


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>9584</b> Accredited to ISO 15189:2012	<b>Gloucestershire Hospitals NHS Foundation Trust</b>	
	Issue No: 002    Issue date: 27 June 2024	
	<b>Trust Headquarters</b> Alexandra House 2nd Floor Cheltenham General Hospital Sandford Road Cheltenham GL53 7AN	<b>Contact: Alison Eades</b> Tel: +44 (0)300 422 5215 E-Mail: <a href="mailto:alison.eades@nhs.net">alison.eades@nhs.net</a> Website: <a href="http://www.gloshospitals.nhs.uk">www.gloshospitals.nhs.uk</a>
<b>Testing performed by the Organisation at the locations specified below</b>		

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

#### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Haematology Department Gloucestershire Royal Hospital Great Western Road Gloucester GL1 3NN	<b>Local contact</b> Alison Eades	Haematology Blood Transfusion Immunology Blood and blood product issue Sickle Cell and Thalassaemia screening programme
<b>Address</b> Haematology Department Cheltenham General Hospital Sandford Road Cheltenham GL53 7AN	<b>Local contact</b> Alison Eades	Haematology Blood Transfusion



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

Location details	Activity	Location code
Stock and Holding Blood Fridge Theatre Blood Fridge Edward Jenner Blood Fridge ED Blood Fridge Plasma Freezer Platelet Incubator  As Above	Blood Fridges	1
Stock Blood Fridge Holding Blood Fridge General Theatre Blood Orthopaedic Blood Fridge Plasma Freezer Platelet Incubator  As Above	Blood Fridges	2
North Cotswold Blood Fridge – North Cotswold Community Hospital Stow Road Moreton-in-Marsh GL56 0DS  Matron: Julie Ellery julie.ellery@ghc.nhs.uk 0300 421 6100	Blood Fridges	3
Stroud Blood Fridge- Stroud General Hospital Trinity Road Stroud Gloucestershire GL2 2HY  Matron: Liz Lovett liz.lovett@ghc.nhs.uk 0300 421 8080	Blood Fridges	4
Winfield Blood Fridge- Winfield Hospital Tewkesbury Road Longford Gloucester GL2 9WH  Matron: Monika Kiss Monika.kiss@ramsayhe alth.co.uk 01452 306009	Blood Fridges	5



