


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>9239 Accredited to ISO 15189:2022</p>	<h3>NHS Blood and Transplant</h3> <p>Issue No: 009 Issue date: 02 July 2024</p>	
	<p><b>Histocompatibility and Immunogenetics Laboratories</b> NHSBT Charcot Road Colindale London NW9 5BG</p>	<p><b>Contact: Diane Irving</b> Tel: +44 (0)7729275353 E-Mail: <a href="mailto:diane.irving@nhsbt.nhs.uk">diane.irving@nhsbt.nhs.uk</a> Website: <a href="http://www.nhsbt.nhs.uk">www.nhsbt.nhs.uk</a></p>
<p><b>Testing performed by the Organisation at the locations specified below</b></p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
H and I Laboratory NHS Blood and Transplant Charcot Road Colindale London NW9 5BG Local Contact: Dr. Colin Brown	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	C
H and I Laboratory NHS Blood and Transplant 75 Cranmer Terrace Tooting London SW17 0RB Local Contact: Dr. Deborah Sage	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	T
H and I Laboratory NHS Blood and Transplant Vincent Drive Edgbaston Birmingham B15 2SG Local Contact: Mr Luke Foster	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	B
H and I and Molecular Diagnostics Laboratory NHS Blood and Transplant 500, North Bristol Park Bristol BS34 7QH Local Contact: Dr. Anthony Poles	Histocompatibility and Immunogenetics and Immunohaematology molecular diagnostic investigations for the purpose of clinical diagnosis	BR
H and I Laboratory NHS Blood and Transplant Barnsley Blood Centre unit D, Capital way Dodworth Barnsley S75 3HG Local Contact: Mr Tim Key	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	BA
H and I Laboratory NHS Blood and Transplant Holland Drive Barrack Road Newcastle-upon-Tyne NE2 4NQ Local Contact: Dr. Arash Akbarzad-Yousefi	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	N



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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 FLUIDS	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Whole blood, Spleen & Lymph nodes	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Complement Dependent Cytotoxicity (CDC) manual method using in house procedures:  SOP3454- Separation of T&B lymphocyte populations SOP3452- Counting and/or viability assessment of lymphocytes  SOP1624 – CDC	B T N          T
Whole blood, Spleen & Lymph nodes	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	SOP506 - Birmingham Protocol for Crossmatching of Solid Organ  Flow cytometry using Beckman Coulter DxFlex Flow Cytometer and in-house procedures:  SOP6163 SOP6164  SOP506 Birmingham Protocol for Crossmatching of Solid Organ Donors  SOP2496 – Barnsley Performing 3 Colour T and B Lymphocyte Flow Cytometry Crossmatching/Autos  SOP1640 - Tooting 3 colour Renal Transplant T&B cell flow cytometry crossmatch  SOP2121 – Newcastle Flow Cytometric Crossmatch for Solid Organ Transplantation	B          BA T N B          B          BA          T          N



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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 FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Whole blood, Spleen & Lymph nodes	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Flow cytometry using Beckman Coulter Navios Flow Cytometer and in-house procedures:  SOP 6163	T
Serum & Plasma	Detection and identification of HLA specific antibodies HLA -A, -B, -C, -DR, -DQ, -DP	SOP1640 - Tooting 3 colour Renal Transplant T&B cell flow cytometry crossmatch  Luminex™ fluorometric microbead array using: One Lambda Labscreen™ and analysis using Fusion.  Immucor Lifecodes™ and analysis using Match It  and in-house procedures:  SOP3453 & SOP711- Sample separation SOP4420 – Start up, Calibration and Shutdown of the Luminex™ Analyser SOP1416, SOP5064 - Labscreen™ SOP1414, SOP5036 - Lifecodes™	T  C TB BR BA N  T B BR BA N



