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:** 017 **Issue date:** 22 September 2026	
	Department of Haematology **University Hospital of Wales** **Heath Park** **Cardiff** **CF14 4XW**	**Contact: Gina Gwynne** **Tel: +44 (0) 2921845059** **E-Mail: georgina.gwynne@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	Gina Gwynne	Haematology Coagulation Blood Transfusion Immunophenotyping Haemoglobinopathy Haemostasis & Thrombosis	UHW
University Hospital Llandough Penlan Road Llandough Penarth CF64 2XX	Gina Gwynne	Haematology Coagulation Blood Transfusion	UHL
Velindre Hospital Velindre Road Whitchurch Cardiff CF14 2TL	Gina Gwynne	Haematology	VEL

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Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

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

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	<u>Haematological examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Blood (EDTA)	FBC: • Haemoglobin • White blood cell count • Red blood cell count • Platelet count • White blood cell differential count • Reticulocytes (UHW only)	Horiba Medical analysers using impedance variation, spectrophotometry, cytochemistry and fluorocytometry. UHW 2 x Yumizen H1500 2 x Yumizen H2500 UHL 1 x Yumizen H1500 1 x Yumizen H2500 Velindre 1 x Yumizen H1500 SOP EI-HAE-H2500H1500&SPSUserManLP-HAE-AHLYUMIZEN	UHW UHL VEL
Citrated Plasma	Routine Haemostasis: • OSPT • APTT • APTT Ratio • Fibrinogen. • INR • D-Dimer • Heparin Screen (TCT)	Werfen TOP Analysers using optical waveform analysis. UHW 2 x ACL TOP 550 UHW 2 x ACL TOP 750 UHL 1x ACL TOP 350 SOP LP-HAE-ACLTOP350CTS EI-HAE-ACL TOP Family 50 Series Operator ManualLP LP-HAE-ACLTOP750LAS	UHW UHL

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
	Haemanitics:	Beckman Coulter Immunoassay 1x UniCel DXI 800	UHW
Serum	Vitamin B12	EI-HAE-HTIN UniCel DxI800 Op Guide	
Serum	Folate	EI-HAE-HTIN UniCel DxI800 Op Guide	
Serum	Ferritin	EI-HAE-HTIN UniCel DxI800 Op Guide	
Serum	Erythropoietin	EI-HAE-HTIN UniCel DxI800 Op Guide	
Serum	Intrinsic Factor Antibodies	EI-HAE-HTIN UniCel DxI800 Op Guide	
		Abbott Alinity – Equipment owned and operated by UKAS 8989 and results reported by 8985	UHW
Serum	Serum Iron	LI-HAE-HTINIronUIBC	
Serum	Total Iron Binding Capacity	LI-HAE-HTINIronUIBC	
Whole Blood (EDTA)	ESR	Alifax analyser	UHW
		SOP EI-HAE-Alifax Test1 User Manual LP-HAE-AutoESR	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
Whole blood (EDTA)	Detection of normal and abnormal morphologies	Horiba Automated Slide Preparation System using May Grunwald/Giemsa Stain	UHW
		Manual MGG staining	UHW
		UHW –1x Yumizen SPS H2500	
		SOP LP-HAE-BLOODFILMS	
		LI-HAE-ConFilmReport	
Bone Marrow aspirate	Detection of normal and abnormal morphologies	Horiba Automated Slide Preparation System using May Grunwald/Giemsa Stain	UHW
		Manual MGG staining	UHW
		UHW –Yumizen SPS H2500	
		SOP LP-HAE- BLOODFILMS LI-HAE-BMReg LI-HAE-ConFilmReport	
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	UHW
		SOP EI-HAE-PI Accusay Mono LP-HAE-InfMono	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haematological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
Whole Blood (EDTA)	Detection and Identification of Plasmodium species: • 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 LP-HAE-BLOODFILMS LP-HAE-MALINVLI-HAE-AHLMalariaStain	UHW
	Blood Transfusion activities for the purpose of clinical diagnosis	Documented in-house procedures with manufacturer's instructions	
EDTA Whole blood	Blood Grouping • ABO • RhD	Automated: Grifols analysers using digital image analysis UHW: 2 x Erytra Eflexis UHL: Eflexis SOP LP-BLD-Erytra 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: 2 x Erytra Eflexis UHL: Eflexis SOP LP-BLD-EflexisLP-BLD-Erytra LP-BLD-InvPosAbs	UHW UHL

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)	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: 2 x 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: 2 x 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 LP-BLD-Erytra	UHW UHL

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)	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 LP-BLD-InvPosAbs	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis	Documented in-house procedures with manufacturer's instructions using BD FACSLyric 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+ cell counting SOP LP-HAE-IPAbsCD34&Auto	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	Immunoplatelet counting	Platelet counting SOP LP-HAE-IPImmunoPlt	UHW

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions using BD FACSLyric flow cytometer	
Blood	Eosin-5-Malemide 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions using BD FACSLyric flow cytometer Cells labelled with fluorescent markers are analysers 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-IPSerousFluids	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 samples	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haemoglobinopathy examination activities for the purpose of clinical diagnosis	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) using Helena SAX-Mx Alk Hb Kit, and SAX-Mx Acid Hb Kits; EPS power pack LP-HAE-OPVariantII	UHW
Blood	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-OPAlkpH LP-HAE-OPAlkpH 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis	Documented in-house procedures with manufacturer's instructions	
Blood Plasma		2 x 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 LP-HAE-SCSCT	UHW
	Silica Clotting Time (SCT)	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-SCACLFACTORS	UHW
	Factor XI Assay (FAC11)	LP-HAE-SCFACTORS	UHW
	Factor XII Assay (FAC12)	LP-HAE-SCFAC12	UHW
	Factor VIII Inhibitor Assay Human (FAC8INHU)	LP-HAE-SCACLINHIBITORS	UHW
	Factor IX Inhibitor Assay (FAC9INH)	LP-HAE-SCACLF9INHU	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures with manufacturer's instructions	
Blood Plasma	Factor XIII Assay	Manual test using the Technochrom Factor XIII Act assay LP-HAW-SCFAC13CHR	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-SCPAN	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis (cont'd)	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
Blood plasma	ADAMTS-13 Inhibitor Assay	Technozyme ADAMTS13 inhibitor assay; Manual chromogenic ELISA: LP-HAE-SCAD13INH	UHW
END			