

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	Liverpool University Hospitals NHS Foundation Trust	
	Issue No: 003 Issue date: 24 June 2020	
	Liverpool Clinical Laboratories (LCL) Department of Histocompatibility and Immunogenetics 8th Floor, Duncan Building Royal Liverpool Hospital Prescot Street L7 8XP	Contact: Ines Santos Tel: +44 (0)151 706 4374 Fax: +44 (0)151 706 5849 E-Mail: Ines.Santos@liverpoolft.nhs.uk Website: www.liverpoolcl.nhs.uk
Testing performed at the above address only		

Laboratory locations:

Location details: Histocompatibility and Immunogenetics Department	Activity: Histocompatibility and Immunogenetics	Location code
Address 8 th Floor Duncan Building Royal Liverpool Hospital	Local contact Angela Parker	Histocompatibility and Immunogenetics A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Genetics Department- Liverpool Women's Hospital	Illumina Miseq Genetic analyser located here. Used in provision of NGS HLA typing service	B
Virology Department- Liverpool Clinical Laboratories	The Roche 480 Lightcycler used for NGS typing are located here	C



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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>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis:</u></p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>DNA extraction and quantitation in support of PCR-SSP, PCR-SSOP, and NGS typing:</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-16 DNA ISOLATION USING QIAGEN QIAamp DSP DNA BLOOD MINI KIT • I&I H&I MOL-SOP-25 DNA isolation using automated QIASymphony and Qiagen DSP DNA Mini kits • I&I-H&I-MOL-SOP-15 DNA quantitation using Quantifluor kit & Glomax <p>PCR-SSP low resolution HLA typing:</p> <p>PCR thermalcyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UVP BioDoc-it</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-11 HLA TYPING BY ONE LAMBDA MICRO SSP • I&I-H&I-MOL-SOP-13 HLA TYPING USING HISTOTYPE SSP KITS • I&I-H&I-MOL-SOP-26 HLA B*27 TYPING USING HISTOTYPE PCR-SSP KITS • I&I-H&I-GEN-SOP-3 Reporting of HLA Typing and Crossmatch Results



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>PCR-SSO intermediate resolution typing:</p> <p>PCR thermalcyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UVP BioDoc-it, Luminex Liquichip 200 LABXpress automated station</p> <p>Labtype HLA-A, -B, -C, DRB1, DRB3,4,5, DQA1, DQB1, DPA1, DPB1</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-6 Routine HLA Typing using Labtype Luminex kits- DNA sample preparation and amplification set up for half volume • I&I-H&I-MOL-SOP-7 LABXPRESS- ROUTINE HLA TYPING USING LABTYPE LUMINEX KITS 24/11/2017 • I&I-H&I-MOL-SOP-8 LABTYPE HLA ANALYSIS USING FUSION 4.1 SOFTWARE • I&I-H&I-GEN-SOP-3 Reporting of HLA Typing and Crossmatch Results on Telepath/11/2017



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>Next Generation Sequencing (NGS) based allele resolution HLA typing:</p> <p>PCR thermalcyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UVP BioDoc-it, Sage Science PippinPrep, Promega Glomax, Roche 480 Lightcycler, Illumina Miseq</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-2 NGS STEP 1: LONG RANGE PCR AMPLIFICATION AND GEL IMAGING • I&I-H&I-MOL-SOP-3 NGS 2: AMPLICON QUANTITATION, NORMALISATION AND EXOSAP CLEAN UP • I&I-H&I-MOL-SOP-4 NGS 3: LIBRARY PREPARATION - Fragmentation, End Repair, Ligation and Ampure Clean-Up. • I&I-H&I-MOL-SOP-10 NGS 4 : SIZE SELECTION OF DNA LIBRARY USING PIPPIN PREP • I&I-H&I-MOL-SOP-12 NGS 5: qPCR of DNA LIBRARY USING LIGHTCYCLER 480 • I&I-H&I-MOL-SOP-14 NGS 6: FINAL LIBRARY PREPARATION AND MISEQ LOADING • I&I-H&I-GEN-SOP-3 Reporting of HLA Typing and Crossmatch Results on Telepath



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum Peripheral blood</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>HLA-specific antibody screening and characterisation:</u></p> <p>Antibody screening and characterisation in support of the following:</p> <ul style="list-style-type: none"> • Pre-transplant HLA-specific alloantibody screening • Post-transplant HLA-specific alloantibody detection and donor specific antibody monitoring <p>HLA-specific antibodies directed against products of the following loci can be detected: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>HLA-Specific Antibody Screening and Characterisation:</p> <p>Antibody screening and characterisation assays are performed using OneLambda Labscreen reagents and analysed using a Liquichip 200 Luminex analyser supported by the LABXpress automated platform.</p> <p>Results are analysed using HLA Fusion version 4.1</p> <ul style="list-style-type: none"> • I&I-H&I-SER-SOP-6 LABXPRESS – HLA ANTIBODY SCREENING AND IDENTIFICATION USING LABSCREEN MIXED BEADS AND LABSCREEN SINGLE ANTIGEN BEADS • I&I-H&I-SER-SOP-7 Reporting of HLA antibody screening results



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cells extracted from peripheral blood, serum, lymph node and spleen tissue</p> <p>Cells extracted from peripheral blood, lymph node and spleen tissue</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of IgG and IgM HLA antibodies to donor lymphocytes</p> <p>Detection of IgG HLA antibodies to donor T and B lymphocytes</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p><u>Manual procedure for Complement dependant lymphocytotoxicity (CDC) testing using fluorescent microscopy</u></p> <ul style="list-style-type: none"> • I&I-H&I-SER-SOP-5 SEROLOGICAL CROSSMATCHING • I&I-H&I-GEN-SOP-3 Reporting of HLA Typing and Crossmatch Results on Telepath/11/2017 <p>Flow cytometry crossmatching using BD FACSCanto II Flow cytometer</p> <ul style="list-style-type: none"> • I&I-H&I-SER-SOP-2 BD FACSCanto-Flow Cytometry Crossmatch-TUBE Method • I&I-H&I-SER-SOP-3 BD FACSCanto-Flow Cytometry Crossmatch-PLATE Method • I&I-H&I-SER-SOP-4 BD FACSCantoll - SET UP AND RUNNING OF CROSSMATCH PROTOCOL IN DIVA 8 SOFTWARE • I&I-H&I-GEN-SOP-3 Reporting of HLA Typing and Crossmatch Results on Telepath/11/2017
END		