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Serum & Plasma	Detection and identification of HPA specific antibodies: GPIV, HLA - A, - B, - C, GPIIb/IIIa, GPIb/IX, GPIa/IIa, (which can define HPA -1, -2, -3, -4, -5)	Luminex™ fluorometric microbead array using Lifematch™ assays and in-house procedures:  SOP3453 - Sample separation SOP4420 – Start up, Calibration and Shutdown of the Luminex™ Analyser SOP4576 - HPA antibody detection using Pak Lx™	BR
Whole blood, spleen, lymph nodes, saliva, buccal cells, Serum/plasma, cord blood, bone marrow, cells	Genotyping	Automated and manual DNA extraction and quantitation using MagNApure and Nanodrop ND1000/2000 SOP583 - DNA extraction MagNA pure SOP666 - Spin columns (ENZA) SOP572 - Nanodrop	C T B BR BA N
Whole blood, saliva, buccal cells, Serum/plasma, cord blood, bone marrow, cells	Genotyping	High throughput automated DNA extraction using Qiagen Symphony and in-house procedures: SOP3668 - DNA extraction using the QIASymphony SOP3421 - Oragene saliva kit	C



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>DNA extracted from sample types above</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Genotyping</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Automated product amplification using thermocyclers and in-house procedures: SOP589 - Use of Thermal Cyclers and: MJ Research PTC-200 MJ Research DNA Engine Tetrad 2 MJ Research PTC-225 Tetrad Fisher Scientific: Veriti Applied Biosystems: GeneAmp 9700. Perkin Elmer: 9700 Bio-Rad: C1000</p>	<p>C T B BR BA N</p>



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HUMAN TISSUES AND FLUIDS (cont'd)  DNA extracted from sample types above	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>  HLA typing: HLA-A, -B, -C, -DRB1, -3 -4, -5, -DQA1, -DQB1, -DPA1, -DPB1	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	C T B BR BA N       T B  T, BR, B. BA  C  B, N  B   T B BR BA N C
		PCR with Sequence Specific Primers (SSP) using either in house developed primer sets or commercial kits.	
		Visualisation using Agarose Gel Electrophoresis and in-house procedures: SOP581 – Operation of Gel Documentation systems in H&I SOP1123 – Interpretation of SSP results	
		SOP2863, SOP1125 or SOP1123- In House PCR SSP	
		SOP1124, SOP2863, SOP1123 HLA B27 by in house SSP	
		SOP3099, SOP2894, SOP4333 HLA B27 by in house SSP	
		SOP2523 & SOP1123 Commercial SSP Kits (Olerup™ & InnoTrain™)	
SOP2523, & SOP1123 Commercial SSP kits (BioRad)			
SOP581 – Operation of Gel Documentation systems in H&I			



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
DNA extracted from sample types above	HFE typing: Gene positions - 63/282	PCR with Sequence Specific Primers (SSP) using in house developed primer sets. Visualisation using Agarose Gel Electrophoresis and in-house procedures: SOP581 – Operation of Gel Documentation systems in H&I SOP2279 - HFE by SSP	C T
DNA extracted from sample types above	HPA typing: HPA -1, -2, -3, -4, -5, -6, -9, -15	PCR with Sequence Specific Primers (SSP) using a commercial kit. Visualisation using Agarose Gel Electrophoresis and in-house procedures: SOP589 Thermocyclers SOP581 – Operation of Gel Documentation systems in H&I SOP2074 - Determining HPA Types by PCR-SSP using the Inno-Train™ Kit SOP2894 – Analysis of PCR products	C



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>DNA extracted from sample types above</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>HLA typing: HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>PCR with Sequence Specific Primers (SSP) with melt curve analysis using QuantStudio™ Dx Real-Time PCR System using LinkSeq assay. and in-house procedures:</p> <p>SOP589 - Use of thermal cyclers SOP5056 &amp; SOP5057 - Set up &amp; analysis of LinkSeq™ kits</p> <p>PCR with Sequence Specific Primers (SSP) with hydrolysis probes for the amplification and real time detection of HLA alleles using QuantStudio Real-Time PCR System using Q type assay and in-house procedures:</p> <p>SOP5928 &amp; SOP5929 - Set up &amp; analysis of Q Type™ kits</p>	<p>B B A T N</p>





