Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

U K A S MEDICAL

Accredited to ISO 15189:2012

East Kent Hospitals University NHS Foundation Trust

Issue No: 003 Issue date: 12 April 2019

Haemostasis & Thrombosis

Laboratory

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Testing performed by the Organisation at the locations specified below

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUID'S	Diagnostic Haemostasis Haemostasis and thrombosis examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:
Blood	Routine Coagulation testing for: Activated partial thromboplastin time (APTT) Prothrombin time (INR) Clauss fibrinogen (FIBC) Thrombin time (TT) Reptilase time (REPT) Activated partial thromboplastin time (APTT) 50/50 Prothrombin time (INR) 50/50 International Normalised ratio	STA-R Max - Viscosity automated analyser, Viscosity Detection method and in-house procedures: HPA-LP-203, HPA-LP-206, HPA- LP-205
Blood	D Dimer	STA-R Max automated analyser, immunoturbidimetric assay using procedure HPA-LP-208.
Blood	Von Willebrand Factor Antigen	STA-R Max Evolution, immunoturbidimetric assay and in-house procedure: HPA-LP-157,
Blood	Free Protein S Assay	STA-R Max, immunoturbidimetric assay and inhouse procedure HPA-LP-159

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Diagnostic Haemostasis (cont'd)	
(,	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:
Blood	Detection of: Factor II Factor V Factor VII Factor X Factor XI Factor XII	STA-R Max - Viscosity method and in-house procedures: HPA-LP-213 and HPA-LP-212
	Inhibitor assay (Bethesda) for the determination of inhibitors to factor VIII and factor IX	Bethesda assay STA-R Evolution automated analyser, viscosity clot detection using procedure HPA-LP-182.
Blood	Detection of Factor VIII Factor VIII refacto Factor IX	STA-R Max – Viscosity method and in-house procedures: HPA-LP-192, HPA-LP-212
Blood	Dilute Russells viper venom time screen & confirmation for detection of Lupus Anticoagulants Kaolin clotting time	STA-R Evolution – Viscosity method and inhouse procedure: HPA-LP-063
Blood	Anti Xa assay LMWH Anti Xa assay rivaroxaban Anti Xa assay apixaban	STA-R Max – Chromogenic assay and in-house procedures: HPA-LP-158, HPA-LP-196- and, HPA-LP-232.
Blood	Protein C chromogenic activity assay Antithrombin chromogenic activity assay	STA-R Max – Chromogenic assay and in-house procedures: HPA-LP-155 and HPA-LP-160
Blood	Platelet function analysis	PFA-100 system, pressure transduction endpoint detection using procedure HPA-LP-041.
Blood	Protein C clotting based Assay	STA-R Evolution – Viscosity method and inhouse procedures: HPA-LP-1698

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HUMAN BODY FLUIDS (cont'd)	Diagnostic Haemostasis (cont'd)		
	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
Blood	Functional Protein S Assay	STA-R Max – Viscosity method and in-house proedures: HPA-LP-169	
Blood	Detection of Factor XIII	Horiba Pentra 400 – Photometric method and in-house procedure: HPA-LP-074	
Blood	Heparin induced thrombocytopenia assay (HIT) von Willebrand Assay CBA Antithrombin antigen assay	Dynex DS2 - Manual ELISA and in-house procedures: HPA-LP-032, HPA-LP-047, HPA-LP-164	
Blood	International Normalised Ratio	Thrombotrak – Viscosity and in-house procedure: HPA-LP-027	
Blood	Von Willebrand Activity Assay(Ristocetin cofactor activity assay) Platelet aggregation studies	PAP 8 Aggregometer, light transmission aggregometry and in-house procedure: HPA-LP-170, HPA-LP-171	
Blood	Platelet nucleotide analysis	GloMax 20/20 Luminometer, Luminescence of the luciferase reaction using in-house procedure: HPA-LP-043	
Blood	Anti-Cardiolipin Antibody assays Anti-Beta-2-Glycoprotein 1 Antibody assays	DS2 - Automated Enzyme-Linked - Immunosorbent assay (ELISA) using in-house procedures: HPA-LP-035 and HPA-LP-030	
	Molecular Haemostasis		
Blood	Detection of: Factor V Leiden Prothrombin G20210A	Light cycler 1.5 - Polymerase Chain Reaction (PCR) with fluorigenic target-specific hybridization and in-house procedures: HPA-LP-134 & HPA-LP-135.	
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