Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8464

Accredited to ISO 15189:2012

Oxford University Hospitals NHS Foundation Trust

Issue No: 002 **Issue date**: 07 December 2018

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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
Level 4 John Radcliffe University Hospital Headley Way Headington Oxford OX3 9DU	Local contact: Andrew Platt (details as above)	• Routine haematology • Routine Coagulation • Blood Grouping and antibody screen • Blood & blood product issue • Immunophenotyping by flow analysis • Haemoglobinopathy analysis • Molecular haematology	JRH
Horton Hospital Oxford Road Banbury OX16 9AL	Haematology: Mrs E Siggs (01923 229369) Blood Transfusion: Miss J Staves (01865 220334)	• Routine haematology • Routine Coagulation • Blood Grouping and antibody screen • Blood & blood product issue	HH
Churchill Hospital Laboratory Medicine Old Road Headington Oxford OX3 7LE	Mr P Baker (01865 857096)	• Routine FBC analysis • Routine Coagulation • Blood & blood product issue	CHLM
Churchill Hospital Oxford Haemophilia and Thrombosis Centre Old Road Headington Oxford OX3 7LE	Mr P Baker (01865 857096)	• Routine Coagulation • Factor Assay analysis • Haemostatic investigations • Thrombophilia investigations	OHTC

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Site activities performed away from the locations listed above:

Location details	**Activity**
Churchill Hospital Porters Lodge Old Road Headington Oxford OX3 7LE	Blood storage & issue Fridge managed by Haematology
Delivery Suite John Radcliffe Hospital Headley Way Oxford OX3 9DU	Blood storage & issue only Fridge managed by Haematology
West Wing Theatres Level 1 John Radcliffe Hospital Headley Way Oxford OX3 9DU	Blood storage & issue only Fridge managed by Haematology
John Radcliffe Theatres John Radcliffe Hospital Headley Way Oxford OX3 9DU	Blood storage & issue only Fridge managed by Haematology
Cardio Thoracic Critical Care John Radcliffe Hospital Headley Way Oxford OX3 9DU	Blood storage & issue only Fridge managed by Haematology
Churchill Theatres Level 1 Old Road Headington Oxford OX3 7LE	Blood storage & issue only Fridge managed by Haematology

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Location details	**Activity**
Day Treatment Unit Level 1 Churchill Hospital Old Road Headington Oxford OX3 7LE	Blood storage & issue only Fridge managed by Haematology
Haematology Ward Level 1 Churchill Hospital Old Road Headington Oxford OX3 7LE	Blood storage & issue only Fridge managed by Haematology
Theatres Nuffield Orthopaedic Centre Windmill Road Headington Oxford OX3 7HE	Blood storage & issue only Fridge managed by Haematology
The Foscote Hospital 2 Foscote Rise Banbury OX16 9XP	Blood storage & issue only Fridge monitored by Haematology
Treatment Centre Oxford Road, Banbury OX16 7FG	Blood storage & issue only Fridge monitored by Haematology

