


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8985 Accredited to ISO 15189:2022	Cardiff and Vale University Health Board	
	Issue No: 014 Issue date: 27 February 2025	
	Department of Haematology University Hospital of Wales Heath Park Cardiff CF14 4XW	Contact: Sue Lawless Tel: +44 (0) 2920 742738 E-Mail: Sue.Lawless@wales.nhs.uk
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	Local contact		
University Hospital of Wales Heath Park Cardiff CF14 4XW	Sue Lawless	Haematology Coagulation Blood Transfusion Immunophenotyping Haemoglobinopathy Haemostasis & Thrombosis	UHW
University Hospital Llandough Penlan Road Llandough Penarth CF64 2XX	Sue Lawless	Haematology Coagulation Blood Transfusion	UHL
Velindre Hospital Velindre Road Whitchurch Cardiff CF14 2TL	Sue Lawless	Haematology	VEL



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
University Hospital of Wales Heath Park Cardiff CF14 4XW	Phlebotomy	UHW
University Hospital Llandough Penlan Road Llandough Penarth CF64 2XX	Phlebotomy	UHL
Barry Hospital Colcot Road Barry CF62 8YH	Phlebotomy	BH
St David's Hospital Cowbridge Road East Cardiff CF11 9XB	Phlebotomy	SDH
Rhosyn Day Unit Velindre Hospital Velindre Road Whitchurch Cardiff CF14 2TL	Management of Blood Fridge	RDU
Haematology Day Centre University Hospital of Wales Heath Park Cardiff CF14 4XW	Management of Blood Fridge	HDC
Rainbow Ward University Hospital of Wales Heath Park Cardiff CF14 4XW	Management of Blood Fridge	RW
Cardiac Theatres University Hospital of Wales Heath Park Cardiff CF14 4XW	Management of Blood Fridge	CT



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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>Haematological examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Blood (EDTA)	FBC: <ul style="list-style-type: none"> • Haemoglobin • White blood cell count • Red blood cell count • Platelet count • White blood cell differential count • Reticulocytes 	Horiba Medical analysers using impedance variation, spectrophotometry, cytochemistry and fluorocytometry. UHW 2 x Yumizen H1500 1 x Yumizen H2500 UHL 1 x Yumizen H1500 Velindre 1 x Yumizen H1500 SOP EI-HAE-Pentra120DXMan LP-HAE-ABXFBC	UHW UHL VEL
Citrated Plasma	Routine Haemostasis: <ul style="list-style-type: none"> • OSPT • APTT • APTT Ratio • 50/50 Correction tests • Fibrinogen. • INR • D-Dimer • Heparin Screen (TCT) 	Werfen TOP Analysers using optical waveform analysis. UHW ACL TOP 550 UHW ACL TOP 750 UHL ACL TOP 350 SOP LP-HAE-ACLTOP350 EI-HAE-ACLTOP750Man LP-HAE-ACLTOP750	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
Serum	Haematinics: B12, Folate, Ferritin, Erythropoietin, Intrinsic Factor Antibodies, Serum Iron, transferrin saturation and total iron binding capacity	Beckman Coulter Immunoassay 1x UniCel DXI 800 Abbott Architect Serum irons/TIBC performed by Biochemistry staff, results reported by Haematology staff LI-HAE-HTINIronUIBC SOP EI-HAE-UnicelDXIMan LP-HAE-Ferritin LP-HAE-Folate LP-HAE- VitB12 LP-HAE-IFAB LP-HAE-EPO	UHW
Whole Blood (EDTA)	ESR	Alifax analyser SOP EI-HAE-AlifaxTest1ESR LP-HAE-AutoESR	UHW
