Schedule of Accreditation

United Kingdom Accreditation Service

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



9899

Accredited to ISO 15189:2022

Birmingham Women's and Children's NHS Foundation **Trust**

Issue No: 008 Issue date: 03 February 2025

Blood Sciences Department Birmingham Children's Hospital

Steelhouse Lane Birmingham

B4 6NH

Contact: Samuel Dev

Tel: +44 (0) 0121 333 9867 Fax: +44 (0) 0121 333 9870

E-Mail: samuel.dey@nhs.net Website: www.bwc.nhs.uk

Testing performed at the above address only

Site activities performed away from the locations listed above:

Location details		Activity
Emergency Department Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH	Contact: Mr Richard Cole, Section Head, Blood Transfusion Tel: 0121 333 9858 Email: richardcole1@nhs.net	Blood storage & issue only
Ward 18 (Blood Room) Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH		Blood storage & issue only
Theatre R Block TH5 Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH		Blood storage & issue only
Main Theatres (Blood Room) Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH		Plasma freezer, storage & issue only
PICU Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH		Blood storage & issue only

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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:	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:
Whole blood	Blood Group by detection and identification of antigens: ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD positive AB RhD negative AB RhD positive AB RhD negative	Automated Rapid Provisional Group ABO and Rh D using Grifols Erytra Elexis analysers and Grifols DG Gel Confirm P Monoclonal Anti-A, Anti-B, Anti D(VI-) and Control: BST/PS/035 2ndautomated check group using Grifols Erytra Elexis analysers and Grifols DG Gel Confirm P Monoclonal Anti-A, Anti-B, Anti D(VI-) and Control. BST/PS/035
Plasma/Whole blood	Blood Group by detection and identification of antigens: ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD positive AB RhD negative AB RhD negative	Automated Full Group – Forward and Reverse group using Grifols Erytra Eflexis analysers and Grifols DG Gel ABO/Rh (2DVI-) HSB026 Monoclonal Anti-A, Anti-B, Anti-AB, Anti-D (VI-) x2, Control, Grifols Serigroup Diana A1 and B cells. BST/PS/035
Whole Blood	Neonatal Blood Group (ABO and RhD) and Direct Antiglobulin Test DAT: ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD positive AB RhD negative AB RhD negative AB RhD negative	Automated analysis using Grifols Erytra Eflexis analysers and Grifols DG Gel Newborn Monoclonal Anti- A, Anti-B, Anti-AB, Anti-D (VI-), Anti-D (VI+), Control, Anti IgG, Polyspecific DAT (Anti-IgG+C3d): BST/PS/035

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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:
Whole Blood	Screening and identification of antibodies to: Rh (C, D, E, c, e, Cw) Kell (K, k, Kpa, Kpb, Jsa, Jsb) Duffy (Fya, Fyb) Kidd (Jka, Jkb) Lewis (Lea,Leb) P1 MNS (M,N,S,s) Lutheran (Lua,Lub) and Xga	Automated analysis using Grifols Erytra Elexis analysers and Grifols DG Gel Coombs (IgG+C3d) plus Grifols Serascan Screening cells 1, 11, 111: BST/PS/035 Automated analysis using Grifols Erytra Elexis analysers and Grifols DG Gel Coombs (IgG+c3d) and Identisera Diana. Grifols DG Gel Neutral and Grifols Identisera Diana P (papain enzyme): BST/PS/035
	Compatibility Testing of patients plasma with donor cells	Automated analysis using Grifols Erytra Elexis analysers and Grifols DG Coombs (IgG+C3d): BST/PS/035
	Direct Antiglobulin Test	Automated analysis using Grifols Erytra Elexis analysers and Grifols DG Coombs (IgG+C3d): BST/PS/035
		Monospecific DAT method using Grifols DG DC Scan monospecific DAT (IgG+C3d, IgG only, C3d only, control): BST/PS/035
	Antigen phenotyping:	Automated analysis using Grifols
	Rh and Kell Phenotype C, D, E, c, e, Kell (K)	Erytra Elexis analysers and Grifols DG Gel Rh Subgroups +Kell Anti-D (VI+), Anti-C, Anti-E, Anti-c, Anti-Cw, Anti-Kell : BST/PS/035
	M Phenotype:	Automated analysis of M antigen phenotyping usingGrifols Erytra Elexis analysers and Grifols M antitoxin reagent method: BST/PS/035

