


# 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>8703</p> <p>Accredited to ISO 15189:2012</p>	<h3>Belfast Health and Social Care Trust</h3> <p>Issue No: 002    Issue date: 17 January 2020</p>	
	<p>Department of Haematology and Transfusion</p> <p>Belfast Health and Social Care Trust</p> <p>Royal Group of Hospitals</p> <p>Grosvenor Road</p> <p>Kelvin Building</p> <p>Belfast</p> <p>BT12 6BA</p> <p>United Kingdom</p>	<p>Contact: Frances McCauley</p> <p>Tel: +44 (0)289 5047 908</p> <p>Fax: +44 (0)289 0745 435</p> <p>E-Mail: <a href="mailto:Frances.McCauley@belfasttrust.hscni.net">Frances.McCauley@belfasttrust.hscni.net</a></p> <p>Website: <a href="http://www.belfasttrust.hscni.net/services/Laboratory-MortuaryServices.htm">www.belfasttrust.hscni.net/services/Laboratory-MortuaryServices.htm</a></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
Belfast City Hospital Lisburn Road Belfast BT9 7AB United Kingdom	Haematology Coagulation Blood Transfusion	BCH
Belfast Royal Victoria Hospital 7 Mulhouse Road Belfast BT12 5DL United Kingdom	Haematology Coagulation Blood Transfusion	RVH
Royal Belfast Hospital for Sick Children 180-184 Falls Road Belfast BT12 6BE United Kingdom	Haematology Blood Transfusion	RBHSC
Mater Infirmorum Hospital 45-51 Crumlin Road BT14 6AB United Kingdom	Haematology Blood Transfusion	MIH



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**Site activities performed away from the locations listed above:**

Location details	Activity
Theatre Reception Belfast City Hospital Lisburn Road Belfast BT9 7AB United Kingdom	Blood storage & issue only Fridge monitored by Haematology
Cardiac Theatre Reception Belfast Royal Victoria Hospital 7 Mulhouse Road Belfast BT12 5DL	Blood storage & issue only Fridge monitored by Haematology
Theatres Level 3 A Block Belfast Royal Victoria Hospital 7 Mulhouse Road Belfast BT12 5DL	Blood storage & issue only Fridge monitored by Haematology
3B RICU Level 3 Belfast Royal Victoria Hospital 7 Mulhouse Road Belfast BT12 5DL	Blood storage & issue only Fridge monitored by Haematology
ICU Royal Belfast Hospital for Sick Children 180-184 Falls Road Belfast BT12 6BE	Blood storage & issue only Fridge monitored by Haematology
Theatres Royal Belfast Hospital for Sick Children 180-184 Falls Road Belfast BT12 6BE	Blood storage & issue only Fridge monitored by Haematology
Royal Jubilee Maternity Hospital (RMH) Delivery Suite 274 Grosvenor Road Belfast BT12 6BA	Blood storage & issue only Fridge monitored by Haematology



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Location details	Activity
Musgrave Park Hospital (MPH) Theatre Reception Stockmans Lane Belfast BT9 7JB	Blood storage & issue only Fridge monitored by Haematology
Ulster Independent Clinic (UIC) Theatre Reception Level 1 245 Stranmillis Road Belfast BT9 5JH	Blood storage & issue only Fridge monitored by Haematology
Kingsbridge Private Hospital (KPH) Theatre Reception Level 2 815 Lisburn Road Belfast BT9 7GX	Blood storage & issue only Fridge monitored by Haematology
Lagan Valley Hospital (LVH) Theatre Hillsborough Road Lisburn BT28 1JP	Blood storage & issue only Fridge monitored by Haematology
Downe Hospital (DH) Level 1 Ward 2 2 Struell Wells Road Downpatrick BT30 6RL	Blood storage & issue only Fridge monitored by Haematology
MIH Resus (Casualty) Mater Infirmorum Hospital 45-51 Crumlin Road BT14 6AB United Kingdom	Blood storage & issue only Fridge monitored by Haematology
MIH Theatre Recovery Mater Infirmorum Hospital 45-51 Crumlin Road BT14 6AB United Kingdom	Blood storage & issue only Fridge monitored by Haematology



