


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p><b>8864</b></p> <p>Accredited to <b>ISO 15189:2012</b></p>	<h3>St Helens and Knowsley Teaching Hospitals NHS Trust</h3> <p><b>Issue No: 001    Issue date: 17 September 2018</b></p>	
	<p><b>Haematology Department</b>  <b>St Helens and Knowsley Teaching Hospitals NHS Trust</b>  <b>Whiston Hospital</b>  <b>Warrington Road</b>  <b>Prescot</b>  <b>L35 5DR</b></p>	<p><b>Contact: Stacy Burrows</b>  <b>Tel: +44 (0) 151 430 2360 / 1838</b>  <b>E-Mail: Stacy.Burrows@sthk.nhs.uk</b>  <b>Website: www.shk.nhs.uk/pathology</b></p>
<p><b>Testing performed by the Organisation at the locations specified below</b></p>		

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

#### Laboratory locations:

Location details	Local contact	Activity	Location code
<p>Haematology Department                      St Helens and Knowsley Teaching Hospitals NHS Trust                      Whiston Hospital                      Warrington Road                      Prescot                      L35 5DR</p>	<p><b>Local contact</b>                      As above</p>	<p>Haematology                      Haemoglobinopathies                      Special Coagulation                      Blood Transfusion                      Management of blood fridges                      Phlebotomy</p>	STHK
<p>Haematology Department                      Southport Hospital                      Town Lane                      Kew                      PR8 6PN</p>	<p><b>Local contact</b>                      As above</p>	<p>Haematology                      Routine Coagulation                      Blood Transfusion                      Management of blood fridges                      Phlebotomy</p>	SOHT
<p>Haematology Department                      Ormskirk District General Hospital                      Wigan Road                      Ormskirk                      L39 2AZ</p>	<p><b>Local contact</b>                      As above</p>	<p>Haematology                      Blood Transfusion                      Management of blood fridges                      Phlebotomy</p>	ORMS
<p>Haematology Department                      St Helens Hospital                      St Helens                      WA9 3DA</p>	<p><b>Local contact</b>                      As above</p>	<p>Haematology                      Routine Coagulation                      Management of blood fridges                      Phlebotomy</p>	STH



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

Location details	Activity	Location code
Emergency Department, Whiston Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	STHK
Delivery Suite, Whiston Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	STHK
Theatres, Whiston Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	STHK
Elyn Lodge, St Helens Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	STH
Lilac Centre, St Helens Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	STH
Fairfield Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	FF
Theatre, Southport Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	SOHT
Maternity, Ormskirk Hospital <b>Local contact</b> As above	Blood issue fridge No testing occurs on this site, blood storage only	ORMS



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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 examination for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	STHK
Whole blood	Full Blood Count	Sysmex XN9000 by flow cytometry, impedance and Spectrophotometry	STHK
	Haemoglobin	SOP 2 XN Running FBC Samples	
	White Blood Cell count		
	Red blood cell count		
	Platelet count		
	Haematocrit	Sysmex XN2000	SOHT
	Mean Cell Volume	SOP 2 XN Running FBC Samples	
	Mean Cell Haemoglobin		
	Mean Cell Haemoglobin concentration	Sysmex XN1000	ORM
	Red Cell Distribution width	SOP 2 XN Running FBC Samples	
	Neutrophil count		
	Lymphocyte count		
	Monocyte count	Sysmex XS1000	STH
	Eosinophil count	SOP 2 XS1000i processing QC &	
	Basophil count		
	Nucleated Red Cell count		
	Reticulocyte count		
Whole blood	Erythrocyte Sedimentation Rate (ESR)	Automated Sysmex Interliner and Auto Compact Westergen method SOP ESR	STHK
Whole blood	Erythrocyte Sedimentation Rate (ESR)	Manual method Westergen method  SOP 54 Aquisel ESR	STHK SOHT ORM