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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Human DNA extracted from sample types above</p> <p>DNA sequence data</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>HLA Typing: HLA-A, -B, -C, -DRB1, -DQB1, -DPB1</p> <p>Determination of HLA type HLA-A, -B, -C, -DRB1, -DQB1, -DPB1</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Next generation sequencing using in house developed primer sets. Analysis using MiSeq™ and in-house procedures:</p> <p>SOP4659 - Preparation of primer mixes for NGS SOP4605 - Use of Aurora sample tracking software SOP4649 - Purification of DNA for NGS SOP4608 - Use of the FiltermaxF3 plate reader SOP4650 - PCR set up for HLA typing by NGS SOP4651 - NGS DNA library preparation SOP4609 - Use of the MiSeq SOP575 - Importing and integration of Analyser results to LIMS SOP5310 - Compilation of NGS Repeat and External Sample Plates</p> <p>Data analysis using commercial software and in-house procedure: SOP4607 - Analysis of HLA NGS data using GenDex NGS Engine</p>	<p>C</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Human DNA extracted from sample types above</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>HLA typing HLA-A, -B, -C, -DRB1, -3 -4, -5, -DQA1, -DQB1, -DPA1, -DPB1</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Next generation sequencing using commercial method. One Lambda AllType kit, Qubit Fluorometer, Thermocyclers and Illumina MiSeq SOP589 - Use of Thermal Cyclers in DTS Laboratories SOP5510 - Quantitation of DNA using a QuBit Fluorometer SOP5506 - Clinical HLA Typing by OneLambda AllType™ Fastplex NGS Assay SOP4609 - Use of the MiSeq</p>	<p>C T B BR BA N</p>
<p>DNA sequence data</p>	<p>Determination of HLA type HLA-A, -B, -C, -DRB1, -3 -4, -5, -DQA1, -DQB1, -DPA1, -DPB1</p>	<p>Data analysis using commercial software from the kit: Primary Analysis SOP5507 - Analysis of Clinical HLA typing by Next Generation Sequencing using TypeStream Visual Software</p>	<p>C T B BR BA N</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Amniotic fluid and Human DNA extracted from sample types above</p> <p>DNA sequence data</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>HPA Typing: HPA -1, - 2, - 3, -4, -5, -6, -9, - 15</p> <p>Determination of HPA type HPA -1, - 2, - 3, -4, -5, -6, -9, - 15</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Sanger PCR-Sequence based Typing (SBT) using in house developed primer sets. Analysis using ABI3500xl and in-house procedures:</p> <p>SOP589 Thermocyclers SOP4858 - ABI3500xl SOP1069 - Primer preparation SOP1059 - SBT Clean up protocols SOP3400 - Use of PCR-SBT for HNA and HPA Genotyping</p> <p>Data analysis using commercial software and in-house procedure: SOP3971 - Use of Mutation Surveyor</p>	<p>BR</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Human DNA extracted from sample types above</p> <p>DNA sequence data</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>HNA Typing: HNA -1, - 3, -4, -5</p> <p>Determination of HNA type HNA -1, - 3, -4, -5</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Sanger PCR-Sequence based Typing (SBT) using in house developed primer sets. Analysis using ABI3500xl and in-house procedures:</p> <p>SOP4858 - ABI3500xl SOP1069 - Primer preparation SOP1059 - SBT Clean up protocols SOP3400 - Use of PCR-SBT for HNA and HPA Genotyping</p> <p>Data analysis using commercial software and in-house procedure: SOP3971 - Use of Mutation Surveyor</p>	<p>BR</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Whole Blood, Bone marrow and DNA extracted from sample types above</p> <p>Whole Blood, Bone marrow and DNA extracted from sample types above</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of chimerisms Engraftment monitoring post stem cell transplant.</p> <p>Detection of chimerisms Engraftment monitoring post stem cell transplant.</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Chimerism detection Amplification using thermocyclers (SOP589) ABI3500xl genetic analyser using Promega Powerplex 16 assay and in-house procedures:</p> <p>SOP4858 – Use of ABI3500xl SOP1288 - Use of Promega Powerplex 16 kits SOP4123 - Measurement of cell purity SOP4772 - Cell separation using Milentyi™ kits</p> <p>Chimerism detection (short tandem repeat analysis) Amplification using thermocyclers (SOP589) ABI3500xl genetic analyser using Promega Geneprint 24 assay and in-house procedures:</p> <p>SOP4858 – Use of ABI3500xl SOP6000 - Use of Promega Geneprint 24 SOP4123 - Measurement of cell purity SOP4772 - Cell separation using Milentyi™ kits</p>	<p>T BA</p> <p>BR</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
DNA sequence data	Detection of chimerisms	Data analysis using commercial software and in-house procedure: SOP4568 - Use of Chimermarker™	BR BA, T
		SOP1222 - Use of genemapper™	T
Cord Blood and DNA extracted from sample types above (cont'd)	Confirmation of identification of cord blood units during issue	Short Tandem repeat analysis: Amplification using thermocyclers listed above and ABI3500xl genetic analyser using Promega assay and in-house procedures: SOP589 Thermocyclers SOP4858 – Use of ABI3500xl SOP1288 - Use of Promega kits	BR
DNA sequence data	Detection of chimerisms	Data analysis using commercial software and in-house procedure  SOP4568 - Use of Chimermarker™	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Human DNA extracted from sample types above	HPA typing (high throughput) HPA-1, -2, -3, -4, -5 -15	Real Time PCR using in house developed primer sets.  Analysis by using QuantStudio™ 7 Flex Real-Time PCR System and in-house procedures:  SOP1051 - HPA typing by Taqman assay: making-up primers and probes. SOP593 - HPA Genotyping using Taqman Assay: Set Up SOP5094 - Set Up of HPA Mass Genotyping Plates Using Beckman NX Liquid Handling Robot SOP5005 - HPA Genotyping using TaqMan assay: Result acquisition and analysis	C
Human DNA extracted from sample types above	Detection of CCR5 delta32 mutation	Real Time PCR using in house developed primer sets. Analysis by using QuantStudio™ 7 Flex Real-Time PCR System and in-house procedures: SOP589 Thermocyclers SOP4277 - CCR5 delta32 mutation detection	C