Whole blood (EDTA)	Detection of normal and abnormal morphologies	Horiba Automated Slide Preparation System using May Grunwald/Giemsa Stain Manual MGG staining UHW –1x Yumizen SPS H2500 SOP LP-HAE-BLOODFILMS LP-HAE-ConFilmReport	UHW UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
Bone Marrow aspirate	Detection of normal and abnormal morphologies	Horiba Automated Slide Preparation System using May Grunwald/Giemsa Stain Manual MGG staining UHW –Yumizen SPS H2500 SOP LP-HAE- BLOODFILMS LP-HAE-ConFilmReport LP-HAE-MGGSTAIN	UHW UHW UHL
Bone Marrow aspirate and stained trephine slides	Detection of normal and abnormal morphologies	LI-HAE-ConFilmReport	UHW
Whole Blood (EDTA)	Detection of mononucleosis	Launch Accusay Mono test kits Direct Solid Phase Immunoassay Test Strip SOP LP-HAE-InfMono	UHW
Whole Blood (EDTA)	Screening for the detection of <i>Plasmodium falciparum</i> and <i>Plasmodium</i> spp. (Including • <i>Plasmodium ovale</i> • <i>Plasmodium falciparum</i> , <i>Plasmodium malariae</i> • <i>Plasmodium vivax</i>)	Humasis Malaria Pf/Pan Antigen Test SOP LP-HAE-MAST	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
Whole Blood (EDTA)	Detection and Identification of Plasmodium species: <ul style="list-style-type: none"> • P.falciparum • P.vivax • P.ovale • P.malariae • P knowlesi 	MGG stained thin films prepared using the Horiba Automated Slide Preparation System Giemsa stained thick films (manual) SOP LI-HAE-Rep&RefBldFilmsTRAK LP-HAE-AHLYUMIZEN LI-HAE-AHLMalariaStain	UHW
EDTA Whole blood	<u>Blood Transfusion activities for the purpose of clinical diagnosis</u> Blood Grouping <ul style="list-style-type: none"> • ABO • RhD 	Documented in-house procedures with manufacturer's instructions Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-Eflexis	UHW UHL
EDTA Plasma	Detection and identification of the following antibodies: Rh – anti-D, anti-C, anti-c, anti-E, anti-e, anti-V, anti-C ^w Kell – anti-K, anti-k, anti-Kp ^a , anti-Kp ^b , anti-Js ^a , anti-Js ^b Duffy – anti-Fy ^a , anti-Fy ^b Kidd – anti-Jk ^a , anti-Jk ^b Lewis – anti-Le ^a , anti-Le ^b , anti-P1, anti-M, anti-N, anti-S, anti-s Lutheran – anti-Lu ^a , anti-Lu ^b , anti-Xg ^a	Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-Eflexis LP-BLD-InvPosAbs	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
EDTA Plasma, Blood units in additive solution	Crossmatch (compatibility testing)	Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-XM	UHW UHL
EDTA Whole blood	Detection of C, c, E, e and K antigens	Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-AgTyp	UHW UHL
EDTA Whole blood	Kleihauer to detect foeto/maternal haemorrhage	ClinTech Kleihauer kit (acid elution) and light microscopy SOP LP-BLD-Kleih	UHW
EDTA Whole blood	DCT and identification of coating	Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-Eflexis	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
EDTA Whole Blood	Blood grouping, ABO and RhD systems	Grifols manual technique using manufacturer's column agglutination, technology cards, reagents, incubator and centrifuge, macroscopic visual detection LP-BLD-ManGrpAbs&DCT	UHW UHL
