


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8464</p> <p>Accredited to ISO 15189:2012</p>	<h3>Oxford University Hospitals NHS Foundation Trust</h3> <p>Issue No: 006 Issue date: 01 October 2021</p>	
	<p>Department of Laboratory Haematology</p> <p>Level 4 John Radcliffe University Hospital</p> <p>Headley Way</p> <p>Headington</p> <p>Oxford</p> <p>OX3 9DU</p>	<p>Contact: Andrew Platt</p> <p>Tel: +44 (0)1865 (8)57663</p> <p>E-Mail: andrew.platt@ouh.nhs.uk</p> <p>Website: www.ouh.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>Level 4 John Radcliffe University Hospital</p> <p>Headley Way</p> <p>Headington</p> <p>Oxford</p> <p>OX3 9DU</p> <p>Local contact: Andrew Platt (details as above)</p>	<ul style="list-style-type: none"> Routine haematology Routine Coagulation Blood Grouping and antibody screen Blood & blood product issue Immunophenotyping by flow analysis Haemoglobinopathy analysis Molecular haematology 	JRH
<p>Horton Hospital</p> <p>Oxford Road</p> <p>Banbury</p> <p>OX16 9AL</p> <p>Haematology: Mrs E Siggs (01923 229369)</p> <p>Blood Transfusion: Miss J Staves (01865 220334)</p>	<ul style="list-style-type: none"> Routine haematology Routine Coagulation Blood Grouping and antibody screen Blood & blood product issue 	HH
<p>Churchill Hospital Laboratory Medicine</p> <p>Old Road</p> <p>Headington</p> <p>Oxford</p> <p>OX3 7LE</p> <p>Mr P Baker (01865 857096)</p>	<ul style="list-style-type: none"> Routine FBC analysis Routine Coagulation Blood & blood product issue 	CHLM
<p>Churchill Hospital Oxford Haemophilia and Thrombosis Centre</p> <p>Old Road</p> <p>Headington</p> <p>Oxford</p> <p>OX3 7LE</p> <p>Mr P Baker (01865 857096)</p>	<ul style="list-style-type: none"> 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



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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:	
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 Iris analyser (JRH) SOP HJ 2559 SOP HJ 2560 SOP HJ 2561 SOP HJ 2562 SOP HJ 2563 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 Iris analyser SOP HJ 2559 SOP HJ 2560 SOP HJ 2561 SOP HJ 2562 SOP HJ 2563	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



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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:	
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 Iris analyser and microtitre plate analysis Haem SOP 439	JRH



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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:	
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
Blood	<u>Haematological examinations for the purpose of clinical diagnosis</u> Erythrocyte Sedimentation Rate (ESR)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Automated Starrsed analysers, modified Westergren method	
		Haem SOP 905 ESR Flex and Auto Compact	JRH HH
		Modified Westergren method (manual) H 543	JRH HH
Plasma	Plasma Viscosity	Benson Viscometers, capillary sheer stress measurements Haem SOP 110	JRH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological 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:	
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



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological 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:	
Blood	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	CareStart commercial kit H 3010	JRH HH
	<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 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



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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: 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
Plasma	Factor assay analysis FVIII FXIII	Sysmex CS5100 automated analysers, chromogenic assay and in-house procedures: Haem SOP 590 Haem SOP 839	OHTC
Plasma	Inherited Thrombophilia Screen: Protein C AT Free Protein S	Haem SOP2604 Haem SOP 1019 Haem SOP 1022	OHTC



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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:	
Plasma	Fibrinolysis Screen: Plasminogen Alpha-2 Anti plasmin	<p>Systemex CS5100 automated analysers, chromogenic assay and in-house procedures:</p> <p>Haem SOP 949 Haem SOP 838</p>	OHTC
Plasma	Anti-Xa	<p>Haem SOP 919</p> <p>Systemex CS5100 automated analysers, latex optical end-point detection and in-house procedures:</p>	JRH
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	Ristocetin Co-Factor (RiCOF)	Systemex CS5100 automated analysers, platelet aggregation HC 1285	OHTC
Plasma	vWD Type 2N analysis	Asserachrom vwf:FVIII B manual ELISA HC 1231	OHTC



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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:	
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
Blood	Platelet aggregation	Light transmission aggregometry AggRam and procedures HC 1335, HC 1264 & HC 1334	OHTC



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Blood Bone marrow	<u>Morphology and immunophenotyping examinations for the purpose of clinical diagnosis</u> Blood / bone marrow film analysis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: May Grunwald-Giemsa staining Manual H 542, HJ 3020 or automated using Sysmex SP-10 (JRH/HH) Haem SOP 895 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
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



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HUMAN BODY FLUIDS (cont'd)	<u>Morphology and immunophenotyping 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:	
Blood	Detection & speciation (thin films) of malaria parasites: <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i>	Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy HJ 3009 H555	JRH HH
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	BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1901 Haem SOP 1902 Haem SOP 1920 Haem SOP 330 HJ 3340	JRH



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p>	<p><u>Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Chronic Leukaemia antigen detection and quantification. Panel to include:</p> <p>CD-8 CD-2 CD-57 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</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1901 Haem SOP 1902 Haem SOP 1920 Haem SOP 330 HJ 3340</p>	<p>JRH</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>CD-103 CD-25 CD-11c CD-2 CD-3 CD-7 CD-57 CD-16 + 56 TCR-a/b TCR-g/d CD-56 CD-138 Cyt Kappa Cyt Lambda</p>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	<p>Paroxysmal nocturnal haemoglobinuria (PNH) clone antigen detection and quantification. Panel to include:</p> <p>CD-24 Flaer CD-14 CD-45 CD-15 CD-33 CD-59 Glyophorin A</p>	<p>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</p>	JRH
Blood, Bone Marrow	<p>Minimal residual disease (MRD) detection in AML</p>	<p>BC Navios analyser, flow cytometry Haem SOP 2567 Haem SOP 2568</p>	JRH



