


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8985 Accredited to ISO 15189:2012	Cardiff and Vale University Health Board	
	Issue No: 009 Issue date: 31 August 2021	
	Department of Haematology University Hospital of Wales Heath Park Cardiff CF14 4XW	Contact: Alun Roderick Tel: +44 (0) 2920 742738 E-Mail: Alun.roderick@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	Alun Roderick	Haematology Coagulation Blood Transfusion Immunophenotyping	UHW
University Hospital Llandough Penlan Road Llandough Penarth CF64 2XX	Greg Andrikopoulos	Haematology Coagulation Blood Transfusion	UHL
Velindre Hospital Velindre Road Whitchurch Cardiff CF14 2TL	Sue Lawless	Haematology	V



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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 Ceri Hooper	Phlebotomy	UHW
University Hospital Llandough Penlan Road Llandough Penarth CF64 2XX Ceri Hooper	Phlebotomy	UHL
Barry Hospital Colcot Road Barry CF62 8YH	Phlebotomy	BH
St David's Hospital Cowbridge Road East Cardiff CF11 9XB Ann Grant	Phlebotomy	SDH
Rhosyn Day Unit Velindre Hospital Velindre Road Whitchurch Cardiff CF14 2TL Samantha McWilliam	Management of Blood Fridge	RDU
Haematology Day Centre University Hospital of Wales Heath Park Cardiff CF14 4XW Rebecca Carnegie	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



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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 V
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-AHLTOP350 EI-HAE-ACLTOP750Man LP-HAE-ACLTOP750 LP-HAE-ILTOPAnalyser	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis.</u> (cont'd)	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 [LP-HAE-IronTIBC] 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 UHL -1x Yumizen SPS H2500 SOP LP-HAE- Bloodfilms LP-HAE-ConFilmReport	UHW UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis.</u> (cont'd)	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 UHL -Yumizen SPS H2500 SOP LP-HAE- Bloodfilms LP-HAE-ConFilmReport LP-HAE-MGGSTAIN	UHW UHL
Bone Marrow aspirate and stained trephine slides	Detection of normal and abnormal morphologies	LI-HAE-ConFilmReport	UHW UHL
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> Detection and Identification of Plasmodium species: <ul style="list-style-type: none"> • P.falciparum • P.vivax • P.ovale • P.malariae • P knowlesi 	Documented in-house procedures with manufacturer's instructions MGG stained thin films prepared using the Horiba Automated Slide Preparation System Giemsa stained thick films (manual) SOP LI-HAE-Rep&RefBldFilmsTRAK LP-HAE-ABXFBC LI-HAE-MalThick	UHW
HUMAN BODY FLUIDS	<u>Blood Transfusion activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
EDTA Whole blood	Blood Grouping <ul style="list-style-type: none"> • ABO • RhD 	Automated: Grifols analysers using digital image analysis UHW: Erytra Eflexis UHL: Eflexis SOP LP-BLD-ErytraEflexis	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-ErytraEflexis	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-ErytraEflexis	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-ErytraEflexis	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-ErytraEflexis	UHW UHL



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>EDTA Whole blood</p>	<p><u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Cold agglutinin screen and Cold agglutinin titre</p>	<p>Documented in-house procedures with manufacturer's instructions</p> <p>Manual: Tube technique using Sarstedt tubes</p> <p>SOP LP-BLD-ColdAgg</p>	<p>UHW</p>



