


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8595</p> <p>Accredited to ISO 15189:2012</p>	<h3>Viapath Analytics LLP</h3> <p>Issue No: 011 Issue date: 02 July 2021</p>	
	<p>Haemostasis & Thrombosis Department St. Thomas' Hospital Westminster Bridge Road London SE1 7EH United Kingdom</p>	<p>Contact: Malinie Naidoo Tel: +44 (0)207 188 6815 Fax: +44 (0)207 188 2726 E-Mail: Malinie.Naidoo@viapath.co.uk Website: www.viapath.co.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>St. Thomas' Hospital Haemostasis and Thrombosis Department 4th Floor North Wing Westminster Bridge Road London SE1 7EH</p> <p>Local contact Malinie Naidoo (Details as above)</p>	<p>Diagnostic Haemostasis (routine and specialist testing) Molecular Haemostasis Nutristasis – Vitamin Assays</p>	T4NW
<p>St. Thomas' Hospital 5th Floor North Wing Westminster Bridge Road London SE1 7EH</p> <p>Local contact Malinie Naidoo (Details as above)</p>	<p>Diagnostic Haemostasis (routine coagulation testing)</p>	T5NW
<p>Guy's Hospital Ground Floor Tabard Annex Great Maze Pond London SE1 9RT</p> <p>Local contact Malinie Naidoo (Details as above)</p>	<p>Diagnostic Haemostasis (routine coagulation testing)</p>	GTA
<p>Guy's Hospital 4th Floor Southwark Wing Great Maze Pond London SE1 9RT</p> <p>Local contact Malinie Naidoo (Details as above)</p>	<p>Diagnostic Haemostasis (routine coagulation testing)</p>	GSW



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Diagnostic Haemostasis</u>		
	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:	
	Routine Coagulation testing for:		
Blood	Activated partial thromboplastin time (APTT) Prothrombin time (INR) Clauss fibrinogen (FIBC) Thrombin time (TT) Reptilase time (REPT)	Sysmex CS2100i automated analyser, Transmitted Light Detection method and in-house procedure: HT-SOP-HSR-035	T4NW T5NW GTA GSW
Blood	Activated partial thromboplastin time (APTT) Prothrombin time (INR)	KC4 coagulometer, mechanical clot detection method and in-house procedure: HT-SOP-HSR-027	T5NW GTA
Blood	Clauss fibrinogen (FIBC)	KC4 coagulometer, mechanical clot detection method and in-house procedure: HT-SOP-HSR-027	T5NW
Blood	D-dimers	Sysmex CS2100i automated analyser, Immunoassay method and in-house procedure: HT-SOP-HSR-035 HT-SOP-HSR-036	T4NW T5NW GSW
Blood	Detection of: FVIII Activity Factor XIII activity FVIII inhibitors by determination of FVIII activity	Sysmex CS2100i, Chromogenic method and in-house procedures: HT-SOP-HSA-049 HT-SOP-HSA-044 HT-SOP-HSA-038 (Nijmegen Bethesda assay)	T4NW



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u> (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: Sysmex CS2100i, one-stage clotting methods and in-house procedures:	T4NW
Blood	Dose response curves for one-stage clotting assays: Factor II, V, VII, VIII, IX, X, XI, XII	HT-SOP-HSA-041	
Blood	High Molecular Weight Kininogen (Fitzgerald factor) Prekallikrein (Fletcher factor)	HT-SOP-HSA-040	
Blood	Intrinsic One-Stage Factor Assays: Factor VIII, IX, XI, XII	HT-SOP-HSA-036	
Blood	Extrinsic factor (VII) and common pathway factors (II, V & X)	HT-SOP-HSA-035	
Blood	Non-FVIII inhibitors	HT-SOP-HSA-037 (Bethesda assay)	
Blood	Anti-factor VIII antibody	Manual ELISA method with endpoint measurement using DYNEX DS2 using in-house procedure: HT-SOP-HSA-032	T4NW
Blood	Platelet dysfunction detection	PFA-100 System, using in-house procedure: HT-SOP-HSP-001	T4NW
Blood	Platelet nucleotide analysis	Luminometer, luminescence of the luciferase reaction using in-house procedure: HT-SOP-HSP-004	T4NW



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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:	
Blood	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) von Willebrand Factor Ristocetin Induced Platelet Aggregation (RIPA)	Platelet aggregation using Biodata PAP-8 Platelet Aggregometer and using in-house procedures: HT-SOP-HSP-006	T4NW
Blood	Platelet function testing	Platelet aggregation, turbidimetric method, using Biodata PAP-8 Platelet Aggregometer and in-house procedure: HT-SOP-012	T4NW
Blood	Platelet aggregation and ATP release	Platelet aggregometry using Chronolog and in-house procedure: HT-SOP-HSP-011	T4NW
Blood	von Willebrand Factor multimer analysis	Pharmacia Phast Method, electrophoresis using in-house procedure: HT-SOP-HSP-014	T4NW
Blood	Plasma and platelet fibrinogen Antigen	DYNEX DS2, Sandwich ELISA using in-house procedures: HT-SOP-HST-088	T4NW



