


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>Velindre University NHS Trust</h3> <p><b>Issue No:</b> 005    <b>Issue date:</b> 30 October 2019</p>	
	<p><b>Welsh Blood Service</b> Ely Valley Road Talbot Green Pontyclun CF71 9WB</p>	<p><b>Contact:</b> Dr Tracey Rees <b>Tel:</b> +44 (0)1443 622000 / (0)1443 622175 <b>Fax:</b> +44 (0)1443 622199 <b>E-Mail:</b> donor.care@wales.nhs.uk <b>Website:</b> <a href="https://portal.welsh-blood.org.uk/wtail/">https://portal.welsh-blood.org.uk/wtail/</a> <a href="https://www.welsh-blood.org.uk/contact-us/">https://www.welsh-blood.org.uk/contact-us/</a></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES and BODY FLUIDS</p> <p>Blood</p>	<p><u>Blood transfusion testing for clinical diagnosis</u></p> <p>Blood grouping: ABO Rh D</p>	<p>In house documented methods and manufacturer's instructions using;-</p> <p>Automated system: Beckman Coulter PK7300 analyser using photometry. Key SOPs: 174/AUT 175/AUT 176/AUT</p> <p>Semi-automated system: Tecan or Bio-Rad HemOS liquid handling systems</p> <p>Microplates</p> <p>HTZ Duet Blood Grouping Reader (photometry system)</p> <p>Key SOPs 067/AUT 168/AUT 184/AUT 146/AUT</p>



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Blood transfusion testing for clinical diagnosis</u> (cont'd)	In house documented methods and manufacturer's instructions using;-
Blood	Antibody Screening for irregular red cell antibodies as follows:  Anti-C,c,D,E,e,M,N,S,s,P1,K,k, Le <sup>a</sup> ,Le <sup>b</sup> ,Fy <sup>a</sup> ,Fy <sup>b</sup> ,Jk <sup>a</sup> and Jk <sup>b</sup> ,	Semi-automated system:  Tecan or Bio-Rad HemOS liquid handling systems  Bio-Rad DiaMed ID Cards  HTZ Duet Blood Grouping Reader (photometry system)  Key SOPs 072/AUT 012/DTR SST051 146/AUT
Blood	Antibody identification for irregular red cell antibodies as follows:  C,Cw,c,D,E,e,M,N,S,s,P1,K,k, Le <sup>a</sup> ,Le <sup>b</sup> ,Fy <sup>a</sup> ,Fy <sup>b</sup> ,Jk <sup>a</sup> and Jk <sup>b</sup> ,	Manual Techniques: Saline haemagglutination test; LISS (low ionic strength solution) anti-human globulin haemagglutination test (Tube technique)  Papain Haemagglutination test; (Bio-Rad DiaMed ID Card technique)  Key SOP 006/PAT
Blood	Antenatal Antibody Titration: Haemolytic Disease of the Foetus & Newborn associated irregular red cell antibodies	Bio-Rad DiaMed ID Cards  Key SOP 016/PAT
Blood	Antenatal anti-D & -c Quantitation	Astoria 2 (Dual channel automated analyser, using the Bromelain Methyl Cellulose (BMC) method.  Key SOP IMM/037 & 038



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Blood transfusion testing for clinical diagnosis</u> (cont'd)	In house documented methods and manufacturer's instructions using;-
Blood	Foetal Maternal Haemorrhage Estimation	Becton Dickinson FACSCanto II Flow Cytometer & IQ Products Fetal Cell Count Kit  Key SOP IMM/051
Blood	Blood Transfusion Compatibility Testing	Manual Techniques: LISS Anti-Globulin Haemagglutination Test (Tube technique)  Key SOP 008/PAT
Blood (Serum)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u>  HLA specific antibody detection (HLA-A, -B, Cw, -DR, -DQ, DP)	In house documented methods and manufacturer's instructions using:  Using Microbead array assays (LABScreen Mixed beads) and Luminex 100/200 Luminex technology  Key SOPs 031/SCR 040/SCR 044/SCR 066/SCR
Blood (Serum)	HLA specific antibody detection (HLA-A, -B, Cw, -DR, -DQ, DP)	Complement dependent cytotoxicity through detection of IgG and IgM using fluorescent microscopy  Key SOPs 005/SCR 001/SER 004/SER 006/SER



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)</u>	In house documented methods and manufacturer's instructions using:
Blood (Serum)	HLA specific antibody definition: HLA-A, -B, Cw, -DR, -DQ, DP	Using Microbead array assays (LABScreen Single Antigen beads) and Lighchip 100/200 Luminex technology  Key SOPs 031/SCR 040/SCR 044/SCR 066/SCR
Blood (Serum)	HLA specific antibody definition: HLA-A, -B, Cw, -DR, -DQ, DP	Complement dependent cytotoxicity through detection of IgG and IgM using fluorescent microscopy  Key SOPs 024/SCR 005/SCR 001/SER 004/SER 006/SER
Blood (cells and plasma)	ABO antibody titre detection	Using 0.8% donor red cells and Bio-Rad DiaMed ID NaCl and Anti-IgG cards  Key SOP 033/SCR