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood, bone marrow	Detection of normal and abnormal morphologies	Blood film examination using Giemsa and May Grunwald (MG) staining and light microscopy	
		Automated Staining using SOP SP10	STHK
		Automated staining SOP Operation of Hematek®	SOHT
		SOP 22 Bone marrow aspiration, slide prep and procedure	
		Microscopy SOP Haematology Bone marrow review and reporting	STHK
		SOP 13 Blood film examination	STHK SOHT
Whole blood	WBC differential	Manual examination light microscopy SOP 13 Blood film examination	STHK SOHT
Blood and bone marrow	Detection of normal and abnormal morphologies detection of haemosiderin	Haemosiderin / iron stain SOP 22 Bone marrow aspiration, slide prep and procedure SOP: Haematology Bone marrow review and reporting	STHK
Whole blood	Detection of infectious mononucleosis heterophile antibodies (Glandular fever)	Clearview® IM II test antigen/antibody test SOP: Glandular fever screening test	STHK SOHT ORM
Whole blood	Malarial parasite screen by detection of antigens <ul style="list-style-type: none"> <li>• <i>P. falciparum</i></li> <li>• <i>P. vivax</i></li> <li>• <i>P. ovale</i></li> <li>• <i>P. malariae</i></li> </ul>	Humasis test Immunochromatographic rapid test SOP: Screening for Malarial parasites	STHK SOHT ORM



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood	Detection and Identification of Plasmodium species: <ul style="list-style-type: none"> <li>• <i>P. falciparum</i></li> <li>• <i>P. vivax</i></li> <li>• <i>P. ovale</i></li> <li>• <i>P. malariae</i></li> <li>• <i>P. knowlesi</i></li> </ul>	Thick and thin films and microscopy  Stains – Field's stain and Giemsa  SOP: Screening for Malarial parasites	STHK SOHT
Whole blood	Sickle cell screen	Microgen S-test Solubility test SOP: Sickle Cell screening test	STHK SOHT
Whole blood	Haemaglobinopathy screen (sickle cell and Thalassaemia / antenatal) <ul style="list-style-type: none"> <li>• HbA2</li> <li>• HbF</li> <li>• HbA</li> <li>• HbS</li> <li>• HbD</li> <li>• HbC</li> </ul>	TOSOH G8 HPLC SOP 44 Haemoglobinopathy screening on Tosoh G8	STHK
Whole blood	Haemaglobinopathy identification and quantitation of <ul style="list-style-type: none"> <li>• HbA2</li> <li>• HbF</li> <li>• HbA</li> <li>• HbS</li> <li>• HbD</li> <li>• HbC</li> <li>• Variant Hb</li> </ul>	Sebia Hydrasys 2 system acid alkali electrophoresis SOP Acid haemoglobin electrophoresis SOP Alkaline haemoglobin electrophoresis SOP 56 Antenatal sickle cell haemoglobinopathy screening SOP 44 Haemoglobinopathy screening on Tosoh G8	STHK



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology (coagulation) examination for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:	
Plasma	Prothrombin time / INR APTT FS (Lupus insensitive) APTT FSL (Lupus sensitive) Fibrinogen	Sysmex CS5100 Light Transmittance – clotting assays SOP: Prothrombin Time SOP 11: Activated Partial Thromboplastin Time SOP 13: Clauss Fibrinogen Assay SOP 42: APTT using Actin FSL SOP 46: PT mixing studies SOP45: APTT mixing studies	STHK
Plasma	PT / INR, APTT, Fibrinogen,	Sysmex CS2500 SOP 12: Prothrombin time SOP 11: APTT FS SOP 13: Clauss Fibrinogen	SOHT
Plasma	PT/ INR, APTT	Sysmex CS2100 SOP 4: Prothrombin Time SOP 5: Activated Partial Thromboplastin Time	STH
Plasma	D-dimer	Sysmex CS5100 Immunoassay SOP 50 - D-dime	STHK
Plasma	D-Dimer	Sysmex CS2500 Immunoturbidometric SOP 15: D-Dimer	SOHT
Plasma	Thrombin time	Sysmex CS5100 Light Transmittance SOP 14 - Thrombin Time	STHK



