	
Clinical Significance:	The cytochrome P450 gene products are responsible for metabolizing a large number of widely prescribed drugs. Clopidogrel (Plavix®) is metabolized by CYP2C19 to its active form. Individuals with poor metabolizer phenotype for CYP2C19 will require alternatives to Clopidogrel (Plavix®) while those with ultra-extensive metabolizer phenotype will require a decreased Clopidogrel (Plavix®) dosage.
Effective Date:	June 1, 2009
Test Code:	16605
CPT Code:	83891, 83892 (x2), 83900 (x2), 83901 (x2), 88385
Specimen Requirements:	5 mL EDTA (lavender-top tube) whole blood
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 30 days Frozen: 49 days
Reference Ranges:	Accompanies report
Methodology:	Microarray, Polymerase Chain Reaction
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

Tamoxifen P450 Genotype	
Clinical Significance:	The cytochrome P450 gene products are responsible for metabolizing a large number of widely prescribed drugs. Tamoxifen is metabolized by CYP2D6 to its active form, endoxifen. Individuals with poor-metabolizer phenotype of CYP2D6 will require alternatives to Tamoxifen such as aromatase inhibitors, while those with ultra-extensive metabolizer phenotype will require a decreased Tamoxifen dosage.
Effective Date:	June 1, 2009
Test Code:	16731
CPT Code:	83891, 83892 (x2), 83900 (x2), 83901 (x2), 88385
Specimen Requirements:	5 mL EDTA (lavender-top tube) whole blood
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 30 days Frozen: 49 days
Reference Ranges:	Accompanies report
Methodology:	Microarray, Polymerase Chain Reaction
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

ER/PR/Ki-67/DNA Image Analysis/HER2 FISH with Interpretation	
Clinical Significance:	Predictive markers in breast cancer management, prognosis and in predicting response to targeted therapies.
Effective Date:	June 8, 2009
Test Code:	16703
CPT Code:	88358, 88360 (x3), 88368 (x2)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Image Analysis, Immunohistochemistry, Fluorescence In-Situ Hybridization
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report.

ER/PR/Ki-67/DNA Image Analysis with Interpretation	
Effective Date:	June 8, 2009
Test Code:	16705
CPT Code:	88358, 88360 (x3)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Image Analysis, Immunohistochemistry
Assay Category:	ASR Class I
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report.

ER/PR/DNA Image Analysis/Her2 IHC with Reflex to HER2 FISH	
Clinical Significance:	Estrogen and progesterone receptor assays are routinely performed on breast carcinomas to assess responsiveness to endocrine therapy and prognosis. DNA Analysis is used to estimate tumor aggressiveness and patient prognosis. HER-2 is associated with cellular proliferation activity. Over-expression is observed in 25-30% of women with breast cancer. These patients are potential candidates for monoclonal therapy.
Effective Date:	June 8, 2009
Test Code:	16713
CPT Code:	88358, 88360 (x3)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Image Analysis, Immunohistochemistry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report. In accordance with the College of American Pathologists' (CAP) recommendation, immunohistochemistry (IHC) results of 2+ are reflexed to HER2 FISH (14620) testing for confirmation (Strategic Science I Meeting, May 4-5, 2002, Chicago, Illinois) at an additional charge (CPT: 88368 (2)).

ER/PR/Ki-67 /DNA Image Analysis/HER2 with Reflex to FISH	
Effective Date:	June 8, 2009
Test Code:	16712
CPT Code:	88358, 88360 (x4)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Image Analysis, Immunohistochemistry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report. In accordance with the College of American Pathologists' (CAP) recommendation, immunohistochemistry (IHC) results of 2+ are reflexed to HER2 FISH (14620) testing for confirmation (Strategic Science I Meeting, May 4-5, 2002, Chicago, Illinois) at an additional charge (CPT: 88368 (2)).

ER/PR/Ki-67/HER2 with Reflex HER2 FISH with Interpretation	
Effective Date:	June 8, 2009
Test Code:	16704
CPT Code:	88360 (x4)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Immunohistochemistry
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report. In accordance with the College of American Pathologists' (CAP) recommendation, immunohistochemistry (IHC) results of 2+ are reflexed to HER2 FISH (14620) testing for confirmation (Strategic Science I Meeting, May 4-5, 2002, Chicago, Illinois) at an additional charge (CPT: 88368 (2)).

ER/PR/DNA Image Analysis/HER2 FISH with Interpretation	
Effective Date:	June 8, 2009
Test Code:	16736
CPT Code:	88358, 88360 (x2), 88368 (x2)
Specimen Requirements:	Formalin-fixed, paraffin-embedded block, submitted in IHC Specimen Transport Kit
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinitely Do not freeze
Reference Ranges:	Accompanies report
Methodology:	Image Analysis, Immunohistochemistry, Fluorescence In Situ Hybridization
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Please submit stained H & E slide and a copy of the pathology report.

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.

