


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8100</p> <p>Accredited to ISO 15189:2022</p>	<h3>University Hospitals of Leicester NHS Trust</h3> <p>Issue No: 009 Issue date: 25 June 2024</p>	
	<p>Transplant Laboratory Leicester General Hospital LE5 4PW</p>	<p>Contact: Clare Collins Tel: +44 (0) 116 258 4606 E-Mail: clare.collins1@uhl-tr.nhs.uk</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
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Blood (cells & serum) Lymph node Spleen</p> <p>Blood Lymph node Spleen</p> <p>DNA extracted from samples above</p>	<p><u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis</u></p> <p><u>Cross-matching</u> Detection of IgG HLA to donor T and B lymphocytes</p> <p>Complement dependent cytotoxicity testing through detection of IgG and IgM HLA antibodies to donor T and B lymphocytes</p> <p><u>HLA Typing</u></p> <p>DNA based low resolution (HLA A, B, C, DRB1*/3*/4*/5*. DQA1*, DQB1*, DPB1*, DPA1*)</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>SOP 1031, 1024, 1381, 1382 & 1400 using Becton Dickinson Flow Cytometers: BD FACS Canto II and BD FACS Lyric SOP 1551 & 1024 using fluorescent microscopy.</p> <p>SOP_1543 DNA Extraction using Maxwell RSC using Maxwell RSC Whole Blood kit, AS1520 Supplied by Promega and Quantification of DNA using Nanodrop Spectrophotometer</p> <p>SOP 1062, 1456 & 1457 using PCR-SSP typing (One Lambda MicroSSP) with thermal cyclers and gel electrophoresis</p> <p>SOP 1577 & 1578 using PCR-SSO typing with LabScan 3D and microbead assays (One Lambda LabType) and / or SOP 1616 QTYPE (CareDx) Real-Time HLA Typing using Roche LightCycler II 480 real-time PCR machine</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant
DNA extracted from samples above	<u>HLA Typing continued</u> DNA based high resolution (HLA DPB1)	SOP 1577 & 1578 using PCR-SSO typing & microbead array assays (One Lambda LabType)
DNA extracted from samples above	DNA based high-resolution (HLA-A, B, C, DR, DQ, DP)	SOP 1684 and 1685 using Next Generation sequencing by NGSgo (GenDx) and analysis by NGSEngine using thermal cyclers and iSeq100
Blood (serum)	<u>HLA-specific antibody monitoring</u> HLA specific antibody detection and definition (HLA-A, B, Cw, DR, DQ, DP)	SOP 1143, 1236 & 1144 using microbead array assays (Labscreen single antigen) with Liquichip 200 Luminex technology and /or Labscan 3D Luminex technology
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