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HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u> (cont'd)		
Blood	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) ADAMTS13 Activity Protein C antigen FVIII antigen ADAMTS13 Inhibitor Assay Thrombin / antithrombin complex Prothrombin fragment 1+2 FIX Antigen Factor XI Antigen Factor X Antigen Factor II Antigen FVII Antigen Factor V Antigen Antiprothrombin antibody assays (IgG and IgM)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods: DYNEX DS2, ligandsorbent ELISA using in-house procedures: HT-SOP-HSA-086 HT-SOP-HST-089 HT-SOP-HST-090 HT-SOP-HST-091 HT-SOP-HST-092 HT-SOP-HST-093 HT-SOP-HST-096 HT-SOP-HST-097 HT-SOP-HST-098 HT-SOP-HST-099 HT-SOP-HST-100 HT-SOP-HST-101 HT-SOP-HST-102	T4NW
Blood	Anticardiolipin antibodies Anti B2 glycoprotein VWF antigen VWF collagen binding VWF RICO F Heparin Induced Thrombocytopenia (HIT) IgG	Werfen Bioflash, chemiluminescent immunoassay using in-house procedures: HT-SOP-HST-109 HT-SOP-HST-112 HT-SOP-HST-112 HT-SOP-HSA-050 HT-SOP-HSA-050 HT-SOP-HSA-050 HT-SOP-HSP-017	T4NW



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HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u> (cont'd)		
Blood	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) Anti Xa Antithrombin and Protein C activity assays Plasminogen activity α 2-antiplasmin activity Liquid chromogenic anti Xa assay for direct FXa inhibitors	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods: Sysmex CS2100i/CS2000i, chromogenic method using in-house procedures: HT-SOP-HST-077 HT-SOP-HST-078 HT-SOP-HST-081 HT-SOP-HST-082 HT-SOP-HST-095	T4NW
Blood	Activated Protein C Resistance Lupus anticoagulant screening	Sysmex CS2100i/CS2000i, clotting assays using in-house procedures: HT-SOP-HST-075 HT-SOP-HST-002 HT-SOP-HST-076 HT-SOP-HST-013	T4NW
Blood	Free protein S Antigen Liatest assay Antithrombin antigen	Sysmex CS2100i/CS2000i, immunoturbidimetric assays using in-house procedures: HT-SOP-HST-080 HT-SOP-HST-104	T4NW



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haemostasis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
Blood	Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis	<u>DNA Extraction</u> Automated using QIAcube and in-house procedures: HT-SOP-MGT-027	T4NW
DNA extracted in-house from blood or received as primary sample type from external source	Name of disease, analysed gene(s) or mutation: GP1BA, GP1BB, GP9 mutation screen for Bernard Soulier Syndrome CBS mutation LMAN1, MCFD2 mutation screen for Combined FV & FIII deficiency F2 mutation F5 mutation F13A + F13B mutation FGA + FGB + FGG mutation ITGA2B + ITGB3 mutation screen for Glanzmann Thrombasthenia NBEAL2 mutation MTHFR mutation GP1BA mutation screen for Platelet / Pseudo VWD Targetted VWF mutation screen VKORC1 mutation screen Factor V Cambridge SNP Factor VII 353 G/A SNP Fibrinogen 148 C/T Polymorphism Fibrinogen 455 G/A	<u>PCR amplification, Sanger sequencing and genotyping</u> Using thermal cyclers: PTC 200 ABI 9700 ABI Veriti Bioer GeneTouch and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-010	T4NW