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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 BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole Blood unless stated	Blood Group /antigens: ABO Forward/Reverse and RhD Group	Ortho Clinical Diagnostics (OCD) Ortho Autovue - column agglutination technology Manual: SOP H-249 Automated: SOP H-296	BCH, MIH and RVH
	Antibody screening/detection	Ortho Autovue - column agglutination technology. Manual: SOP H-262 Automated: SOP H-296	BCH, MIH and RVH
	Antibody Identification Rh -C,D,E,c,e, Cw Kell -K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Ortho Autovue - column agglutination technology. Manual: SOP H-45 Automated: SOP H-44	BCH, MIH and RVH
	Rhesus/ K Phenotype	Ortho Autovue column agglutination technology Manual Genotype SOP H-272 Automated: Phenotype SOP H-242 Genotype SOP H-252	BCH, MIH and RVH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole Blood unless stated	Direct Coombs for detection of red cell sensitisation.	Ortho Autovue - column agglutination technology Manual: SOP H-263 Automated: SOP H-264 & H-265	BCH, MIH and RVH
Donor Red Cells	Cross-match to determine compatibility	Ortho Biovue column agglutination technology - IAT Automated H-293 Manual H-261	BCH, MIH and RVH
	Feto-Maternal Haemorrhage	Kleihauer elution technique SOP H-295	RVH only
	RhD Negative screen for atypical antibodies in the presence of passively acquired Anti-D	Ortho Autovue - column agglutination technology Manual: SOP H-312 Automated: SOP H-312	RVH only
	Newborn Test to determine the cell group of infants under 4 months old and IgG sensitisation	Ortho Biovue column agglutination technology Automated: SOP H-265	RVH
	Cord Group to determine forward group of infants born to RhD neg. mothers	Ortho Biovue column agglutination technology Automated: SOP H-281	RVH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole Blood in EDTA unless stated	Complete Blood Count (CBC) for the following parameters:  Haemoglobin Estimation  Haematocrit  White Cell Count (WCC)  Red cell Count (RCC)  Mean Cell Volume (MCV)  Mean Cell Haemoglobin Concentration (MCHC)  Mean Cell Haemoglobin (MCH)  Platelets  Neutrophil Count  Lymphocyte Count  Eosinophil Count  Basophil Count  Monocyte Count	Sysmex XE-2100 SOP H-595  SLS Hb detection method (light absorbance)  RBC cumulative pulse height detection method  Flow cytometry method using semiconductor laser  Hydrodynamic focusing  Calculations using Sysmex analysers  Calculations using Sysmex analysers  Calculations using Sysmex analysers  Hydrodynamic focusing  Flow cytometry method using semiconductor laser  Flow cytometry method using semiconductor laser  Flow cytometry method using semiconductor laser  Flow cytometry method using semiconductor laser  Flow cytometry method using semiconductor laser	BCH, MIH, RVH and RBHSC



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole Blood in EDTA unless stated (cont'd)	Complete Blood Count (CBC) for the following parameters: (cont'd)	Sysmex XE-2100 cont'd	BCH, MIH, RVH and RBHSC
	Nucleated Red Cell count	Flow cytometry method using semi-conductor laser	
	Reticulocyte count	Flow cytometry method using semi-conductor laser	
	Blood Film: Leucocyte differential count	Manual microscopic analysis SOP H-631, H-628	BCH, MIH, RVH and RBHSC
	HbA1c	BioRad Variant II Turbo	RVH and MIH
		Adams A1c HA8180T Reverse phase ion exchange chromatography H-1604, 2082	BCH
	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium falciparum</i> , <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	Immunochromatographic Assay by BinaxNow Kit. SOP H-603	RVH
	<i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i> <i>Plasmodium knowlesi</i>	Giemsa R66 formulation Stain by Gurr and Microscopic Examination SOP H-603	RVH
CSF	Haematological cell type	Manual cell count & Cytospin Examination SOP H-637 and H-636	RBHSC



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:  Sysmex CS2100i Photo-optical clot detection	
Citrated plasma unless stated	Prothrombin Time / INR	SOP H-556	BCH, MIH and RVH
	Activated Partial Thromboplastin Time (APTT)	SOP H-556	BCH, MIH and RVH
	Fibrinogen	SOP H-556	BCH, MIH and RVH
	D-Dimer	SOP H-540	RVH and MIH
	APTT Mixing Studies	SOP H-556	BCH and RVH
	ADAMTS13	ELISA SOP H-2216	RVH
Whole Blood unless stated	<u>Molecular haemostasis</u>		
	Screening for the following mutations:	Applied Biosystems 2700 Thermal Cycler / 3300 DNA Sequencer	
	F8 Gene: Coding Sequence	SOP H-564	BCH
	F8 Gene: Intron 1 Inversion	SOP H-574	BCH
	F8 Gene: Intron 22 Inversion	SOP H-511	BCH
	F9 Gene: Coding Sequence	SOP H-561	BCH
	VWF Gene: Screen for Type 2 VWD Mutations	SOP H-619	BCH
Mutations Associated with VWD	SOP H-550	BCH	





