

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8508</b> Accredited to ISO 15189:2012	<b>Sheffield Teaching Hospitals NHS Foundation Trust</b>	
	Issue No: 003    Issue date: 20 July 2020	
	<b>Haematology Department</b> <b>Laboratory Medicine Centre</b> <b>(North Lane)</b> <b>North General</b> <b>Hospital Herries Road</b> <b>Sheffield</b> <b>S5 7AU</b>	<b>Contact: Richard Wardle</b> <b>Tel: +44 (0) 114 2712621</b> <b>E-Mail: Richard.wardle@sth.nhs.uk</b>
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> Richard Wardle	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> Richard Wardle	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
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 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 (Three XN-10) 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-10 and manual method using SOPs HMORPH012 HMORPH002 HMORPH009 HMORPH0011	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	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 Carestart Rapyd Test, SOP HMORPH006	A, B
Blood	ESR	Sysmex Interliner Westergren method and SOP HAUTO037	A, B
Plasma	Detection of Infectious Mononucleosis heterophile antibody	Biokit monogen latex agglutination kit and SOP HMORPH005	A, B
Blood	Screen for Sickle Haemoglobin	TCS Biosciences solubility test, SOP RHHS001	A, B
Blood	G6PD assay	Pointe Scientific assay kit and Camspec M501 Single-beam scanning UV/Visible Spectrophotometer, SOP RHHS029	A
Blood	G6PD screen	Trinity biotech Kit 203-A Qualitative fluorescent spot method, SOP RHHS029	A
Blood	Detection of abnormal haemoglobin (HbA2 and HbF) and putative identification of Hb variants Hb S, C, D- Punjab, E, O- Arab, Lepore	Sebia Capillarys 2 flex piercing analyser using capillary electrophoresis, SOP RHHS055	A
Blood	Quantification of HbA1c	Sebia Capillarys 3 Tera Analyser using Capillary Electrophoresis, SOP RHHS056	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	Confirmation of haemoglobin variants	Haemoglobin Electrophoresis for confirmation of identity of Hb variants detected by CE. Helena SAS-MX Acid and Alkaline electrophoresis gel kits and Helena electrophoresis baths and power supplies, SOPs RHHS009, RHS010, RHHS041	A
Plasma	Quantitative measurement of Plasma Viscosity	Benson Plasma Viscometer, SOP RHHS030	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	Quantitative determination of total glycated haemoglobin	Alere Afinion analyser using a Boronate Affinity colorimetric method, SOP RHHS049	A
Blood	<u>Immunophenotyping examinations for the purposes of clinical diagnosis</u> techniques as described below	In-house documented procedures based on equipment manuals as relevant. Performed on a BD FACSCanto II flow cytometer or BD FACSLyric flow cytometer	
Blood	Lymphocyte subset analysis, percentage and absolute number of: CD3, CD3/4, CD3/8, CD19, CD16/56, CD4/CD8 ratio	Using both manual pipetting and BD Sample Preparation Assistant (SPA III) RHCM057, RHCM016, RHCM062	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 FACSLyric flow cytometer	
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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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood, bone marrow, CSF, body fluids</p>	<p><u>Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>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.</p>	<p>In-house documented procedures based on equipment manuals as relevant. Performed on a BD FACSCanto II flow cytometer or BD FACSLyric flow cytometer</p> <p>RHCM065</p>	<p>A</p>
<p>Blood, bone marrow, CSF, body fluids</p>	<p>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</p>	<p>RHCM013</p>	<p>A</p>



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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	T cell purity assessment of sample undergoing lineage specific chimerism. Expressed as a % of nucleated cells	Immunophenotyping technique using SOP RHCM075.	A
Blood	Platelet glycoprotein analysis using CD61, CD41 and CD42b to determine normal, reduced or absent antigen expression	BD FACSCanto II flow cytometer (only) 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
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
Blood	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 RHBB010, NHBB006	A, B
Blood	Blood group (ABO and Rh D type)	Manual method using tube group and SOP RHBB011	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:  Chromogenic Antithrombin (IIa and Xa)	ACL TOP analyser using chromogenic, latex immunoturbidimetry, end point clotting and immunoassay, SOPs  RGT026, RGT009	A
	Chromogenic Protein C Antithrombin Antigen Progressive Antithrombin Clotting Protein C Activity Clotting Protein S Activity Free Protein S Factor V Leiden screen Homocysteine Plasminogen	RGT026 RGT040 RGT011 RGT047 RGT047  RGT026 RGT026 RGT027 RGT052	
Plasma	Quantitative measurement of the following clotting factor levels:  Factor II, V, VII, VIII, IX, X, XI, XII	Sysmex CS5100 analyser  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 RGRCS-202, RGR-CS210 RGRCS-202, RGR-CS210 RGRCS-202 RGRCS-205 RGRCS-205 RGRCS-205 RGR-CS206/203 RGRCS-208 RGRCS-208 RGRCS-207 RGRCS-209	A, B
	Prothrombin time INR PT +50% correction APTT APTT ratio APTT +50% correction Fibrinogen (Clauss & derived) Thrombin time Thrombin time and Protamine Sulphate Correction D-Dimer Reptilase time		
	Alpha 2 antiplasmin	RGR-CS215	
	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
Plasma	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
Plasma	Quantitative measurement of Von Willebrand Factor Antigen	Immunoturbidimetric assay using antibody against VWF performed on Sysmex CS5100. SOP RGA034	A
Plasma	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 RGR-CS200	A, B
Plasma	Direct IIa inhibitors	Dilute thrombin time assay using SOP RGR-CS212, RGRCS303	A
Plasma	Direct Xa inhibitors	Chromogenic anti-Xa assay using SOPs RGR-CS014, RGRCS302	A, B
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



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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	
	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
	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	



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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	
Serum	Quantitative measurement of the following:  Anti-Cardiolipin IgG and IgM antibodies  Anti-B-2-Glycoprotein-1	ACL Acustar analyser  Chemiluminescent assay and SOP RGL017  Chemiluminescent assay and SOP RGL017	A A
Serum	Heparin induced thrombocytopenia screen for the detection of associated IgG antibody	ACL Acustar analyser using chemiluminescence and SOP RGP022	A
Plasma	Quantitative measurement of fibrinogen antigen	Radial Immunodiffusion using RGT024	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
Plasma	Quantitative measurement of thrombin production	Thermo Fluoroskan microplate fluorometer using SOP RGA008	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	DNA extraction	Using heating block and SOPs RGT021 and RGT022	A
DNA extracted in-house using the above method	Detection of thrombophilia mutations for Factor V Leiden and Prothrombin 20210G>A	PCR using Roche Lightcycler and SOPs RGT021 and RGT022	A
END			