


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>NHS Blood and Transplant</h3> <p>Issue No: 001 Issue date: 27 September 2018</p>	
	<p>Histocompatibility and Immunogenetics Laboratories NHSBT Charcot Road Colindale London NW9 5BG</p>	<p>Contact: Diane Irving Tel: +44 (0)7729275353 E-Mail: diane.irving@nhsbt.nhs.uk Website: www.nhsbt.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address H and I Laboratory NHS Blood and Transplant Charcot Road Colindale London NW9 5BG</p> <p>Local contact: Dr. Colin Brown</p>	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	C
<p>H and I Laboratory NHS Blood and Transplant 75 Cranmer Terrace Tooting London SW17 0RB</p> <p>Dr. Deborah Sage</p>	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	T
<p>H and I Laboratory NHS Blood and Transplant Vincent Drive Edgbaston Birmingham B15 2SG</p> <p>Prof. David Briggs</p>	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	B
<p>H and I Laboratory NHS Blood and Transplant 500, North Bristol Park Bristol BS34 7QH</p> <p>Dr. Anthony Poles</p>	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	BR
<p>H and I Laboratory NHS Blood and Transplant Longley Lane Sheffield S5 7JN</p> <p>Mr Tim Key</p>	Histocompatibility and Immunogenetics investigations for the purpose of clinical diagnosis	S
<p>H and I Laboratory NHS Blood and Transplant Holland Drive Barrack Road Newcastle-upon-Tyne NE2 4NQ</p> <p>Dr. Vaughan Carter</p>	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 and IgM 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 SOP1797 – CDC	B T N T N
Whole blood, Spleen & Lymph nodes	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Flow cytometry using BD FacsCanto II Flow Cytometer and in-house procedures: SOP506 - Birmingham Protocol for Crossmatching of Solid Organ Donors SOP3061- Flow Crossmatch	C B B C
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: SOP2496 - Performing 3 Colour T and B Lymphocyte Flow Cytometry Crossmatching/Autos Cytometry Crossmatching/Autos SOP1640 - 3 colour Renal Transplant T&B cell flow cytometry crossmatch	S T S T



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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, Spleen & Lymph nodes	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Flow cytometry using Beckman Coulter FC500 Flow Cytometer and in-house procedures:	N T
		SOP1640 - 3 colour Renal Transplant T&B cell flow cytometry crossmatch	T
		SOP2121 - Flow Cytometric Crossmatch for Renal Transplantation Using FC500 Flow Cytometer	N
Serum & Plasma	Detection and identification of HLA specific antibodies HLA -A, -B, -C, -DR, -DQ, -DP	Luminex™ fluorometric microbead array using Labscreen™ and Lifecodes™ assays and in-house procedures:	C T B BR S N
		SOP3453 & SOP711- Sample separation	
		SOP4420 – Start up, Calibration and Shutdown of the Luminex™ Analyser	
		SOP1416, SOP5064 - Labscreen™	
		SOP1414, SOP5036 - Lifecodes™	



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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 SOP3421 - Oragene saliva kit SOP2901 –Buccal swabs SOP3091 – Salting out DNA	C T B BR S 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	T C



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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	Genotyping	Automated product amplification using thermocyclers and in-house procedures: SOP589 - Use of Thermal Cyclers and: BioRad: C1000 Touch & G-STORM. Perkin Elmer: 9700, MJ Research Tetrad PTC 240, Tetrad PTC225 & Tetrad, PTC-100, PTC-200. Techne: TC-512 & Touchgene. Applied Biosystems: GeneAmp 9700. Thermofisher: Veriti	CT B BR SN
DNA extracted from sample types above	HLA typing: HLA-A, -B, -C, -DRB1, -3 -4, -5, -DQA1, -DQB1, -DPA1, -DPB1	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 SOP 3486 or SOP1621- Visualisation of PCR Amplified Products by Agarose Gel Electrophoresis SOP701 & SOP698 - BioRad SSP SOP2863 - In House PCR SSP SOP3218 - Setting up Invitrogen SSP SOP4553 & SOP4582 - HLA typing using One Lambda PCR-SSP tray SOP2523 - Setting up commercial SSP Kits (Olerup™ & InnoTrain™) SOP1124 - HLA B27 by SSP SOP1125 - HLA B57:01 by SSP	CT B BR SN BN CT B BR SN TC BR BN T BR