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HUMAN BODY FLUIDS (cont'd)	<u>Molecular haemostasis examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole Blood unless stated (cont'd)	Screening for the following mutations: (cont'd)	Applied Biosystems 2700 Thermal Cycler / 3300 DNA Sequencer	
	F7 Gene: Coding Sequence	SOP H-437	BCH
	F11 Gene: Coding Sequence	SOP H-620	BCH
	F10 Gene: Coding Sequence	SOP H-620	BCH
	VWF Gene: Screen for Type 2N VWD Mutations	SOP H-622	BCH
DNA from whole blood unless stated	<u>Molecular red cells examinations for the purpose of clinical diagnosis</u>	MagNpure Compact SOP H-625	
	Haemoglobin variants	ABI2700 PCR instrument, ABI DNA sequencer SOP H-539	BCH
	Beta Thalassaemia gene mutations	ABI2700 PCR instrument, ABI DNA sequencer SOP H-544	BCH
	Alpha Thalassaemia common mutations 3.7,4.2	ABI2700 PCR instrument SOP H-555	BCH
	Alpha Variants/Alpha Thalassaemia - point mutations	ABI2700 PCR instrument, ABI DNA sequencer SOP H-611	BCH
	JAK2 exon 12 screen	Roche Lightcycler 480 PCR analysis SOP H-558	BCH
	MPL exon 10 screen	Roche Lightcycler PCR analysis SOP H-572	BCH



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular red cells examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
DNA from whole blood	JAK2 V617F screen	ABI2700 PCR instrument, ABI DNA sequencer SOP H-569	BCH
Whole Blood	Haemachromatosis (HFE) gene mutations H63D, S65C, C282Y	MagNapure & LC480 LightCycler PCR analysis SOP H-625 & H-566	BCH
	<u>Haemato-oncology examinations for the purpose of clinical diagnosis</u>		
Bone Marrow	Iron deposits/stores and presence of ringed sideroblasts	Cytochemical stain Perls Prussian Blue SOP H-2078	BCH
Peripheral Blood	Paroximal nocturnal haemoglobinuria (PNH) clone	FACScanto II, Becton Dickinson Lyse Wash Assistant, Sysmex XE2100 Flow Cytometry and use of fluorescence labelled antibodies to identify target cells SOP H-893	BCH
CSF	Malignant white cells	FACScanto II Manual microscopic analysis and flow cytometry SOP H-875 & SOP H-883	BCH
Peripheral Blood, Bone Marrow, PBSC Harvests	CD 34 Emumeration	FACScanto II Flow Cytometry SOP H-881	BCH
Urine	Haemosiderin	Cytochemical stain - Perls Prussian Blue Manual microscopic analysis	BCH



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HUMAN BODY FLUIDS (cont'd)	<u>Haemato-oncology examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Lymph Node, Spleen	Malignant cells	FACScanto II, Becton Dickinson Lyse Wash Assistant, Sysmex XE2100 Immunophenotypic examinations Manual microscopic analysis and flow cytometry SOP H-874, H-882, H-883	BCH
Plural Fluid, Ascitic Fluid, Peritoneal Fluid	Malignant cells	FACScanto II, Becton Dickinson Lyse Wash Assistant, Sysmex XE2100 Immunophenotypic examinations Manual microscopic analysis and flow cytometry SOP H-874 & H-883	BCH
Peripheral Blood, Bone Marrow	Absolute Lymphocyte Counts	FACScanto II Measured by Flow Cytometry SOP H-2076	BCH
Cellular Fluid	Malignant cells	FACScanto II, Becton Dickinson Lyse Wash Assistant, Sysmex XE2100  Immunophenotypic examinations Manual microscopic analysis and flow cytometry SOP H-882 & H-883	BCH
Peripheral Blood	Hereditary spherocytosis	EMA binding assay FACScanto II Flow cytometry SOP H-2077	BCH
Peripheral Blood	Platelet Glycoproteins	FACScanto II Measured by Flow Cytometry SOP H-895	BCH



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HUMAN BODY FLUIDS (cont'd)	<u>Special red cells examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Peripheral blood unless Stated	G6PD	Unicam Spectrophotometer SOP H-525	BCH
	Haemoglobin variants	Iso-electric focussing Flat Bed screen SOP H-519	BCH
Plasma	Haemoglobin	Unicam Spectrophotometer SOP H-492	BCH
	Erythropoietin	Quantitative method by R&D Systems EPO ELISA Kit SOP H-496	BCH
	Sickle Cell Screen for HbS	Qualitative test using Sickledex kit SOP H-546	RVH and BCH
	HbF and HbA2	Adams A1c HA8180T High Pressure Liquid Chromatography SOP H-2070	BCH
	Pyruvate Kinase Assay	Unicam Spectrophotometer SOP H-529	BCH



