


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9397 Accredited to ISO 15189:2022	East Kent Hospitals University NHS Foundation Trust	
	Issue No: 006 Issue date: 12 December 2024	
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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	<u>Diagnostic Haemostasis</u>	
	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>	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 immunoturbidimetric assay and in-house procedure: HPA-LP-157,
Blood	Free Protein S Assay	STA-R Max, immunoturbidimetric assay and in-house 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)	<u>Diagnostic Haemostasis</u> (cont'd)	
	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (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	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



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HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u> (cont'd)	
	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods
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	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	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
END		