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Blood Transfusion examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Plasma	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens	Automated using Immunocor Neo analyser (JRH) HJ 2562 NEO HJ 2559 NEO HJ 2560 NEO Automated using Immunocor Echo analyser (HH) Haem SOP 677 Haem SOP 678 Haem SOP 679	JRH HH
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb Lutheran –Lua P–P1 Anti-Chido/Rogers	Automated using Immunocor Neo analyser HJ 2562 NEO HJ 2559 NEO HJ 2560 NEO	JRH
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Automated using Immunocor Echo analyser Haem SOP 677 Haem SOP 678 Haem SOP 679	HH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Plasma	Blood Group by detection and identification of antigens: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb P–P1 Anti-Chido/Rogers	Manual tube spin agglutination using Diamed Column gel technology HJ 2513 (JRH) Haem SOP 462 (HH)	JRH HH
Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Manual Diamed Column gel IAT technology HJ 2551	JRH HH
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using Diamed Column gel IAT technology HJ 2531 (JRH) HH 2639 (HH)	JRH HH
Blood	Direct Antiglobulin Test (DAT)	Diamed Column gel IAT technology HJ 2590	JRH HH
Blood Plasma	ABO titrations	Immunocor Neo analyser and microtitre plate analysis Haem SOP 439 NEO	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Plasma	Antibody investigation by detection, identification and quantification of: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Diamed Column gel IAT technology HJ 2603 HJ 2597 HJ 2609 HJ 2604 HJ 2737 HJ 2605 HJ 2594 HJ 2576 HJ 2516 for including elution's, auto and cross absorptions	JRH HH
Blood	Foetal Maternal Haemorrhage	Clin Tech Shepard kits Kleihauer Acid Elution Technique HJ 2569	JRH
	Haematological examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Erythrocyte Sedimentation Rate (ESR)	Automated Starrsed analysers, modified Westergren method	
		Haem SOP 905 ESR Auto Compact	JRH HH
		Haem SOP 854 ESR Flex	JRH
		Modified Westergren method (manual) H 543	JRH HH
Plasma	Plasma Viscosity	Benson Viscometers, capillary sheer stress measurements Haem SOP 110	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	Sysmex XN automated analysers, differential laser light scatter Haem SOP 879	JRH CHLM HH
Plasma Serum	Glandular Fever Screen	Biokit Monogen commercial kit, latex micro particle immunoassay H 559	JRH HH
Blood	G6PD	Commercial (Pointe Scientific) kit, functional enzyme colourimetric assay G6PD SOP: H 541	HH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematological examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Malarial antigens of: *Plasmodium falciparum* and pan-detection for: *Plasmodium malariae, Plasmodium ovale & Plasmodium vivax*	CareStart commercial kit H 3010	JRH HH
	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Sysmex CS5100 automated analysers, optical end-point detection and in-house procedures:	
Plasma	Routine Coagulation testing for: Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) Thrombin Time (TT)	 Haem SOP 808 Haem SOP 809 Haem SOP 855 Haem SOP 830 H 1016	JRH HH CHLM OHTC
Plasma	Anti-IIa (Dabigatran)	Haem SOP 1045	OHTC
Plasma	Reptilase	Haem SOP 943	OHTC
Plasma	Echis Time	Haem SOP 847	OHTC
Plasma	High Molecular Weight Kininogen (HMWK)	Haem SOP 953	OHTC

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
		Sysmex CS5100 automated analysers, optical end-point detection and in-house procedures:	
Plasma	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	 Haem SOP 817 Haem SOP 818 Haem SOP 819 Haem SOP 834 Haem SOP 835 Haem SOP 820 Haem SOP 836 Haem SOP 837	OHTC
Plasma	Factor Acquired Inhibitor Screen FVIII FIX	HC 1222 HC 1225	OHTC
Plasma	Factor Inhibitor (Bethesda) analysis	Modified Nijmegen HC 1224	OHTC
Plasma	Acquired Thrombophilia (Lupus) Screen (DRVVT screen / confirm, Actin FSL)	Haem SOP 1046	OHTC
		Sysmex CS5100 automated analysers, chromogenic assay and in-house procedures:	
Plasma	Factor assay analysis FVIII FXIII	 Haem SOP 590 Haem SOP 839	OHTC
Plasma	Inherited Thrombophilia Screen: Protein C AT	 Haem SOP 1012 Haem SOP 1019	OHTC

