



A LabCorp Company

December 5, 2009

Esoterix Coagulation Service Update

Test Title: Various Coagulation assays, see attached table

Test Code: See attached table

Effective Date: January 5, 2010

Explanation of change: Esoterix is committed to keeping our clients informed of changes, updates, and enhancements to our testing services as they occur. A complete list of service changes is included with this letter and has been posted to our website at www.esoterix.com.

For additional information, please call us at 800.444.9111. We value you as a customer and thank you for choosing Esoterix.

Esoterix Coagulation Service Update

Test Name/Test Code (Profile Components)	Reference Range	Specimen Requirement	CPT Code	Change/Comments
Assay Changes Effective January 5, 2010				
300040 - Activated Partial Thromboplastin Time (PTT)	No Change	No Change	No Change	Report comment added to all reports: "This test has not been validated for monitoring unfractionated heparin therapy. aPTT-based therapeutic ranges for unfractionated heparin therapy have not been established. Consider test code 300600 Heparin anti-Xa (unfractionated).
300727 - Homocysteine	No Change	Serum is the only acceptable sample type. We no longer accept citrated plasma.	No Change	Change in methodology from fluorescence polarization to nephelometry. Serum is the only acceptable sample type. We no longer accept citrated plasma.
300215 - Factor X Chromogenic Activity - (not on Oral Anticoagulant)	No Change	No Change	No Change	Test Discontinued. Order 300211 Factor X Chromogenic activity, Vitamin K antagonist therapy
300531 - HPA-1a (PLA-1 Platelet Antigen) Genotyping (PLA2 Polymorphism Detection)	HPA1-a1 - HPA1-a1 (PLA1-PLA1)	No Change	83891, 83892 x 2, 83894 x 2, 83912	Methodology Change from PCR RFLP to ARMS. CPT code change due to change in methodology. Previous CPT codes: 83891, 83892, 83894, 83898, 83912.
300415 - D-dimer Quantitative (Automated)	<0.50 ug/mL FEU	No Change	No Change	Change in reporting units from ng/mL D-dimer units to ug/mL FEU (fibrinogen equivalent units). 1 ug/mL FEU = 500 ng/mL D-dimer units. Change cutoff value for negative predictive value for exclusion of thrombosis from 250 ng/mL D-dimer units to 0.50 ug/mL FEU.
300611 - Stypven Time**	19.9-28.0 seconds	No Change	No Change	Change in reference range from 22.3 -32.0 seconds due to reformulation of reagents.
Test Name Changes Effective January 5, 2010				
300520 - Indirect Antiplatelet Alloantibody Profile	No Change	No Change	No Change	Name change from: Platelet Antibody Screen, Indirect
300524 - Platelet HPA-1a/1b Antibody Identification	No Change	No Change	No Change	Name change from: Platelet Specific Antibody (GP IIB/IIIA)
300211 - Factor X Chromogenic Activity, Vitamin K antagonist therapy	No Change	No Change	No Change	Name change from: Factor X Chromogenic Activity, Oral Anticoagulant Therapy
300995 - Pathologist Interpretation	No Change	No Change	No Change	Name change from: Pathologist Consultation

Test Name/Test Code (Profile Components)	Reference Range	Specimen Requirement	CPT Code	Change/Comments
New Profiles Available January 5, 2010				
304564 - Ristocetin Induced Platelet Aggregation Profile (Ristocetin 1.0mg/mL, Ristocetin 0.25 mg/mL)	See Components Below	Four 5mL blue top tubes or six 2.7mL blue top tubes. Keep as whole blood at room temperature; must be delivered to Esoterix Coagulation facility within 1 hour of collection. (Having courier on site before sample collection is recommended) Samples can be collected by Esoterix, call for appointment, 720-568-4382.	See Components below	New Profile Available to local Colorado clients only.
Ristocetin 1.0mg/mL	>=5 Ohms		85576	
	<= 1.5 Ohms		85576	
Ristocetin 0.25 mg/mL				
304584 - Clopidogrel CYP2C19 genotype**	homozygous wild type *1/*1	7mL EDTA (lavender top) or ACD (yellow top) whole blood, or 2 LabCorp buccal swab kit. Maintain at room temperature or refrigerate at 4C.	83891, 83892, 83894 x 2, 83898, 83900, 83912	Test sent to LabCorp CMBP.
New Tests Now Available				
304457 - Factor XI Antigen**	60 - 150%	1mL frozen citrated plasma	85270	This assay measures the amount of Factor XI protein and is NOT a functional activity assay.
304451 - Factor IX Chromogenic Activity**	60 - 150%	1mL frozen citrated plasma	85250	This assay measures the Factor IX activity using a non-clot based (chromogenic) method. This is useful in patients with a clotting inhibitor such as a lupus anticoagulant.
300560 - Angiotensin Converting Enzyme Insertion/Deletion Mutation**	Negative for the ACE deletion (I/I)	5mL EDTA (preferred), ACD, or Citrate whole blood room temperature. (Informed consent required for NY patients.)	83891, 83894, 83898, 83912	Reported as Negative (I/I), heterozygous (I/D) or homozygous (D/D) for the deletion mutation.
300565 - Factor XIII Val34Leu Mutation**	No mutation present Val34Leu (Normal-Normal)	5mL EDTA (preferred), ACD, or Citrate whole blood room temperature. (Informed consent required for NY patients.)	83891, 83892, 83894, 83898, 83912	Reported as No mutation present Val34Leu (Normal-Normal); Positive: heterozygous mutation present (Normal-Mutant); Positive: homozygous mutation present (Mutant-Mutant).
304499 - Activated Factor VII Activity**	23 - 163 mU/mL	1mL frozen citrated plasma. Sample MUST be frozen immediately after removing the plasma layer, and must NOT be refrigerated.	85230	

**This procedure may be considered by Medicare and other carriers as investigational and, therefore, may not be payable as a covered benefit for patients.