Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to ISO 15189:2022

M13 9WL

United Kingdom

Manchester University NHS Foundation Trust

Issue No: 008 Issue date: 01 April 2025

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Manchester

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
Address Haematology Department Manchester University NHS Foundation Trust Manchester M13 9WL United Kingdom	Local contact Claire Whitehead	Diagnostic Testing	A
Address Haematology Department Trafford General Hospital Moorside Road M14 5SL	Local contact Claire Whitehead	Diagnostic Testing	В
Address Directorate of Haematology North Manchester General Hospital Delaunays Road Crumpsall Manchester M8 5RB	Local contact Claire Whitehead	Diagnostic Testing	С
Address Haematology Department Wythenshawe Hospital Southmoor Road Manchester M23 9LT	Local contact Gareth Davies Gareth.Davies@mft. nhs.uk	Diagnostic Testing	D

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Site activities performed away from the locations listed above:

Location details		Activity	Location code
Blood issue fridges at: Adult A&E Paediatric A&E Central Delivery Suite Paediatric Theatre Adult Theatre Haematology Ward		Storage and issue of blood and blood products	A
Trafford General Hospital, Pathology		Storage and issue of blood and blood products	В
Blood Issue Fridge Essential Service Laboratory Central Delivery Unit Main Theatre		Storage and issue of blood and blood products	С
Wythenshawe Hospital Blood issues fridges at: Maternity Accident & Emergency Cardiothoracic theatres Main theatre Acute theatres Acute ICU Treatment and Diagnostics centre	Local contact Margaret Evans Margaret.Evans@mft. nhs.uk	Storage and issue of blood and blood products	D

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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	Haematology examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant	
Blood	Full Blood Count White Blood Cell Count Neutrophils Lymphocytes Monocytes Eosinophils Basophils Red Blood Cell Count Haemoglobin Haematocrit	Sysmex XN 9000, 1000 and 450 Analyser modules by flow cytometry, impedance and Spectrophotometry SOPs LP-HAEM GH5 LP-HAEM-GH6	A, C
	Mean Cell Volume Red Cell Distribution width. Mean Cell Haemoglobin Mean Cell Haemoglobin concentration. Platelets Mean Platelet volume Nucleated Red Blood cells (not XN450) Reticulocyte count	Sysmex XN2000 analyser by flow cytometry, impedance and spectrophotometry LP-HAEM-GH5 LN HAEM GH48	В

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
		Sysmex XN 9000 and XSi analysers, cytometry semiconductor laser:	D
		RBC,HCT,MCH,MCHC,RDW-CV, and Plt count measured through Hydrodynamic focussing DC detection.	
		HGB is measured through SLS Cyanide-free HB method.	
		WBC and WBC Differential measured using fluorescence flow cytometry	
	WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count	HA-S-17 HA-S-20 HA-S-18 HA-S-22 HA-S-21	D
	Reticulocytes	Sysmex XN 9000 and XSi analysers, cytometry semiconductor laser	D

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
EDTA Plasma	Plasma Viscosity	Benson Viscometers, capillary method Haem HA-S-26	
Blood	Blood film assessment for detection of abnormal cell types, morphology and numbers	SP10 automated slide maker stainer and May Grunwald and Giemsa stain examined by light microscopy, LP- HAEM-GH14	A, C
		Manual blood film preparation and automated staining using RAL stainer and May Grunwald and Giemsa stain examined by light microscopy using LP HAEM GH13 LP HAEM GH20	A, B
		Sysmex SP10 HA-S-16 HA-S-48	D
		HA-I-26 Slides stained with May Grunewald Giemsa Stain	D
Blood	Iron stain	Manual Perl's Prussian Blue stain examined by light microscopy SOP LP_HAEM_GH17	С
Blood	Malaria screen for P. falciparum P. vivax P. ovale P. malariae	Using Giemsa/Fields Staining for thin smears and manual microscopy LP LP_HAEM_GH10 (in combination with BINAX NOW)	A, B
	P. knowlesi	HA-S-7	D
Blood	Malaria screen for P. falciparum P. vivax	BINAX NOW Malarial screen kit and SOP LP-HAEM BCM 202	A, B, C
	P. ovale P. malariae	HA-S-49	D

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Blood	Qualitative detection of infectious mononucleosis heterophile antibody	Clearview kit using HAEM BCM PRO 203	A, B, C
Plasma	Detection of Infectious mononucleosis heterophile antibodies	Accusay MONO kit using solid phase immunoassay	D
Blood	Estimation of Erythrocyte Sedimentation Rate	Automated method using Sysmex Interliner and Westergren method, LP- HAEM GH7	A
		Automated method using Starrsed Autocompact and Westergren method, LP_HAEM GH7	В
		Autocompact ESR analyser- Trafford	Α
		Inversa analyser by Westergren method	С
		StaRRsed inversa using Westergren method	D
Bone marrow	Bone marrow assessment for detection of abnormal cell types, morphology and	Sysmex SP10 slide stainer and Romanowski stain, LP HAEM GH16	A, C
	numbers	RAL staining machine and Romanowski stain, LP HAEM GH13	В
Serum	Folate Ferritin	Roche Cobas 6000 analyser, CB_TRAF_PROC-27	В