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
		Sysmex CS5100 automated analysers, chromogenic assay and in-house procedures:	
Plasma	Fibrinolysis Screen: Plasminogen Alpha-2 Anti plasmin	 Haem SOP 949 Haem SOP 838	OHTC
Plasma	Anti-Xa	Haem SOP 919	JRH
		Sysmex CS5100 automated analysers, latex optical end-point detection and in-house procedures:	
Plasma	D-Dimer	Haem SOP 864	JRH CHLM OHTC HH
Plasma	vWD analysis (Antigen)	HC 1286	OHTC
Plasma	vWD analysis (Activity)	HC SOP 591	OHTC
Plasma	Inherited Thrombophilia Screen: Free Protein S	 Haem SOP 1022	OHTC
Plasma	Ristocetin Co-Factor (RiCOF)	Sysmex CS5100 automated analysers, platelet aggregation HC 1285	OHTC
Plasma	vWD Type 2N analysis	Asserachrom vwf:FVIIIB manual ELISA HC 1231	OHTC
Plasma	Collagen Binding Assay (CBA)	Reads Corgenix manual ELISA HC 1279	OHTC

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma	Collagen Binding Assay (CBA)	AcuStar coagulation analyser**;** Haem SOP 2084 IL AcuStar-Collagen Binding Activity Haem SOP 2082 IL AcuStar-Overview and maintenance	OHTC
Blood	Heparin Induced Thrombocytopenia Screen (HIT)	AcuStar coagulation analyser**;** Haem SOP 2085 IL AcuStar -HIT IgG (PF4) Haem SOP 2082 IL AcuStar-Overview and maintenance	OHTC
	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone marrow	Blood / bone marrow film analysis	May Grunwald-Giemsa staining Manual H 542, HJ 3020 or automated using Sysmex SP-10 (JRH) Haem SOP 895 or Siemens Hematek (HH) H 504 HJ 3021 Routine Staining of Blood Films and Bone Marrows-Shandon staining machine Varistain 24-4 (JRH) Manual light microscopy HJ 3004 (blood) HJ 3006 (blood) HJ 3012 (bone marrow) HJ 3013 (bone marrow) HC2309 (bone marrow)	JRH HH JRH HH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone marrow	Blood / bone marrow film analysis	Automated blood film analysis using Sysmex DM analyser, light microscopy Haem 33913 HJ3400 HJ3401 Haem SOP 900	JRH
Blood Bone Marrow Urine	Iron deposits	Light microscopy following Perl's Prussian Blue iron staining using commercial (TCS Biosciences) Kit HJ 3103	JRH
Blood	Detection & speciation (thin films) of malaria parasites: *Plasmodium falciparum* *Plasmodium malariae* *Plasmodium ovale* *Plasmodium vivax*	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy HJ 3009 H555	JRH HH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone Marrow	Acute Leukaemia antigen detection and quantification. Panel to include: CD-45 CD-7 CD-33 CD-10 CD-19 CD-34 CD-15 CD-117 HLA-DR CD-13 CD-14 CD-64 CD-41 CD-38 CD-11c Glycophorin-A CD-56 NG2 CD-9 CD-20 IgM CD-25 CD-1a CD-4 CD-8 CD-2 CD-57	BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1901 Haem SOP 1902 Haem SOP1920 Haem SOP 330 HJ 3340	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone Marrow	Chronic Leukaemia antigen detection and quantification. Panel to include: sCD-3 CD-16 + 56 Cyt MPO Cyt CD-79a Cyt TdT Cyt Lysozyme Cyt CD-3 Cyt IgM CD-25 IgG1 PE IgG1 FITC CD-19 CD-20 CD-22 CD-23 FMC-7 CD-79b CD-79a sKappa sLambda CD-5 CD-4 CD-8 CD-45 CD-38 CD-200 sIgM CD-10 CD-103 CD-25 CD-11c CD-2 CD-3 CD-7	BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1901 