


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|--|---|
|  <p>UKAS MEDICAL 9326</p> <p>Accredited to ISO 15189:2012</p> | <h3>Velindre University NHS Trust</h3> <p>Issue No: 010 Issue date: 15 November 2023</p> | |
| | <p>Welsh Blood Service Ely Valley Road Talbot Green Pontyclun CF71 9WB</p> | <p>Contact: Dr Tracey Rees Tel: +44 (0)1443 622000 / (0)1443 622175 Fax: +44 (0)1443 622199 E-Mail: : wbs_transfusionlabhods@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: |
| Blood | Blood grouping: ABO Rh D | Automated system: Beckman Coulter PK7300 analyser using photometry. AUT-174 AUT-175 AUT-176 |
| 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 , | Bio-Rad DiaMed ID Cards AUT-072 LAB-064 LAB-065 LAB-066 LAB-067 LAB-068 |
| 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 |



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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 | 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 | <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 Lighchip 100/200 Luminex SCR-031 SCR-040 SCR-044 SCR-066 |
| 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 |
| Blood | Detection of B27 antigen | Two monoclonal antibodies and analysing using the BC DX Flex and DX autoloader flow cytometer. FLO-030 |
| 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 |
| DNA extracted from blood or cells | 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 | PCR-SSOP Applied Biosystems Veriti 96 well thermocycler Immucor Lifecodes kits acquisition by Luminex analysis by MatchIT DNA software with manual review MOL-097 MOL-098 MOL-099 MOL-100 |



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| HUMAN TISSUES and BODY FLUIDS | <u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u> | In house documented methods and manufacturer's instructions using: |
| DNA extracted from blood or cells | 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 | Real Time PCR (RT-PCR) using LinkSeq kits acquisition by QuantStudioDX analysis by SureTyper software with manual review or Roche Lightcycler 480 II instrument MOL-093 MOL-094 MOL-095 MOL-096 MOL-884 |
| Blood | 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 EX microplate photometer PLA-043 PLA-044 PLA-045 |
| DNA extracted from blood, spleen or lymph | HPA typing: HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-7 HPA-8 HPA-9 HPA-10 HAP-11 HPA-15 | Commercial Real-Time PCR (RT-PCR) kit using an Applied Biosystems QuantStudio-DX instrument or Roche Lightcycler 4800 II instrument and One Lambda LinkSeq kits MOL-875 MOL-876 MOL-884 MOL-876 |



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| HUMAN TISSUES and BODY FLUIDS Human DNA, derived from multiple sources | <u>Histocompatibility and Immunogenetics testing for clinical diagnosis</u> HLA typing by Next Generation Sequencing (NGS) | In house documented methods and manufacturer's instructions using: 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 883-MOL 879-MOL |
| END | | |