


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8543</p> <p>Accredited to ISO 15189:2012</p>	<p>The Newcastle upon Tyne Hospitals NHS Foundation Trust</p> <p>Issue No: 014 Issue date: 21 January 2022</p>	
	<p>Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN</p>	<p>Contact: Dr Helen Bourne, Consultant Immunologist Tel: +44 (0) 191 2336161 E-Mail: helen.bourne2@nhs.net Website: www.newcastle-hospitals.org.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 Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN</p> <p>Local contact Dr H Bourne (as above)</p>	<ul style="list-style-type: none"> • Routine haematology • Routine Coagulation • Blood Grouping and antibody screen • Blood & blood product issue • Haematinics • Haemostasis.Thrombophilia • Routine Biochemistry • Special Chemistry 	FH
<p>Address Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP</p> <p>Local contact Dr H Bourne (as above)</p>	<ul style="list-style-type: none"> • Routine haematology • Routine Coagulation • Blood Grouping and antibody screen • Blood & blood product issue • Haemostasis and Haemophilia • Haemoglobinopathies • Flow Cytometry • Autoimmunity screening service • Routine Biochemistry • Endocrine chemistry • Protein screening service • Paediatric Metabolic Biochemistry • Maternal screening services • Neonatal screening services • Foetal anomaly screening • Newborn blood spot screening • Sickle cell and thalassaemia screening 	RVI



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Site activities performed away from the locations listed above:

Location details	Activity
Cardiology Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Blood storage & issue only Fridge managed by Blood Transfusion
Central Ops Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Blood storage & issue only Fridge managed by Blood Transfusion
Institute of Transplantation Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Blood storage & issue only Fridge managed by Blood Transfusion
Ward 36 Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Blood storage & issue only Fridge managed by Blood Transfusion
Adult and Paediatric Theatres Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Blood storage & issue only Fridge managed by Blood Transfusion
Leazes Theatres Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Blood storage & issue only Fridge managed by Blood Transfusion
Delivery Suite Fridge Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Blood storage & issue only Fridge monitored by Blood Transfusion



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Location details	Activity
A&E Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Blood storage & issue only Fridge monitored by Blood Transfusion