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>DNA extracted from sample types above</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>HFE typing: Gene positions - 63/282</p> <p>HPA typing: 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>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 SOP1123 – Interpretation of SSP results SOP 3486 or SOP1621 - Visualisation of PCR Amplified Products by Agarose Gel Electrophoresis SOP2279 - HFE by SSP</p> <p>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</p>	<p>CTBSN</p> <p>C</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 extracted from sample types above	HLA typing: HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	PCR with Sequence Specific Primers (SSP) using QuantStudio TM Dx Real-Time PCR System using Linkage Biosciences assay. and in-house procedures: SOP589 - Use of thermal cyclers SOP5056 & SOP5057 - Set up & analysis of LinkSeq™ kits	B S T N
DNA extracted from sample types above	HLA typing: HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	PCR-Sequence specific oligonucleotide probes (SSOP) Luminex™ fluorometric microbead array using LabType™ LifeCodes™ and in-house procedures: SOP4420 – Start up, Calibration and Shutdown of the Luminex™ Analyser SOP569 & SOP4216 - Typing using LabType™ SSO kits SOP4861 & SOP571 HLA typing using LifeCodes™	C T B BR N S



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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	HLA Typing: (high throughput) HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	PCR-Sequence specific oligonucleotide probes (SSOP) Luminex™ fluorometric microbead array using LabType™ assays and in-house procedures: Set up & detection using liquid handling robots: SOP604 - EpMotion 5075 robot SOP4383 & SOP4383 - BioMek robots SOP4384 - Automated Liquichip LABType detection Set up & detection – manual method - SOP600 & SOP603 SOP4420 – Start up, Calibration and Shutdown of the Luminex™ Analyser	C
Human DNA extracted from sample types above	HLA Typing: HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	Sanger PCR-Sequence based Typing (SBT) using either in house developed primer sets or commercial kits. Analysis by using ABI3130xl or ABI3500xl and in-house procedures: SOP1063 & SOP1065 - ABI 3130xl SOP4858 - ABI3500xl SOP1058 - Set up SOP1059 - SBT Clean u protocols SOP1069 - Primer Preparation SOP1056 - Primer Preparation	C B BR T S N N T B BR S C T BR S C T C B BR T S N B



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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	HLA Typing: HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	Sanger PCR-Sequence based Typing (SBT) using either in house developed primer sets or commercial kits. Analysis using ABI3130xl or ABI3500xl and in-house procedures:	C B BR T S N
DNA Sequence data	Determination of HLA type HLA -A, -B, -C, -DRB1, 3, 4, 5, -DQA1, -DQB1, -DPA1, -DPB1	SOP1057 - Use of GenDx SBT Excellerator™ kits Analysis using commercial software and in-house procedure:	N T C
		SOP1066 – Analysis using Assign	S B BR
		SOP909 – Analysis using SBT engine	N T C



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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>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>	BR



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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>	BR



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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>Detection of genes associated with inherited platelet disorders: <i>ITGA2B</i> <i>ITGB3</i> <i>GPIba</i> <i>GPIbβ</i> <i>GPIX</i></p> <p>Detection of genes associated with inherited platelet disorders: <i>ITGA2B</i> <i>ITGB3</i> <i>GPIba</i> <i>GPIbβ</i> <i>GPIX</i></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: SOP589 Thermocyclers SOP4858 - ABI3500xl SOP1069 - Primer preparation SOP1059 - SBT Clean up protocols SOP4233 - Sequencing genes associated with inherited platelet disorders</p> <p>Data analysis using commercial software and in-house procedure: SOP3971 - Use of Mutation Surveyor</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, Bone marrow and DNA extracted from sample types above	Detection of chimerisms Engraftment monitoring post stem cell transplant.	Chimerism detection Amplification using thermocyclers (SOP589) ABI3500xl genetic analyser using Promega assay and in-house procedures: SOP4858 – Use of ABI3500xl SOP1288 - Use of Promega kits SOP4123 - Measurement of cell purity SOP4772 - Cell separation using Milentyi™ kits	BR T S
DNA sequence data	Detection of chimerisms	Data analysis using commercial software and in-house procedure: SOP4568 - Use of Chimermarker™ SOP1222 - Use of genemapper™	BR S 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 C
DNA sequence data	Detection of chimerisms	Data analysis using commercial software and in-house procedure SOP4568 - Use of Chimermarker™ SOP1222 - Use of genemapper™	BR S



