Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9811

Accredited to ISO 15189: 2022

Legal entity

Issue No: 004 Issue date: 15 May 2025

Regional Histocompatibility & Immunogenetics Laboratory

First Floor Northern Ireland Blood Transfusion Building

Belfast City Hospital

Lisburn Road

Belfast BT9 7TS

United Kingdom

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E-Mail: Elaine.Boyle@belfasttrust.hscni.net Website: http://www.belfasttrust.hscni.net

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Regional Histocompatibility & Immunogenetics Laboratory	Contact: Elaine Boyle Tel: +44 (0) 2895044529 (44529)	Histocompatibility and Immunogenetics testing for clinical	A
First Floor Northern Ireland Blood Transfusion Building		diagnosis	
Belfast City Hospital			
Lisburn Road			
Belfast			
BT9 7TS			
United Kingdom			
Genetics Laboratory First Floor Belfast City Hospital Tower Block	Contact: Elaine Boyle Tel: +44 (0) 2895044529 (44529)	Histocompatibility and Immunogenetics testing for clinical diagnosis	В
Belfast City Hospital			
Lisburn Road			
Belfast			
BT9 7TS			
United Kingdom			

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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES and BODY FLUIDS	Histocompatibility and Immunogenetics testing for clinical diagnosis	In house documented methods and manufacturer's instructions using:	
	Extraction and Standardisation of DNA		А
Blood, buffy coat, spleen cells		Promega Maxwell CSC system using Whole Blood DNA Isolation kit. SOP HI-1047 DNA Extraction: Promega Maxwell CSC Instrument	
Blood, buffy coat, spleen cells		QIAmp DSP mini kits SOP HI-220 DNA Extraction: QIAamp DSP DNA Blood Mini Kit	
DNA		Nanodrop 2000C. SOP: HI-232 Assay & Standardization of Chromosomal DNA using the Nanodrop 2000C	
	Molecular based determination of HLA type:		
Genomic DNA extracted from the above sample types	HLA-A, -B, -C, -DRB1, - DRB3,4,5, -DQA1, -DQB1, - DPA1 and -DPB1	PCR SSO typing and Luminex Labscan technology, including gel electrophoresis.	A
		Luminex Analyser and HLA Fusion Software	
		SOPs: HI-215 Luminex HLA Typing Half Volume Beads; HI-227 Luminex HLA typing using full beads HI-223 Agarose Gel Electrophoresis HI-226 LABType HLA Analysis using HLA Fusion Software	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES and BODY FLUIDS (cont'd)			
Genomic DNA extracted from the above sample types	HLA-A, -B, -C, -DRB1, - DRB3,4,5, -DQA1, -DQB1, - DPA1 and -DPB1.	QType PCR using RT-PCR data analysis using Score 6 software, Roche Light Cycler 480 II colour compensation,	A
		SOPs: HI-879 QTYPE Real Time PCR HI-881 Analysing QType Plates using Score 6 software HI-888 Light Cycler 480 II Colour Compensation	
Genomic DNA extracted from the above sample types	HLA-B*27	RT-PCR using FastQ B*27 and Roche Light Cycler 480 II	А
		SOP: HI-918 HLA-B*27 typing using FastQ B*27 and analysis	
	HLA-B*57	RT-PCR using LinkSeq	А
Lymphocytes, serum	Serological Testing Cross-matching for the	SOP: HI-1015 HLA-B*57:01 Identification using LinkSeq kit Analysis using three colour	А
	detection of HLA IgG antibodies to donor T and B lymphocytes	immunofluoresence flow cytometry on Becton Dickinson FACSLyric	
		SOPs: HI-961 3 Colour Flow Crossmatching for living & deceased donors on the BD FACSLyric. HI-1065 Isolation of total lymphocytes from peripheral blood, spleen & lymph node by Ficoll- Paque Plus. HI-212 Pronase Treatment of Peripheral Blood Lymphocytes	

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HUMAN TISSUES and BODY FLUIDS (cont'd)				
Lymphocytes, Serum	Cross-matching for the detection of HLA specific antibodies	Complement Dependant Cytotoxicity (CDC) to reduce IgM antibody using DTT, Fluorescent Microscope, Autoscope	A	
		SOPs: HI-202 CDC Crossmatching using DTT to Reduce IgM Antibody HI-920 Lymphocyte Isolation from Peripheral Blood & Tissues by Negative Selection		
Human DNA	HLA Molecular Typing (Next Generation Sequencing): (HLA-A, -B, -C, -DRB1, - DRB3,4,5, - DQA1, -DQB1, - DPA1 and -DPB1)	Ilumina MiSeq Instrument, AllType Fastplex NGS 11-loci Flex kit SOP: HI-979 HLA Typing by Next Generation Sequencing using Ilumina MiSeq Instrument	В	
END				

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