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods:
Whole Blood	Full Blood Count: Haemoglobin platelet count red blood cell count mean cell volume haematocrit mean cell haemoglobin mean cell haemoglobin concentration white blood cell count white blood cell differential	Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method, hydrodynamic focussing DC detection, SLS haemoglobin method SOP - FBC Validation (BSAH/PS/16)
	Reticulocyte count	Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method. SOP - FBC Validation (BSAH/PS/16)
	Nucleated red cell count	Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method. SOP - FBC Validation (BSAH/PS/16)
Peripheral blood	Microscopic analysis of blood films to determine morphological abnormalities	Hematek stain machine, microscope. Method – Staining (modified Wright's stain), microscopic examination.
		SOP - Performing a manual differential using the Extended- Intelligent Processing Unit (EPU) (BSAH/PS/13)
		SOP - Blood and Bone Marrow Film Preparation (HSR0287)
		SOP - Microscopic film examination (HSR0023)

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HUMAN BODY FLUIDS (cont'd)	Haematology 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:
Whole Blood	Malaria screening for: Plasmodium Falciparum and / or other species (P. Ovale, P. Malariae, P. Vivax, P. Knowlesi).	Commercial kit - Carestart malaria rapydtest. Method - Immunoassay. SOP - CareStart Malaria RDT (HSR0467)
	Detection & speciation (thin films) of	Manual staining:
	malaria parasites: Plasmodium Falciparum, P. Ovale P. Malariae P. Vivax P.Knowlesi.	SOP - Giemsa Stain pH 7.2 (HSR0360)
	Glucose 6 Phosphate Dehydrogenase screen	Commercial kit - Trinity Biotech G6PD Deficiency, Longwave UV light source. Method - Visual fluorescence screening.
		SOP - G6PD Screen (HSR0293)
Whole blood, Plasma (citrate or EDTA), Serum.	Detection of infectious mononucleosis heterophile antibodies	Commercial kit - Clearview® IM II Test for Infectious Mononucleosis. Method - Immunoassay.
		SOP - Clearview® IM II Test for Infectious Mononucleosis (BS/PS/17)
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Commercial kit - Sarstedt Microvette CB200. Manual method - Sedimentation.
		SOP - ESR Examination - Sarstedt method (BSAH/PS/17)

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HUMAN BODY FLUIDS (cont'd)	Haematology 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:
Whole Blood	Haemoglobinopathy analysis by detection of haemoglobin variants:	
	Hb S detection	Commercial kit - Microgen Bioproducts S-Test
		SOP - Sickle Solubility Test (HSR0357)
	Special Coagulation examinations to assist in clinical investigations	Sysmex CS2000i Analyser - using Manufacturer's Reagent
Citrated Plasma	Prothrombin Time (PT)	SOP: HSC0484
	Activated Partial Thromboplastin Time (APTT)	SOP: SOP HSC0486
	Clauss Fibrinogen (Fbg)	SOP HSC0491
	Thrombin Time / Protamine Sulphate Time (TT/TTPS)	SOP HSC0487
	International Normalised Ratio (INR)	SOP HSC0485
	Anti-Xa Assays (LMWH and UFH) (Chromogenic assay)	SOP BSSH/PS/60

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	Equipment/Techniques used
Special Coagulation 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:
	Sysmex CS2000i Analyser - using Manufacturer's Reagent
Bethesda Assay for VIII Neutralising Inhibitors	SOP HSC0500
Factor II Assay (One-Stage) (PT based clotting)	SOP HSC0505
Factor V Assay (One-Stage) (PT based clotting)	SOP HSC0506
Factor VII Assay (One-Stage) (PT based clotting)	SOP HSC0507
Factor VIII Assay (One-Stage) (APTT based clotting)	SOP HSC0494
Factor VIII Assay (Chromogenic)	SOP HSC0501
Factor IX Assay (One-Stage) (APTT based clotting)	SOP HSC0495
Factor X Assay (One-Stage) (PT based clotting)	SOP HSC0508
Factor XI Assay (One-Stage) (APTT based clotting)	SOP HSC0496
Factor XII Assay (One-Stage) (APTT based clotting)	SOP HSC0497
Factor XIII Assay (chromogenic)	SOP HSC0509
Von Willebrand Factor (vWF) Antigen Assay	SOP HSC0490
Von Willebrand Factor (vWF) Activity Assay	SOP HSC0511
	to assist in clinical investigations (cont'd) Bethesda Assay for VIII Neutralising Inhibitors Factor II Assay (One-Stage) (PT based clotting) Factor V Assay (One-Stage) (PT based clotting) Factor VIII Assay (One-Stage) (PT based clotting) Factor VIII Assay (One-Stage) (APTT based clotting) Factor VIII Assay (Chromogenic) Factor IX Assay (One-Stage) (APTT based clotting) Factor X Assay (One-Stage) (PT based clotting) Factor XI Assay (One-Stage) (APTT based clotting) Factor XII Assay (One-Stage) (APTT based clotting) Factor XII Assay (One-Stage) (APTT based clotting) Factor XIII Assay (chromogenic) Von Willebrand Factor (vWF) Antigen Assay