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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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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/whole blood	Detection of HPA specific antibodies	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	BR
Serum/plasma	Detection of HPA specific antibodies including: HPA -1, -2, -3, -5, -6, -9 15 GPIIb/IIIa, GPIb/IX, GPIa/IIa, GPIV, GPV Quinine-Dependent Platelet Antibodies Teicoplanin-dependant platelet antibodies Other drug-dependant platelet antibodies	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: SOP5046 – Running CytoFLEX flow cytometer SOP3043 AcT 5diff Haematology analyser SOP615 - The Indirect Platelet Immunofluorescence Test (PIFT) SOP901 - Detection of Quinine-Dependent Platelet Antibodies by the Indirect PIFT SOP3242- Investigation of teicoplanin-dependant platelet antibodies by indirect PIFT SOP4118 - Investigation of drug-dependent platelet antibodies by indirect PIFT	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: HPA specific antibodies: HPA -1, -2, -3, -5, -6 -9 -15 GPIIb/IIIa, GPIb/IX, GPIa/IIa, GPIV, GPV Quinine-dependent Platelet Antibodies Teicoplanin-dependent platelet antibodies Other drug-dependent platelet antibodies	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: 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 SOP1449 & SOP608 - Monoclonal Antibody Immobilisation of Platelet Antigen (MAIPA) SOP4970 - Detecting drug dependent specific antibodies using the MAIPA assay	BR
Whole blood	Determination of the expression of glycoproteins: GPIIb/IIIa GPIb/IX GPIa/IIa GPIV	Platelet Glycoprotein Expression using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures: SOP5046 – Running CytoFLEX flow cytometer SOP3043 - AcT 5diff Haematology analyser SOP758 - Determination of the level of Platelet Glycoprotein Expression using a direct PIFT	BR



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

NHS Blood and Transplant

Issue No: 001 **Issue date:** 27 September 2018

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
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	Platelet Immunofluorescence testing (PIFT) (direct or indirect auto) using CytoFLEX Flow Cytometer and AcT 5 diff Haematology analyser and in-house procedures: 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&I	BR
Whole blood / isolated platelets	Determination of HPA-1a phenotype	Flow cytometry using CytoFLEX flow cytometer and in-house procedures: SOP770 - Determination of HPA-1a Phenotype using FITC Labelled IgG Monoclonal Human HPA-1a Antibody SOP5046 – Running CytoFLEX flow cytometer	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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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	Determination of the biological activity of granulocyte antibodies by determining their ability to promote phagocytosis of sensitised granulocytes by human FCGR bearing mononuclear cells	Granulocyte chemiluminescence test (GCLT) Manual ELISA using Biotek plate washers and FLUOstar Omega microplate reader and in-house procedures: SOP3914 – Use and Maintenance of Biotek ELx50 Well Washer SOP3950 – Operation of the FLUOstar Omega SOP768 - Granulocyte chemiluminescence test (GCLT)	BR
Whole blood	Toxicity testing of drugs implicated in drug related neutropenia	Granulocyte Immunofluorescence test (GIFT) using CytoFLEX Flow Cytometer and in-house procedures: SOP5046 – Running CytoFLEX flow cytometer SOP766 - Investigation of drug-related neutropenia by indirect GIFT SOP912 - Toxicity testing of drugs implicated in drug related neutropenia	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 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
END			