EDTA Plasma	Antibody Screen and Identification to detect: Rh – anti-D, anti-C, anti-c, anti-E, anti-e, anti-V, anti-C ^w Kell – anti-K, anti-k, anti-Kp ^a , anti-Kp ^b , anti-Js ^a , anti-Js ^b Duffy – anti-Fy ^a , anti-Fy ^b Kidd – anti-Jk ^a , anti-Jk ^b Lewis – anti-Le ^a , anti-Le ^b anti-P1, anti-M, anti-N, anti-S, anti-s Lutheran – anti-Lu ^a , anti-Lu ^b anti-Xg ^a	Grifols Manual Technique using manufacturer's column agglutination technology cards, reagents, incubator and centrifuge, macroscopic visual detection. Procedure; LP-BLD-ManGrpAbs&DCT	UHW UHL
EDTA Plasma, blood units in additive solution	Crossmatch (compatibility testing)	Grifols Manual Technique using manufacturer's column agglutination technology cards, reagents, incubator and centrifuge, macroscopic visual detection. Procedure; LP-BLD-MXM	UHW UHL
EDTA Whole Blood	DCT and identification of coating	Grifols Manual Technique using manufacturer's column agglutination technology cards, reagents, incubator and centrifuge, macroscopic visual detection. Procedure; LP-BLD-ManGrpAbs&DCT	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
EDTA Whole Blood	Detection of C, c, E, e and K antigens	Grifols Manual Technique using manufacturer's column agglutination technology cards, reagents, incubator and centrifuge, macroscopic visual detection. Procedure; LP-BLD-AGTYP	UHW UHL
EDTA Whole Blood	Antigen detection: Kell – K Duffy – Fya, Fyb Kidd – Jka, Jkb Lewis – Lea, LebP1, M, N, S, s	Grifols Manual Technique using manufacturer's column agglutination technology cards, reagents, incubator and centrifuge, macroscopic visual detection. Procedures; LP-BLD-AGTYP and LI-BLD-AGTYPGrif	UHW
EDTA Whole blood	Cold agglutinin screen	Manual: Tube technique using Sarstedt tubes SOP LP-BLD-ColdAgg	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions using BD FACSLytic flow cytometer	
Blood, apheresis harvest	CD34+ and/or CD3 cell enumeration in therapeutic products used for Haemopoietic Stem Cell Transplantation	Single platform pipetting methodology and CD34+ and/or CD3+ cell counting SOP LP-HAE-IPAbsCD34&Auto LP-HAE-IPAbsCD34&CD3AlloViability LP-HAE-IPAbsCD3SCPU	UHW
Blood	Lymphocyte subset enumeration in immunocompromised Haematology patients (post BMT or on chemotherapy)	Single platform pipetting methodology and CD3+, CD3+/CD4+, CD3+/CD8+ cell counting SOP LP-HAE-IPAbsSubSets	UHW
Blood	T-cell enumeration in patients following renal transplantation	Single platform pipetting methodology and CD2+/CD3+ cell counting SOP LP-HAE-IPAbsCD3Renal	UHW
Blood	Immunoplatelet counting	Platelet counting SOP LP-HAE-IPImmunoPlt	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions using BD FACSLytic flow cytometer	
Blood	Eosin-5-Maleimide dye binding test, screening test for Hereditary Spherocytosis	Dye binding of patient red cells compared to normal control samples. Dye binding measured as fluorescence. SOP LP-HAE-IPHSScreen	UHW
Blood	Detection and enumeration of GPI-deficient cell clones in patients with Paroxysmal Nocturnal Haemoglobinuria, Aplastic Anaemia and Myelodysplasia. For diagnosis and follow up.	Cells deficient in GPI-linked markers are detected and quantified SOP LP-HAE-IPPNH	UHW
