## **Schedule of Accreditation**

issued by

# **United Kingdom Accreditation Service**

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

# UKAS MEDICAL

9677

Accredited to ISO 15189:2012

# **University Hospitals Sussex NHS foundation Trust**

Issue No: 006 Issue date: 05 March 2025

The Department of Haematology Brighton and Sussex Pathology The Royal Sussex County Hospital Adj Thomas Kemp Tower

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**BN2 5BE** 

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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
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)	<ul> <li>Routine haematology</li> <li>Routine and Specialised Coagulation</li> <li>Blood Grouping and antibody screen</li> <li>Blood &amp; blood product issue</li> <li>Immunohematology by flow analysis</li> <li>Management of Blood Fridges</li> </ul>	RSCH
Princess Royal Hospital Lewes Rd Haywards Heath RH16 4EX	Local contact: Liza Faustino (details as above)	<ul> <li>Routine haematology</li> <li>Routine Coagulation</li> <li>Blood Grouping and antibody screen</li> <li>Blood &amp; blood product issue</li> <li>Haemoglobinopathy analysis</li> <li>Management of Blood Fridges</li> </ul>	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

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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	Blood Transfusion examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods:	
Blood	Blood Group by detection and identification of antigens:  A Rh D Positive	Automated using Ortho Vision analysers and procedure: SOP LPc-HBT-OVA	RSCH PRH
	ARI 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	Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH
Blood Plasma	Antibody Screen by detection of antibodies to:	Automated using Ortho Vision analyser and procedure: SOP LPc-HBT-OVA	RSCH PRH
	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	Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH
Blood Plasma	Antibody identification by detection of antibodies to:	Automated using Ortho Vision analyser and procedure: SOP LPc-HBT-OVA	RSCH PRH
	Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Ortho Vison Max and procedure SOP LPc-HBT-OVA	RSCH

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ISO 15189:2012

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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 inhouse 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

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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 inhouse 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:	OrthoVision: Column Agglutination IAT technology and procedure: SOP LPc-HBT-OVA	RSCH PRH
	Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb		
Blood	Foetal Maternal Haemorrhage	Kleihauer Acid Elution Technique Using Guest Medical kit : 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 inhouse procedures by the following methods:	
Blood	Erythrocyte Sedimentation Rate (ESR)	Automated Starrsed analysers, modified Westergren method SOPs LPc-HHA-ESRAutoComp	RSCH PRH

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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 inhouse procedures by the following methods:	
Blood	Full Blood Count (FBC) analysis of the following parameters:	Sysmex XN automated analysers, differential laser light scatter:  Sysmex XN-2000 SOP LPc-HHA-ProcFBC	PRH
	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-9000 SOP LPc-HHA- ProcFBC	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  Haemoglobinopathy examinations for the purpose of clinical diagnosis	CareUS Malaria test kit SOP LPc-HHA-CareUSMalaria	RSCH PRH
Blood	Sickle cell solubility	Streck Sickledex Solubililty Kit SOP LPc-HHA-SICKLEDEX	RCSH PRH

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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 inhouse procedures by the following methods:  Documented in-house methods to meet the requirements of the NHS Sickle Cell Thalassemia antenatal screening programme(s) as defined in the laboratory QA evidence requirements	
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-HBElect	PRH
	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse 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

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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 inhouse 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 FVIII FIX FX FXI	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 VI 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 XI Assay LPc-HCO-Star Max Factor XII Assay	RSCH

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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 inhouse procedures by the following methods:	
Blood	Blood film analysis	May Grunwald-Giemsa staining Manual microscopy SOPs LPc-HHA-FILMPREPEXAM	RSCH PRH
Blood	Blood film analysis	Automated Aerospray slide stainer SOP LPc-HHA-AEROSPRAY	RSCH PRH
		Automated Stainer SP50 SOP LPa-HHA-SP50Use	RSCH
Blood	Detection & speciation (thin films) of malaria parasites:	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy LPc-HHA-BLOODPARA	RSCH PRH
	Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax		
Bone Marrow	Iron deposits Bone Marrow Film	Light microscopy following Perl's Prussian Blue iron staining using procedure:LPA-HHA-BoneFe	RSCH
		Light microscopy following staining with May Grunwald-Giemsa stain using procedure LPa-HHA-BoneMarrow	
Blood Bone Marrow	Acute Leukaemia antigen detection and quantification. Panel to include (cont'd):	BD FacsCanto II analyser, flow cytometry SOP LPa-HIM-ACLEUKACAN	RSCH
	CD-64 CD-117 HLA-DR Cy-CD-3 Cy-CD-79a Cy-MPO Cy-TDT		

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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 inhouse 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-38 CD-45	BD FacsLyric 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-45 CD-56 CD-79b CD-103 HLA-DR / FMC7	BD FacsLyric analyser, flow cytometry SOP LPa-HIM-CHLEUKACAN	RSCH

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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 inhouse procedures by the following methods:	
	Chronic Leukaemia antigen detection and quantification. Panel to include: (cont'd) Kappa Lambda CD138 CD25 Cy-Kappa Cy-Lambda		
Blood	Immune Monitoring CD3, CD4 and CD8 (percentage and absolute count)	BD FACSLyric Flow Cytometer SOP LPa-HIM-CD4+8	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 FACSLyric Flow Cytometer SOP LPa-HIMB&T	RSCH
Blood	HLA-B27 typing	BD FACSLyric Flow Cytometer SOP LPa-HIM-HLAB27	RSCH
Blood	Foetal Maternal haemorrhage	BD FACSLyric Flow Cytometer SOP LPa-HIM-FMHLYRIC	RSCH

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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 inhouse 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 FacsLyric analyser, flow cytometry SOP LPa-HIM-PNH	RSCH
END			

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