Cholinesterase, Plasma			
Clinical Significance:	Approximately 1 in every 2500 individuals has inherited defective or deficiency of the enzyme (pseudocholinesterase) that metabolizes succinylcholine (an anesthetic agent). With "normal" dosage, these individuals have prolonged apnea. Such individuals are responsive at much smaller concentrations of this anesthetic agent than the general population. Low concentrations of pseudocholinesterase are observed in individuals exposed to organophosphorous insecticides and patients with hepatic dysfunction.		
Effective Date:	August 3, 2009		
<i>Former Test Name:</i>	<i>Cholinesterase, Serum or Plasma</i>		
Test Code:	335		
Specimen Requirements:	1 mL plasma EDTA (lavender-top) (minimum 0.5 mL) Centrifuge and transfer plasma specimens to clean, plastic, screw-capped vial(s). Serum is not acceptable.		
Reject Criteria:	Hemolysis		
Specimen Stability:	Room temperature and Refrigerated: 21 days Frozen: 30 days		
Reference Ranges:	Cholinesterase, Plasma:	MALE 3334-7031	IU/L
		FEMALE 2504-6297	IU/L
Methodology:	Kinetic Spectrophotometric		
Additional Information:	Update specimen requirements, stability, reject criteria, test name , reference ranges , methodology , and test and result codes.		

Cholinesterase, RBC and Plasma		
Effective Date:	August 3, 2009	
<i>Former Test Name:</i>	<i>Cholinesterase, RBC & Plasma</i>	
Test Code:	338	
Specimen Requirements:	Whole blood and Plasma	
	Whole blood	Plasma
	5 mL (minimum: 4 mL) EDTA (lavender-top) (preferred) Sodium heparin (green-top) (acceptable)	1 mL (minimum: 0.5 mL) EDTA (lavender-top) (preferred) Sodium heparin (green-top) (acceptable)
	<p>Draw two lavender-top (EDTA) tubes of whole blood. Spin one tube to separate plasma. Pour plasma into plastic aliquot tube and refrigerated until shipping. Ship both whole blood and plasma samples refrigerated. Do not send packed cells. Do not send one tube of whole blood. Plasma cholinesterase results, as well as the calculated RBC cholinesterase results, are not accurate if plasma sample is not separated from the RBC's in a timely manner.</p> <p>If only a single tube is received for this test, the client should be contacted to verify that two tubes were collected for that patient. Since there is a limited stability for those samples, particularly the whole blood, it is imperative to check with the client as soon as possible to find out whether the missing sample is still in transit, or whether it was not collected at all. If the client confirms that only a single tube of whole blood was collected, the test should be cancelled, and new specimens drawn.</p> <p>Hemolyzed plasma samples are not acceptable. Hemolysis can lead to apparent increases in plasma cholinesterase activity, and could mask an enzyme deficiency. If samples received ambient, put on Problem Hold and contact the BCG Medical Director or Scientific Director for a final decision on whether to cancel the sample.</p>	
Reject Criteria:	Received room temperature; Received frozen; Hemolyzed plasma; Receipt of only a single tube of whole blood; Hemolysis and lipemia	
Specimen Stability:	Room temperature: 24 hours Refrigerated: 7 days Frozen: Unacceptable	
Reference Ranges:	Cholinesterase, RBC: 9572-15031 Cholinesterase, Plasma: MALE 3334-7031 FEMALE 2504-6297	IU/L IU/L IU/L
Methodology:	Kinetic Spectrophotometric	
Additional Information:	Update test and result codes specimen requirements, stability, reference ranges, and method.	

Cholinesterase, Serum	
Effective Date:	August 3, 2009
<i>Former Test Name:</i>	<i>Cholinesterase, Serum or Plasma</i>
Test Code:	37965
Specimen Requirements:	1 mL serum (minimum 0.5 mL) Centrifuge and transfer serum specimens to clean, plastic, screw-capped vial(s). Plasma is not acceptable
Reject Criteria:	Hemolysis
Specimen Stability:	Room temperature and Refrigerated: 21 days Frozen: 30 days
Reference Ranges:	MALE: 3342-7586 IU/L FEMALE: 2673-6592 IU/L
Methodology:	Kinetic Spectrophotometric
Additional Information:	Update test and result code, test name , methodology , specimen requirements, stability, reject criteria and reference ranges.

Cholinesterase, Serum, Plasma, RBC			
Effective Date:	August 3, 2009		
Test Code:	39481		
Specimen Requirements:	Serum	and Plasma	and Whole blood
	1 mL	1 mL EDTA (lavender-top)	5 mL EDTA (lavender-top) (minimum: 4 mL)
	5 mL refrigerated uncentrifuged whole blood (4 mL minimum) and 1 mL refrigerated plasma (0.5 mL minimum) drawn in lavender-top (EDTA) tubes. AND, 1 mL refrigerated serum (0.5 mL minimum). Transfer plasma and serum to plastic transport tubes and send refrigerated with whole blood.		
Reject Criteria:	Hemolyzed and lipemia		
Reference Ranges:	Cholinesterase, Serum:	MALE 3342-7586 FEMALE 2673-6592	IU/L IU/L
	Cholinesterase, RBC:	9572-15031	IU/L
	Cholinesterase, Plasma:	MALE 3334-7031 FEMALE 2504-6297	IU/L IU/L
Additional Information:	Update test and result code, sample volume, and reference ranges.		

