

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 7878</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Manchester University NHS Foundation Trust</b></p> <p>Issue No: 008    Issue date: 10 November 2020</p>	
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<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 fluids and tissues as identified below: Blood Buccal swabs Spleen Lymph node Serum</p> <p>Genomic DNA extracted in house from the above sample type or received as a primary sample from external source</p>	<p><u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity</u></p> <p><b>Immunogenetics Examinations</b></p> <p><b>Human Leucocyte Antigen (HLA) Typing –</b> (HLA-A, B, C, DRB1, 3, 4 &amp; 5, DQA, DQB, DPA &amp; DPB, KIR)</p>	<p>DNA extraction using the DNA EZI system and quantitation of DNA using the Nanodrop instrument by in-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p> <p>In-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p> <p>SOP-IT001 / IT028/ IT035 / IT038 using PCR SSO typing and Luminex Labscan 3D technology SOP IT058</p> <p>HLA typing using Real Time PCR technology on Roche 480 II Light Cyclers, LinkSeq kits and Sure Typer analysis software SOP - IT063 / IT064</p> <p>Disease association and Drug Hypersensitivity testing SOP - IT001/ IT028/ IT035 /IT038 using PCR SSO typing and Luminex Labscan 3D technology SOP - IT058</p> <p>High Resolution HLA typing using NGS on Illumina Miseq Sequencer Using SOP IT065 and IT066</p>



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Blood Bone Marrow	<p><b>Immunogenetics Examinations</b> (cont'd)</p> <p>Haemopoetic Progenitor Stem cell Transplantation Engraftment Monitoring - reported as % donor engraftment</p>	<p>In-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p> <p>SOP-IB007, IB0017, IB008, ID010, ID021, IB026 by fragment analysis using GenePrint 24short tandem repeat markers and an ABI 3500XL genetic analyser</p>
Human fluids and tissues as identified below: Blood Spleen Lymph node Serum	<p><b>Histocompatibility Examinations</b></p>	<p>In-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p>
Blood	<p>The detection and definition of HLA Specific Antibodies for the purpose of clinical diagnosis for Transplantation (HLA-A, -B, Cw, -DR, -DQ, DP) Pre Transplant HLA specific allo antibody screening</p> <p>Post Transplant HLA specific allo antibody monitoring</p>	<p>SOP - S063 / S065 and using Microbead array assays and Luminex technology SOP – S066 SOP - S064 and using Microbead array assays and Luminex Labscan 3D technology SOP – S066 SOP- S057 using Microbead array assays and Luminex Labscan 3D technology SOP - S035</p>
Blood (cells & serum) Spleen Lymph node	<p>Crossmatch testing for solid organ transplantation Detection of IgG HLA antibodies to donor T and B lymphocytes</p> <p>Complement dependent cytotoxicity (CDC) testing for solid organ transplantation through detection of IgG and IgM HLA antibodies to donor lymphocytes</p>	<p>Using Immunofluorescence flow cytometry on a Beckman Coulter Navios Flow Cytometer according to SOPs: XM030, XM033, XM034 and XM035</p> <p>CDC test using cell viability staining SOP-XM002, XM004 and inverted fluorescent microscopy-</p>
<p>END</p>		