


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2022</p>	<h3>Velindre University NHS Trust</h3> <p>Issue No: 017 Issue date: 03 October 2025</p>	
	<p>Welsh Blood Service Ely Valley Road Talbot Green Pontyclun CF72 9WB</p>	<p>Contact: Peter Richardson Tel: +44 (0)1443 622129 E-Mail: peter.richardson2@wales.nhs.uk WBS.WTAIL@wales.nhs.uk Website: https://portal.welsh-blood.org.uk/wtail/ https://www.welsh-blood.org.uk/contact-us/</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES and BODY FLUIDS	<u>Blood transfusion testing for clinical diagnosis</u>	In house documented methods and manufacturer's instructions using:
Whole Blood	Blood grouping: ABO Rh D	Automated system: Beckman Coulter PK7400 analyser using photometry. 210/AUT 211/AUT 212/AUT
Whole blood EDTA	Blood grouping: ABO Rh D	Automated system: Immucor Neo Iris LAB-064 LAB-065 LAB-066 LAB-067 LAB-068
Whole blood EDTA	Antibody Screening for irregular red cell antibodies as follows: Anti-C,c,D,E,e,M,N,S,s,P1,K,k, Le ^a ,Le ^b ,Fy ^a ,Fy ^b ,Jk ^a and Jk ^b ,	Automated system Immunocor Neo Iris AUT-072 LAB-064 LAB-065 LAB-066 LAB-067 LAB-068



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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:
Whole blood EDTA	Antibody identification for irregular red cell antibodies: C,Cw,c,D,E,e,M,N,S,s,P1,K,k, Lea,Leb,Fya,Fyb,Jka and Jkb,	Manual Techniques: Saline haemagglutination test; LISS (low ionic strength solution) Anti-human globulin haemagglutination test (tube) Papain Haemagglutination test (Bio-Rad DiaMed ID Card) PAT-152
Blood	Antenatal Antibody Titration: Haemolytic Disease of the Foetus & Newborn associated irregular red cell antibodies	Bio-Rad DiaMed ID Cards PAT-155
Blood	Antenatal anti-D and anti-c Quantitation	Astoria 307 (Dual channel automated analyser, using Bromelain Methyl Cellulose (BMC) IMM-037 IMM-038
Blood	Foetal Maternal Haemorrhage Estimation	Becton Dickinson FACSCanto II Flow Cytometer & IQ Products Fetal Cell Count Kit IMM-051
Blood	Blood Transfusion Compatibility Testing	Manual Techniques: LISS anti-globulin Haemagglutination test (tube) PAT-153



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u>	In house documented methods and manufacturer's instructions using:
Blood (Serum)	HLA specific antibody detection HLA-A HLA-B HLA-Cw HLA-DR HLA-DQ HLA- DP	Microbead array assays (LABScreen Mixed beads) and Liquichip 100/200 Luminex SCR-031 SCR-040 SCR-044 SCR-066
Blood (Serum)	HLA specific antibody specification: HLA-A HLA-B HLA-Cw HLA-DR HLA-DQ HLA- DP	Microbead array assays (LABScreen Single Antigen beads and Lifecodes Single Antigen beads) and Liquichip 100/200 Luminex SCR-031 SCR-040 SCR-044 SCR-066 SCR-083 SCR-087
Blood (Serum)	HNA Specific antibody detection HNA-1 HNA-2 HNA-3 HNA-4 HNA-5	Standard Specifications: Microbead array assays (LABScreen Multi beads) and Liquichip 100/200 Luminex SCR-031 SCR-089
Blood (Serum)	Qualitative detection of IgG antibodies to: HPA-1 HPA-2 HPA3 HPA4 HPA5 GPIV	Platelet-specific antibody definition using Immucor Pak LX kit and Luminex 200 analyser 054/PLA 053/PLA
Blood (cells and plasma)	ABO antibody titre detection	0.8% donor red cells and Bio-Rad DiaMed ID NaCl and Anti-IgG cards SCR-033



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u> (cont'd)	In house documented methods and manufacturer's instructions using:
Blood (Serum) and 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 DX BC Flex and DX autoloader flow cytometer. FLO-001 FLO-005 FLO-031
Whole blood	Detection of B27 antigen	Commercial IVD accredited genetic testing kit (FastQ® B*27) using: Roche Lightcycler 480 II instrument Applied Biosystems QuantStudio-DX instrument MOL-894 MOL-895 MOL-896 MOL-897 TTO-004
Human DNA, derived from multiple sources	Molecular level HLA typing: HLA-A HLA-B HLA-C HLA-DRB1 HLA-DQB1 HLA-DQA1 HLA-DPA1 HLA-DPB1 HLA-DRB3 HLA-DRB4 HLA-DRB5	DNA extraction using: Manual method (Puregene) QIAGEN EZ2 Connect MDx (EZ2) Real Time PCR (RT-PCR) LinkSeq kits Acquisition by: Applied Biosystems QuantStudio-DX instrument Roche Lightcycler 480 II instrument Analysis by: SureTyper software with manual review MOL-025 MOL-881 MOL-093 MOL-094 MOL-095 MOL-096 MOL-884



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HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u> (cont'd)	In house documented methods and manufacturer's instructions using:
Blood (plasma and serum)	HPA antibody detection and identification: HPA-1 HPA-2 HPA-3 HPA-5 HPA-15	Monoclonal Antibody-Specific Immobilization of Platelet Antigens (MAIPA) test: ELISA method using Thermo Scientific Multiskan FC microplate photometer PLA-043 PLA-044 PLA-045
Human DNA, derived from multiple sources	HPA typing: HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-7 HPA-8 HPA-9 HPA-10 HPA-11 HPA-15	DNA extraction using: Manual method (Puregene) . QIAGEN EZ2 Connect MDx (EZ2) Commercial Real-Time PCR (RT-PCR) kit using: Applied Biosystems QuantStudio-DX instrument Roche Lightcycler 4800 II instrument One Lambda LinkSeq kits MOL-025 MOL-881 MOL-875 MOL-876 MOL-884



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<p>HUMAN TISSUES and BODY FLUIDS (cont'd)</p> <p>Human DNA, derived from multiple sources</p>	<p><u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u> (cont'd)</p> <p>HLA typing by Next Generation Sequencing (NGS)</p> <p>HLA-A HLA-B HLA-C HLA-DRB1 HLA-DQB1 HLA-DQA1 HLA-DPA1 HLA-DPB1 HLA-DRB3 HLA-DRB4 HLA-DRB5</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>DNA extraction using: Manual method (Puregene) QIAGEN EZ2 Connect MDx (EZ2)</p> <p>HLA typing by NGS using: One Lambda Alltype FASTplex reagents kits</p> <p>Amplified and barcoded using: Applied Biosystems Veriti 96-well Thermal Cycler</p> <p>Sequenced using: Illumina MiSeq instrument with analysis by TSV software with manual review. MOL-025 MOL-881 MOL-883 MOL-879</p>
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