

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



Accredited to  
ISO 15189:2022

### Sheffield Teaching Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 19 February 2025

Haematology Department  
Laboratory Medicine Centre (North Lane)  
North General Hospital  
  
Herries Road  
Sheffield  
S5 7AU

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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
<b>Address</b> Haematology Department Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF  <b>Local contact</b> Dean Tazzyman	Haematology Blood Transfusion Coagulation Blood Issue fridge	A
<b>Address</b> Haematology Department Laboratory Medicine Centre (North Lane) North General Hospital Herries Road Sheffield S5 7AU  <b>Local contact</b> Dean Tazzyman	Haematology Blood Transfusion Coagulation Blood issue fridge	B



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

Location details	Activity
Blood Issue fridge A floor, Theatre Royal Hallamshire Hospital	Storage and issue of blood and blood products
Blood Issue Fridge Jessop Wing Theatre Royal Hallamshire Hospital	Storage and issue of blood and blood products
Blood Issue fridge O2 Day Ward	Storage and issue of blood and blood products
Blood Issue Fridge Weston Park Hospital	Storage and issue of blood and blood products
Blood Issue fridge Huntsman Ward North General Hospital	Storage and issue of blood and blood products
Blood Issue Fridge Chesterman (cardiac) Theatre Recovery North General Hospital	Storage and issue of blood and blood products
Blood Issue Fridge Spinal Injury Unit, Osborn Theatre Recovery North General Hospital	Storage and issue of blood and blood products
Blood Issue Fridge A&E Resus Fridge North General Hospital	Storage and issue of blood and blood products



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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
<b>HUMAN BODY FLUIDS</b>	<u>Haematology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Full Blood Count Haemoglobin White Blood Cell Count Red Blood Count Platelet Count Haematocrit Mean Cell Volume Mean Cell Haemoglobin Mean Cell Haemoglobin Concentration Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Reticulocyte count Nucleated Red Cells	Sysmex XN9000 (Two XN-10 and one XN-20) by flow cytometry, impedance and Spectrophotometry SOPs HAUTO042, HAUTO019	A, B
Blood	Quantification of haemoglobin	Haemocue photometer and SOP HAUTO018	A, B
Blood	Blood film assessment for the detection of abnormal cell types, morphology and numbers	Automated using Sysmex slide maker stainer SP-50 and manual method using SOPs HMORPH0016, HMORPH0017, HMORPH0018 HMORPH002 HMORPH0009	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 including documented in-house methods to meet the requirements of the SCT screening programme* as defined in the laboratory QA evidence requirements	
Blood	Detection of abnormal haemoglobin* (HbA2 and HbF) and putative identification of Hb variants Hb S, C, D- Punjab, E, O- Arab, Lepore	Haemoglobinopathy Primary Screening:  Sebia Capillarys 3 Tera Analyser using capillary electrophoresis, SOP RHHS055	A
Blood	Screen for Sickie Haemoglobin	Clin-Tech Sickie Test SOP RHHS001	A, B
Blood	Confirmation of haemoglobin variants	Haemoglobin Electrophoresis for confirmation of identity of Hb variants detected by CE. Sebia Hydrasys Haemoglobin Electrophoresis SOP RHHS065	A
Blood	Identification of any haemoglobin variant	Electrospray-Ionisation Mass Spectrometry (ESI-MS) method using the Thermo Fisher TSQ Quantum Ultra LC-MS system Mass Spectrometer, With reference to the online database of Hb Variants: <a href="http://globin.bx.psu.edu/hbvar/menu.html">http://globin.bx.psu.edu/hbvar/menu.html</a> SOP RHHS052, RHHS053	B
Blood	Detection and quantitation of malarial parasites; Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae, Plasmodium knowlesi	Manual staining of thin film (pH7.2) and thick films using Fields stain and CareUs Test, SOP HMORPH006	A, B
Blood	ESR	Sysmex Interliner Westergren method and SOP HAUTO037	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 including documented in-house methods to meet the requirements of the SCT screening programme* as defined in the laboratory QA evidence requirements	
Plasma	Detection of Infectious Mononucleosis heterophile antibody	Biokit monogen latex agglutination kit and SOP HMORPH005	A, B
Blood	G6PD assay	Pointe Scientific assay kit and Camspec M209T single beam scanning spectrophotometer, SOP RHHS029	A
Blood	G6PD screen	Trinity biotech Kit 203-A Qualitative fluorescent spot method, SOP RHHS029	A
Blood	Quantification of HbA1c	Sebia Capillarys 3 Tera Analyser using Capillary Electrophoresis, SOP RHHS056	A



