



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Esoterix, Inc. dba Colorado Coagulation
8490 Upland Drive, Suite 100
Englewood, Colorado 80112-7116 USA

Fulfills the requirements of

ISO 15189:2022

In the field of

MEDICAL AND CLINICAL LABORATORIES

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to be 'J. Stine', is positioned above a horizontal line.

Jason Stine, Vice President

Expiry Date: 17 January 2027

Certificate Number: AM-2650



This medical laboratory is accredited in accordance with the recognized International Standard ISO 15189:2022.
This accreditation demonstrates technical competence for a defined scope and the operation of a medical laboratory
quality management system ([refer to joint IAF-ILAC-ISO Communiqué dated November 2021](#)).



SCOPE OF ACCREDITATION TO ISO 15189:2022

Esoterix, Inc. dba Colorado Coagulation

8490 Upland Drive, Suite 100
Englewood, Colorado 80112-7116 USA

Roxy Gode, Quality Manager
fajdar@labcorp.com (720) 568-4389

MEDICAL/CLINICAL TESTING

Valid to: **January 17, 2027**

Certificate Number: **AM-2650**

Hematology

Sub-Specialty	Test-Analyte	Method	Matrix
Coagulation	Antithrombin Activity	Chromogenic	Citrated Plasma
Coagulation	Antithrombin Antigen	Nephelometry	Citrated Plasma
Coagulation	Activated Partial Thromboplastin Time (aPTT)	Clot detection	Citrated Plasma
Coagulation	Activated Protein C Resistance (APC-R)	Clot detection	Citrated Plasma
Coagulation	Plasmin Inhibitor Activity (α 2-Antiplasmin)	Chromogenic	Citrated Plasma
Coagulation	Apixaban level Anti-factor Xa	Chromogenic	Citrated Plasma
Coagulation	C4b Binding Protein	Latex Immunoagglutination	Citrated Plasma
Coagulation	Platelet Aggregation, Comprehensive	Platelet Aggregation	Citrated Whole Blood
Coagulation	D-Dimer Quantitative (Automated)	Latex Immuno-agglutination	Citrated Plasma
Coagulation	Dilute Russell's Viper Venom Test (dRVVT)	Clot detection	Citrated Plasma
Coagulation	Edoxaban level Anti-factor Xa	Chromogenic	Citrated Plasma

Hematology

Sub-Specialty	Test-Analyte	Method	Matrix
Coagulation	Euglobulin Lysis Time	Turbidimetric	Citrated Plasma
Coagulation	Factor II Activity (Prothrombin Activity)	Clot detection	Citrated Plasma
Coagulation	Factor II Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor V Activity	Clot detection	Citrated Plasma
Coagulation	Factor V Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor VII Activity	Clot detection	Citrated Plasma
Coagulation	Factor VII Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor VIII Activity, Chromogenic	Chromogenic	Citrated Plasma
Coagulation	Factor VIII Inhibitor, Nijmegen modification	Clot detection	Citrated Plasma
Coagulation	Factor VIII Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor VIII Inhibitor Nijmegen modification	Chromogenic	Citrated Plasma
Coagulation	Factor VIII Activity One Stage Clot	Clot detection	Citrated Plasma
Coagulation	Factor IX Activity One Stage Clot	Clot detection	Citrated Plasma
Coagulation	Factor IX Activity Chromogenic	Chromogenic	Citrated Plasma
Coagulation	Factor IX Inhibitor Bethesda Titer	Clot detection	Citrated Plasma
Coagulation	Factor IX Inhibitor Nijmegen modification	Clot detection	Citrated Plasma
Coagulation	Factor X Activity One Stage Clot	Clot detection	Citrated Plasma
Coagulation	Factor X Activity Chromogenic	Chromogenic	Citrated Plasma

Hematology

Sub-Specialty	Test-Analyte	Method	Matrix
Coagulation	Factor X Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor XI Activity	Clot detection	Citrated Plasma
Coagulation	Factor XI Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor XII Activity	Clot detection	Citrated Plasma
Coagulation	Factor XII Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor XIII Activity	Chromogenic	Citrated Plasma
Coagulation	Fibrin Degradation Products	Latex Agglutination	Citrated Plasma
Coagulation	Fibrinogen Activity	Clot detection	Citrated Plasma
Coagulation	Fibrinogen Antigen	Nephelometry	Citrated Plasma
Coagulation	Fitzgerald Factor Assay (High Molecular Weight Kininogen)	Clot detection	Citrated Plasma
Coagulation	Fletcher Factor Assay (Prekallikrein)	Clot detection	Citrated Plasma
Coagulation	Fondaparinux level Anti-factor Xa	Chromogenic	Citrated Plasma
Coagulation	Low Molecular Weight Heparin Anti-factor Xa	Chromogenic	Citrated Plasma
Coagulation	Unfractionated Heparin level Anti-factor Xa	Chromogenic	Citrated Plasma
Coagulation	Heparin Cofactor II	Chromogenic	Citrated Plasma
Coagulation	Hexagonal Phospholipid Neutralization	Clot detection	Citrated Plasma
Coagulation	Kaolin Clotting Time	Clot detection	Citrated Plasma
Coagulation	Mixing Studies	Clot detection	Citrated Plasma