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Citrated plasma unless stated	Prothrombin Time	Stago Compact Max Clotting method SOP H-633	BCH
	Prothrombin Time Correction time	Clotting method SOP H-621	BCH
	APTT	Clotting method SOP H-585	BCH and RVH
	APTT correction time	Clotting method SOP H-623	BCH and RVH
	Fibrinogen	Clotting method SOP H-614	BCH and RVH
	D-dimer	Immuno-turbidimetric assay SOP H-671	BCH
	INR	Clotting method SOP H-633	BCH and RVH
	Factor II	Clotting method SOP H-470	BCH
	Factor V	Clotting method SOP H-473	BCH
	Factor VII	Clotting method SOP H-462	BCH
	Factor VIII clotting	Clotting method SOP H-626	BCH and RVH
	Chromogenic Factor VIII	Chromogenic Assay SOP H-629	BCH and RVH
	Factor IX	Clotting method SOP H-674	BCH



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Citrated plasma unless stated (cont'd)	Factor X	Stago Compact Max Clotting method SOP H-467	BCH and RVH
	Factor XI	Clotting method SOP H-508	BCH
	Factor XII	Clotting method SOP H-504	BCH
	Factor XIII	Spectrophotometer Chromogenic Assay SOP H-689	BCH
	Factor IX inhibitor status	Stago Compact Max Clotting method SOP H-445	BCH
	Factor VIII inhibitor	Clotting method SOP H-445	BCH
	Von Willebrand Factor Antigen	Immuno-turbidimetric assay SOP H-659	BCH
	Von Willebrand Factor Activity Latex	Immuno-turbidimetric assay SOP H-667	BCH
	Activated Protein C Resistance	Stago Compact Max, IL APC Resistance kit Clotting method SOP H-455	BCH
	Antithrombin Antigen	Immuno-turbidimetric assay SOP H-2449	BCH
Immunological Fibrinogen	Binda RID fib - Radial Immunodiffusion SOP H-664	BCH	



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Citrated plasma unless stated (cont'd)	Fondaparinux	Stago Compact Max Chromogenic Assay SOP H-656	BCH
	Protein S Activity	Clotting method SOP H-513	BCH
Serum	Heparin associated antibody	GTI-PF4 ELISA Kit ELISA technique SOP H-575	BCH
Citrated plasma unless stated	Incubated APTT	Stago Compact Max Clotting method SOP H-527	BCH
	Unfractionated Heparin assay	Chromogenic Assay SOP H-656	BCH
	Lupus Anticoagulant Screen	Clotting method SOP H-680	BCH
	LA Sensitive APTT / Correction	Clotting method SOP H-685	BCH
Citrated plasma unless stated	Plasminogen	Stago Compact Max Chromogenic Assay SOP H-451	BCH
	Plasminogen Activator Inhibit	Chromogenic Assay SOP H-451	BCH
	Protein C Antigen	ELISA technique SOP H-2372	BCH
	Reptilase Time	Stago Compact Max Clotting method SOP H-589	



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HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Citrated plasma	Thrombin Clotting Time	Stago Compact Max Clotting method SOP H-609	BCH
Whole Blood	<u>Molecular haemato-oncology examinations for the purpose of clinical diagnosis</u>		
Bone Marrow, Peripheral Blood, Tissue, Body Fluids	FactorVLeiden & PT 20210 (FVL & PT20)	MagNapure & LC480 LightCycler PCR SOP H-625 & H-598	BCH
Extracted RNA	BCR-ABL	DNA/RNA extraction Qiagen DNeasy Tissue kit Qiagen RNeasy PlusMini Kit	BCH
Extracted DNA	Immunoglobulin Gene Rearrangements	High Capacity cDNA Reverse transcription kit from Applied Biosystems SOP H-2149	BCH
Bone Marrow, Peripheral Blood, Tissue, Body Fluids	T-Cell Receptor Gene Rearrangements	AB Thermocycler GeneAmp2700 PCR analysis SOP H-596 & H-618	BCH
Bone Marrow, Peripheral Blood, Tissue, Body Fluids	t(14;18) Translocation	Horizon electrophoresis gel apparatus (Life technologies) SOP H-618, H-507, H-596 & H-582	BCH
Bone Marrow, Peripheral Blood, Tissue, Body Fluids	t(14;18) Translocation	Horizon electrophoresis gel apparatus (Life technologies) Qiagen DNeasy Tissue Kit SOP H-618, H-507, H-596 & H-591 AB Thermocycler GeneAmp2700	BCH





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Bone Marrow, Peripheral Blood, Tissue, Body Fluids	t(11;14) Translocation	Horizon electrophoresis gel apparatus (Life technologies) Qiagen DNeasy Tissue Kit, SOP H-618, H-507, H-596 & H-506 AB Thermocycler GeneAmp2700	
END			