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HUMAN BODY FLUIDS (cont'd)	Special Coagulation 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:
		Sysmex CS2000i Analyser - using Manufacturer's Reagent
Citrated Plasma (cont'd)	Antithrombin Activity Assay (AT)	SOP HSC0499
	Protein S (Free) Antigen Assay	SOP BSSH001
	Protein C Activity Assay	SOP HSC0498
	Lupus Anticoagulant Screen (dRVVT)	BSSH/PS/64
		Beckman Coulter Navios Flowcytometer:
Peripheral Blood	Peripheral Blood Stem Cell Assay CD34	SOP: BSSH/PS/7
	Lymphocyte Subsets (Immune Monitoring) CD3, CD4, CD8, CD19, CD16/56	SOP: BSSH/PS/8
	EMA for Hereditary Spherocytosis	SOP: BSSH/PS/5
	Platelet Glycoprotein Assay CD41, CD42b, CD61, CD62p	SOP: BSSH/PS/9

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods:
Plasma	3-Hydroxy Butyrate	Roche Cobas 501 – enzymatic method– 3 rd party (Randox) SOP I/S/H/025
Plasma/Serum	Alanine Amino Transferase	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/A/062
Plasma/Serum	Albumin	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/A/064
Plasma/Serum	Alkaline Phosphatase	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/A/065
Plasma	Ammonia	Roche Cobas 501 – enzymatic method– 3 rd party (Randox) SOP S/S/A/095
Plasma/Serum, Urine, Fluid	Amylase	Roche Cobas 501 – enzymatic colorimetric method – Roche reagent SOP S/S/A/066
Plasma/Serum	Aspartate Transaminase	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/A/063
Plasma/Serum	Bilirubin -Total	Roche Cobas 501 – colorimetric diazomethod – Roche reagent SOP S/S/B/102
Plasma/Serum, Urine	Bilirubin - Direct	Roche Cobas 501 – colorimetric method – 3 rd party(WAKO) reagent SOP S/S/B/112.
Plasma/Serum, Urine	Bicarbonate	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/B/067

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HUMAN BODY FLUIDS (cont'd)	Biochemistry 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:
Plasma/Serum	C-reactive Protein	Roche Cobas 501 – particle enhanced immunoturbidemetric method – Roche reagent SOP S/S/C/073
Plasma/Serum, Urine Fluid	Calcium	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/C/068
Plasma/Serum, Urine Fluid	Creatinine	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/C/075
Plasma/Serum	Cholesterol	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/C/072
Plasma/Serum, Urine Fluid	Chloride	Roche Cobas 501 – indirect ISE– Roche reagent SOP S/S/C/069
Plasma/Serum	Creatine Kinase	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/C/074
Plasma/Serum	Free Fatty Acids	Roche Cobas 501 – colorimetric method– 3 rd party (Randox) SOP I/S/F/029
Plasma/Serum	Gamma-Glutamyl transferase	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/G/076
Plasma/Serum, Urine	Glucose	Roche Cobas 501 – enzymatic reference method with hexokinase– Roche reagent SOP S/S/G/086

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HUMAN BODY FLUIDS (cont'd)	Biochemistry 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:
Plasma/Serum, Urine	High Density Lipoprotein Cholesterol	Roche Cobas 501 – Homogenous enzymatic colorimetric method– Roche reagent SOP S/S/H/108
		Roche Cobas 501:
Plasma/Serum	Immunoglobulins IgA, IgM, IgG	Roche Cobas 501 – immunoturbidemetric method – Roche reagent SOP S/S/I/104
Plasma/Serum	Iron	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/I/107
Plasma/Serum	Lactate Dehydrogenase	Roche Cobas 501 - Optimized standard method according to the Deutsche Gesellschaft für Klinische Chemie (DGKC). Roche reagent SOP S/S/L/096
Plasma/Serum / CSF	Lactate	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/L/082
Serum/Plasma	Magnesium	Roche Cobas 501 – colorimetric endpoint method – Roche reagent SOP S/S/M/098
Serum	Methotrexate	Roche Cobas 501 – Homogenous enzyme immunoassay method– 3 rd party (ARK reagent) SOP BSAC/PS/1
Plasma/Serum	Paracetamol	Roche Cobas 501 – Homogenous enzyme immunoassay method Roche reagent SOP S/S/P/099