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haemostasis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	T4NW
DNA extracted in-house from blood or received as primary sample type from external source (cont'd)	Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis (cont'd)	<u>PCR amplification, Sanger sequencing and genotyping</u> (cont'd)	
DNA extracted in-house from blood or received as primary sample type from external source (cont'd)	Name of disease, analysed gene(s) or mutation: (cont'd) MTHFR 1298 polymorphism PAI 1 4G/5G promoter polymorphism Apo E Genotype Warfarin Sensitivity/Resistance SNPs Confirmation of familial mutation (any of the diseases, genes or mutations listed above)	HT-SOP-MGD-007 HT-SOP-MGD-004 HT-SOP-MGD-005	T4NW
DNA extracted in-house from blood or received as primary sample type from external source	Apo E Genotype	<u>Amplification Refractory Mutation System (ARMS) PCR and genotyping</u> Using thermal cycler: ABI Veriti and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-020	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>DNA extracted in-house from blood or received as primary sample type from external source</p>	<p><u>Molecular Haemostasis (cont'd)</u></p> <p>Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis (cont'd)</p> <p>Name of disease, analysed gene(s) or mutation: F8 mutation for haemophilia A F9 mutation for haemophilia B F7 mutation F10 mutation Full VWF mutation screen Antithrombin Gene (SERPINC1) mutation PROC mutation PROS1 mutation MYH9 mutation F11 mutation</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:</p> <p><u>PCR amplification, Sanger sequencing and genotyping, and Multiplex Ligation-Dependent Probe Amplification (MLPA)</u></p> <p>Using thermal cyclers: PTC 200 ABI 9700 ABI Veriti Bioer GeneTouch and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-010</p> <p>HT-SOP-MGD-010 & 017</p>	<p>T4NW</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haemostasis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
DNA extracted in-house from blood or received as primary sample type from external source (cont'd)	F8 intron 1 and intron 22 inversions for severe haemophilia A	Inverse PCR and gel electrophoresis detection method using: Using thermal cyclers: PTC 200 ABI 9700 ABI Veriti Bioer GeneTouch and in-house procedures: HT-SOP-MGD-011 HT-SOP-MGD-013	T4NW
DNA extracted in-house from blood or received as primary sample type from external source	Factor V Leiden SNP MTHFR 677C/T polymorphism PT20210 SNP	Allelic Discrimination using ABI 7500 genetic analyser and in-house procedures: HT-SOP-MGD-014	T4NW
Chorionic Villus Amniotic fluid	Pre-natal Diagnosis of inherited bleeding disorders	<u>DNA Extraction</u> Manual using in-house procedures: HT-SOP-MGT-014	T4NW
DNA extracted in-house from Chorionic Villus, Amniotic fluid or received as primary sample type from external source	Name of disease, analysed gene(s) or mutation: GP1BA, GP1BB, GP9 mutation screen for Bernard Soulier Syndrome CBS mutation LMAN1, MCFD2 mutation screen for Combined FV & FIII deficiency	<u>PCR amplification, Sanger sequencing and genotyping</u> Using thermal cyclers: PTC 200 ABI 9700 ABI Veriti Bioer GeneTouch and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-008 HT-SOP-MGD-015	T4NW



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>DNA extracted in-house from Chorionic Villus, Amniotic fluid or received as primary sample type from external source (cont'd)</p>	<p><u>Molecular Haemostasis</u> (cont'd)</p> <p>Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis (cont'd)</p> <p>Pre-natal Diagnosis of inherited bleeding disorders. Name of disease, analysed gene(s) or mutation:</p> <p>F2 mutation F5 mutation F13A + F13B mutation FGA + FGB + FGG mutation ITGA2B + ITGB3 mutation screen for Glanzmann Thrombasthenia NBEAL2 mutation MTHFR mutation GP1BA mutation screen for Platelet / Pseudo VWD Targetted VWF mutation screen F8 mutation screen for haemophilia A F9 mutation screen for haemophilia B F7 mutation F10 mutation Full VWF mutation screen Antithrombin Gene (SERPINC1) mutation PROC mutation PROS1 mutation MYH9 mutation F11 mutation</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:</p> <p><u>PCR amplification, Sanger sequencing and genotyping</u> (cont'd)</p>	<p>T4NW</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Nutristasis testing</u> Nutristasis 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	Vitamin B1 (thiamin diphosphate)	Waters Alliance HPLC with fluorescence detection using in-house procedures: HT-SOP-VKB1-001	T4NW
Blood CSF	Vitamin B2 (FAD, FMN and riboflavin)	HT-SOP-VKB2	
	Vitamin B6 (pyridoxal-5'-phosphate)	HT-SOP-VKB6-001	
	5-methyltetrahydrofolate	HT-SOP-VKF-001	
Blood	Vitamin C (L-Ascorbic acid)	Waters Alliance HPLC with ultraviolet detection using in-house procedures: HT-SOP-VKLAA-001	T4NW
Blood	Methylmalonic acid (MMA)	Liquid chromatography tandem mass spectrometry detection using: Gerstel Multi-Purpose Sampler, Agilent LC-MS/MS and in-house procedures: HT-SOP-VKD-004	T4NW
	Vitamins D2 and D3	HT-SOP-VKD-003	
	25-OH-Vitamin D2/D3 and 3-Epi-25-OH Vitamin D2/D3	HT-SOP-VKR-1	
	Vitamin K1 (phylloquinone) and Vitamin K1 2,3-epoxide	HT-SOP-VKF-007	
Blood	Vitamins A and E	Liquid chromatography tandem mass spectrometry detection using: Gerstel Multi-Purpose Sampler, Waters Acquity UPC ² , Waters Xevo TQS micro MS/MS and in-house procedures: HT-SOP-VKD-008	T4NW



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HUMAN BODY FLUIDS (cont'd) Blood	<u>Nutristasis testing (cont'd)</u> Nutristasis examinations for the purpose of clinical diagnosis (cont'd) Ferritin Vitamin B12 Serum Folate Red Cell Folate 25-OH Vitamin D assay Total Homocysteine Active B12 (Holotranscobalamin) PIVKA II	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods: Abbott Architect i2000SR, Chemiluminescent microparticle immunoassay using in-house procedures: HT-SOP-VKARC-001 HT-SOP-VKH-005 HT-SOP-VKHolo-001 HT-SOP-VKM-013	T4NW
END			