


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 8867  Accredited to ISO 15189:2012	<b>Blackpool Teaching Hospitals NHS Foundation Trust</b>	
	Issue No: 013 Issue date: 03 December 2024	
	Department of Haematology Blackpool Victoria Hospital Whinney Heys Road Blackpool FY3 8NR United Kingdom	Contact: Dr Sharran Grey Tel: +44 (0)1253 300 000 E-Mail: sharran.grey@nhs.net Website: www.bfwh.nhs.uk

**Testing performed by the Organisation at the locations specified below**

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details		Activity
<b>Address</b> Department of Haematology Blackpool Victoria Hospital Whinney Heys Road Blackpool FY3 8NR United Kingdom	<b>Local contact</b> Dr Sharran Grey	Haematology Blood Transfusion Immunology Phlebotomy  Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme as defined in the laboratory QA evidence requirements: <ul style="list-style-type: none"><li>• Review of Family Origin Questionnaire and Full Blood Count screen</li><li>• Subsequent testing at a laboratory accredited to ISO 15189 for detection of haemoglobin variants via HPLC</li><li>• Clinical interpretation and reporting</li></ul>



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#### Site activities performed away from the locations listed above:

Location details	Activity
Blood Fridge Cardiac Theatre Blackpool Teaching Hospital Whinney Heys Road Blackpool FY3 8NR United Kingdom	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Fridge Haematology Ward Blackpool Teaching Hospital Whinney Heys Road Blackpool FY3 8NR United Kingdom	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Fridge Spire Fylde Coast Hospital St Walburgs Road Blackpool FY3 8BP United Kingdom	Blood issue fridge for storage of blood products only; no testing occurs at this site



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Haematology examination activities for the purposes of clinical diagnosis:</u>	In house documented procedures based on equipment manuals and standard methods as specified below:
EDTA Blood	Full Blood Count (white blood cells, red blood cells, Hb, PCV, MCV, MCH, MCHC, RDW, Platelets, MPV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, LUCs, Reticulocytes)	SOPs HG-115-119 by flow cell and colorimetric methods using Siemens Advia 2120i
Blood	Blood Film assessment and manual differential	SOP HM-114, HMI-114 & HM-110 Romanowsky staining on Aerospray Hematology Pro Stainer and microscopy
Blood	Detection of Malarial antigens	SOP HM-111 CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo
Blood	Malaria blood film to detect malaria parasites	SOP HM-111 Romanowsky staining on Aerospray Hematology Pro Stainer at pH7.2, manual Field stain and microscopy
EDTA Blood	Erythrocyte sedimentation rate (automated)	SOP HG-124 using automated StaRRSed RS



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below: (cont'd)
EDTA Blood/Plasma	Detection of Infectious Mononucleosis heterophile antibodies	SOP HMI-125 using Alere Clearview IM II rapid
EDTA Blood	Sickle Cell Haemoglobin Screening Test	SOP HMI-113 by qualitative solubility using TCS Biosciences Sickle-Check Hb-S Test Kit
Citrated Plasma (unless otherwise stated)	<u>Coagulation examination activities for the purposes of clinical diagnosis</u>	In-house procedures using ACL TOP 550 with reference to:
	INR Prothrombin time (PT)	SOP HC-401 by optical clot detection
	Activated partial thromboplastin time (aPTT)	SOP HC-401 by optical clot detection
	Fibrinogen	SOP HC-401 by optical clot detection and Clauss technique
	D-Dimer	SOP HC-403 HemosIL HS 500 by turbidometric latex enhanced immunoassay.
	Intrinsic factor assays (Factor VIII, IX, XI or XII levels)	SOP HC-602 by optical clot detection
	Extrinsic factor assays (Factor II, V, VII or X levels)	SOP HC-603 by optical clot detection
	Inhibitor assays - Differentiating factor deficiency from inhibitor.	SOPs HC-607 & 608 by optical clot detection
	Factor VIII or IX inhibitor	
	Lupus Anticoagulant Screen (dRVVT)	SOP HC-610 by optical clot detection
	Protein C	SOP HC-612 by chromogenic assay