Haem SOP 1902 Haem SOP 1920 Haem SOP 330 HJ 3340	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd) CD-57 CD-16 + 56 TCR-a/b TCR-g/d CD-56 CD-138 Cyt Kappa Cyt Lambda	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Paroxsymal nocturnal haemoglobinuria (PNH) clone antigen detection and quantification. Panel to include: CD-24 Flaer CD-14 CD-45 CD-15 CD-33 CD-59 Glyophorin A	BC Navios analyser, flow cytometry Haem SOP 1899 Haem SOP 1898 – Red cell assay Haem SOP 1900 – White cell assay Haem SOP 1901 Haem SOP 1902 Haem SOP 1920	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Haemoglobinopathy 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:	
Blood	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E	BioRad Variant II analyser, HPLC HC 2029 HC 2006 HC 2039 HC 2030	JRH
Blood Dried Blood Spots	Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb F Hb S Hb C Hb D Punjab Hb E	Perkin Elmer DBS Puncher and BioRad Variant NBS, HPLC HC 2026 HC 2027 HC 2028 BIO-J-LP-ScrePunOp	JRH
Blood	2nd Line Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E	Perkin Elmer (Resolve FR9120), iso-electric focussing method HC 2005	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haemoglobinopathy examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Sickle cell solubility	Microgen Bioproducts commercial kit, modified Itano solubility technique H 1509	JRH HH
HUMAN TISSUES AND FLUIDS	Molecular genetic analysis for genetic mutations and variants	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood Bone Marrow CVS Amniotic Fluid FFPE tissue		Manual and automated DNA extraction and quantification using the QIAGEN Symphony and in-house procedures: Haem SOP 940 HC 2254 HC 2531 HC 2271 HC 2316	JRH
Blood Bone Marrow		Manual and semi-automated RNA extraction and cDNA preparation using the QIAGEN Qiacube and in house procedures HC 2302	JRH
Blood CVS Amniotic Fluid	Clotting deficiency: F8 gene Intron1 and 22 inversion mutations	In house method for Inversion PCR using Biometra thermocyclers HC 2252 HC 2251 HC 2100	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS Cont'd	Molecular genetic analysis for genetic mutations and variants Cont'd	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood CVS Amniotic Fluid	Clotting deficiencies: F5, F7, F8, F9, F10, F11, F13A genes Coagulation disorder: VWF gene Abnormal Fibrinogen: FGA, FGB, FGG genes Abnormal Antithrombin: SERPINC1 gene	In house method for Sanger sequencing using the ABI 3730 Genetic Analyser, Hotspot and full sequencing HC 2100	JRH
Blood	FVL / PG20210A mutation detection	In house, multiplex PCR using Biometra thermocyclers, Qiagen Multiplex Kit and restriction digest HC 2380	JRH
Blood CVS Amniotic Fluid	Platelet disorders: GP1BA, GB1BB, GP9, MYH9, ITGA2B, ITG3B genes	In house method for Sanger sequencing using the ABI 3730 Genetic Analyser, Hotspot and full sequencing HC 2100	JRH
Blood CVS Amniotic fluid	F7, F8, F9, F10, F11, SERPINC1 and VWF genes, deletions and duplications	Commercial MRC Holland kit for MLPA using ABI 3130 Genetic analyser system Haem SOP 612	JRH