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Plasma	Quantitative measurement of Plasma Viscosity	Benson Plasma Viscometer BV1 SOP RHHS030	A
Blood	Quantitative determination of total glycated haemoglobin	Alere Afinion analyser using a Boronate Affinity colorimetric method, SOP RHHS049	A
HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant. Performed on a BD FACSCanto II flow cytometer or BD FACSLytic flow cytometer	
	Techniques as described below:		
Blood	Lymphocyte subset analysis, percentage and absolute number of: CD3, CD3/4, CD3/8, CD19, CD16/56, CD4/CD8 ratio	SOPs RHCM016, RHCM062	A
Blood	CD34 enumeration, measuring absolute number of haemopoietic stem cells	RHCM022, RHCM063	A
Blood	Screen and high resolution assay for demonstration of paroxysmal nocturnal haemoglobinuria. Neutrophils, monocytes and red blood cells are analysed using FLAER and CD24 for detection of a PNH clone in neutrophils, FLAER and CD14 in monocytes, and CD59 in red blood cells. Clone size reported as a %	RHCM073	A
Blood	Screen and quantitation of Foetal Hb in maternal blood for FMH determination	STHBB017	A



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HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant. Performed on a BD FACSCanto II flow cytometer or BD FACSLytic flow cytometer	
Blood, bone marrow, CSF, body fluids	Techniques as described below:  Acute leukaemia panel to identify immunophenotype of leukaemic blast cells, to assess cell lineage, maturation stage, prognostic markers, and diagnose type of haematological malignancy using the following antibodies CD3, CD7, CD10, CD13, CD14, CD15, CD16, CD19, CD20 CD25, CD33, CD34, CD38, CD45, CD117, HLADR, CD64, CD2, Cytoplasmic MPO, CD22, CD3, CD79a and TDT, CD4, CD5, CD8, CD56, CD1A, CD26, CD11c CD11b, CD41, CD61, CD235a.	RHCM065	A
Blood, bone marrow, CSF, body fluids	Lymphoproliferative panel: For identification of leukaemic lymphoid cells to assess maturation stage, possible prognostic markers, and sub- classify type of leukaemia/ lymphoma/myeloma using antibodies CD19, CD20, CD10, FMC7, CD23, CD79b, CD3, CD5, CD200, CD43, CD103, CD11C, CD25, Kappa, Lambda, CD1A, CD2, CD7, CD26, CD4, CD8, HLADR, CD56, CD16, CD138, CD38, Cytoplasmic CD3, CD79a, CD22, and TDT	RHCM013	A



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HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant. Performed on a BD FACSCanto II flow cytometer or BD FACSLytic flow cytometer	
CD3+ T Cell fraction, selected from blood	Techniques as described below:  T cell purity assessment of sample undergoing lineage specific chimerism. Expressed as a % of nucleated cells	Immunophenotyping technique using SOP RHCM075.  BD FACSCanto II flow cytometer (only)	A
Blood	Platelet glycoprotein analysis using CD61, CD41 and CD42b to determine normal, reduced or absent antigen expression	RHCM067	A
Blood	Immuno platelet counting utilising CD61, CD41 and CD42b to determine the platelet count	RHCM066	A
Bone marrow aspirate	Bone marrow morphological examination: assessment for detection of abnormal cell types, morphology and numbers	Manual and Lamb Stainmate staining using May Grunwald and Giemsa and examined using light microscopy. SOP RHMO006, RHHODS003	A
Bone marrow	Assessment of iron (Haemosiderin) and detection of ringed sideroblasts in bone marrow smears	Manual slide staining using Perls stain and SOP RHCM052	A





