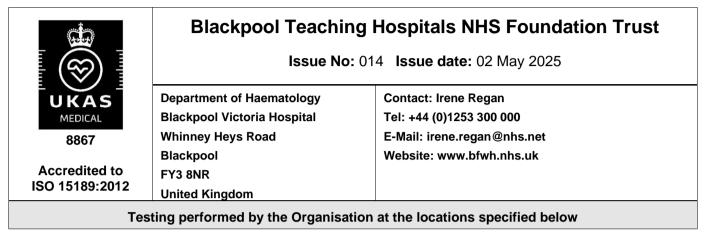
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity
Address	Local contact	
Department of Haematology Blackpool Victoria Hospital Whinney Heys Road Blackpool FY3 8NR United Kingdom	Irene Regan	 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: Review of Family Origin Questionnaire and Full Blood Count screen Subsequent testing at a laboratory accredited to ISO 15189 for detection of haemoglobin variants via HPLC Clinical interpretation and reporting

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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 Kingdon	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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Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis:	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (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)	Coagulation examination activities for the purposes of clinical diagnosis	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



ISO 15189:2012

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Type of test/Properties Standard specifications/ Materials/Products tested measured/Range of Equipment/Techniques used measurement HUMAN BODY FLUIDS (cont'd) Coagulation examination In house documented procedures Citrated Plasma (unless otherwise based on equipment manuals and activities for the purposes of stated) clinical diagnosis (cont'd) 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 Chromogenic assay, **Direct Xa Inhibitors** 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunological examination activities for the purposes of clinical diagnosis: Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified below: Using Beckman Coulter Navios with reference to:
EDTA blood or bone marrow	Immunophenotyping:	SOPs IMM414
	% 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	
EDTA blood or bone marrow	Immune monitoring:	SOP IMM411
	% and absolute CD3, CD4, CD8, CD19, CD56.	
	Absolute lymphocyte count	
	CD4/CD8 ratio	
EDTA blood & harvested stem cells	CD34	SOP IMM412
Serum	Rheumatoid factor	SOP IMM110 using Siemens Atellica Neph 630



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis:	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 and0137 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion 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
EDTA blood	Direct Coombs test (DCT)	Manual tube technique – SOPs BST.0109 & BST.0128 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	·