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HUMAN BODY FLUIDS	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions using BD FACSLyric flow cytometer	
Blood, apheresis harvest, bone marrow	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, Bone Marrow Aspirates and Trephine biopsies	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, Bone Marrow Aspirates and Trephine biopsies	T-cell enumeration in patients following renal transplantation	Single platform pipetting methodology and CD2+/CD3+ cell counting SOP LP-HAE-IPAbsCD3Renal	UHW
Blood, Bone Marrow Aspirates and Trephine biopsies	Immunoplatelet counting	Platelet counting SOP LP-HAE-IPImmunoPlt	UHW
Blood, Bone Marrow Aspirates and Trephine biopsies	Detection and enumeration of foetal cells in maternal blood sample to assess level of foeto-maternal haemorrhage	Foetal cells counted using Rhesus D measurement SOP LP-HAE- IPFMHRhD	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 FACSLyric 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, Bone Marrow Aspirates and Trepine biopsies	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 Trepine biopsies	Detection and characterisation of B-cell Lymphoproliferative disorders.	Cells labelled with fluorescent markers are analysed using flow cytometry SOP LP-HAE-IPBCell LPD LP-HAE-IPCellProlifKi67	UHW
Bone marrow Aspirates and Trephines, blood, CSF & serous fluids	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, blood, occasionally trephines.	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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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Lymph node excision samples, lymph node biopsies, fine needle aspirates, bone marrow, blood, serous fluids</p> <p>Lymph node excision samples, lymph node biopsies, fine needle aspirates, bone marrow, blood, serous fluids</p>	<p><u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and characterisation of Lymphoma.</p>	<p>Documented in-house procedures with manufacturer's instructions using BD FACSLyric flow cytometer</p> <p>Cells labelled with fluorescent markers are analysed using flow cytometry</p> <p>SOP LP-HAE-IPLymphNode</p>	<p>UHW</p>
	<p>Tandem assessment of Ki-67 cell proliferation with BCL2 expression as an indication of lymphoma grade.</p>	<p>SOP LP-HAE-IPCellProlifKi67</p>	<p>UHW</p>
<p>Bone marrow, blood, occasionally trephines, rarely tissues for chloromas</p>	<p>Detection and characterisation of acute leukaemia and enumeration of blasts and monocytes in Myelodysplastic syndrome.</p>	<p>SOP LP-HAE-IPAcuteLeuk</p>	<p>UHW</p>
<p>Bone marrow, blood, lymph node excision samples, lymph node biopsies, fine needle aspirates.</p>	<p>Assessment of intracellular antigens during investigation of acute leukaemia, Lymphoproliferative disorders, and lymphoma.</p>	<p>SOP LP-HAE-IPAcuteLeuk LP-HAE-IPLNode&SerousFluid</p>	<p>UHW</p>
<p>Bone marrow</p>	<p>Measurable residual disease detection in acute leukaemia</p>	<p>SOP LP-HAE-IPAcuteLeukMRD</p>	<p>UHW</p>
<p>CSF</p>	<p>Flow cytometric assessment of CNS disease in Acute Leukaemia and Lymphoproliferative Disorders</p>	<p>Cells in CSF are labelled with fluorescent markers appropriate to the suspected disease lineage, and are analysed using flow cytometry.</p> <p>SOP LP-HAE-IPCSFCytometry</p>	



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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	
Cerebrospinal fluid	Morphological assessment of cell types present inCSF	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
HUMAN BODY FLUIDS	<u>Haemoglobinopathy examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Blood	Haemoglobinopathy Testing: <ul style="list-style-type: none"> • Hb A2 • Hb F • Quantitations of variant Hb fractions • Analysis of variant Haemoglobins to characterise the variant or type of thalassaemia present. 	BioRad Variant II HPLC analysers (x2) Helena Bioscience electrophoresis systems, EPS power packs, and Thermo Power packs Microgen S-Test Sickle solubility tests SOP LP-HAE-OPVariantII LP-HAE-OPUrgHbS LP-HAE-OPHbSSol LP-HAE-OPAlkpH LP-HAE-OPAcGel LP-HAE-OPHbH	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	<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-SCACLAPIXA	UHW
	Dabigatran Assay (DAB)	LP-HAE-SCACLDABI	UHW
	Rivaroxaban Assay (RIVA)	LP-HAE-SCACLRIVA	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-SCACLFACTORS	UHW
	Factor V Assay (FAC5)	LP-HAE-SCACLFACTORS	UHW
	Factor VII Assay (FAC7)	LP-HAE-SCACLFACTORS	UHW
	Factor VIII Assay (FAC8)	LP-HAE-SCACLFACTORS	UHW
	Factor VIII B-Domain Depleted Assay (FAC8BDD)	LP-HAE-SCACLFACTORS	UHW
	Factor IX Assay (FAC9)	LP-HAE-SCACLFACTORS	UHW
	Factor X Assay (FAC10)	LP-HAE-SCACLFACTORS	UHW
	Factor IX Assay (FAC11)	LP-HAE-SCFACTORS	UHW
	Factor XII Assay (FAC12)	LP-HAE-SCACLFACTORS	UHW
	Factor VIII Inhibitor Assay Human (FAC8INH)	LP-HAE-SCACLINHIBITORS	UHW
	Factor IX Inhibitor Assay (FAC9INH)	LP-HAE-SCACLINHIBITORS	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-SCACUSTARVWF	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	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)	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	UHW
Blood plasma	Von Willebrand factor collagen binding assay	Werfen AcuStar	UHW
Blood plasma	Von Willebrand factor GP1Br binding assay	LP-HAE-SCACUSTARVWF	
	Von Willebrand Factor Antigen Assay (VWFAG)	LP-HAE-SCACUSTARVWF	UHW
	ADAMTS13 Assay (ADAMTS)	LP-HAE-SCACUSTARAD13	UHW
		Helena Bioscience AggRAM Platelet Aggregometer. Optical detection of platelet aggregation.	
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)	Haemostasis and thrombosis examination activities for the purpose of clinical diagnosis (cont'd)	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			