Cholinesterase, Serum, with Dibucaine Inhibition			
Clinical Significance:	The Pseudocholinesterase phenotype can be determined by analysis of Pseudocholinesterase and the percent inhibition by Dibucaine. Approximately 96% of the population has normal activity, approximately 4% will exhibit decreased activity that leads to prolonged paralysis, following use of succinylcholine, and 1 in 3000 patients will exhibit severe, prolonged paralysis following anesthetic exposure.		
Effective Date:	August 3, 2009		
Former Test Name:	<i>Dibucaine Number & Cholinesterase, Serum</i>		
Test Code:	7961		
Specimen Requirements:	1 mL serum		
Specimen Stability:	Room temperature and Refrigerated: 21 days Frozen: 30 days		
Reference Ranges:	Cholinesterase, Serum:	MALE: 3342-7586	IU/L
		FEMALES: 2673-6592	IU/L
	Dibucaine Number:	81.6-88.3	% inhibition
	Reference ranges for Cholinesterase with Dibucaine Inhibition:		
	Phenotype**	% Inhibition	
	U	83.6	
A*	19.9		
AS*	20.7		
S1*	5.3		
S2*	67.6		
F*	71.8		
AF*	60.2		
FS*	76.7		
UA	72.7		
UF	79.8		
US	84.4		
	* Phenotype reportedly associated with prolonged apnea.		
	** Reference: A.A. Dietz et al: Colorimetric determination of serum cholinesterase and its genetic variants by the propiopylthiocholine-dithiobis (nitrobenzoic acid) procedure. Clinical Chemistry 19: 1309-1313, 1973.		
Methodology:	Kinetic Spectrophotometric		
Additional Information:	Update test name specimen volume, stability, test and result codes, and reference ranges.		

Macroamylase	
Clinical Significance:	Macroamylase is a laboratory, not a clinical entity. Amylase can complex with immunoglobulins or other high molecular weight proteins. Serum amylase appears falsely elevated. No clinical symptoms are associated with macroamylasemia.
Effective Date:	August 3, 2009
Former Test Name:	<i>Macroamylase, Serum</i>
Test Code:	5499
Methodology:	Polyethylene Glycol Precipitation
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update test and result name and methodology.

Protein Electrophoresis Panel 1

Includes: Protein Electrophoresis, Serum Protein, Total *Kappa/Lambda Light Chain, Total * Immunofixation, Serum *Immunoglobulin Profile, Serum*

Clinical Significance:	Protein electrophoresis evaluates the major protein fractions (i.e., albumin, alpha1, alpha2, beta, and gamma proteins) to determine if there are deficiencies or excesses as seen with macroglobulinemia, monoclonal gammopathy of undetermined significance (MGUS), and multiple myeloma. Immunofixation is useful in characterizing M-components observed in the protein electrophoresis.
Effective Date:	August 3, 2009
<i>Former Test Name:</i>	<i>Electrophoresis & Immunofixation, Serum with Tracing</i>
Test Code:	38940
Specimen Requirements:	5 mL serum (minimum volume 2.1 mL) Plasma is not acceptable
Reject Criteria:	Hemolysis
Methodology:	Electrophoresis, Spectrophotometry, Fixed Rate Time Nephelometry, Immunofixation
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update test name, specimen requirements, reject criteria, and method.

Protein S Activity with Reflex to Protein S Antigen, Total and Free

Effective Date:	August 3, 2009
Test Code:	17494
Specimen Requirements:	3 mL 3.2% Sodium Citrate (lt. blue-top) plasma [1 mL x3] 3.8% Sodium Citrate (lt. blue-top) is unacceptable Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: Unacceptable Frozen: 14 days; -70 degrees: 1 year
Additional Information:	Update specimen requirements and stability.

Protein S, Free	
Effective Date:	August 3, 2009
Test Code:	10170
Specimen Requirements:	1 mL 3.2% Sodium Citrate (lt. blue-top) plasma Draw blood in light blue-top tube containing 3.2% sodium citrate, mix gently by inverting 3-4 times. Centrifuge 15 minutes at 1500 g within 1 hour of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial(s). Freeze immediately and transport on dry ice.
Specimen Stability:	Room temperature and Refrigerated: 24 hours Frozen: 14 days; -70 degrees: 1 year
Additional Information:	Update specimen requirements and stability. Please note this test is included in the following test codes: 36457-Protein S Antigen and Protein S, Free; 11343-Protein S Panel; 11327-Thrombophilia Screen II, Inherited.

Discontinued Tests

Protein Electrophoresis and Kappa/Lambda Light Chains, Serum with Tracing	
Effective Date:	August 3, 2009
Test Code:	38763
Additional Information:	This test will be discontinued. The recommended alternative test code is 17099 -Protein Electrophoresis (SPEP) and Kappa/Lambda Light Chains, Serum

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