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HUMAN BODY FLUIDS (cont'd) Citrated Plasma (unless otherwise stated)	<u>Coagulation examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods as specified below: (cont'd)
	Free Protein S	SOP HC-613 by turbidimetric latex ligand immunoassay.
	Antithrombin	SOP HC-611 by chromogenic assay
	Von Willebrand Factor	SOP HC-604 by turbidimetric latex enhanced immunoassay.
	Anti Factor Xa	SOPHC-605 by by chromogenic assay SOP HC-606 (DOAC AFXA) Chromogenic assay
	Anti-Factor Xa Assay for Direct Xa Inhibitors	Chromogenic assay, SOP SOPHC-605 LP-HAE-  SOP HC 606 DOAC– Apixaban
	Manual INR	SOP HC-133 using manual tube tilt technique
Manual aPTT	SOP HC-132 using manual tube tilt technique	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examination activities for the purposes of clinical diagnosis:</u> Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified below:
EDTA blood or bone marrow	Immunophenotyping:  % positive cell populations CD2, CD4, CD8, CD5, CD19, CD10, CD20, CD34, CD7, CD13, CD33, CD117, HLA DR, CD45, CD14, FMC7, CD79b, CD23, CD22, CD3, cytoplasmic MPO, cytoplasmic CD79a, cytoplasmic CD3, cytoplasmic TDT, kappa , lambda	Using Beckman Coulter Navios with reference to:  SOPs IMM414
EDTA blood or bone marrow	Immune monitoring:  % and absolute CD3, CD4, CD8, CD19, CD56.  Absolute lymphocyte count  CD4/CD8 ratio	SOP IMM411
EDTA blood & harvested stem cells	CD34	SOP IMM412
Serum	Rheumatoid factor	SOP IMM110 using Siemens Atellica Neph 630



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u>	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:
EDTA Blood	Automated blood group:  A Rh D positive A Rh D negative O Rh D positive O Rh D negative B Rh D positive B Rh D negative AB Rh D positive AB Rh D negative	SOPs BST.0148-0155 using Ortho Vision Blood Grouping Analyser
EDTA Blood	Manual Blood Group	SOPs BST.0121, 0104 and 0137 using manual Tube group and cassette group
EDTA plasma	Antibody detection:  Rh: C,D,E,c,e, Cw Kell: K, k, Kp (a) MNS: S, s, M, N Lewis: Le (a), Le (b) Duffy: Fy (a), Fy (b) Kidd: Jk (a), Jk (b)	SOPs BST.0148-0155 using Ortho Vision Blood Grouping Analyser
EDTA plasma	Manual antibody detection	SOPs BST.0130 & 0129 using manual Tube AHG and Biovue cassette
EDTA plasma (and donor cells)	Serological crossmatch	SOP BST.0102 by manual method using Biovue IAT poly-specific AHG cassettes
EDTA plasma (and donor cells)		SOP BST.0111 using manual Tube AHG



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion</u> examination activities for the purposes of clinical diagnosis (cont'd):	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:
EDTA plasma	Antibody identification and Direct Coombs test:  Rh: C, D, E, c, e, Cw Kell: K, k, Kp (a) MNS: S, s, M, N Lewis: Le (a), Le (b) Duffy: Fy (a), Fy (b) Kidd: Jk (a), Jk (b)	SOPs BST.0126 & BST.0109 by manual method using Biovue IAT poly-specific cassettes  Biovue Enzyme in Neutral – SOP BST.0136  IAT tube technique BST.0123  Manual tube technique – SOPs BST.0109 & BST.0128
EDTA blood	Direct Coombs test (DCT)	SOPs BST.0126 & BST.0109 by manual method using Biovue IAT poly-specific cassettes
EDTA Blood	Antigen typing  Rh: C, D, E, c, e, Cw Kell: K, k, Kp (a) MNS: S, s, M, N Lewis: Le (a), Le (b) Duffy: Fy (a), Fy (b) Kidd: Jk (a), Jk (b)A1, P1	SOP BST.0112, 0139 by manual method using Biovue genotype cassettes and specific typing sera
EDTA Blood	Measurement of Foetal RBC in maternal blood for FMH determination  Reported as < 2mL Bleed or if positive as actual volume in mL	SOP BST.0105 Kleihauer using Guest Medical acid elution kit
END		