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<p>HUMAN TISSUES and BODY FLUIDS (cont'd)</p> <p>DNA extracted from blood, spleen or lymph.</p>	<p><u>Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)</u></p> <p>HPA typing: HPA-1, -2, -3, -4, -5, -6, -15</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>In-house PCR-SSP using the following equipment:</p> <p>Thermocyclers 11 X Eppendorf Nexus Mastercycler</p> <p>Electrophoresis tanks: 1 X Flowgen – MH3025B 1 X Flow 3025 BAG 1 X VWR 700-0154 – kurogel maxi plus 25 electrophoresis horizontal</p> <p>Power packs: 3 x Fisher scientific Power 608</p> <p>Detection using fluorescence on agarose gel.</p> <p>Key SOPs 001/MOL 022/MOL 034/MOL 040/MOL</p>
<p>Cells extracted from blood, spleen and lymph Blood (serum)</p>	<p>Cross-matching for the detection of cytotoxic IgG and IgM HLA antibodies to donor lymphocytes</p>	<p>Complement dependant cytotoxicity test. Performed using Hamilton syringes, Lamda jet dispensers and analysed using inverted fluorescence microscopes.</p> <p>Key SOPs 001/SER 002/SER 004/SER 003/TYP 009/TYP 020/TYP 026/TYP 034/SER 057/TYP 067/TYP</p>



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)</u>	In house documented methods and manufacturer's instructions using:
Cells extracted from blood, spleen and lymph	Cross-matching for the detection of IgG antibodies to donor T and B lymphocytes	Detection of antibodies using the three colour immunofluorescence flow cytometry cross match.  Analysis using a Coulter FC500 flow cytometer.  Key SOPs 001/FLO 005/FLO 006/FLO
Blood	Detection of B27 antigen	Using two monoclonal antibodies and analysing using the Coulter FC500 flow cytometer.  Key SOP: 015/FLO
DNA extracted from blood, spleen or lymph	HLA typing: HLA-A, -B, -C, -DRB1, -DQB1, -DQA1, -DPB1	Sanger PCR-SBT using either in-house developed primer sets or commercial kits, amplified using the following equipment:  Thermocyclers: 11 X Eppendorf Nexus Mastercycler  Analysis using an AB3730 capillary sequencer.  Key SOPs: 058/MOL 080/MOL 061/MOL 082/MOL



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<p>HUMAN TISSUES and BODY FLUIDS (cont'd)</p> <p>Cells extracted from blood, spleen and lymph</p> <p>DNA extracted from blood or cells</p> <p>DNA extracted from blood or cells</p>	<p><u>Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)</u></p> <p>Cell based, serological phenotyping: HLA-A, HLA-B, HLA-Cw</p> <p>Molecular level HLA typing: HLA-A, B, C, DRB1, DQB1, DQA1, DPA1, DPB1, DRB3/4/5</p> <p>Molecular level HLA typing HLA-A, B, C, DRB1, DQB1, DQA1, DPA1, DPB1, DRB3/4/5</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>Complement dependent cytotoxicity test using 'in-house' serum panels. Performed using Lamda jet dispensers and analysed using inverted fluorescence microscopes.</p> <p>Key SOPs: 001/SER 002/SER 004/SER 006/SER 034/SER 035/SER 042/SER</p> <p>PCR-SSOP using 2 x Applied Biosystems Veriti 96 well thermocyclers, Immucor Lifecodes kits, acquisition by Luminex and analysis by MatchIT DNA software with manual review</p> <p>Key SOPs: SOP 097/MOL SOP 098/MOL SOP 099/MOL SOP 100/MOL</p> <p>Real Time PCR (RT-PCR) using LinkSeq kits, acquisition by QuantStudioDX and analysis by SureTyper software with manual review</p> <p>Key SOPs SOP 093/MOL SOP 094/MOL SOP 095/MOL SOP 096/MOL</p>



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<p>HUMAN TISSUES and BODY FLUIDS (cont'd)</p> <p>Blood</p>	<p><u>Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)</u></p> <p>HPA antibody detection and identification: HPA-1 HPA-2 HPA-3 HPA-5 HPA-15</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>Monoclonal Antibody-Specific Immobilization of Platelet Antigens (MAIPA) test: ELISA method using ThermoScientific Multiskan EX microplate photometer</p> <p>Key SOPs 043/PLA 044/PLA 045/PLA</p>
<p>END</p>		