

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8650 Accredited to ISO 15189:2012	Manchester University NHS Foundation Trust	
	Issue No: 003 Issue date: 26 March 2021	
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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 B

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	B



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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	<u>Haematology examinations for the purposes of clinical diagnosis</u>	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 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 XN 9000, 1000 and 450 Analyser modules by flow cytometry, impedance and Spectrophotometry SOPs LP-HAEM-BC19 LP-HAEM-BC20 LP-HAEM-BC31	A
		Sysmex XN2000 analyser by flow cytometry, impedance and spectrophotometry LP-HAEM-BC19 LI_TGH_H19	B
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-LP-HAEM-BC34	A
		Manual blood film preparation and automated staining using RAL stainer and May Grunwald and Giemsa stain examined by light microscopy using LP-LP-HAEM-BC33	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Malaria screen for P. falciparum P. vivax P. ovale P. malariae P. knowlesi	Using Giemsa/Fields Staining for thin smears and manual microscopy LP HAEM BCM 202 (in combination with BINAX NOW)	A,B
Blood	Malaria screen for P. falciparum P. vivax P. ovale P. malariae	BINAX NOW Malarial screen kit and SOP LP-HAEM BCM 202	A, B
Blood	Qualitative detection of infectious mononucleosis heterophile antibody	Clearview kit using HAEM BCM PRO 203	A, B
Blood	Estimation of Erythrocyte Sedimentation Rate	Automated method using Sysmex Interliner and Westergren method, LP-HAEM-BC29	A
		Automated method using Starrsed Autocompact and Westergren method, LP_TGH_H8 Autocompact ESR analyser- Trafford	B A
Bone marrow	Bone marrow assessment for detection of abnormal cell types, morphology and numbers	Manual ACQUISEL Westergren Micro System, LP-HAEM-BC18	A
		Sysmex SP10 slide stainer and Romanowski stain, HAEM BCM PRO 401	
		RAL staining machine and Romanowski stain, LI-HAEM-BC33	B



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum	Ferritin Vitamin B12	Roche Cobas c8000 analyser using photometry and electrochemiluminescence and SOP CB-Auto-PRO-019	A
Serum	Vitamin B12 Folate Ferritin	Roche Cobas 6000 analyser, CB_TRAF_PROC-27	B
	<u>Coagulation</u>		
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
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
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



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	<u>Coagulation</u> (cont'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 methods LP_TGH_H5	B
Plasma	Coagulation Factor Assays: Factor II, V, VII, VIII, IX, X, XI, XII Factor VIII Refacto Chromogenic Factor VIII and XIII Von Willebrand antigen level Ristocetin Cofactor level	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 LP_HAEM-COAG47 LP_HAEM_COAG47	A



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HUMAN BODY FLUIDS (cont'd) Citratd Plasma	<u>Haematology examinations for the purposes of clinical diagnosis</u> (cont'd) <u>Coagulation</u> (cont'd) Inhibitor assays: Nijmegen modification Bethesda assay <ul style="list-style-type: none"> • FVIII • FIX <u>Monitoring of Factor replacement Therapies</u> <u>FVIII</u> <u>Factors Assays</u> FV, FII, FVII, FX FVIII, FIX, FXI, FXII	In-house documented procedures based on equipment manuals as relevant 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 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 CaCl ₂ LP_HAEM-COAG48	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Platelet function analysis	Siemens Innovance PFA-200 system using high-shear force dynamic flow, LP_HAEM_COAG17	A
Blood	Platelet aggregation and nucleotide release	Lab Medics Chronolog 700 platelet aggregometer, LP_HAEM_COAG50	A
Blood	Quantification of Zinc Protoporphyrin	Helena Protofluor Z Spectrophotometer and LP_HAEM_RC14 ZPP	A
Blood	Sickle solubility test for presence of sickle haemoglobin (HbS)	Clinitech Sickle Test kit and HAEM RBC PRO 006.	A
Serum	Detection of: Intrinsic factor antibody Erythropoietin	Beckman Access 2 analyser and LI_HAEM_RC22, RC21, RC18	A
		Documented in-house methods to meet the requirement of the Sickle cell and thalassaemia screening programme as defined in the July 2018 'Sickle cell and thalassaemia screening: laboratory QA evidence requirements	
	Sickle cell and Thalassemia screen for beta trait and evidence of alpha trait.	Biorad Variant II HPLC analyser, LP_HAEM_RC19 Variant II Operation.	B
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, HAEM RBC PRO 005 IEF	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	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 Pointe Scientific G6PD assay kit, HAEM RBC PRO 007 G-6-PDH Enzyme Assay	A
	<u>Blood Transfusion examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Urine	Detection of haemosiderin	Manual staining using Clinitech Perl's staining kit, HAEM RBC PRO 010 Haemosiderin	A, B
Blood	Serological Cross match	Automated cross match using Grifols Erytra analyser and LP_HAEM_BT75 Manual cross match using Grifols cards and LP_HAEM_BT78	A, B
Blood	Determination of blood group (ABO, RhD) and Antibody screening using the following panel: NBS cellstab 2 cell panel (CE) covering D, C, E, c, e, C ^w , K, k, Kp ^a , Js ^a , Fy ^a , Fy ^b , Jk ^b , Le ^a , Le ^b , P ₁ , M, N, S, s, Kp ^b , Lu ^b	Automated using Grifols Erytra analyser, LP_HAEM_BT09 Manual using Grifols cards and LP_HAEM_BT77	A, B
Blood	Antibody identification and phenotyping Using Griffols IAT and ENZ panels panel to ID: D, C, E, c, e, C ^w , K, k, Kp ^a , Js ^a , Fy ^a , Fy ^b , Jk ^a , Jk ^b , Le ^a , Le ^b , P ₁ , M, N, S, s, Lu ^a , Co ^b , Xg ^a	Automated using Grifols Erytra analyser and manual method using Grifols cards and LP_HAEM_BT14	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
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	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
END			