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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 as specified below:	<u>Haematological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Whole Blood	Full Blood Count with Automated Differential: White cell count Red cell count Haemoglobin Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Red cell distribution width Platelet count Neutrophil (% and abs) Lymphocytes (% and abs) Monocytes (% and abs) Eosinophils (% and abs) Basophils (% and abs)	Beckman-Coulter Unicel DxH 800 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	2
		Beckman-Coulter Unicel DxH 900 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	1
EDTA Whole Blood	Full Blood Count without Differential: White cell count Red cell count Haemoglobin Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Red cell distribution width Platelet count	Beckman-Coulter Unicel DxH 800 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	2
		Beckman-Coulter Unicel DxH 900 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
EDTA Whole Blood	Full Blood Count with Automated Differential, Cells and Reticulocytes: White cell count Red cell count Haemoglobin Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Red cell distribution width Platelet count Neutrophil (% and abs) Lymphocytes (% and abs) Monocytes (% and abs) Eosinophils (% and abs) Basophils (% and abs) Reticulocytes (% and abs)	Beckman-Coulter Unicel DxH 900 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	1
		Beckman-Coulter Unicel DxH 800 Coulter Cellular analysis System using impedance counting and VCS technology. HASOPR 005	2
Citrated Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Sarstedt Sedivette 3.8% Sodium Citrate tube Westergren Sedimentation Rate HASOPR 046	1, 2
EDTA Plasma	Plasma viscosity	Benson Plasma Viscometer. Flow of known volume of plasma through a capillary. HASOPR 001	1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
EDTA Whole Blood	Blood Film Examination Cellular Morphology	Peripheral Blood Smear Preparation using the Hematek 3000 Slide Stainer (Modified Wright's Stain) HASOPF 045 Making and Staining Blood Films HASOPF 010 Film Section Results Reporting HASOPF 043 Policy for Blood Film Examination HAPOL 004	1, 2
EDTA Whole Blood	Malaria Parasite Screen Antigen Test	DIAQUICK Malaria P.F. Pan Antigen Test HASOPF 041	1, 2
	Examination of Thick and Thin Films	Laboratory Diagnosis of Malaria HASOPF 006	1, 2
Bone Marrow Aspirate	Bone Marrow Film Detecting Cellular Structure and Contents by Light Microscopy	Bone Marrow Processing by MGG with/without Iron Staining HASOPG 112	1
		BHODS sample registration, transport, first reporting HASOP-114	1, 2
Serum or EDTA Plasma	Glandular Fever IM Heterophile Antibody	Biokit Monogen Rapid Latex Particle Agglutination Slide Test HASOPR 019	1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
Serum	Serum Vit B12 and Serum Folate	Beckman-Coulter Unicel Dxl 800 Access Immunoassay System; Access Vitamin B12 reagent; Access Vitamin Folate reagent HASOP 101	2
Serum	Intrinsic Factor	Beckman-Coulter Unicel Dxl 800 Access Immunoassay System; Access Intrinsic Factor reagent HASOP 101	2
Serum or EDTA Plasma	Ferritin	Beckman-Coulter Unicel Dxl 800 Access Immunoassay System; Access Ferritin reagent HASOP 101	
Citrated Plasma	Prothrombin Time (PT)	Werfen UK. ACL TOP (550) Optical end-point detection Prothrombin Time on the ACL TOP HASOPC 603  Establishing the Mean Normal PT – HASOPC 314	1
		Werfen UK. ACL TOP (350) Optical end-point detection Prothrombin Time on the ACL TOP HASOPC 603  Establishing the Mean Normal PT – HASOPC 314	2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
Citrated Plasma	Activated Partial Thromboplastin Time (APTT)	Werfen UK. ACL TOP (550) Optical end-point detection APTT and APTT ratio on the ACL HASOPC 605  Establishing the Mean Normal APTT HASOPC 324	1
Citrated Plasma	Clauss Fibrinogen	Werfen UK. ACL TOP (350) Optical end-point detection APTT and APTT ratio on the ACL HASOPC 605  Establishing the Mean Normal APTT HASOPC 324	2
Citrated Plasma	Clauss Fibrinogen	Werfen UK. ACL TOP (550) Optical end-point detection Clauss Fibrinogen on the ACL TOP HASOPC 607	1
Citrated Plasma	Clauss Fibrinogen	Werfen UK. ACL TOP (350) Optical end-point detection Clauss Fibrinogen on the ACL TOP HASOPC 607	2
Citrated Plasma	D-dimer	Werfen UK. ACL TOP (550) Turbidimetric Immunoassay on the ACL TOP HASOPC 611	1
Citrated Plasma	D-dimer	Werfen UK. ACL TOP (350) Turbidimetric Immunoassay on the ACL TOP HASOPC 611	2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
Citrated Plasma	International Normalised Ratio (INR)	Werfen UK. ACL TOP (550) Optical end-point detection Establishing the Mean Normal PT HASOPC 314  Production of the INR Chart HASOPC 315	1
Citrated Plasma	Factor Assay Factor VII (Clotting) Factor VIII (Clotting) Factor IX (Clotting) Factor XI (Clotting) Factor XII (Clotting)	Werfen UK. ACL TOP (350) Optical end-point detection Establishing the Mean Normal PT HASOPC 314  Production of the INR Chart HASOPC 315	2
Citrated Plasma	Factor Assay Factor VII (Clotting) Factor VIII (Clotting) Factor IX (Clotting) Factor XI (Clotting) Factor XII (Clotting)	Werfen UK. ACL TOP (550) Optical end-point detection Factor Assays on the ACL TOP HASOPC 614	1
Citrated Plasma	Dilute Russell's Viper Venom Time (DRVVT)	Werfen UK. ACL TOP (550) Optical end-point detection Dilute Russell's Viper venom Time (DRVVT) on the ACL TOP HASOPC 612	1
Citrated Plasma	Anti-thrombin III (ATIII)	Werfen UK. ACL TOP (550) Chromogenic end-point detection. Antithrombin assay on the ACL TOP HASOPC 618	1





