Schedule of Accreditation

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Synnovis Analytics LLP

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

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

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 Routine Coagulation testing for:	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
Blood	Activated partial thromboplastin time (APTT) Prothrombin time (INR) Fibrinogen Clauss (FIBC) Thrombin time (TT)	Sysmex CN6000 (T5NW), CN3000 and CN6500 (T4NW), CN3000 (GSW) automated analyser, Transmitted Light Detection method and in-house procedure: HT-SOP-HSR-047	T5NW T4NW GSW
	Reptilase time (REPT)		GSW T4NW
Blood	PT APTT Clauss Fibrinogen	Stago KC4 Delta analyser semi-automated Mechanical Clot Detection System and in house procedure: HT-SOP-HSR-045	T4NW
Blood	D-dimers	Sysmex CN6000 (T5NW), CN3000 and CN6500 (T4NW), CN3000 (GSW) automated analyser, Immunoassay method and in-house procedure: HT-SOP-HSR-047	T5NW T4NW 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

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-200 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	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
Plasma	von Willebrand Factor Multimer analysis	Sebia Hydrasys 2 semi-automated gel electrophoresis system using Gelscan Sebia PN 1206, PHORESIS software version 8.63 Sebia Hydragel 11 von Willebrand Multimers kit and Sebia von Willebrand Multimer Visualisation kit HT0SOP-HST-121	T4NW
Blood	Total Protein S	Manual ELISA method with endpoint measurement using DYNEX DS2 Manual Total Protein S ELISA assay and in house procedure: HT-SOP-HST-108	T5NW

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:	
		DYNEX DS2, ligandsorbent ELISA using in-house procedures:	T4NW
Blood	ADAMTS13 Activity	HT-SOP-HSA-086	
	FVIII antigen	HT-SOP-HST-090	
	ADAMTS13 Inhibitor Assay	HT-SOP-HST-091	
	Thrombin / antithrombin complex	HT-SOP-HST-092	
	Prothrombin fragment 1+2	HT-SOP-HST-093	
	FIX Antigen	HT-SOP-HST-096	
	Factor XI Antigen	HT-SOP-HST-097	
	Antiprothrombin antibody assays (IgG and IgM)	HT-SOP-HST-102	
		Werfen Bioflash, chemiluminescent immunoassay using in-house procedures:	T4NW
Blood	Anticardiolipin antibodies	HT-SOP-HST-109	
	Anti B2 glycoprotein	HT-SOP-HST-112	
	VWF antigen	HT-SOP-HST-112	
	VWF collagen binding	HT-SOP-HSA-050	
	VWF RICOF	HT-SOP-HSA-050	
	Heparin Induced Thrombocytopenia (HIT) IgG	HT-SOP-HSA-050	
		HT-SOP-HSP-017	

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/CS2000i, chromogenic method using in-house procedures:	T4NW
Blood	Anti Xa	HT-SOP-HST-077	
	Antithrombin and Protein C activity assays	HT-SOP-HST-078	
	Plasminogen activity	HT-SOP-HST-081	
	α2-antiplasmin activity	HT-SOP-HST-082	
	Liquid chromogenic anti Xa assay for direct FXa inhibitors	HT-SOP-HST-095	
Blood	Anti Xa:	Sysmex CN6000 (T5NW), CN6500 (T4NW), CN3000 (GSW) automated analyser, Biophen Chromogenic method using in house procedures:	T5NW T4NW & GSW
	Low Molecular Weight Heparin level	HT-SOP-HST-077	
	Ultrafactionated Heparin level		
	Antithrombin activity (IIa based)	HT-SOP-HST-120	T5NW
		Sysmex CN3000 and CN6500 clotting assays using in-house procedures:	T4NW
Blood	Activated Protein C Resistance	HT-SOP-HST-075	
	Lupus anticoagulant screening by DRVVT, DAPTT, TSVT	HT-SOP-HST-076 HT-SOP-HST-013	
		Sysmex CN3000 and CN6500 chromagenic assay using in house procedures:	T4NW
	Antithrombin activity	HT-SOP-HTR-047	
		Sysmex CN3000 and CN6500 Immune-turbidimetric method using Hyphen Liaphen Protein C kit and in house procedures	
Blood	Protein C Antigen	HT-SOP-HST-125	T4NW

