Schedule of Accreditation

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9677 **Accredited to ISO 15189:2012**	**University Hospitals Sussex NHS foundation Trust** **Issue No:** 004 **Issue date**: 07 December 2022	
	The Department of Haematology **Brighton and Sussex Pathology** **The Royal Sussex County Hospital** **Adj Thomas Kemp Tower** **Eastern Road** **Brighton** **BN2 5BE** **United Kingdom**	**Contact: Liza Faustino** **Tel: +44 (0) 1273 696955 ext 3678** **E-Mail: liza.faustino@nhs.net** **Website: www.frontierpathology.nhs.uk/pug/**
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
The Department of Haematology Brighton and Sussex Pathology The Royal Sussex County Hospital Adjacent Thomas Kemp Tower Eastern Road Brighton BN2 5BE	**Local contact:** Liza Faustino (details as above)	• Routine haematology • Routine and Specialised Coagulation • Blood Grouping and antibody screen • Blood & blood product issue • Immunohematology by flow analysis • Management of Blood Fridges	RSCH
Princess Royal Hospital Lewes Rd Haywards Heath RH16 4EX	**Local contact:** Liza Faustino (details as above)	• Routine haematology • Routine Coagulation • Blood Grouping and antibody screen • Blood & blood product issue • Haemoglobinopathy analysis • Management of Blood Fridges	PRH

Site activities performed away from the locations listed above:

Location details	Activity
Queen Victoria Hospital Holtye Road East Grinstead West Sussex RH19 3DZ	Blood storage & issue Fridge managed by Haematology

