

issued by

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



East Kent Hospitals University NHS Foundation Trust

Issue No: 007 Issue date: 01 October 2025

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Testing performed by the Organisation at the locations specified below

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> Routine Coagulation testing for:	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:
Citrated plasma	Activated partial thromboplastin time (APTT) Prothrombin time (PT) Clauss fibrinogen (FIBC) Thrombin time (TT) APTTR ratio (APTTR) International Normalised ratio (INR) Reptilase time (REPT) Extended APTT	STA-R Max 3- analyser by chronometric method and in-house procedures: HPA-LP-203 HPA-LP-254 HPA-LP-255
Citrated plasma	D Dimer	STA-R Max 3 automated analyser, immunoturbidimetric assay using procedure HPA-LP-253
Citrated plasma	Von Willebrand Factor Antigen	STA-R Max immunoturbidimetric assay and in-house procedure: HPA-LP-157,
Citrated plasma	Free Protein S Assay	STA-R Max, immunoturbidimetric assay and in-house procedure HPA-LP-159



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Schedule of Accreditation
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United Kingdom Accreditation Service
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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:
Citrated plasma	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
Citrated plasma	Detection of inhibitors to factor VIII and factor IX	Bethesda assay using STA-R Max automated coagulation analyser by one sage viscosity-based clot detection HPA-LP-256
Citrated plasma	Detection of Factor VIII Factor VIII refacto Factor IX	STA-R Max – Viscosity method and in-house procedures: HPA-LP-192, HPA-LP-212
Citrated plasma	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.
Citrated plasma	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
Citrated plasma	Lupus anticoagulant detection: Dilute Rissell Viper Venom (dRVVT) APTT	STA-R Max automated coagulation analyser by viscosity-based clot detection HPA-LP-251



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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
Citrated plasma	Detection of Factor XIII	Horiba Pentra 400 – Photometric method and in-house procedure: HPA-LP-074
Serum	Heparin induced thrombocytopenia assay (HIT)	Dynex DS2 - Manual ELISA and in-house procedures: HPA-LP-032
Citrated plasma	von Willebrand Assay CBA Antithrombin antigen assay	Dynex DS2 - Manual ELISA and in-house procedures: HPA-LP-047, HPA-LP-164
Citrated plasma	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
Serum	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
EDTA whole blood	Prothrombin gene mutation (G20210A)	PCR using GeneXpert analyser HPA-LP-248
EDTA whole blood	Factor V Leiden G1691A genotyping	PCR using GeneXpert analyser HPA-LP-248
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