

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

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|---|---|---|
|  7878 Accredited to ISO 15189:2022 | Manchester University NHS Foundation Trust | |
| | Issue No: 013 Issue date: 18 May 2025 | |
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| 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 fluids and tissues as identified below: Blood Buccal swabs Spleen Lymph node Serum Bone Marrow | <u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity</u> DNA Extraction - quantitation of genomic DNA | In-house documented procedures based on manufactures guidelines and equipment manuals as relevant P072 Flexible Scope Policy and associated master list 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. |



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| Genomic DNA extracted in house from the above sample type or received as a primary sample from external source | <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>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> |



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| Blood Bone Marrow | <u>Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity (cont'd)</u> Immunogenetics Examinations (cont'd) Haemopoetic Progenitor Stem cell Transplantation Engraftment Monitoring - reported as % donor engraftment | In-house documented procedures based on manufactures guidelines and equipment manuals as relevant Fragment analysis using GenePrint 24short tandem repeat markers and an ABI 3500XL genetic analyser SOPs: IB007, IB017, IB008, ID010, ID021, IB026 |
| Human fluids and tissues as identified below: Blood Spleen Lymph node Serum | Histocompatibility Examinations | In-house documented procedures based on manufactures guidelines and equipment manuals as relevant |
| Blood | 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 Post Transplant HLA specific allo antibody monitoring | Microbead array assays and Luminex technology using Luminex Labscan 3D technology SOPs: S057, S063, S064, S065 and S066 |
| Blood (cells & serum) Spleen Lymph node | Crossmatch testing for solid organ transplantation Detection of IgG HLA antibodies to donor T and B lymphocytes Complement dependent cytotoxicity (CDC) testing for solid organ transplantation through detection of IgG and IgM HLA antibodies to donor lymphocytes | Using Immunofluorescence flow cytometry on a Beckman Coulter Navios Flow Cytometer according to SOPs: XM030, XM033, XM034 and XM035 CDC Cross matching using cell viability and inverted fluorescent Microscopy staining SOPs: XM002, XM004 |
| END | | |