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Coagulation examination activities for the purpose of clinical diagnosis		
Plasma	Prothrombin time Prothrombin time correction with normal plasma APTT APTT correction with normal plasma Clauss fibrinogen D Dimer Low molecular weight heparin	Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance LP_HAEM_COAG38 and LP_HAEM_COAG40	A
	Prothrombin Time / INR Activated Partial Thromboplastin time (aPTT) Fibrinogen (Derived) Fibrinogen (Clauss) D-Dimer	Sysmex CS-2500 LP_HAEM_COAG38 and LP_HAEM_COAG40	С
Plasma	Prothrombin Time / INR Activated Partial Thromboplastin time (aPTT) Fibrinogen (Clauss) D-Dimer	Sysmex CS5100i Coagulation analyser LP_HAEM_COAG38	D
	Thrombin time Factor VIII, IX, XI Von Willebrands Factor antigen Anti Xa levels	CO-S-99 CO-S-105 CO-S-102	
Plasma	Thrombophilia screening: Anti-thrombin 3 activity Protein C activity Free Protein S level Thrombin time Reptilase time	Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance LP_HAEM_COAG45, LP_HAEM_COAG30	A

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Coagulation (cont'd)		
Plasma	Lupus anticoagulant testing: APTT Dilute Russell Viper venom time Dilute Russell Viper venom confirmation	Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance LP_HAEM_COAG43	A
	Anti Xa levels	CO-S-15	D
	Von Willebrands factor antigen	CS-S-102	D
Plasma	Novel Anticoagulant levels: Dabigatran Rivoroxaban Apixaban Edoxaban Fondaparinux	Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance LP_HAEM_COAG40	A
Plasma	Coagulation: Prothrombin time APTT D-Dimer Thrombin time Fibrinogen	Roche Cobas 8100 and Sysmex CS2500i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance and chromogenic methodsLP_TGH_H5	В
Plasma	Coagulation Factor Assays: Factor II, V, VII, VIII, IX, X, XI, XII Factor VIII Refacto Chromogenic Factor VIII and XIII	Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immune-turbidometry, chromogenic and optical absorbance LP_HAEM_COAG46 LP_HAEM_COAG35 LP_HAEM_COAG36 and COAG37	A
	Von Willebrand antigen level Ristocetin Cofactor level	LP_HAEM-COAG47	
		LP_HAEM_COAG47	
		Werfen/IL Accustar using chemiluminescent immunoassay	D

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Coagulation (cont'd)		
Serum	Collagen Binding For Von Willebrands Activity	CO-S-93	D
	Heparin Induced Thrombocytopenia (HIT) Screen	CO-S-94	D
Citrated Plasma	Inhibitor assays: Nijmegan modification Bethesda assay • FVIII • FIX	Semi-automated technique with manual initial set up and automated Roche Cobas 8100 and Sysmex CS5100i coagulation analyser using immuno-turbidimetry, chromogenic and optical absorbance and chromogenic methods LI_HAEM_COAG31	A
	Monitoring of Factor replacement Therapies FVIII Factors Assays FV, FII, FVII, FX FVIII, FIX, FXI, FXII	One stage clotting assay Emicizumab-modified FVIII assay(standard human plasma for calibration curve replaced by Emicizumab LP_HAEM-COAG48 Dade Innovin PT reagent LP_HAEM-COAG48 Actin FS – APTT reagent LP_HAEM-COAG48 CaCl2 LP_HAEM-COAG48	

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Blood	Platelet aggregation and nucleotide release	Lab Medics Chronolog 700 platelet aggregometer, LP_HAEM_COAG50	А
Blood	Sickle solubility test for presence of sickle haemoglobin (HbS)	Streck Sickledex qualitative solubility and LP_HAEM_RC32	A,B
	Haemoglobin (Hb3)	Streck SICKLEDEX 100 test kit HA-S-43	D
Blood	Sickle cell screen	Streck Sickledex qualitative solubility test HA-S-43	С
Serum	Detection of: Intrinsic factor antibody Erythropoietin	Beckman Access 2 analyser and LP HAEM GH9	A
		Documented in-house methods to meet the requirement of the Sickle cell and thalassaemia screening progamme as defined in the July 2018 'Sickle cell and thalassaemia screening:laboratory QA evidence requirments	
	Sickle cell and Thalassemia screen for beta trait and evidence of alpha trait.	Biorad Variant II HPLC analyser, LP_HAEM_RC19 Variant II Operation.	В
Blood	Detection of abnormal haemoglobin including HBS, C, D, E, OArab, Lepore, and Dpunjab	Amersham Biosciences Mutiphor II iso-electric focussing, Perkin Elmer staining kit and Neonatal staining kit, LP_HAEM_RC33	В