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum/plasma/whole blood</p> <p>Serum/plasma</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of HPA specific antibodies: HPA -1, -2, - 3, -5, -6 -9 - 15 GPIIb/IIIa, GPIb/IX, GPIa/IIa, GPIV, GPV</p> <p>Detection of HPA specific antibodies including: HPA -1, -2, - 3, -5, -6, -9 15 GPIIb/IIIa, GPIb/IX, GPIa/IIa, GPIV, GPV</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Sample and reagent preparation SOP760 - Thawing Frozen Platelets for use in PIFT and MAIPA Assay SOP1451- Platelet Panel Preparation, Freezing and Stock Management SOP903 - Platelet Isolation from Platelet Rich Plasma SOP904 - Platelet Isolation by Density Gradient SOP3276 - Sample Processing SOP3172 - Production of Laboratory Reagents</p> <p>Indirect Platelet Immunofluorescence test (PIFT) using flow cytometry and differential counts using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures:</p> <p>SOP5046 – Running CytoFLEX flow cytometer SOP3043 AcT 5diff Haematology analyser SOP615 - The Indirect Platelet Immunofluorescence Test (PIFT)</p>	<p>BR</p> <p>BR</p>





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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Serum/plasma	Detection and identification of: HPA specific antibodies: HPA -1, -2, -3, -5, -6 -9 -15 GPIIb/IIIa, GPIb/IX, GPIa/IIa, GPIV, GPV	<p>Monoclonal Antibody Immobilisation of Platelet Antigens (MAIPA) using differential counts on AcT 5 diff Haematology analyser, Biotek plate washers, FLUOstar Omega Microplate reader and in-house procedures:</p> <p>SOP3043 –AcT5 diff haematology analyser  SOP3420 - Use of Ascent software  SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer  SOP584 Maintenance and Performance Checks for Plate Washers in H&amp;I  SOP3950 – Operation of the FLUOstar Omega  SOP1449 &amp; SOP608 - Monoclonal Antibody Immobilisation of Platelet Antigen (MAIPA)  SOP4970 - Detecting drug dependent specific antibodies using the MAIPA assay</p>	BR
Whole blood	Determination of the expression of glycoproteins: GPIIb/IIIa GPIb/IX GPIa/IIa GPIV	<p>Platelet Glycoprotein Expression using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures:</p> <p>SOP5046 – Running CytoFLEX flow cytometer  SOP3043 - AcT 5diff Haematology analyser SOP758 - Determination of the level of Platelet Glycoprotein Expression using a direct PIFT</p>	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Serum/ plasma	Detection of HPA incompatibility	Platelet crossmatching using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures:  SOP5046 – Running CytoFLEX flow cytometer SOP3043 - AcT 5diff Haematology analyser SOP1074 - Platelet crossmatching by indirect PIFT	BR
Serum/plasma	Detection of HPA incompatibility	Monoclonal Antibody Indirect Platelet Assay (MAIPA) using differential counts on AcT 5 diff Haematology analyser, Biotek plate washers, FLUOstar Omega Microplate reader and in-house procedures:  SOP3043 –AcT5 diff haematology analyser SOP3420 - Use of Ascent software SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP584 Maintenance and Performance Checks for Plate Washers in H&I SOP3950 – Operation of the FLUOstar Omega SOP608 - Monoclonal Antibody Immobilisation of Platelet Antigen (MAIPA) SOP902 - Platelet crossmatch by indirect Monoclonal Antibody Indirect Platelet Assay (MAIPA)	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Whole blood / isolated platelets	Detection of auto platelet antibodies	<p>Platelet Immunofluorescence testing (PIFT) (direct or indirect auto) using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures:</p> <p>SOP5046 – Running CytoFLEX flow cytometer SOP1294 – Direct and indirect auto platelet immunofluorescence SOP3043 –AcT5 diff haematology analyser SOP608 - Monoclonal Antibody Immobilisation of Platelet Antigen (MAIPA) SOP3420 - Use of Ascent software SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP584 Maintenance and Performance Checks for Plate Washers in H&amp;I</p>	BR