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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Determination of blood group (ABO and RhD type)	Grifols Erytra analysers using column agglutination, STHBB073  Manual method by Grifols Erytra gel cards or tube using SOP STHBB091	A, B
Plasma	Antibody screening for red cell antibodies to: C, D, E, c, e, M, N, S, s, P1, K, k, Lea, Leb, Fya, Fyb, Jka, Jkb	Grifols Erytra analysers using column agglutination (indirect anti- globulin test) and STHBB073  Manual method using Grifols Gel Card (indirect anti-globulin test) and SOP STHBB092	A, B
Plasma	Antibody identification of red cell antibodies to: C, D, E, c, e, Cw, M, N, S, s, P1, Lua, K, k, Kpa, Lea, Leb, Fya, Fyb, Jka, Jkb	Grifols Erytra analysers using column agglutination (indirect anti- globulin and saline enzyme test) and SOP STHBB083  Manual method using Grifols Gel Card (indirect anti-globulin test, saline enzyme test, indirect anti-globulin test enzyme, saline room temperature test) and SOP STHBB083	A, B  A
Blood and plasma	Serological cross match or electronic issue	Grifols Erytra analysers using column agglutination (indirect anti- globulin test) and SOP STHBB025  Manual method using Grifols Gel Card (indirect anti-globulin test) and SOP STHBB025, STHBB045	A, B
Blood	Phenotyping: Rh, C, c, E, e	Grifols Erytra analysers using column agglutination and SOP STHBB084  Manual method using Grifols Gel Card and SOP STHBB084	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Neonatal group and direct antiglobulin test	Grifols Erytra analysers using column agglutination and SOP STHBB073  Manual method using Grifols Gel Card (indirect anti-globulin test) and SOP STHBB091	A
	Direct Antiglobulin Test including anti-IgG and anti-C3d	Grifols Erytra analysers using column agglutination and SOP STHBB094  Manual method using Grifols Gel Card and SOP STHBB094	A, B
Blood	Blood group (ABO and Rh D type)	Manual method using tile group and SOP STHBB0107	A, B
Blood	Blood group (ABO and Rh D type)	Manual method using tube group and SOP STHBB0107	A
Plasma	Titration of Anti-A and Anti B	Manual method using indirect antiglobulin test, saline test and SOP STHBB089	A
Blood	Kleihauer-Screen for Foetal Hb in maternal blood for FMH determination	Manual method using CLIN-TECH Sheperds stain and SOP STHBB056	A



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Plasma	Quantitative measurement of FXIII antigen	Latex Immunoturbidimetric performed on ACL TOP. SOP RGA039	A
Plasma	Quantitative measurement of the following for diagnosis of thrombophilia:	ACL TOP analyser using chromogenic, latex immunoturbidimetry, end point clotting and immunoassay, SOPs	A
	Chromogenic Antithrombin (IIa and Xa)	RGT026, RGT009	
	Chromogenic Protein C Antithrombin Antigen	RGT026	
	Progressive Antithrombin	RGT040	
	Clotting Protein C Activity	RGT011	
	Clotting Protein S Activity	RGT047	
	Free Protein S	RGT047	
	Factor V Leiden screen	RGT026	
	Homocysteine	RGT026	
	Plasminogen	RGT027	
		RGT052	
Plasma	Quantitative measurement of the following clotting factor levels:	Sysmex CS5100 analyser	
	Factor II, V, VII, VIII, IX, X, XI, XII	Clotting end point assay and SOP RGA027	A, B
	High molecular weight kininogen and prekallikrein	Clotting end point assay and SOP RGA037	A
	Two stage Factor VIII, an incubation step for production of FXa and second step to determine the amount of FXa proportional to FVIII level	Two step assay using SOP RGA030	A
	Chromogenic FVIII-determination of FVIII level relative to FX activation	Chromogenic assay using SOP RGA038	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Plasma (cont'd)	Quantitative measurement of the following clotting factor levels:	Sysmex CS5100 analyser	
	Chromogenic FIX-determination of FIX level relative to FX activation	Chromogenic assay using SOP RGA040	A
	Chromogenic FIX activity determination and Refixia (N9-GP) monitoring	Chromogenic assay using Rossix kit and SOP RGA040	A
	FXIII Assay	Chromogenic ammonia release assay. SOP RGA007	A
Plasma	Fibrinogen antigen	Latex immunoassay using SOP RGRCS-301	A
Plasma	Automated coagulation screen tests:	Tests performed on Sysmex CS5100 using light transmission, optical change or immunoturbidimetry	A, B
	Prothrombin time INR	COAG11	
	PT +50% correction APTT	COAG10	
	APTT ratio	COAG14	
	APTT +50% correction	COAG13	
	Fibrinogen (Clauss & derived)	COAG15	
	Thrombin time		
	Thrombin time and Protamine Sulphate Correction	COAG15 COAG8	
	D-Dimer Reptilase time	COAG7	
	Alpha 2 antiplasmin	RGR-CS221	
	Quantitative measurement of the following clotting factor inhibitors:	Sysmex CS5100 analyser	A
	Quantitative assay of VIII Bethesda inhibitor	Based on the amount of FVIII inactivated by test plasma. SOP RGA032	A



