



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](http://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
<b>Assay Changes Effective January 5, 2010</b>				
<b>300040 - Activated Partial Thromboplastin Time (PTT)</b>	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).
<b>300727 - Homocysteine</b>	No Change	<b>Serum</b> is the only acceptable sample type. We no longer accept citrated plasma.	No Change	Change in methodology from fluorescence polarization to nephelometry. <b>Serum</b> is the only acceptable sample type. We no longer accept citrated plasma.
<b>300215 - Factor X Chromogenic Activity - (not on Oral Anticoagulant)</b>	No Change	No Change	No Change	Test Discontinued. Order 300211 Factor X Chromogenic activity, Vitamin K antagonist therapy
<b>300531 - HPA-1a (PLA-1 Platelet Antigen) Genotyping (PLA2 Polymorphism Detection)</b>	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.
<b>300415 - D-dimer Quantitative (Automated)</b>	<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.
<b>300611 - Stypven Time**</b>	19.9-28.0 seconds	No Change	No Change	Change in reference range from 22.3 -32.0 seconds due to reformulation of reagents.
<b>Test Name Changes Effective January 5, 2010</b>				
<b>300520 - Indirect Antiplatelet Alloantibody Profile</b>	No Change	No Change	No Change	Name change from: <b>Platelet Antibody Screen, Indirect</b>
<b>300524 - Platelet HPA-1a/1b Antibody Identification</b>	No Change	No Change	No Change	Name change from: <b>Platelet Specific Antibody (GP IIB/IIIA)</b>
<b>300211 - Factor X Chromogenic Activity, Vitamin K antagonist therapy</b>	No Change	No Change	No Change	Name change from: <b>Factor X Chromogenic Activity, Oral Anticoagulant Therapy</b>
<b>300995 - Pathologist Interpretation</b>	No Change	No Change	No Change	Name change from: <b>Pathologist Consultation</b>

Test Name/Test Code (Profile Components)	Reference Range	Specimen Requirement	CPT Code	Change/Comments
<b>New Profiles Available January 5, 2010</b>				
<b>304564 - Ristocetin Induced Platelet Aggregation Profile</b> (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				
<b>304584 - Clopidogrel CYP2C19 genotype**</b>	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.
<b>New Tests Now Available</b>				
<b>304457 - Factor XI Antigen**</b>	60 - 150%	1mL frozen citrated plasma	85270	This assay measures the amount of Factor XI protein and is NOT a functional activity assay.
<b>304451 - Factor IX Chromogenic Activity**</b>	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.
<b>300560 - Angiotensin Converting Enzyme Insertion/Deletion Mutation**</b>	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.
<b>300565 - Factor XIII Val34Leu Mutation**</b>	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).
<b>304499 - Activated Factor VII Activity**</b>	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.