Whole blood / isolated platelets	Determination of HPA-1a phenotype	<p>Flow cytometry using CytoFLEX flow cytometer and in-house procedures:</p> <p>SOP770 - Determination of HPA-1a Phenotype using FITC Labelled IgG Monoclonal Human HPA-1a Antibody SOP5046 – Running CytoFLEX flow cytometer</p>	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Serum or Plasma	Detection of Heparin associated platelet antibodies: PF4 (IgG/IgM)	Manual ELISA assay using Biotek washer and FLUOstar Omega microplate reader and in-house procedures: SOP2722 - Zymutest HIA IGG/IgM ELISA SOP3420 - Use of Ascent software. SOP3950 - Operation of the FLUostar Omega SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP584 Maintenance and Performance Checks for Plate Washers in H&I	BR
Serum or Plasma	Detection of Heparin associated platelet antibodies: PF4 (HAT13G, HAT45G, X-HAT13 or X-HAT45)	Manual ELISA assay using Biotek washer and FLUOstar Omega microplate reader and in-house procedures: SOP612 - GTI PF4 ELISA SOP3420 - Use of Ascent software. SOP3950 - Operation of the FLUostar Omega SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP584 Maintenance and Performance Checks for Plate Washers in H&I	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Whole Blood	Detection of Granulocyte specific antibodies	Isolation of granulocytes and monocytes Manual density gradient centrifugation followed by CytoFLEX flow cytometry and in-house procedures:  SOP767 - White cell isolation by GLAM  SOP776 - Granulocyte and Lymphocyte isolation SOP773 - Counting granulocytes and lymphocytes by flow cytometry SOP768 Monocyte Isolation and the Granulocyte chemiluminescence Test (GCLT) - Microplate Method	BR
Whole blood/ isolated granulocytes	Detection of Granulocyte specific antibodies including anti-HNA -1, CD16, -2, -3, -4 - 5	Granulocyte Immunofluorescence test (GIFT) flow cytometry using CytoFLEX flow cytometer and in-house procedures:  SOP5046 - Running CytoFLEX flow cytometer SOP775 - Direct and "indirect auto" Granulocyte Immunofluorescence test and Granulocyte phenotyping SOP875 - The granulocyte and Lymphocyte immunofluorescence test SOP3262 - HNA phenotyping using monoclonal antibodies and indirect labelling	BR



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Serum / plasma	Detection and identification of HNA-3a/b specific antibody	Granulocyte Immunofluorescence test (GIFT) Flow cytometry using CytoFLEX flow cytometer and in-house procedures:  SOP5046 - Running CytoFLEX flow cytometer SOP3936 - Recovery of recombinant HNA-3a and HNA-3b cell lines and their use in Antibody Detection using the GIFT	BR
Serum	Detection and identification of HNA specific antibodies: HLA-1a, 1b, 1c, 1d, CD16, HNA-2, CD177, HNA-3, -4, -5 or CD11/18	Monoclonal Antibody Immobilisation of Granulocyte antigens (MAIGA) Manual ELISA using Biotek cell washers and FLUOstar microplate readers and in-house procedures:  SOP3420 - Use of Ascent software SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP584 Maintenance and Performance Checks for Plate Washers in H&I SOP3950 – Operation of the FLUOstar Omega SOP1447 - Monoclonal Antibody Immobilisation of Granulocyte antigens (MAIGA)	BR



