



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

Esoterix, Inc. dba Colorado Coagulation

8490 Upland Drive, Suite 100

Englewood, Colorado 80112-7116 USA

has been assessed by ANAB and meets the requirements of international standard

ISO 15189:2012

while demonstrating technical competence in the fields of

MEDICAL AND CLINICAL LABORATORIES

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AM-2650

Certificate Number



ANAB Approval

Certificate Valid Through: 01/17/2021
Version No. 001 Issued: 01/17/2019



SCOPE OF ACCREDITATION TO ISO 15189:2012

Esoterix, Inc. dba Colorado Coagulation

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MEDICAL/CLINICAL TESTING

Valid to: **January 17, 2021**

Certificate Number: **AM-2650**

Hematology

Sub-Specialty	Test-analyte	Method	Matrix
Coagulation	Heparin, Anti-IIa	Chromogenic	Citrated Plasma
Coagulation	Antithrombin Activity	Chromogenic	Citrated Plasma
Coagulation	Heparin, Anti-Xa	Chromogenic	Citrated Plasma
Coagulation	aPTT	Clot detection	Citrated Plasma
Coagulation	Clopidogrel (Plavix) Response by Whole Blood Lumi-Aggregation	Platelet Aggregation	Citrated Whole Blood
Coagulation	Comprehensive Platelet Aggregation	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, Anti-Xa	Chromogenic	Citrated Plasma
Coagulation	Euglobulin Lysis Time	Turbidimetric	Citrated Plasma
Coagulation	Factor Inhibitor Screen	Clot detection	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

Hematology

Sub-Specialty	Test-analyte	Method	Matrix
Coagulation	Factor VII Activity	Clot detection	Citrated Plasma
Coagulation	Factor VII Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor VIII Activity	Clot detection	Citrated Plasma
Coagulation	Factor VIII Activity (LA Insensitive)	Clot detection	Citrated Plasma
Coagulation	FVIII Chromogenic	Chromogenic	Client Product
Coagulation	FVIII Chromogenic	Chromogenic	Citrated Plasma
Coagulation	FVIII Nijmegen	Clot detection	Citrated Plasma
Coagulation	FVIII Nijmegen	Clot detection	Client Product
Coagulation	Factor VIII Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	FVIII One Stage Clot	Clot detection	Citrated Plasma
Coagulation	FVIII One Stage Clot	Clot detection	Client Product
Coagulation	Factor IX Activity	Clot detection	Citrated Plasma
Coagulation	Factor IX Activity (LA Insensitive)	Clot detection	Citrated Plasma
Coagulation	Factor IX Bethesda Titer (F IX Activity and Bethesda Titer only)	Clot detection	Citrated Plasma
Coagulation	FIX Nijmegen	Clot detection	Citrated Plasma
Coagulation	Factor IX activity One Stage Clot	Clot detection	Client Product
Coagulation	Rebinyx FIX Activity	Clot detection	Citrated Plasma
Coagulation	Rebinyx FIX Inhibitor	Clot detection	Citrated Plasma
Coagulation	Factor X Activity	Clot detection	Citrated Plasma
Coagulation	Factor X Chromogenic Activity, Vitamin K Antagonist Therapy	Chromogenic	Citrated Plasma
Coagulation	Factor X Inhibitor (Bethesda Titer)	Clot detection	Citrated Plasma
Coagulation	Factor XI Activity	Clot detection	Citrated Plasma

Hematology

Sub-Specialty	Test-analyte	Method	Matrix
Coagulation	Factor XI Activity (LA Insensitive)	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 (Research Use Only)	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 (HMW Kininogen)	Clot detection	Citrated Plasma
Coagulation	Fletcher Factor Assay (Prekallikrein)	Clot detection	Citrated Plasma
Coagulation	Heparin Anti-Xa Fondaparinux	Chromogenic	Citrated Plasma
Coagulation	Heparin Anti-Xa LMWH	Chromogenic	Citrated Plasma
Coagulation	Heparin Anti-Xa Unfractionated	Chromogenic	Citrated Plasma
Coagulation	Heparin Cofactor II (Research Use Only)	Chromogenic	Citrated Plasma
Coagulation	Hexagonal Phospholipid Neutralization	Clot detection	Citrated Plasma
Coagulation	Kaolin Clotting Time	Clot detection	Citrated Plasma
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

Hematology

Sub-Specialty	Test-analyte	Method	Matrix
Coagulation	Prothrombin Time / INR	Clot detection	Citrated Plasma
Coagulation	Prothrombin Time Mixing Studies	Clot detection	Citrated Plasma
Coagulation	Reptilase Time	Clot detection	Citrated Plasma
Coagulation	Ristocetin Induced Platelet Aggregation (VWD Type 2B Evaluation)	Platelet Aggregation	Citrated Whole Blood
Coagulation	Thrombin Generation Assay	Fluorometric	Citrated Plasma
Coagulation	Thrombin Time	Clot detection	Citrated Plasma
Coagulation	Thrombin Time Mixing Studies	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 Multimers	Electrophoresis / Western Blot	Citrated Plasma
Molecular	CYP450 3A4/3A5	Multiplex PCR	Buccal Swab, EDTA/ACD Whole Blood
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	Methylene tetrahydrofolate reductase (MTHFR) C677T and A1298C mutations	PCR	EDTA (preferred), ACD, or Citrate
Molecular	CYP450 CYP2C19 Genotyping	Multiplex PCR, Allele Specific Primer Extension, Bead Hybridization	EDTA, ACD, whole blood, or 4 buccal swab pack.
Molecular	CYP450 CYP2D6 Genotyping	Multiplex PCR, Allele Specific Primer Extension, Bead Hybridization	EDTA, ACD, whole blood, or 4 buccal swab pack.
Molecular	Plasminogen Activator Inhibitor-1, 4G/5G Mutation	PCR & RFLP	EDTA (preferred), ACD, or Citrate

Hematology

Sub-Specialty	Test-analyte	Method	Matrix
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	Collagen Binding Assay	ELISA	Citrated Plasma
Diagnostic Immunology	D Dimer	ELISA	Citrated Plasma
Diagnostic Immunology	F VII Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Factor VIII Antibody (Immunologic)	ELISA	Citrated Plasma
Diagnostic Immunology	F VIII Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	F IX Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	F X Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	F VIII antigen B-Domain Deleted	ELISA	Citrated Plasma
Diagnostic Immunology	Heparin-Induced Antibody (includes HITA and normalized OD ratio)	ELISA	Frozen serum
Diagnostic Immunology	Plasmin-antiplasmin Complex	ELISA	Citrated Plasma
Diagnostic Immunology	Plasminogen Activator Inhibitor type I (PAI-1) Antigen	ELISA	Citrated Plasma
Diagnostic Immunology	Plasminogen Activator Inhibitor type I (PAI-1) Activity	ELISA	Citrated Plasma
Diagnostic Immunology	Platelet Factor IV	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



Chemistry

Sub-Specialty	Test-analyte	Method	Matrix
Diagnostic Immunology	Total Tissue Factor Pathway Inhibitor Antigen	ELISA	Citrated Plasma
General	High Sensitivity C-Reactive Protein	Nephelometry	Frozen serum
General	Homocysteine	Nephelometry	Frozen serum
General	Lipoprotein (a)	NEPHELOMETRY	Frozen serum
General	MMP-9 (Matrix Metalloproteinase-9) (Research Use Only)	ELISA	Frozen serum

Note:

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



Vice President