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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>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for	
Serum/Lithium Heparin Plasma unless otherwise stated	Quantitative determination of:	Roche Cobas 8000 c702 Module : Immunoturbidometric	RVI
	Alpha 1- Antitrypsin	BS-SOP-OP-Biochem-17	
	Beta 2 Microglobulin	BS-SOP-OP-Biochem-15	
	ApoA1	BS-SOP-OP-Biochem-112	
	ApoB100	BS-SOP-OP-Biochem-113	
	C3	BS-SOP-OP-Biochem-66	
	C4	BS-SOP-OP-Biochem-66	
	Caeruloplasmin	BS-SOP-OP-Biochem-8	
	CRP (High sensitivity)	BS-SOP-OP-Biochem-3	
	CRP	BS-SOP-OP Biochem-29	FH/RVI
	Haptoglobin	BS-SOP-OP-Biochem-133	
Serum only	IgA	BS-SOP-OP-Biochem-67	
Serum only	IgG		
Serum only	IgM		
	Lp(a)	BS-SOP-OP-Biochem-39	RVI
	Rheumatoid Factor	BS-SOP-OP-Biochem-63	RVI
	Transferrin	BS-SOP-OP-Biochem-73	FH
CSF	Protein	BS-SOP-OP-Biochem-62	RVI
Urine	albumin	BS-SOP-OP-Biochem-97	FH/RVI
Urine	Protein	BS-SOP-OP-Biochem-62	FH/RVI
		Roche Cobas 8000 c702 Module : Photometry	
Serum Only	ACE	BS-SOP-OP-Biochem-21	RVI
	Albumin	BS-SOP-OP-Biochem-98	FH/RVI
	Alkaline Phosphatase	BS-SOP-OP-Biochem-18	FH/RVI
	ALT	BS-SOP-OP-Biochem-22	FH/RVI
	Ammonia	BS-SOP-OP-Biochem-102	FH/RVI
	Amylase	BS-SOP-OP-Biochem-16	FH/RVI
	AST	BS-SOP-OP-Biochem-23	FH/RVI
	Bicarbonate	BS-SOP-OP-Biochem-13	FH/RVI
	Bile Acids	BS-SOP-OP-Biochem-12	RVI
	Bilirubin total	BS-SOP-OP-Biochem-10	FH/RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Lithium Heparin Plasma unless otherwise stated	Quantitative determination of: (cont'd)	Roche Cobas 8000 c702 Module : Photometry (cont'd)	
	Calcium	BS-SOP-OP-Biochem-7	FH/RVI
	Cholesterol	BS-SOP-OP-Biochem-5	FH/RVI
	CK	BS-SOP-OP-Biochem-28	FH/RVI
	Creatinine	BS-SOP-OP-Biochem-2	FH/RVI
	Ethanol	BS-SOP-OP-Biochem-19	FH/RVI
	GGT	BS-SOP-OP-Biochem-34	FH/RVI
FI-Oxalate only	Glucose	BS-SOP-OP-Biochem-45	FH/RVI
	HDL- Cholesterol	BS-SOP-OP-Biochem-46	FH/RVI
	Iron	BS-SOP-OP-Biochem-48	FH/RVI
FI-oxalate only	Lactate	BS-SOP-OP-Biochem-49	FH/RVI
	LDH	BS-SOP-OP-Biochem-37	FH/RVI
	Lipase	BS-SOP-OP-Biochem-108	FH
	Magnesium	BS-SOP-OP-Biochem-52	FH/RVI
	Paracetamol	BS-SOP-OP-Biochem-56	RVI
	Phosphate	BS-SOP-OP-Biochem-59	FH/RVI
	Salicylate	BS-SOP-OP-Biochem-64	RVI
	Total Protein	BS-SOP-OP-Biochem-96	FH/RVI
	Triglyceride	BS-SOP-OP-Biochem-74	FH/RVI
	Urea	BS-SOP-OP-Biochem-76	FH/RVI
	Urate	BS-SOP-OP-Biochem-77	FH/RVI
FI-oxalate CSF	Glucose	BS-SOP-OP-Biochem-45	RVI
FI-oxalate CSF	Lactate	BS-SOP-OP-Biochem-49	RVI
Urine	Calcium	BS-SOP-OP-Biochem-7	FH/RVI
Urine	Creatinine	BS-SOP-OP-Biochem-2	FH/RVI
Urine	Magnesium	BS-SOP-OP-Biochem-52	FH/RVI
Urine	Phosphate	BS-SOP-OP-Biochem-59	FH/RVI
Urine	Uric Acid	BS-SOP-OP-Biochem-77	FH/RVI
Urine	Urea	BS-SOP-OP-Biochem-76	FH/RVI
		Roche Cobas 8000 c702 Module : Using EMIT measurements:	
	Methotrexate	BS-SOP-OP-Biochem-53	RVI
		Roche Cobas 8000 c702 Module : Photometry	
Serum only	Lithium	BS-SOP-OP-Biochem 50	RVI



