Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9326

Accredited to ISO 15189:2022

Velindre University NHS Trust

Issue No: 015 Issue date: 28 March 2025

Welsh Blood Service Ely Valley Road **Talbot Green** Pontyclun **CF72 9WB**

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/

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES and BODY FLUIDS	Blood transfusion testing for clinical diagnosis	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES and BODY FLUIDS (cont'd)	<u>Blood transfusion testing for clinical</u> <u>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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	Type of test/Properties	Standard specifications/
Materials/Products tested	measured/Range of measurement	Equipment/Techniques used
HUMAN TISSUES and BODY FLUIDS (cont'd)	Histocompatibility and Immunogenetics testing for clinical diagnosis	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES and BODY FLUIDS (cont'd)	Histocompatibility and Immunogenetics testing for clinical diagnosis (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 immunofluoresence flow cytometry cross match. Analysis using a DX BC Flex and DX autoloader flow cytometer. FLO-001 FLO-005 FLO-031
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) or Roche MagNAPure 24 instrument Real Time PCR (RT-PCR) using LinkSeq kits Acquisition by QuantStudioDX or Roche Lightcycler 480 II instrument with analysis by SureTyper software with manual review MOL-025 MOL-025 MOL-094 MOL-095 MOL-096 MOL-884
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



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HUMAN TISSUES and BODY FLUIDS (cont'd)	Histocompatibility and Immunogenetics testing for clinical diagnosis (cont'd)	In house documented methods and manufacturer's instructions using:
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) or Roche MagNAPure 24 instrument. Commercial Real-Time PCR (RT- PCR) kit using an Applied Biosystems QuantStudio-DX instrument or Roche Lightcycler 4800 II linstrument and One Lambda LinkSeq kits MOL-025 MOL-881 MOL-875 MOL-876 MOL-884
Human DNA, derived from multiple sources	HLA typing by Next Generation Sequencing (NGS) 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) or Roche MagNAPure 24 instrument HLA typing by NGS using One Lambda Alltype FASTplex reagents kits, amplified and barcoded using an Applied Biosystems Veriti 96- well Thermal Cycler, and sequenced using an Illumina MiSeq instrument with analysis by TSV software with manual review. MOL-025 MOL-881 MOL-883 MOL-879
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