Blood CVS Amniotic Fluid	Alpha thalassemia: Identification of all known point mutations and deletions within the alpha globin gene cluster. Mutations listed on the Globin Gene Server: http://globin.cse.psu.edu/	In house method, Gap-PCR using Biometra thermocyclers, Sanger sequencing using the ABI 3130 DNA analysis system, and commercial MRC Holland MLPA kit used for large deletions. Pyrosequencing using Qiagen Pyromark Q24. HC 2041 HC 2047 HC 2050 HC 2052 HC 2054 HC 2057	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood CVS Amniotic Fluid	Beta thalassemia: Identification of all known point mutations and deletions within the beta globin gene cluster. Mutations listed on the Globin Gene Server:- http://globin.cse.psu.edu/	In house method, Gap-PCR ARMS-PCR, RE-PCR using Biometra thermocyclers, Pyrosequencing using Qiagen Pyromark Q24. Sanger sequencing using ABI 3130 DNA analysis system and commercial MRC Holland MLPA kit for large deletions. HC 2101 HC 2124 HC 2106 HC 2115 HC 2122 HC 2075 HC 2130 HC 2142 HC 2138 HC 2143 HC 2148	JRH
Blood CVS Amniotic Fluid	Delta-Beta thalassemia / HPFH: Identification of all known deletions within the beta globin gene cluster. Mutations listed on the Globin Gene Server:- http://globin.cse.psu.edu/	In house method, Gap-PCR using Biometra thermocyclers, Sanger sequencing using the ABI 3130 DNA analysis system and commercial MRC Holland MLPA kit for large deletions. HC 2107 HC 2108 HC 2110 HC 2111 HC 2112 HC 2128 HC 2054	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood CVS Amniotic Fluid	Haemoglobin S investigations	In house method, Gap-PCR, ARMS-PCR, RE-PCR using Biometra thermocyclers, Sanger sequencing using the ABI 3130 DNA analysis system, Pyrosequencing using the QIAGEN pyromark Q24. HC 2062 HC 2074 HC 2067	JRH
Blood CVS Amniotic Fluid	Haemoglobin Variants: Identification of all structural variants within the beta globin gene and alpha globin gene clusters. Mutations listed on the Globin Gene Server: http://globin.cse.psu.edu/	In house method, Gap-PCR, ARMS-PCR, RE-PCR using Biometra Thermocyclers, Pyrosequencing using Qiagen Pyromark Q24, Sanger sequencing using ABI 3130 DNA analysis system HC 2075 HC 2106 HC 2074 HC 2061 HC 2063 HC 2066 HC 2064 HC 2068	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood DNA	Iron metabolism disorder diagnostic gene panel. Mutations in: TFR2; (NM_003227.3), SCL40A1, (NM_014585.5), HFE; (NM_139006.2), HFE2; (NM_213653.3), HAMP; (NM_021175.2), FTH1; (NM_002032.2), Atransferrinaemia: TF; (NM_001063.3), Hyperferritinaemia: SCL40A1, (NM_014585.5), FTL; (NM_000146.3), Hereditary Hyperferritinaemia Cataract Syndrome (HHCS): FTL; (NM_000146.3) , Iron-refractory iron deficiency anaemia (IRIDA): SLC11A2; (NM_001174125.1), TMPRSS6; (NM_153609.2, Iron deficiency: HEPH; (NM_138737.3), iron and neurodegeneration:- , CP (Aceruloplasminaemia), (NM_000096.3), FTL (Hereditary ferritinopathy), X-linked Sideroblastic anaemia:- ALAS2 ; (NM_000032.4)., Genes involved in the BMP/SMAD pathway:- BMP4; (NM_001202.3), BMP6; (NM_001718.4) SMAD4; (NM_005359.5).	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510	JRH