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HUMAN BODY FLUIDS (cont'd) Serum/Lithium Heparin Plasma unless otherwise stated	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd) Quantitative determination of: (cont'd)	Documented in house methods and manufacturers instructions for Roche Cobas 8000 c702 Module : Using WAKO Vanadate oxidation kit	
	Conjugated bilirubin	BS-SOP-OP-Biochem 11 Roche Cobas 8000 c702 Module : Using KIMS Immunoassay:	FH/RVI RVI
	Carbamazepine Phenobarbitone Phenytoin Theophylline	BS-SOP-OP-Biochem-6 BS-SOP-OP-Biochem-57 BS-SOP-OP-Biochem-58 BS-SOP-OP-Biochem-70 Roche Cobas 8000 c702 Module : Using Indirect ISE:	RVI RVI
Urine Urine Urine	Chloride Potassium Sodium Chloride Potassium Sodium	BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36	FH/RVI RVI RVI/FH RVI/FH
	Valproate	Roche Cobas 8000 c702 Module : Using EIA: BS-SOP-OP-Biochem-79	RVI
	Macroprolactin screen (inc. % recovery and bioactive monomeric prolactin)	Roche Cobas 8000 e602 Module : Using ECLIA and Calculation: BS-SOP-OP-Biochem-51	RVI
Faeces	Faecal Calprotectin	Roche Cobas 8000 c702 Module : Using Buhlmann immunoturbidimetric assay: BS-SOP-OP-Biochem 102	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum or Lithium Heparin Plasma unless otherwise stated	Quantitative determination of: (cont'd)	Roche Cobas 8000 e602 Module : Using ECLIA:	
EDTA plasma only	Calcitonin Cortisol B-Ctx DHEAS Digoxin Ferritin Folate FSH fT3 fT4 hCG	BS-SOP-OP-Endo-4 BS-SOP-OP-Biochem-4 BS-SOP-OP-Biochem-14 BS-SOP-OP-Biochem-30 BS-SOP-OP-Biochem-43 BS-SOP-OP-Biochem-44 BS-SOP-OP-Biochem-135 BS-SOP-OP-Biochem-31	RVI RVI RVI RVI RVI RVI FH/RVI RVI
Serum only	IgE LH NT-Pro BNP Oestradiol Progesterone Prolactin	BS-SOP-OP-Biochem-121 BS-SOP-OP-Biochem-38 BS-SOP-OP-Biochem-54 BS-SOP-OP-Biochem-55 BS-SOP-OP-Biochem-60	RVI RVI RVI RVI RVI
EDTA plasma only	PTH SHBG Testosterone Thyroglobulin antibody Thyroid peroxidase antibody Troponin-T TSH Vitamin B12	BS-SOP-OP-Biochem-47 BS-SOP-OP-Biochem-41 BS-SOP-OP-Biochem-69 BS-SOP-OP-Biochem-71 BS-SOP-OP-Biochem-72 BS-SOP-OP-Biochem-75 BS-SOP-OP-Biochem-42 BS-SOP-OP-Biochem-136	FH/RVI RVI RVI RVI RVI FH/RVI FH/RVI FH/RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum or Li-Hep plasma unless otherwise stated	Quantitative determination of:	Roche Cobas 8000 e801 Module : Using ECLIA:	
	AFP	BS-SOP-OP-Biochem-20	FH
	CA125	BS-SOP-OP-Biochem-24	FH
	CA15-3	BS-SOP-OP-Biochem-25	FH
	CA19-9	BS-SOP-OP-Biochem-26	FH
	CEA	BS-SOP-OP-Biochem-27	FH
	Ferritin	BS-SOP-OP-Biochem-158	FH
	ft3	BS-SOP-OP-Biochem-160	FH
	ft4	BS-SOP-OP-Biochem-156	FH
	hCG	BS-SOP-OP-Biochem-35	FH
	PSA	BS-SOP-OP-Biochem-40	FH
	Troponin T	BS-SOP-OP-Biochem-159	FH
	TSH	BS-SOP-OP-Biochem-155	FH
	Vitamin D	BS-SOP-OP-Biochem-165	FH
Calculated equations	Calculated determination of:		
	Adjusted Calcium	BS-SOP-OP-Biochem-7	FH/RVI
	eGFR	CKD-EPI equation	FH/RVI
	LDL Cholesterol	BS-SOP-OP-Biochem-2 Friedwald equation	FH/RVI
	Non-HDL Cholesterol	BS-SOP-OP-Biochem-5	FH/RVI
	Transferrin saturation	BS-SOP-OP-Biochem-48	FH/RVI
	Free testosterone	Wu formula BS-SOP-OP-Biochem-69	RVI
	ALP isoenzymes	Electrophoresis: BS-SOP-OP-Prot-1	RVI
		In house assay using ultracentrifugation (Beckman) and Roche cholesterol/triglyceride assays (Cobas 8000) also lipoprotein fractionation using Sebia Hydrasys electrophoresis:	
EDTA plasma	Beta Quantification (lipoprotein fractionation)	BS-SOP-OP-Endo-26	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/plasma unless otherwise stated	Quantitative determination of: (cont'd)	UVIKON-XS Spectrophotometer : Using Spectrophotometry:	
CSF Urine	Xanthochromia PBG	BS-SOP-OP-Biochem-117 BS-SOP-OP-Biochem-129	RVI RVI
EDTA or Fluoride Oxalate	HbA1c	Tosoh G8 HPLC: BS-SOP-OP-Biochem-109	FH/RVI
Serum/Urine/Faeces/plasma	Osmolality	Advanced Micro-Osmometer: BS-SOP-OP-Biochem-105	FH/RVI
Urine	hCG	Alere Urine OBC Kit BS-SOP-OP-Biochem-127	FH/RVI
Urine	Urine Free Cortisol	Thermofisher Trace ISQ GC-MS: BS-SOP-OP-Endo-22	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/Lithium Heparin Plasma unless otherwise stated	Quantitative determination of: (cont'd)	Beckman Access II using Chemiluminescent immunoassay:	
	Thyroglobulin	BS-SOP-OP-Endo-20	RVI
		Brahms Kryptor using fluorescent immunoassay:	
Serum Only	TRAb	BS-SOP-OP-Endo-25	RVI
Serum only	Chromogranin A	BS-SOP-OP-Endo-27	
Serum only	Copeptin	BS-SOP-OP-Endo-29	
		IDS iSYS using chemiluminescent immunoassay:	
EDTA Plasma	GH	BS-SOP-OP-Endo-10	RVI
EDTA plasma	IGF-1	BS-SOP-OP-Endo-13	
	Aldosterone	BS-SOP-OP-Endo-02	
	Renin	BS-SOP-OP-Endo-17	
		Beckman ELISA:	
Lithium Heparin Plasma/serum/EDTA	Insulin	BS-SOP-OP-Endo-12	RVI
Lithium Heparin Plasma/serum/EDTA	C-Peptide	BS-SOP-OP-Endo-07	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Lithium Heparin plasma/CSF/Urine EDTA plasma/ accepted	Quantitative determination of: (cont'd) Amino Acids to include: 2-Aminobutyric acid Alanine Arginine Asparagine Aspartic Acid Citrulline Cystine Glutamic Acid Glutamine Glycine Histidine Histidine 1-methyl Histidine 3-methyl Homocystine Isoleucine Leucine Lysine Methionine Ornithine Proline Serine Taurine Threonine Tryptophan Valine	Biochrom Amino Acid Analyser using HPLC: BS-SOP-OP-MNS-8	RVI
Urine/EDTA Plasma/Dry Blood Spot	Acylcarnitine Analysis	Tandem mass Spectrometry BS-SOP-OP-Paeds-31 BS-SOP-OP-Paeds-29 BS-SOP-OP-Paeds-28 BS-SOP-OP-Paeds 21	RVI