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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Haematological 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:	
Citrated Plasma	Protein C	Werfen UK. ACL TOP (550) Chromogenic end-point detection. Protein C assay on the ACL TOP HASOPC 616	1
Citrated Plasma	Free Protein S	Werfen UK. ACL TOP (550) Turbidimetric immunoassay. Free Protein S assay on the ACL TOP HASOPC 617	1
Citrated Plasma	Anti-Xa Assay – Low Molecular Weight Heparin	Werfen UK. ACL TOP (550) Chromogenic end-point detection HASOPC 615	1
EDTA Whole Blood	Factor V Leiden (FVL) and Prothrombin gene G20210A (PMG)	Cepheid GeneXpert Dx system with Xpert FII and FV cartridges for the automation, purification, amplification and detection of the target genetic sequence using real-time Polymerase Chain Reaction (PCR) assays HASOPC 502	1
EDTA Whole Blood	Unusual Haemoglobin Identification and Quantification	Bio-Rad Variant II Haemoglobin Testing System High Pressure Liquid Chromatography (HPLC)	1
	Haemoglobin F Identification and Quantification	Running samples on the Variant II HASOPA 012	
	Haemoglobin A2 identification and quantification	Maintenance, Cartridge Change and decontamination. HASOPA 003	
		Requesting and reporting Haemoglobinopathy samples – antenatal and non-antenatal HASOP-115	



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<p>HUMAN BODY FLUIDS as specified below (cont'd):</p> <p>EDTA Whole Blood</p> <p>EDTA Whole Blood</p>	<p><u>Haematological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Unusual Haemoglobin Identification and Quantification for antenatal screening</p> <p>Haemoglobin F Identification and Quantification</p> <p>Haemoglobin A2 identification and quantification</p> <p>Sickle Solubility Screening Test</p>	<p>In-house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia screening programme as defined in the "Sickle Cell and Thalassaemia screening laboratory QA evidence requirements"</p> <p>Bio-Rad Variant II Haemoglobin Testing System High Pressure Liquid Chromatography (HPLC)</p> <p>Running samples on the Variant II HASOPA 012</p> <p>Maintenance, Cartridge Change and decontamination. HASOPA 003</p> <p>Requesting and reporting Haemoglobinopathy samples – antenatal and non-antenatal HASOP-115</p> <p>Clin-Tech Sickle-Check Screening Kit HASOPA 009</p>	<p>1</p> <p>1</p>