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology (coagulation) examination for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for:	
Plasma	Detection of <ul style="list-style-type: none"> <li>• FII</li> <li>• FV</li> <li>• FVII</li> <li>• FVIII</li> <li>• FIX</li> <li>• FX</li> <li>• FXI</li> <li>• FXII</li> </ul>	Sysmex CS5100 Light transmittance SOP 26 - Intrinsic factor assays SOP 25 - Extrinsic factor assays	STHK
Plasma	Detection of <ul style="list-style-type: none"> <li>• Anti-Xa (LMWH)</li> <li>• Direct oral anti-coagulants</li> </ul>	Sysmex CS5100 Chromogenic assays SOP 19: LMWH determination SOP 27: DOAC assays	STHK
Plasma	Platelet function aggregation (PFA)	PFA-100 Platelet aggregation SOP: Platelet Function Screening PFA 100	STHK
Whole blood	Detection of Factor V Leiden and Prothrombin gene mutation	Cepheid Gene Expert PCR SOP: Factor II and Factor V gene mutation	STHK
Plasma	Detection of <ul style="list-style-type: none"> <li>• IgG and IgM for Anti-cardiolipin antibodies</li> <li>• IgG for Beta glycoprotein 1</li> </ul>	Phadia 250 Immunoassay EliA fluorescence enzyme immunoassay SOP 19: ACA and B2GPI on the Phadia 250	STHK
Plasma	Quantitation of: <ul style="list-style-type: none"> <li>• Protein S</li> <li>• Protein C</li> <li>• Anti-thrombin</li> </ul>	Sysmex CS5100 chromogenic immunoassay SOP 34 Free Protein S SOP 12 Anti-thrombin Immunoturbidimetric SOP 15 Protein C	STHK
Plasma	Detection of: <ul style="list-style-type: none"> <li>• Lupus anticoagulant</li> </ul>	Sysmex CS5100 SOP18: Lupus Coagulant	STHK



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology (coagulation) examination for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for:	
Plasma	Detection of vWF antigen	Sysmex CS5100 SOP16 Von Willebrand antigen immunoassay	STHK
	vWF activity	Sysmex CS5100 SOP 17 Immunoturbidometric assay	STHK
	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood	Blood Grouping by antigen and antibody detection: <ul style="list-style-type: none"> <li>• A B and O groups</li> <li>• RhD group</li> </ul>	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 047	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 047	SOHT
		Manual method by Grifols gel cards using SOP BT 049	STHK SOHT ORM
Whole blood	Antenatal prophylactic anti-D panel	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 008	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 008	SOHT
		Manual method by Grifols gel cards using BT 008	STHK SOHT ORM





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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood	Infant Blood grouping Neonatal blood group + DAT <ul style="list-style-type: none"> <li>• A B and O groups</li> <li>• RhD group</li> </ul>	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 047	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 047	SOHT
		Manual method by Grifols gel cards using BT 049	STHK SOHT ORM
Whole blood	Detection of the following Antibodies:  Rhesus blood group antibodies: anti-Cw, anti-C, anti-c, anti-D, anti-E, anti-e  Kell system blood group antibodies: anti-K, anti-k, anti-Kpa  Kidd blood group antibodies: anti-Jka, anti-Jkb  Duffy blood group antibodies: anti-Fya, anti-Fyb  Lutheran blood group antibodies: anti-Lua  MNS blood group antibodies: anti-M, anti-N, anti-S, anti-s  Lewis blood group antibodies: anti-Lea, anti-Leb  P blood group antibodies: anti-P1	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 008 SOP BT 047  Automated using Grifols Eflexis analysers using column agglutination SOP BT 008 SOP BT 047  Manual method by Grifols gel cards using SOP BT 008 SOP BT 047	STHK    SOHT  ORM



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood	Red cell phenotyping for Antigens of the following systems: <ul style="list-style-type: none"> <li>• Rh – C, D, E, c, e</li> <li>• Kell – K,</li> </ul>	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 008	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 008	SOHT
		Manual method by Grifols gel cards using BT008	ORM
Whole blood	Red cell phenotyping for Antigens of the following systems: <ul style="list-style-type: none"> <li>• Duffy – Fya, Fyb</li> <li>• Kidd – Jka,</li> <li>• Ss - S, s</li> </ul>	Manual Ortho tubes SOP BT 008	STHK SOHT
Whole blood	Manual cross match	Manual using Grifols cards SOP BT 010	STHK SOHT ORM
Whole blood	Automated cross match	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 053	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 053	SOHT



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for:	
Whole blood	Direct Coombs Test (DCT)	Automated using Grifols Erytra and Grifols Eflexis analysers using column agglutination SOP BT 047	STHK
		Automated using Grifols Eflexis analysers using column agglutination SOP BT 047	SOHT
		Manual using Grifols cards SOP BT 049	ORM
Whole blood	Foetal/maternal haemorrhage screen	Source Bioscience Fetal Cell Detection kit acid elution SOP BT 604 Kleihauer	SOHT
Whole blood	Foetal/maternal haemorrhage screen	Guest Medical Kleihauer Testing Kit - Acid Elution SOP BT 11 Cord Sample, Kleihauer Testing and Anti-D Administration	STHK
END			