Peripheral Blood, Bone Marrow Aspirates and Trephine biopsies	Detection and characterisation of B-cell Lymphoproliferative disorders.	Cells labelled with fluorescent markers are analysed using flow cytometry SOP LP-HAE-IPBCell LPD	UHW
Bone marrow Aspirates and Trephines, blood	Detection and characterisation of T-cell/NK-cell Lymphoproliferative disorders.	Cells labelled with fluorescent markers are analysed using flow cytometry SOP LP-HAE-IPT&NKCellLPD	UHW
Bone marrow.	Detection and characterisation of plasma cell disorders (Myeloma, Monoclonal Gammopathy of Unknown Significance) and Plasmacytoma.	Cells labelled with fluorescent markers are analysed using flow cytometry SOP LP-HAE-IPPlasmaCells	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions using BD FACSLytic flow cytometer Cells labelled with fluorescent markers are analysed using flow cytometry	
Bone marrow, blood, occasionally trephines, rarely tissues for chloromas	Detection and characterisation of acute leukaemia and enumeration of blasts and monocytes in Myelodysplastic syndrome.	SOP LP-HAE-IPAcuteLeuk	UHW
Bone marrow, blood, lymph node excision samples, lymph node biopsies, fine needle aspirates.	Assessment of intracellular antigens during investigation of acute leukaemia, Lymphoproliferative disorders, and lymphoma.	SOP LP-HAE-IPAcuteLeuk LP-HAE-IPLNode&SerosusFluid	UHW
Bone marrow	Measurable residual disease detection in acute leukaemia	SOP LP-HAE-IPAcuteLeukMRD	UHW
Cerebrospinal fluid	Morphological assessment of cell types present in CSF	Cells are centrifuged onto slides using a Thermo Scientific cytocentrifuge. After staining, cell morphology is examined under the Olympus BX41 microscope. SOP LP-HAE-IPCytospins	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haemoglobinopathy examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Blood	Detection and Quantification of Haemoglobin Fractions: HbA, HbA2, HbS, HbD, HbE, HbC, HbF, HbO Arab, Hb Lepore, HbH, HbBarts, delta chain variants, uncharacterised haemoglobin variants.	BioRad Variant II analysers using High Performance Liquid Chromatography (HPLC) LP-HAE-OP	UHW
Blood	Detection of Haemoglobin Fractions: HbA, HbA2, HbS, HbD, HbE, HbC, HbF, HbO Arab, Hb Lepore, delta chain variants, uncharacterised haemoglobin variants	Helena Bioscience manual electrophoresis using Helena SAX-Mx Alk Hb Kit, and SAX-Mx Acid Hb Kits; EPS power pack LP-HAE-OPA1kPH LP-HAE-OPAcGel	UHW
	Qualitative Visual Assessment and Confirmation of Haemoglobin Fractions: HbA, HbA2, HbS, HbD, HbE, HbC, HbF, HbO Arab, Hb Lepore, delta chain variants, uncharacterised haemoglobin variants	Thermo Power pack, Helena electrophoresis tanks LP-HAE-OPA1kPH LP-HAE-OPAcGel	
Blood	Sickle Solubility Screening	Clin-Tech Sickle Test Kit LP-HAE-OPHbSSol	UHW
Blood	G6 PD deficiency screen	Fluorescent spot technique using Trinity biotech Glucose-6-phosphate dehydrogenase (G-6-PDH) kit SOP LP-HAE-OPG6PD	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Blood Plasma		Werfen ACL TOP 550, chromogenic substrate assay	UHW
	Antithrombin Activity Assay (ATAA)	LP-HAE-SCACLAT	UHW
	Apixaban Assay (APIXA)	LP-HAE-SCACLAPIX	UHW
	Dabigatran Assay (DAB)	LP-HAE-SCACLDABI	UHW
	Rivaroxaban Assay (RIVA)	LP-HAE-SCACLRIV	UHW
