


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9397</p> <p>Accredited to ISO 15189:2012</p>	<h3>East Kent Hospitals University NHS Foundation Trust</h3> <p>Issue No: 004 Issue date: 28 February 2022</p>	
	<p>Haemostasis & Thrombosis Laboratory East Kent Haemophilia and Thrombosis Centre Kent and Canterbury Hospital Ethelbert Road Canterbury CT1 3NG United Kingdom</p>	<p>Contact: Kim Elliott Tel: +44 (0) 1227 866329 E-Mail: kim.elliott1@nhs.net Website: www.ekhuft.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

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>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:</p> <p>STA-R Max - Viscosity automated analyser, Viscosity Detection method and in-house procedures: HPA-LP-203, HPA-LP-206, HPA-LP-205</p> <p>STA-R Max automated analyser, immunoturbidimetric assay using procedure HPA-LP-208.</p> <p>STA-R Max immunoturbidimetric assay and in-house procedure: HPA-LP-157,</p> <p>STA-R Max, immunoturbidimetric assay and in-house procedure HPA-LP-159</p>
Blood	<p><u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u></p> <p>Routine Coagulation testing for:</p> <p>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</p>	
Blood	D Dimer	
Blood	Von Willebrand Factor Antigen	
Blood	Free Protein S Assay	



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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	Dilute Russells viper venom time screen & confirmation for detection of Lupus Anticoagulants Kaolin clotting time	STA-R Evolution – Viscosity method and in-house 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 in-house procedures: HPA-LP-1698



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HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods: STA-R Max – Viscosity method and in-house proedures: HPA-LP-169 Horiba Pentra 400 – Photometric method and in-house procedure: HPA-LP-074 Dynex DS2 - Manual ELISA and in-house procedures: HPA-LP-032, HPA-LP-047, HPA-LP-164 Thrombotrak – Viscosity and in-house procedure: HPA-LP-027 PAP 8 Aggregometer, light transmission aggregometry and in-house procedure: HPA-LP-170 , HPA-LP-171 DS2 - Automated Enzyme-Linked - Immunosorbent assay (ELISA) using in-house procedures: HPA-LP-035 and HPA-LP-030
	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (cont'd)	
Blood	Functional Protein S Assay	
Blood	Detection of Factor XIII	
Blood	Heparin induced thrombocytopenia assay (HIT) von Willebrand Assay CBA Antithrombin antigen assay	
Blood	International Normalised Ratio	
Blood	Von Willebrand Activity Assay(Ristocetin cofactor activity assay) Platelet aggregation studies	
Blood	Anti-Cardiolipin Antibody assays Anti-Beta-2-Glycoprotein 1 Antibody assays	
END		