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HUMAN BODY FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Blood	G6PD screen and assay	Trinity Biotech G6PD screening test kit, LP-HAEM RBC 50 G-6-PDH Screen	A
		Pointe Scientific G6PD assay kit, HAEM RBC PRO 007 G-6-PDH Enzyme Assay	
Urine	Detection of haemosiderin	Manual staining using Clinitech Perl's staining kit, HAEM RBC PRO 010 Haemosiderin	A, B
	Blood Transfusion examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant	
Blood	Serological Cross match	Automated cross match using Grifols Erytra analyser and LP_HAEM_BT75	A, B
		Manual cross match using Grifols cards and LP_HAEM_BT78	
Blood	Cross match	Ortho Vision analyser using column agglutination technology BB-S-19	С
Blood	Determination of blood group (ABO, RhD) and Antibody screening using the following panel: NBS cellstab 2 cell	Automated ABO Blood Group typing and Antibody screening using Grifols Erytra analyser, LP_HAEM_BT76	A, B
	panel (CE) covering D, C, E, c, e, C ^w , K, k, Kp ^a , Js ^a , Fy ^b , Jk ^b , Le ^a , Le ^b , P ₁ , M, N, S, s, Kp ^b , Lu ^b	Manual Grouping and Antibody screening using Grifols cards and LP_HAEM_BT77	
Blood	Blood Group, A, B, O and AB groups Rh groups, antigen D and antibody screen using Ortho Surgiscreen 3 cell panel	Ortho Vision analyser using column agglutination technology BB-S-23	С
	Rh groups, antigen D and antibody screen using Ortho		

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Blood	Antibody panels of the following systems: Rh-hr, KELL, DUFFY, KIDD, LEWIS, MNS, P and	Ortho Vision analyser using column agglutination technology Resolve Panel C SOP BB-S-5	D
	LUTHERAN	Resolve Panel B SOP BB-S-25	С
		Manual method using NHSBT panel 1 in CellStab SOP BB-S-3	D
Blood	Antibody identification and phenotyping Using Griffols IAT and ENZ panels panel to ID: D, C, E, c, e, Cw, K, k, Kpa, Jsa, Fya, Fyb, Jka Jkb, Lea, Leb, P1, M, N, S, s, Lua, Cob, Xga	Automated using Grifols Erytra analyser and manual method using Grifols cards and LP_HAEM_BT14	A, B
Blood	Direct antiglobulin test for detection of antibody bound red cells	Automated method using Grifols Erytra analyser and manual method using Grifols cards and LP_HAEM_BT21	A, B
Blood	Direct antiglobulin test	Ortho Vision analyser using column agglutination technology SOP BB-S-12	C, D
Blood	Determination of Rhesus and Kell Phenotyping (D, C, E, c, e, C ^w , K)	Automated using Grifols Erytra analyser and manual using Grifols Cards and LP_HAEM_BT14	A, B
Blood	Measurement of foetal Hb in maternal blood for FMH determination	Using the Kleihauer technique with acid elution and the Clin-Tech Shepard's stain kit, LP_HAEM_BT61	A, C

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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Whole Blood: EDTA samples	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	Agglutination using manual tubemethods: BB-S-11: Manual Grouping Methods BB-S-9: Manual Blood Group Control and Manual cross match control	D
Whole Blood: EDTA samples	Crossmatch	Manual method BioRad using Gel card agglutination. BB-S-4	D
Whole Blood :EDTA Plasma	Atypical antibody screen and red blood cell phenotyping by detection of antibodies to: Rh: C, D, E, c, e, f, Cw and V. Kell: K, k, Kp(a), Kp(b), Js(a) and Js(b). Duffy: Fy(a) and Fy(b). Kidd: JK(a) and Jk(b). Sex Linked: Xg(a). Lewis: Le(a) and Le(b). MNS: S, s, M and N P: P1 Lutheran: Lu(a) and Lu(b).	Column Agglutination using Ortho Vision using: BB-S-17 Ortho Vision Sample processing Column Agglutination technology using Ortho Vision autoamted techniques methods using: BB-S-20 Manual Bio Vue methods using: BB-S-5: BioVue Untreated Cell Panel and Ficin Treated Cell Panel BioRad LISS/Coombs method using: BB-S-3: NHSBT Cell panel	D

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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant		
EDTA Plasma	Four Cell Anti-D Screening Test	Manual Column Agglutination technology using Ortho BioVue methods:	D	
		BB-S-7: Investigation of RhD Negative Women with a Positive Antibody Screen Following Administration of Anti-D Prophylaxis.		
EDTA Whole Blood	Foetal Maternal Haemorrhage	Kleihauer - Shepard's Stain Kit using acid elution staining technique. BB-S-1: Mother and Cord Testing. BB-S-2: Estimation of Foeto-Maternal Haemorrhage	D	
END				

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