

Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>7878</p> <p>Accredited to ISO 15189:2022</p>	<p>Manchester University NHS Foundation Trust</p> <p>Issue No: 014 Issue date: 08 January 2026</p>	
	<p>Transplantation Laboratory Manchester Royal Infirmary Oxford Road Manchester M13 9WL</p>	<p>Contact: Dr Kay Poulton Tel: +44 (0) 161 276 6397 Fax: +44 (0) 161 276 6148 E-Mail: kay.poulton@mft.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 fluids and tissues as identified below:</p> <ul style="list-style-type: none"> Blood Blood Spots Buccal swabs Spleen Lymph node Serum Bone Marrow 	<p><u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity</u></p> <p>DNA Extraction - quantitation of genomic DNA</p>	<p>In-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p> <p>P072 Flexible Scope Policy and associated master list</p> <p>Using metallic particle technology and quantitation of DNA using spectrophotometry and 260/280 260/230 ratios on automated commercially available equipment methodology with appropriate kits.</p>



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<p>Genomic DNA extracted in house from the above sample type or received as a primary sample from external source</p> <p>Blood Bone Marrow</p>	<p><u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity (cont'd)</u></p> <p>Immunogenetics Examinations</p> <p>Human Leucocyte Antigen (HLA) Typing –</p> <p>HLA-A, B, C, DRB1, DRB3/4/5, DQB1, DQA1, DPB1 and DPA1 to the level of resolution (2nd field).</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>P072 Flexible Scope Policy and associated master list</p> <p>using rapid-cycle or real time PCR assay for DNA with real-time fluorescent monitoring and melting curve analysis using commercially available HLA typing assays and commercially available analytical software.</p> <p>PCR SSO typing and Luminex Labscan 3D technology SOPs: IT001, IT028, IT058</p> <p>Disease association and Drug Hypersensitivity testing SOP - IT001/ IT028 using PCR SSO typing and Luminex Labscan 3D technology SOP: IT058</p> <p>NGS High Resolution HLA typing using Illumina Miseq Sequencer SOPs: IT065 and IT066</p> <p>Fragment analysis using GenePrint 24short tandem repeat markers and an ABI 3500XL genetic analyser SOPs: IB007, IB017, IB008, ID010, ID021, IB026</p>



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<p>Human fluids and tissues as identified below: Blood Spleen Lymph node Serum</p>	<p><u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity</u> (cont'd)</p> <p>Histocompatibility Examinations</p>	<p>In-house documented procedures based on manufactures guidelines and equipment manuals as relevant</p>
<p>Blood</p>	<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>Microbead array assays and Luminex technology using Luminex Labscan 3D technology</p> <p>SOPs: S057, S063, S064, S065 and S066</p>
<p>Blood (cells & serum) Spleen Lymph node</p>	<p>T and B cell Isolation</p>	<p>Using MACSprep HLA T cell isolation kit lot</p>
<p>Blood (cells & serum) Spleen Lymph node</p>	<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>P072 Flexible Scope Policy and associated Master List</p> <p>Immunofluorescence flow cytometry using IgG FITC, CD19 PC7, and CD3 APC antibodies</p> <p>CDC Cross matching using cell viability and inverted fluorescent Microscopy staining SOPs: XM002, XM004</p>
<p>END</p>		