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)		
	Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
		Sysmex CS2100i/CS2000i, immunoturbidimetric assays using in-house procedures:	T4NW
Blood	Free protein S Antigen Liatest assay	HT-SOP-HST-080	
	Antithrombin antigen	HT-SOP-HST-104	
		UPC2-MS/MS using Waters Xevo TQ-S micro mass spectrometer	T4NW
Blood	Warfarin Superwarfarin acenocoumarin	HT-SOP-VKD-012	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haemostasis</u> Detection of nucleic acid sequence variants, deletions, and/or copy number changes for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods:	
Blood		<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 9700ABI Veriti Bioer GeneTouch and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-010	T4NW

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Molecular Haemostasis (cont'd)		
	Detection of nucleic acid sequence variants, deletions, and/or copy number changes 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:	
DNA extracted in-house from blood or received as primary sample type from external source (cont'd)		PCR amplification, Sanger sequencing and genotyping (cont'd)	T4NW
	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	
DNA extracted in-house from blood or received as primary sample type from external source	Apo E Genotype	Amplification Refractory Mutation System (ARMS) PCR and genotyping Using thermal cycler: ABI Veriti and ABI 3130XL DNA Analyser and in-house procedures: HT-SOP-MGD-020	T4NW

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Molecular Haemostasis (cont'd)		
	Detection of nucleic acid sequence variants, deletions, and/or copy number changes 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:	
DNA extracted in-house from blood or received as primary sample type from external source (cont'd)		PCR amplification, Sanger sequencing and genotyping, and Multiplex Ligation-Dependent Probe Amplification (MLPA) Using thermal cyclers: PTC 200 ABI 9700 ABI Veriti Bioer GeneTouch and ABI 3130XL DNA Analyser	T4NW
	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	and in-house procedures: HT-SOP-MGD-010	
	F11 mutation	HT-SOP-MGD-010 & 017	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Molecular Haemostasis</u> (cont'd)		
	Detection of nucleic acid sequence variants, deletions, and/or copy number changes 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:	
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Molecular Haemostasis (cont'd)		
	Detection of nucleic acid sequence variants, deletions, and/or copy number changes 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:	
DNA extracted in-house from Chorionic Villus, Amniotic fluid or received as primary sample type from external source (cont'd)	Pre-natal Diagnosis of inherited bleeding disorders. Name of disease, analysed gene(s) or mutation: 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	PCR amplification, Sanger sequencing and genotyping (cont'd)	T4NW

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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:	
		Waters Alliance HPLC with fluorescence detection using in-house procedures:	T4NW
Blood	Vitamin B2 (FAD, FMN and riboflavin)	HT-SOP-VKB2	
Blood CSF	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
		Liquid chromatography tandem mass spectrometry detection using: Gerstel Multi-Purpose Sampler, Agilent LC-MS/MS and in-house procedures:	T4NW
Blood	Methylmalonic acid (MMA) Vitamins D2 and D3 Vitamin K1 (phylloquinone) and Vitamin K1 2,3-epoxide	HT-SOP-VKD-004 HT-SOP-VKD-003 HT-SOP-VKD-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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Nutristasis testing	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods	
		Liquid chromatography electrospray ionisation tandem mass spectrometry detection using: Gerstel Multi-Purpose Sampler, Agilent LC-ESI-MS/MS and in-house procedures:	T4NW
Blood	Vitamin B1 (Thiamine Pyrophosphate)	HT-SOP-VKD-015	
	Vitamin 6 (Pyridoxl-5'-phosphate)	HT-SOP-VKD-014	
		Abbott Architect i2000SR, Chemiluminescent microparticle immunoassay using in-house procedures:	T4NW
Blood	Ferritin Vitamin B12 Serum Folate Red Cell Folate 25-OH Vitamin D assay Total Homocysteine Active B12 (Holotranscobalamin) PIVKA II	HT-SOP-VKARC-001	
END			