Hematology

Sub-Specialty	Test-Analyte	Method	Matrix
Coagulation	Plasminogen Activity	Chromogenic	Citrated Plasma
Coagulation	Plasminogen Antigen	Nephelometry	Citrated Plasma
Coagulation	Platelet Neutralization Procedure (PNP)	Clot detection	Citrated Plasma
Coagulation	Protein C Activity (Chromogenic)	Chromogenic	Citrated Plasma
Coagulation	Protein S Activity	Clot detection	Citrated Plasma
Coagulation	Protein S Antigen, Free	Immuno-turbidimetric	Citrated Plasma
Coagulation	Protein S Antigen, Total	Immuno-turbidimetric	Citrated Plasma
Coagulation	Prothrombin Time / INR	Clot detection	Citrated Plasma
Coagulation	Reptilase Time	Clot detection	Citrated Plasma
Coagulation	Thrombin Time	Clot detection	Citrated Plasma
Coagulation	Tissue Thromboplastin Inhibition Test	Clot detection	Citrated Plasma
Coagulation	Von Willebrand Factor activity (ristocetin cofactor)	Platelet Agglutination	Citrated Plasma
Coagulation	von Willebrand Factor Antigen	Immunoagglutination	Citrated Plasma
Coagulation	von Willebrand Factor Antigen	ELISA	Citrated Plasma
Coagulation	von Willebrand Factor Inhibitor	Platelet Agglutination	Citrated Plasma
Coagulation	von Willebrand Factor Multimers	Electrophoresis / Western Blot	Citrated Plasma
Coagulation	Thrombin Generation Assay	Fluorometric	Citrated Plasma
Molecular	Apolipoprotein E genotyping	PCR	EDTA (preferred), ACD or Citrate whole blood

Hematology

Sub-Specialty	Test-Analyte	Method	Matrix
Molecular	Factor II G20210A (Prothrombin Gene) mutation	PCR	EDTA (preferred), ACD or Citrate
Molecular	Factor V Mutation (Leiden)	PCR	EDTA (preferred), ACD, or Citrate
Molecular	HPA-1a (PLA1 Platelet Antigen) Genotyping (PLA2 Polymorphism Detection)	ARMS	EDTA (preferred), ACD, or Citrate
Molecular	Plasminogen Activator Inhibitor-1, 4G/5G Mutation	PCR & RFLP	EDTA (preferred), ACD, or Citrate
Molecular	R2 Haplotype (A4070G) By PCR-RFLP (Factor V R2 DNA Analysis)	PCR	EDTA (preferred), ACD, or Citrate

Chemistry

Sub-Specialty	Test-Analyte	Method	Matrix
Diagnostic Immunology	Aspirin Works 11-dehydrothromboxan B2	ELISA	Urine
Diagnostic Immunology	Collagen Binding Assay	ELISA	Citrated Plasma
Diagnostic Immunology	D Dimer	ELISA	Citrated Plasma
Diagnostic Immunology	Factor VII Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Factor VIII Antibody (Immunologic)	ELISA	Citrated Plasma
Diagnostic Immunology	Factor VIII Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Factor VIII antigen B-Domain Deleted	ELISA	Citrated Plasma
Diagnostic Immunology	Factor IX Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Factor X Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Matrix Metalloproteinase-9 (MMP-9)	ELISA	Serum
Diagnostic Immunology	Plasminogen Activator Inhibitor type I (PAI-1) Activity	ELISA	Citrated Plasma



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Sub-Specialty	Test-Analyte	Method	Matrix
Diagnostic Immunology	Plasminogen Activator Inhibitor type I (PAI-1) Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Protein C Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Prothrombin Fragment 1.2	ELISA	Citrated Plasma
Diagnostic Immunology	Thrombin-Antithrombin Complex	ELISA	Citrated Plasma
Diagnostic Immunology	Tissue-type Plasminogen Activator (tPA) antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Total Tissue Factor Pathway Inhibitor Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Anticardiolipin Antibodies IgG, IgA, IgM	ELISA	Serum
Diagnostic Immunology	Anti-β2 Glycoprotein I Antibodies IgG, IgA, IgM	ELISA	Serum
Diagnostic Immunology	Antiphosphatidylserine Antibodies, IgG, IgA, IgM	ELISA	Serum
Diagnostic Immunology	Antiprothrombin Antibodies, IgG	ELISA	Serum
Diagnostic Immunology	Anti-phosphatidylserine/prothrombin (PS/PT) complex antibodies, IgG, IgM	ELISA	Serum
Diagnostic Immunology	Anti-Annexin V Antibodies, IgG, IgM	ELISA	Serum
General	C-Reactive Protein, high sensitivity	Nephelometry	Serum
General	Homocysteine	Nephelometry	Serum
General	Lipoprotein (a)	NEPHELOMETRY	Serum

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AM-2650.

Jason Stine, Vice President