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>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens	Automated using Ortho Vision analysers and procedure: SOP LPc-HBT-OVA Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH PRH RSCH
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua P–P1 Anti-Chido/Rogers	Automated using Ortho Vision analyser and procedure: SOP LPc-HBT-OVA Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH PRH RSCH
Blood Plasma	Antibody identification by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Automated using Ortho Vision analyser and procedure: SOP LPc-HBT-OVA Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH PRH RSCH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Rh and K phenotyping Rh – C, D, E, c, e Kell - K	Automated using Ortho Vision analysers and procedure SOP LPc-HBT-OVA	RSCH PRH
		Ortho Vision Max at RSCH and procedure: SOP LPc-HBT-OVA	RSCH
Blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens	Manual tube spin agglutination using procedure: SOP LIC-HBT-ManTubeBG	RSCH PRH
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb P–P1 Anti-Chido/Rogers	Manual agglutination using Ortho Column Agglutination and procedure: SOP LPc-HBT-ManOT	RSCH PRH
Plasma	Antibody identification by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Manual agglutination using Ortho Column Agglutination and procedure: SOP LPc-HBT-ManOT	RSCH PRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Plasma	Rh and K phenotyping Rh – C, D, E, c, e Kell - K	Manual agglutination using Ortho Column Agglutination and procedure: SOP LPc-HBT-ManOT	RSCH PRH
Blood Plasma	Compatibility testing of patient's plasma with donor cells	Cross matching using OrthoVision: column agglutination and procedure: SOP LPc-HBT-OVA	RSCH PRH
Blood	Direct Antiglobulin Test (DAT)	OrthoVision: Column Agglutination Technology based on Antibody / Antigen reactions and procedure: SOP LPc-HBT-OVA	RSCH PRH
Blood Plasma	Antibody investigation by detection, identification and quantification of: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	OrthoVision: Column Agglutination IAT technology and procedure: SOP LPc-HBT-OVA	RSCH PRH
Blood	Foetal Maternal Haemorrhage	Kleihauer Acid Elution Technique Using procedure: SOP LPC-HBT-KLEIHAUER	RSCH PRH
	Haematological examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Erythrocyte Sedimentation Rate (ESR)	Automated Starrsed analysers, modified Westergren method SOPs LPc-HHA-ESRAutoComp	RSCH PRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	Sysmex XN automated analysers, differential laser light scatter: Sysmex XN-2000 SOP LPc-HHA-ProcFBC Sysmex XN-9000 SOP LPc-HHA-ProcFBC	 PRH RSCH
Plasma Serum	Infectious Mononucleosis Screening (IM heterophile antibodies)	Biokit Monogen commercial kit, latex micro particle immunoassay SOP LPc-HHA-GFScreen	RSCH PRH
Blood	Malaria pLDH and HRP2 antigens	CareStart Malaria test kit SOP LPc-HHA-CareSMalaria	RSCH PRH
	Haemoglobinopathy examinations for the purpose of clinical diagnosis		
Blood	Sickle cell solubility	Streck Sickledex Solubililty Kit SOP LPc-HHA-SICKLEDEX	RCSH PRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemoglobinopathy examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Haemoglobinopathy analysis (Adult and Antenatal) by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E	BioRad Variant II analyser, HPLC SOP LPb-HHA-HBOPATHVARII	PRH
	Detection and confirmation of: HbAC HbAE HbSS HbSC	SebiaHydrasys electrophoresis SOP LPb-HHA-HBE	PRH
	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma	Routine Coagulation testing for: Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) International Normalised Ratio (INR) D-Dimer	Stago STA-Rmax- Viscosity and photometric based end point detection and in-house procedures: LPc-HCO-STARMaxRout LPc-HCO-STARMaxddim LPc-HCO-STARMaxMaint	RSCH PRH
Plasma	Inhibitor Screen	LPc-HCO-Inhibitor	RSCH
	Thrombin Time Reptilase Time	LPc–HCO-Star Max Thrombin and Reptilase Time	RSCH PRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma	Inherited Thrombophilia Screen: Antithrombin activity Protein C activity Free Protein S antigen APC resistence Lupus Anticoagulant (DRVVT)	Stago STAR Max- Photometric technique and in-house procedures: LPc-HCO-Star Max Antithrombin LPc-HCO-Star Max Protein C LPc-HCO-Star Max Free Protein S LPc-HCO-Star Max APC Resistance LPc-HCO-Star Max DRVVT	RSCH
Plasma	VWF analysis - antigen and activity	Photometric technique LPc–HCO-Star Max VWF:Antigen and LPc–HCO-Star Max VWF:RCoF	RSCH
Plasma	Anti-Xa DOACs: Rivaroxaban, Apixaban, Edoxaban and Dabigatran. LMW heparins	Stago STA-R Max. Photometric technique LPc-HCO-AntiXa LPc-HCO-Dabigatran	RSCH PRH
Plasma	HIT screen	STiC Expert HIT -Technique based on lateral flow and procedure: LPc–HCO-STiC Expert HIT	RSCH PRH
Plasma	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	Stago STA-Rmax Photometric Technique optical end-point detection and in-house procedures: LPc-HCO-Star Max Factor II Assay LPc-HCO-Star Max Factor V Assay LPc-HCO-Star Max Factor VII Assay LPc-HCO-Star Max Factor VIII Assay LPc-HCO-Star Max Factor IX Assay LPc-HCO-Star Max Factor X Assay LPc-HCO-Star Max Factor XI Assay LPc-HCO-Star Max Factor XII Assay	RSCH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone marrow	Blood / bone marrow film analysis	May Grunwald-Giemsa staining Manual microscopy SOPs LPc-HHA-Filmprep	RSCH PRH
Blood	Blood film analysis	Automated Aerospray slide stainer SOP LPc-HHA-AEROSPRAY Automated Stainer SP10 SOP LPa-HHA-SP10Use	RSCH PRH RSCH
Blood	Detection & speciation (thin films) of malaria parasites: *Plasmodium falciparum* *Plasmodium malariae* *Plasmodium ovale* *Plasmodium vivax*	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy LPc-HHA-BLOODPARA	RSCH PRH
Bone Marrow	Iron deposits	Light microscopy following Perl's Prussian Blue iron staining using procedure: LPa-HHA-BoneMarrow	RSCH
Blood Bone Marrow	Acute Leukaemia antigen detection and quantification. Panel to include (cont'd): CD-64 CD-117 HLA-DR Cy-CD-3 Cy-CD-79a Cy-MPO Cy-TDT	BD FacsCanto II analyser, flow cytometry SOP LPa-HIM-ACLEUKACAN	RSCH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone Marrow	Acute Leukaemia antigen detection and quantification. Panel to include: CD-2 CD-3 CD-4 CD-5 CD-7 CD-10 CD-11b CD-13 CD-14 CD-15 CD-19 CD-33 CD-34 CD-38 CD-45	BD FacsCanto analyser, flow cytometry SOP LPa-HIM-ACLEUKACAN	RSCH
Blood Bone Marrow	Chronic Leukaemia antigen detection and quantification. Panel to include: CD-2 CD-3 CD-4 CD-5 CD-7 CD-8 CD-10 CD-11b CD-19 CD-20 CD-22 CD-23 CD-38 CD-45 CD-56 CD-79b CD-103 HLA-DR / FMC7	BD FacsCanto II analyser, flow cytometry SOP LPa-HIM-CHLEUKACAN	RSCH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd) Chronic Leukaemia antigen detection and quantification. Panel to include: (cont'd) Kappa Lambda CD138 CD25 Cy-Kappa Cy-Lambda	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Immune Monitoring CD3, CD4 and CD8 (percentage and absolute count)	BD FACSCanto Flow Cytometer SOP LPa-HIM-CD4+8Canto	RSCH
Blood	BTNK (Lymphocyte subsets) CD3, CD19 and CD16+56 (percentage and absolute counts). Reported according to cell line rather than specific marker: CD3 reported as T cells CD19 reported as B cells CD16+56 reported as NK cells	BD FACSCanto Flow Cytometer SOP LPa-HIMB&T	RSCH
Blood	HLA-B27 typing	BD FACSCanto Flow Cytometer SOP LPa-HIM-HLAB27	RSCH
Blood	Foetal Maternal haemorrhage	BD FACSCanto Flow Cytometer SOP LPa-HIM-FMHCANTO	RSCH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Paroxsymal nocturnal haemoglobinuria (PNH) clone antigen detection and quantification. Panel to include: CD-24 Flaer CD-14 CD-45 CD-15 CD-59 CD64 Glycophorin A	BD FacsCanto II analyser, flow cytometry SOP LPa-HIM-PNH	RSCH
END			