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>Molecular genetic analysis for genetic mutations and variants</u> (cont'd	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood / DNA	Coagulation / Thrombosis disorder diagnostic 40 gene panel. Mutations in PLAT PLAUR PLG TFP1 PLAU SERPINC1 PROC PROS1 THBD PROCR PROZ LMAN1 MCFD2 F2 F5 F7 F8 F9 F10 F11 F13a F13b KNG1 KLKB1 FGA FGB FGG VKORC1 GGCX VWF SMAD4 ENG ACVRL1 ADAMTS13 COL1A1 COL3A1 TNXB GP1BA	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 DNA SOP 2017 441	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood / DNA	Coagulation / Thrombosis disorder diagnostic 57 gene panel. Mutations in P2RY12 VIPAS39 VPS33B ANKRD26 GP1BA & GP1BB, GP9 & GP6 MPL PLA2G4A NBEA RUNX1 TBXAS1 ITGA2B & ITGB3 NBEAL2 GFI1B AP3B1 & AP3D1 BLOC1S3 BLOC1S6 DTNBP1 HPS1 & HPS3 & HPS4 FERMT3 ACTN1 FLNA TUBB1 MYH9 RASGRP2 PLAU HOXA11 ANO6 ABCA1 ABCG5 & ABCG8 STIM1 THPO RBM8A TBXA2R WAS GATA1 GNAS & GNAQ MASTL MLPH	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 DNA SOP 2017 441	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood / DNA (cont'd)	LYST A2M P2RX1 GP5 ITGA2 ADRA2A VWF F11	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 DNA SOP 2017 441	JRH
Blood DNA	Somatic myeloid disorder diagnostic gene panel. Mutations in: ASXL1 (NM_015338.5), ATRX (NM_000489.3), CBL (NM_005188), CBLB (NM_170662.3), CBLC (NM_012116.3), CSF3R (NM_156039.3), DNMT3A (NM_022552), ETV6 (NM_001987.4), EZH2 (NM_004456.4), HRAS (NM_005343.2), IDH1 (NM_005896.2), IDH2 (NM_002168.2), FLT3 (NM_004119), JAK2 (NM_004972.3), KIT (NM_000222.2), KRAS (NM_033360.2), MPL (NM_005373), NPM1 (NM_002520.6), NRAS (NM_002524.4), PDGFRA (NM_006206.4), PHF6 (NM_032458.2), PTEN (NM_000314), RUNX1 (NM_001754.4), SETBP1	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 Haem SOP 1186	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood DNA (cont'd)	Somatic myeloid disorder diagnostic gene panel. Mutations in: (cont'd) (NM_015338.5), SF3B1 (NM_012433.2), SRSF2 (NM_001195427.1), TET2 (NM_001127208.2), TP53 (NM_000546.5), U2AF1 (NM_001025203.1), WT1 (NM_024426.4) and ZRSR2 (NM_005089.3)	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 Haem SOP 1186	JRH
Blood / DNA	Rare anaemia diagnostic gene panel. Mutations in: ABCB7 (NM_004299.3), ALAS2 (NM_000032.4), ALDOA (NM_000034.3), ANK1 (NM_000037.3), C15orf41 (NM_001130010.1), CDAN1 (NM_138477.2), ENO1 (NM_001428.3), EPB41 (NM_004437.3), EPB42 (NM_000119.2), G6PD (NM_001042351.2), GATA1 (NM_002049.3), GATA2 (NM_032638.4), GCLC (NM_001498.3), GPI (NM_000175.3), GPX1 (NM_000581.2), GSR (NM_000637.3), GSS (NM_000178.2), HK1 (NM_000188.2), KIF23 (NM_138555.2), KLF1 (NM_006563.3), LPIN2 (NM_014646.2), NT5C3A (NM_016489.12),	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 HC 2154 HC 2054 HC 2149 HC 2152 HC 2151	JRH