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Biochemistry 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:
Potassium	Roche Cobas 501 – indirect ISE– Roche reagent BS/SOP/676
Phosphate	Roche Cobas 501 – Molybdate UV photometric– Roche reagent SOP S/S/P/101
Total Protein	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/T/079
CSF Protein	Roche Cobas 501 – turbidimetric method – Roche reagent SOP S/S/P/007
Sodium	Roche Cobas 501 – indirect ISE– Roche reagent SOP S/S/S/070
Salicylate	Roche Cobas 501 – photometric method – Roche reagent SOP S/S/S/100
Triglyceride	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/T/106
Urea	Roche Cobas 501 – kinetic photometric method – Roche reagent SOP S/S/U/103
Uric Acid	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/U/078
	Biochemistry examinations to assist in clinical investigations (cont'd) Potassium Phosphate Total Protein CSF Protein Sodium Salicylate Triglyceride Urea

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HUMAN BODY FLUIDS (cont'd):	Biochemistry 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:
Plasma/Serum	Unbound Iron binding capacity	Roche Cobas 501 –colorimetric method– Roche reagent SOP S/S/U/093
Serum/Lithium Heparin Plasma	Vitamin D	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent SOP S/S/133
Serum	Prolactin	Roche Cobas 601 – sandwich chemiluminescent immunoassay – Roche reagent SOP BSAC/PS/46
Serum	Macroprolactin	Roche Cobas 601 and PEG PPT – sandwich chemiluminescent immunoassay – Roche reagent SOP BSAC/PS/47
Plasma/Serum	Alpha-Fetoprotein	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/A/094
Serum	Ferritin	Roche Cobas 601 – sandwich chemiluminescent immunoassay – Roche reagent SOP S/S/116 Ferritin
Plasma/Serum	Free Thyroxine	Roche Cobas 601 –competitive chemiluminescent immunoassay– Roche reagent SOP S/S/F/084
Serum	Oestradiol	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent. SOP BS/SOP/702

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HUMAN BODY FLUIDS (cont'd):	Biochemistry 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:
Plasma/Serum	Free Tri-iodothyronine (FT3)	Roche Cobas 601 –competitive chemiluminescent immunoassay–Roche reagent SOP BSAC/PS/37
Serum	Folate	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent SOP S/S/115 Folate
Plasma/Serum	Follicle Stimulating Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/F/089
Plasma/Serum	Growth Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/G/097
Plasma/Serum	Luteinising Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/L/091
Serum	Parathyroid Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/P/099
Plasma/Serum	Cortisol	Roche Cobas 601 –competitive chemiluminescent immunoassay–Roche reagent SOP S/S/C/088
Serum	Vitamin B12	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent SOP S/S/114 Vitamin B12

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HUMAN BODY FLUIDS (cont'd):	Biochemistry 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	Glycated Haemoglobin A1c (HbA1c)	Roche Cobas 501 turbidimetric inhibition immunoassay – Roche Reagent SOP S/S/H/025
Urine	Microalbumin	Roche Cobas 501 immunoturbidimetric– Roche Reagent SOP S/S/M/087
Lithium Heparin Plasma	D-Lactate	Roche Cobas 501 – megazyme enzymatic absorbance of NADH SOP DOC353
Serum	Serum Haptoglobin Quantitation	Roche Cobas 501 – immunoturbidimetric assay SOP BSAC/PS/86
Sweat	Chloride -Sweat	Collection -pilocarpine iontophoresis using Webster sweat inducer Collected via Wescor macroduct sweat collection system SOP BSAC/PS/21
		Analysis Sherwood 926S Chloride Analyser MK II via Coulometric titration BSAC/PS/10
Sweat	Sweat Conductivity	Westcor sweat check conductivity meter conductivity BSAC/PS/10
Plasma/ Serum / Urine	Osmolality	Vitech 3320 Freezing Point Osmometer: SOP S/S/O/033
Faeces	Detection of occult blood	Hema screen – guaiac peroxidase colour change BSAC/PS/11

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HUMAN BODY FLUIDS (cont'd):	Biochemistry 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	Detection of Immunosuppressants: Tacrolimus Sirolimus Ciclosporin	LC/MS/MS Waters Xevo TQD 2 SOP BSSC/PS/1		
Blood	Detection of Immunosuppressants: Tacrolimus Sirolimus Ciclosporin	LC/MS/MS Waters Xevo TQ-s Micro System SOP S/S/I 109		
Lithium Heparin Plasma	Ammonia	Fujifilm Dri-Chem System XN10N Dry-Slide Colourimetric SOP BSAC/PS/39		
END				

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