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Plasma (cont'd)	Quantitative assay of non-specific clotting factor inhibitors	Based on the amount of factor inactivated by test plasma, SOP RGA033	A
	Quantitative assay of Von Willebrand Factor inhibitor assay	Based on the amount of VWF inactivated by test plasma, SOP RGA010	A
Plasma	Quantitative measurement of Von Willebrand Factor Activity	Immunoturbidimetric assay using antibody to Gp1b performed on Sysmex CS5100. SOP RGA035	A
	Quantitative measurement of Von Willebrand Factor Antigen	Immunoturbidimetric assay using antibody against VWF performed on Sysmex CS5100. SOP RGA034	A
	Dilute Russell Viper Venom Time	Sysmex CS5100 analyser using clotting end point for detection of antiphospholipid antibodies. SOP RGL019	A
Plasma	Quantitative measurement of the following anticoagulants: Low molecular weight heparin Heparinoid Unfractionated heparin Fondaparinux	Sysmex CS5100 analyser:  Chromogenic anti-Xa assay using SOP COAG12	A, B
	Direct IIa inhibitors	Dilute thrombin time assay using SOP RGR-CS212, RGRCS303	A
	Direct Xa inhibitors	Chromogenic anti-Xa assay using SOPs COAG12	A, B
Citrated Plasma	In vitro measurement of Heparin and their analogues: Low molecular weight Heparin Orgaran Unfractionated Heparin Fondaparinux Rivaroxaban Apixaban Edoxaban	Chromogenic Biophen Heparin LRT assays using SOPs RGNCS038 and COAG12	A, B



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Plasma	VWF multimers	Agarose gel electrophoresis and immunofixation with the Hydrasys 2 RGA060	A
Plasma	Quantitative measurement of Protein C antigen	Manual ELISA using polyclonal antibody to protein C and Genscript labelled HRP labelled antibody. SOP RGT005	A
	Quantitative measurement of Factor X antigen	Manual ELISA using polyclonal antibody to Factor X and Genscript labelled HRP labelled antibody. SOP RGT005	A
	Quantitative measurement of VWF antigen	Manual ELISA using polyclonal antibody to protein VWF and HRP labelled antibody. SOP RGA010	A
	Quantitative measurement of Factor VII antigen	Manual ELISA using polyclonal coat to Factor VII and peroxidase labelled antibody. SOP RGT039	A
	Quantitative measurement of Total and Free Protein S	Manual ELISA using polyclonal antibody to protein S and HRP labelled antibody. SOP RGT012	A
	Quantitative measurement of Antithrombin Antigen	Manual ELISA using polyclonal antibody to antithrombin and HRP labelled antibody. SOP RGT013	A
	Quantitative measurement of ADAMTS-13 Activity	Manual Chromogenic ELISA for the determination of ADAMTS-13 activity in human plasma. SOP RGA026	A
	Quantitative measurement of ADAMTS-13 Antibody	Manual Chromogenic ELISA for determination of human autoantibodies (IgG) against ADAMTS-13. SOP RGA049	A



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Plasma	Qualitative measurement FVIII binding	Manual ELISA using monoclonal capture antibody to FVIII and chromogenic assay to quantitate bound FVIII. Sop RGA006	A
	Quantitative measurement of collagen binding of vWF	Manual Bio-immunoassay based on the ability of vWF to bind collagen. SOP RGA005	A
Serum	Quantitative measurement of the following:	ACL Acustar analyser	A
	Anti-Cardiolipin IgG and IgM antibodies	Chemiluminescent assay and SOP RGL017	
	Anti-B-2-Glycoprotein-1	Chemiluminescent assay and SOP RGL017	
Serum	Heparin induced thrombocytopenia screen for the detection of associated IgG antibody	ACL Acustar analyser using chemiluminescence and SOP RGP022	A
Citrated Plasma	ADAMTS-13 activity	ACL Acustar analyser using chemiluminescence (IL reagents) and SOP RGADAMTS-13	A
Plasma	Manual coagulation tests as follows: PT APTT Thrombin time Fibrinogen	Visual endpoint tilt tube assay using SOPs RGRM01 RGRM02 RGRM03 RGRM04	A, B
Plasma	Qualitative detection of heparin binding site defects in antithrombin	Two dimensional electrophoresis on agarose gels using SOP RGT031	A
Blood	Detection of whole blood haemostasis	Rotational thromboelastometry (ROTEM) analyser using SOP RGA009	A



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Whole blood	Detection of Factor V Leiden (FVL) mutation	Loop Mediated Isothermal Amplification (LAMP) using MIC-4 thermal cycler for melting curve analysis for presence of:	
Whole Blood	Detection of Prothrombin Allele mutation (p20210a)	FVL mutation, La Car MDx reagents SOP RGT055	
		p20210a mutation, La Car MDx reagents SOP RGT056	
END			