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>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood / DNA (cont'd)	Rare anaemia diagnostic gene panel. Mutations in: PFKM (NM_000289.5), PGK1 (NM_000291.3), PIEZO1 (NM_001142864.2), PKLR (NM_000298.5), RHAG (NM_000324.2), RPL11 (NM_000975.3), RPL26 (NM_000987), RPL27 (NM_000988.3), RPL35A (NM_000996.2), RPL5 (NM_000969.3), RPL9 (NM_000661.4), RPS10 (NM_001014.4), RPS17 (NM_001021.3), RPS19 (NM_001022.3), RPS24 (NM_033022.3), RPS26 (NM_001029.3), RPS27 (NM_001030.4), RPS29 (NM_001032.4), RPS7 (NM_001011.3), SBDS (NM_016038.2), SEC23B (NM_006363.4), SLC11A2(NM_000617.2), SLC25A38(NM_017875.2), SLC2A1 (NM_006516.2), SLC4A1 (NM_000342.3), SPTA1 (NM_003126.2), SPTB (NM_000347.5), TMPRSS6(NM_153609.2), TPI1(NM_000365.5).	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 HC 2154 HC 2054 HC 2149 HC 2152 HC 2151	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	HFE gene screen (C282Y / H63D)	In house method RE-PCR using Biometra thermocyclers HC 2263	JRH
Blood DNA	HFE, HFE2, HAMP, SLC40A1 and TFR2 genes / DNA	ABI 3130 Genetic Analyser and commercial MRC Holland MLPA kit used for large deletions HC 2297	JRH
Blood Bone Marrow	BCR-ABL analysis (ALL, CML) Diagnosis and monitoring of MRD (p210, p190 only)	Published Multiplex RT-PCR method using Qiagen, Rotorgene, Commercial QPCR (Qiagen) kit for MRD, Pyrosequencing using QIAGEN Pyromark Q24 HC 2301 HC 2302 HC 2303 HC 2306	JRH
	Acute Leukaemia Diagnosis:	RE-PCR using Biometra Thermocycler	
Blood Bone Marrow	FLT-3 D835	HC 2118	JRH
	NPM1	In house fragment analysis method using ABI 3130 Genetic Analyser HC 2119	JRH
	c-KIT D816V	Pyrosequencing using QIAGEN Pyromark Q24 HC 2123	JRH
Blood Bone Marrow	Acute Leukaemia MRD monitoring (PML-RARA, Inv16, AML-ETO)	Commercial QPCR (Qiagen) kit for MRD using QIAGEN Rotorgene, HC 2304	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Acute Leukaemia Diagnosis (cont'd):		
Blood Bone Marrow Tissue	Lymphoma B Clonality (IgH rearrangements)	Commercial (Invivoscribe) fragment analysis using ABI 3130 Genetic Analyser Haem SOP 1163	JRH
	Lymphoma T Clonality (TCR re-arrangements)	HC 2268 HC 2267 Haem SOP 1163	JRH
Blood Bone Marrow	TP53 gene mutation analysis exons 2- 10 for treatment stratification in CLL	MiSeq Next Generation Sequencing and custom designed commercial panel (Illumina TSCA v1.5 assays) HC 2507 HC 2509 HC 2510 HC 2312	JRH
Bone Marrow			
Blood Bone Marrow	Jak-2 mutation screen (V617F)	In house ARMS-PCR using Biometra thermocycler, Pyrosequencing using the QIAGEN Rotorgene HC 2261	JRH
Blood Bone Marrow	Chimerism analysis	Promega Powerplex Fusion commercial kit, Q-PCR using ABI Real Time 7500 HC 2381	JRH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic analysis for genetic mutations and variants (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
FFPE DNA	EGFR common mutation screen	COBAS 4800 system, RT-PCR and commercial (COBAS) kits Haem SOP 578	JRH
FFPE DNA	BRAF mutation screen (V600E)	COBAS 4800 system, RT-PCR and commercial (COBAS) kits Haem SOP 579	JRH
FFPE DNA	Somatic Cancer 50 gene diagnostic panel. Mutations in: TP53 NM_000546.5, PTEN NM_000314.4, PIK3CA NM_006218.2, PDGFRA NM_006206.4, KRAS NM_004985.3, NRAS NM_002524.4, KIT NM_000222.2, EGFR NM_005228.3, BRAF NM_004333.4. ERBB4, FGFR1, ERBB2, MET, FLT3, FGFR3, GNAS, SMARCB1, CTNNB1, CDKN2A, ABL1, NOTCH1, ATM, PTPN11, SMO, SMAD4, VHL, NPM1, MPL, CSF1R, HRAS, JAK3, AKT1, IDH1, CDH1, FGFR2, SRC, KDR, ALK, JAK2, RB1, MLH1, HNF1A, APC, RET, STK11, FBXW7, EZH2, GNA11, GNAQ and IDH2	Thermofisher Ampliqseq Next Generation Sequencing commercial panel and Ion Torrent next generation sequencing. Haem SOP 624 Haem SOP 491 Haem SOP 625	JRH
END			