Blood Plasma		Werfen ACL TOP 550, Clotting tests,	UHW
	Lupus Anticoagulant Screen (LAS)	LP-HAE-SCACLRV	UHW
	Silica Clotting Time (SCT)	LP-HAE-SCSCT LP-HAE-SCACLSCT	UHW
Blood Plasma		Werfen ACL TOP 550, Clotting factor assay	UHW
	Factor II Assay (FAC2)	LP-HAE-SCPTFACASSAY	UHW
	Factor V Assay (FAC5)	LP-HAE-SCPTFACASSAY	UHW
	Factor VII Assay (FAC7)	LP-HAE-SCPTFACASSAY	UHW
	Factor VIII Assay (FAC8)	LP-HAE-SCACLFAC8	UHW
	Factor IX Assay (FAC9)	LP-HAE-SCACLFAC9	UHW
	Factor X Assay (FAC10)	LP-HAE-SCACLFAC10	UHW
	Factor XI Assay (FAC11)	LP-HAE-SCFAC11	UHW
	Factor XII Assay (FAC12)	LP-HAE-SCFAC12	UHW
	Factor VIII Inhibitor Assay Human (FAC8INH)	LP-HAE-SCACLINHIBITORS	UHW
	Factor IX Inhibitor Assay (FAC9INH)	LP-HAE-SCACLF9INH	UHW
	Factor XIII Antigen Assay	LP-HAE-SCFAC13AG	UHW
	Factor VIII Bovine chromogenic assay	LP-HAE-SCBOV8ASSAY	UHW
	Emicizumab Assay	LP-HAE-SCACLEMI	UHW
	Von Willebrand Factor Antigen Assay (VWFAG)	LP-HAE-SCACUSTARVWFAg	UHW
	Factor VIII Bovine Inhibitor Assay (BOV8INSHU)	LP-HAE-SCACLF8INHBOV	UHW
	Factor VIII Chromogenic Assay (FAC8CHR)	LP-HAE-SCFAC8CHROMO	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures with manufacturer's instructions	
Blood Plasma	Factor XIII Assay	Manual test LP-HAW-SCFAC13CHR	UHW
Blood plasma	Platelet Function Analyser 100 Analysis (PFA100)	Dade PFA 100 Analyser, ADP/Collagen and ADP/Epinephrine occlusion time. SO LP-HAE-SCPFA]	UHW
Blood plasma	Heparin/PF4 Antibody ELISA (HITEL)	BioTek Synergy HT microplate reader, Manual ELISA test, Asserachrom HPIA –IgG SOP LP-HAE-SCHPIA	UHW
Platelet rich plasma	Platelet Adenine Nucleotide Assay (PAN)	BioOrbit 1250 Luminometer. Manual in house luminometric method. SOP LP-HAE-SPAN	UHW
Blood plasma	Protein C Functional Assay (PRCA)	Werfen ACL TOP 550, Chromogenic assay, SOP LP-HAE-SCACLPC	UHW
Blood plasma	Plasminogen Chromogenic Assay (PLGCHR)	Werfen ACL TOP 550, Chromogenic assay, SOP LP-HAE-SCACLPLGCHR	UHW
	Anti Factor Xa Assay (XA)	Werfen ACL TOP 550, Chromogenic assay, SOP LP-HAE-SCACLANTIXA	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
Blood plasma	Protein S Immunological Assay (PRSA)	Werfen ACL TOP 550, Latex immunoassay, SOP LP-HAE-SCACLPS Werfen AcuStar	UHW
Blood plasma	Von Willebrand factor collagen binding assay	LP-HAE-SCACUSTARVWFCB	UHW
Blood plasma	Von Willebrand factor GP1Br binding assay	LP-HAE-SCACUSTARVWFGP1b	UHW
	Von Willebrand Factor Antigen Assay (VWFAG)	LP-HAE-SCACUSTARVWFAG	UHW
	ADAMTS13 Assay (ADAMTS)	LP-HAE-SCACUSTARAD13 Helena Bioscience AggRAM Platelet Aggregometer. Optical detection of platelet aggregation.	UHW
Platelet rich plasma	Platelet Aggregation Studies (PLTAGG)	LP-HAE-SCPLATAGG	UHW
Blood plasma	von Willebrand Factor Ristocetin Cofactor (VWRIC)	LP-HAE-SCVWFACT	UHW
Blood plasma	Ristocetin Induced Platelet Aggregation (RIPA)	LP-HAE-SCRIPA	UHW



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions	
Blood plasma	ADAMTS-13 Inhibitor Assay	Technozyme ADAMTS13 inhibitor assay; Manual chromogenic ELISA: LP-HAE-SCAD13INH	UHW
Blood plasma	Fibrinogen antigen	Manual ELISA LP-HAE-SCFIBELMANUAL	UHW
Blood plasma	Von Willebrand factor propeptide	Manual ELISA LP-HAE-SCVWFPP	UHW
END			