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum</p>	<p><u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Determination of the biological activity of granulocyte antibodies by determining their ability to promote phagocytosis of sensitised granulocytes by human FCGR bearing mononuclear cells</p>	<p>Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:</p> <p>Granulocyte chemiluminescence test (GCLT) Manual ELISA using Biotek plate washers and FLUOstar Omega microplate reader and in-house procedures:</p> <p>SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP3950 – Operation of the FLUOstar Omega SOP768 - Granulocyte chemiluminescence test (GCLT)</p>	<p>BR</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for key equipment as specified (where relevant) in conjunction with in-house documented methods:	
Whole blood	Detection of HNA phenotypes: HNA -1, -2	Granulocyte Immunofluorescence test (GIFT) (direct and indirect auto) Flow cytometry using CytoFLEX flow cytometer and in-house procedures:  SOP5046 – Running CytoFLEX flow cytometer SOP775 - Direct and 'indirect auto' granulocyte immunofluorescence test and granulocyte phenotyping SOP3262 - HNA phenotyping using monoclonal antibodies and indirect labelling	BR
Whole blood	Detection of HNA incompatibilities	Flow Cytometry using CytoFLEX flow cytometer and in-house procedures:  SOP5046 – Running CytoFLEX flow cytometer SOP769 - Cross Match and Phenotyping of Patients involved in cases of Transfusion Related Acute Lung Injury SOP774 - Cross Match and Typing of Patients involved in Suspected Cases of Neonatal Alloimmune Neutropenia SOP775 - Direct and 'indirect auto' granulocyte immunofluorescence test and granulocyte phenotyping	BR





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Whole blood EDTA, maternal plasma, amniocytes, chorionic villus samples	<u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis</u>	Automated DNA extraction using QIA-symphony and manual DNA extraction using manufacturer's instructions SOP4095 / SOP4092 /SOP5195 SOP5813	BR
DNA extracted from samples listed above:		DNA Quantification of DNA using Nanodrop 2000 SOP5276 (SOP572)	
HUMAN TISSUE AND FLUIDS (cont'd)	<u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for BASIS BioArray Solutions imaging system BioArray AIS400 Beadchip technology (elongation mediated multiplexed analysis of polymorphisms) and C1000 Touch thermal cycler and in-house procedure:	
DNA	Determination of red cell antigen type: D, C, c, E, e, V, VS M, N, S, s, U, K, k, Kpa/Kpb, Jsa, Jsb Fya, Fyb, Fyx, Jka, Jkb, Doa, Dob, Hy+/-, Joa, Job Lua, Lub, Dia/b, Coa/b Lw1/Lw2	SOP4214	
DNA	Determination of red cell antigen type: C, c, E, e, M, N, S, s, U, K, k, Kpa/Kpb, Jsa, Jsb, Fya, Fyb, Jka, Jkb, Doa, Dob, Lua, Lub ABO	Real time PCR allelic discrimination Quantstudio 12K, and Dx system and in-house procedures. Biomek NXP automation workstation.  SOP4098, SOP4984	
DNA	D,C, c	Allele-specific PCR / gel electrophoresis PCR using BioRad C1000 Touch Thermal Cycler SOP4097	



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DNA  DNA derived from maternal plasma  DNA provided by customers	Determination of fetal blood group genotype:  D, C, c, E, K1  DNA sequence	Semi quantitative real time PCR using manufacturer's instructions for Biomek NXP automation workstation, Quantstudio 12K, and Dx system and in-house procedures:  SOP4093 / SOP4102/ SOP4103 SOP4104/ SOP4105 / SOP4107  DNA sequencing using: manufacturer's instructions for Sanger sequencing (dideoxynucleotide chain termination) with Bio-Rad C1000 Thermal cycler and 3500 XL genetic analyser SOP5233	
END			