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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: Documented in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening, Programme as defined in the July 2018 Newborn (Blood Spot) and antenatal; Sickle Cell and Thalassaemia Screening: laboratory QA evidence requirements'	
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



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HUMAN BODY FLUIDS (cont'd)	<u>Haemoglobinopathy 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: Documented in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening, Programme as defined in the July 2018 Newborn (Blood Spot) and antenatal; Sickle Cell and Thalassaemia Screening: laboratory QA evidence requirements'	
Blood Dried Blood Spots	2 nd 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 (Migele TM tank)), iso-electric focussing method HC 2005	JRH
Blood	Sickle cell solubility	Microgen Bioproducts commercial kit, modified Itano solubility technique H 1509	JRH HH



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HUMAN TISSUES AND FLUIDS	<u>Molecular genetic analysis for genetic mutations and variants</u>	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		Automated DNA extraction and quantification using the QIAGEN Symphony and in-house procedures: Haem SOP 940 HC 2531 HC 2271 HC 2315	JRH
Blood Bone Marrow		Semi-automated RNA extraction and cDNA preparation using the QIAGEN Qiacube and in house procedures HC 2302	JRH
Blood Bone Marrow FFPE		Automated Paramagnetic particle nucleic acid extraction and purification using the Promega Maxwell system; Haem SOP 2599: DNA using AS1321 kit Haem SOP 2608: RNA using AS410 kit Haem SOP 2611: FFPE using RSC FFPE DNA plus kit	JRH
Sanger sequencing traces received from Oxford Regional Genetics (UKAS 8694)	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/	Analysis and reporting of data only using Mutation Surveyor software HC 2153 Haem SOP 2457	JRH



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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:	
Sanger sequencing traces received from Oxford Regional Genetics (UKAS 8694)	Beta thalassaemia: 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/	Analysis and reporting of data only using Mutation surveyor software HC 2153 Haem SOP 2457	JRH
Sanger sequencing traces received from Oxford Regional Genetics (UKAS 8694)	Delta-Beta thalassaemia / HPFH: Identification of all known deletions within the beta globin gene cluster. Mutations listed on the Globin Gene Server:- http://globin.cse.psu.edu/	Analysis and reporting of data only using Mutation surveyor software HC 2153 Haem SOP 2457	JRH
Sanger sequencing traces received from Oxford Regional Genetics (UKAS 8694)	Haemoglobin S investigations	Analysis and reporting of data only using Mutation surveyor software HC 2153 Haem SOP 2457	JRH
Sanger sequencing traces received from Oxford Regional Genetics (UKAS 8694)	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/	Analysis and reporting of data only using Mutation surveyor software HC 2153 Haem SOP 2457	JRH



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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	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 (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)	NextSeq 550 Next Generation Sequencing and custom designed commercial panel (SeqCap EZ HyperCap (Roche)) Haem SOP 2623 Haem SOP 2621 Haem SOP 2618 Haem SOP 2619	



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Issue No: 006 Issue date: 01 October 2021

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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>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:	JRH
Next Generation Sequencing Data in the form of BAM files, variant lists, and gene-level coverage data received from Oxford Regional Genetics (UKAS 8694)	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), 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),	Analysis and reporting of data only using Alamut Visual and IGV software HC 2154 HC 2152 Haem SOP 2457	



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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:	
Next Generation Sequencing Data in the form of BAM files, variant lists, and gene-level coverage data received from Oxford Regional Genetics (UKAS 8694)	<u>Rare anaemia diagnostic gene panel (cont)</u> . Mutations in: <u>RPS19 (NM_001022.3)</u> , <u>RPS24 (NM_033022.3)</u> , <u>RPS26 (NM_001029.3)</u> , <u>RPS27 (NM_001030.4)</u> , <u>RPS29 (NM_001032.4)</u> , <u>RPS7 (NM_001011.3)</u> , <u>SBDS (NM_016038.2)</u> , <u>SEC23B (NM_006363.4)</u> , <u>SLC11A2 (NM_000617.2)</u> , <u>SLC25A38 (NM_017875.2)</u> , <u>SLC2A1 (NM_006516.2)</u> , <u>SLC4A1 (NM_000342.3)</u> , <u>SPTA1 (NM_003126.2)</u> , <u>SPTB (NM_000347.5)</u> , <u>TMPRSS6 (NM_153609.2)</u> , <u>TPI1 (NM_000365.5)</u> .	Analysis and reporting of data only using Alamut Visual and IGV software HC 2154 HC 2152 Haem SOP 2457	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 2304 HC 2306	JRH



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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 Bone Marrow	Acute Leukaemia Diagnosis: FLT-3 D835 NPM1	RE-PCR using Biometra Thermocycler HC 2118 In house fragment analysis method using ABI 3130 Genetic Analyser HC 2119	JRH 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
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	Jak-2 mutation screen (V617F)	In house ARMS-PCR using Biometra thermocycler, Pyrosequencing using the QIAGEN Rotorgene HC 2261	JRH
Blood Bone Marrow	Chimerism STR pattern analysis (Chimerism) to detect mixed samples (e.g. Maternal contamination / Chimerism)	Promega Powerplex Fusion commercial kit, ABI identifier Kit. Q-PCR using ABI Real Time 7500 HC 2381 HC 2141	JRH
Blood Bone Marrow FFPE	Detecting L265P point mutation of the MYD88 gene	Allelic specific real-time PCR assay using hydrolysis probes ABI Real Time 7500 Haem SOP 2468.	JRH



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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:	
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 HC 2411 HC 2408	JRH
END			