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
EDTA Whole Blood and Plasma	Automated Adult ABO and Rh D Blood Grouping Anti-A Anti-B Anti-D Control A1 cells B cells	Ortho Vision Analysers using Ortho Biovue Column Technology BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2
EDTA Cord/ Whole Blood and Plasma	Automated Neonatal ABO and Rh D Blood Grouping Anti-A Anti-B Anti-A,B Anti-D Control Anti-IgG	Ortho Vision Analysers using Ortho Biovue Column Technology BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2
EDTA Plasma	Automated Antibody Screening using 3 Cell Screen  Antibody Identification by: IAT Enzyme Saline RT	Ortho Vision Analysers using Ortho Biovue Column Technology BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2
EDTA Whole Blood and Plasma	Red Cell Phenotyping: Rh/K – C,D,E,c,e,K Biovue cassette Duffy –Fya, Fyb Ortho Sera MNSs - M, N, S, s Ortho sera Kidd – JKa, Jkb Ortho Sera Lewis – Lea, Leb Ortho Sera	Ortho Vision analysers using Ortho Biovue column technology and Ortho Sera BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Blood Transfusion 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:	
EDTA Whole Blood and Plasma	Manual Tube Group Anti-A Anti-B Anti-A,B Anti-D (Rum-1) Anti-D (MS-201) A1 cells B cells  Manual Adult Blood Grouping and antibody screening using Ortho Technology Anti-A Anti-B Anti-D Control A1 cells B cells Surgiscreen antibody screening cells	Manual Tube Technique BTSOP 148 Manual Grouping and Further Investigations using Ortho Technology	1, 2
EDTA Cord/ Whole Blood and Plasma	Manual Neonatal ABO and D blood grouping Anti-A Anti-B Anti-A,B Anti-D Control Anti-IgG	Manual Blood Grouping using Ortho Biovue technology BTSOP 148 Manual Grouping and Further Investigations using Ortho Technology	1, 2
EDTA Whole Blood and Plasma	Direct Antiglobulin Test (DCT) Monospecifics Anti-IgG Anti-C3d/ -C3b	Ortho Vision analysers using Ortho Biovue Monospecific cassette column technology BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Blood Transfusion 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:	
EDTA Whole Blood and Plasma	Antibody Titration NHSBT Titration Cells 1 and 2	Ortho Vision analysers using Ortho Biovue column technology BTSOP 123 Processing samples for Blood Grouping and Further Investigations on the Ortho Vision	1, 2
EDTA Cord Blood (Positive control)	Estimation and Quantitation of Foeto-Maternal Haemorrhage	Guest Medical Kleihauer Foetal Red Cell Detection Kit (Kleihauer Kit) BTSOP 001 Estimation and Quantitation of Feto-Maternal Haemorrhage	1
EDTA Maternal and Adult Male (negative control) Whole Blood and Plasma			
EDTA Whole Blood and Plasma	Full Serological Crossmatch	Automated (Ortho Vision analysers) and manual crossmatching using Ortho Biovue technology BTSOP 149 Crossmatching using Ortho Technology	1, 2
EDTA Whole Blood and Plasma	Electronic Issues of Red Cells	Electronic issue of red cells BTSOP 083 Electronic issue	1, 2
EDTA Whole Blood and Plasma	Neonatal and Paediatric Transfusion of Blood Components	BTSOP 010 Neonatal and Paediatric Transfusions	1, 2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Specific IgE: d1; e1; e3; e5; e6; e82; e84; e87; e88; f1; f2; f3; f4; f10; f13; f14; f17; f18; f20; f23; f24; f25; F33; f36; f37; f40; f41; f44; F49; f75; f84; F87; F92; f93; f201; f202; f203; f208; f209; f256; C1; C2; i1; i3; m3; fx1; fx2; fx5; gx3; ex70; ex71; ex72; mx1; tx8; wx3; k82; Fx73; F81; Fx3	Thermofisher ImmunoCAP 250 Photometric Technique IMSOP IC 005	1
Serum	Total IgE	Thermofisher ImmunoCAP 250 Photometric Technique IMSOP IC 007	1
Serum	Tissue transglutaminase (TTG) IgA	Thermofisher ImmunoCAP 250 Photometric EliA IgA Antibody Technique IMSOP IC 001	1
Serum	Anti-Thyroid Peroxidase (TPO)  IgG Anti-Cardiolipin antibodies  Double stranded DNA antibodies Extractable nuclear antigens Screen Extractable nuclear antigen typing SSA (Ro), SSB (La), nRNP, Sm, Scl70, Jo-1  Cyclic citrullinated protein antibodies 2nd generation – CCP  Anti-Centromere antibodies	Thermofisher ImmunoCAP 250 IgG Antibody Photometric Technique IMSOP IC 002	1



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Serum	IgG, IgA, IgM level, Complement C3c component, Complement C4 component, Haptoglobin, Alpha 1 antitrypsin, Serum total protein, and Rheumatoid factor quantitation	Roche COBAS C501/6000 Immunoturbidometric Technique IMSOP IR 001	1
Serum	Serum Electrophoresis Quantitation of Paraproteins	Sebia Octa/Capillary 3 Capillary Zone Electrophoresis Sebia Hydrasis 2 Agarose gel electrophoresis with staining, image capture and scanning IMSOP IE 009	1
Serum	Immunotyping of Paraproteins	Sebia Octa/Capillary 3 Capillary Zone Electrophoresis/ Immunosubtraction IMSOP IE 005  Sebia Hydrasis 2 Agarose gel electrophoresis with staining, image capture and scanning IMSOP IE 009	1
END			