Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS MEDICAL

9811

Accredited to ISO 15189: 2022

Belfast Health and Social Care Trust

Issue No: 005 Issue date: 01 July 2025

Regional Histocompatibility & Immunogenetics Laboratory

First Floor Northern Ireland Blood

Transfusion Building

Belfast City Hospital

Lisburn Road

Belfast

BT9 7TS

United Kingdom

Contact: Dr Kerry Sweet Tel: +44 (0) 2895043386

E-Mail: Kerry.Sweet@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:

Location details		Activity	Location code
Address Regional Histocompatibility & Immunogenetics Laboratory First Floor Northern Ireland Blood Transfusion Building Belfast City Hospital Lisburn Road Belfast BT9 7TS United Kingdom	Local contact Contact: Dr Kerry Sweet Tel: +44 (0) 2895044529 (44529)	Histocompatibility and Immunogenetics testing for clinical diagnosis	A
Address Genetics Laboratory First Floor Belfast City Hospital Tower Block Belfast City Hospital Lisburn Road Belfast BT9 7TS United Kingdom	Local contact Contact: Louise McArt Tel: +44 (0) 028 909 72400)	HLA Molecular Typing (Next Generation Sequencing)	В

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Belfast Health and Social Care Trust

Issue date: 01 July 2025 **Issue No:** 005

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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	

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Issue date: 01 July 2025 **Issue No:** 005

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	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	
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,	А
		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
		SOP: HI-1015 HLA-B*57:01 Identification using LinkSeq kit	

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Materials/Products tested	Tune of test/Dreporties	Ctandard analifications/	Location
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Molecular based determination of HLA type:		
Genomic DNA extracted from the above sample types	HLA Molecular Typing (Next Generation Sequencing): (HLA-A, -B, -C, -DRB1, - DRB3,4,5, - DQA1, -DQB1, - DPA1 and -DPB1)	NGS set-up AllType Fastplex NGS 11-loci Flex kit	A
		Ilumina MiSeq Instrument	В
		SOP: HI-979 HLA Typing by Next Generation Sequencing using Ilumina MiSeq Instrument	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Serological Testing		A
Lymphocytes, serum	Cross-matching for the detection of HLA IgG antibodies to donor T and B lymphocytes	Analysis using three colour 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	
Lymphocytes, Serum	Cross-matching for the detection of HLA specific antibodies	Complement Dependant Cytotoxicity (CDC) to reduce IgM antibody using DTT, Fluorescent Microscope, Autoscope SOPs: HI-202 CDC Crossmatching using DTT to Reduce IgM Antibody HI-920 Lymphocyte Isolation from Peripheral Blood & Tissues by Negative Selection	A

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Serological Testing		
Serum	HLA Antibody Screening and Detection		
	HLA antibody screening (HLA class I and/or class II)	One Lambda Labscreen Mixed Screening kits, Luminex acquisition and HLA-Fusion analysis	
		SOPs: HI-347 HLA specific antibody screening and identification using One Lambda LABScreen at half volume	
	HLA specific antibody definition: (HLA-A, -B, Cw, - DR, -DQ, DP)	One Lambda Labscreen Single Antigen beads (SAB), Luminex acquisition and HLA-Fusion analysis	
		SOP: HI-347 HLA specific antibody screening and identification using One Lambda LABScreen at half volume	
END			

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