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in house methods and manufacturers instructions for	
EDTA plasma/Serum/Urine	Free Carnitine	BS-SOP-OP-Paeds-07	RVI
Lithium Heparin Plasma accepted	Total Carnitine	BS-SOP-OP-Paeds-21	RVI
Lithium heparin Plasma	Phenylalanine Tyrosine	BS-SOP-OP-Paeds-13	RVI
	Quantitative determination of intermediary metabolites:	BMG Flurostar Omega multi plate reader by enzymatically linked fluorometry:	
Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA EDTA plasma/serum plasma	3 OH Butyric acid Alanine Glycerol Pyruvic acid Glucose NEFA Biotinidase	BS-SOP-OP-MNS-13 BS-SOP-OP-Paeds-16 BS-SOP-OP-Paeds-32	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
EDTA-Plasma EDTA plasma EDTA plasma EDTA plasma EDTA plasma EDTA plasma EDTA plasma	Quantitative determination of sterols and acids: Campesterol Cholesterol Cholestanol 7-Dehydrocholesterol Lathosterol Desmosterol Sitosterol	GC Mass Spectrometry: BS-SOP-OP-Paeds-19	RVI
Urine Urine Urine Urine	Methylmalonic acid Hexanoylglycine Organic acids Orotic acid Very long chain acids:	BS-SOP-OP-MNS-1 BS-SOP-OPMNS-12 BS-SOP-OP-Paeds-23 BS-SOP-OP-MNS-2	RVI
EDTA plasma EDTA plasma EDTA plasma EDTA plasma EDTA plasma	C22:0 Behenic Acid C24:0 Lignoceric Acid C26:0 Cerotic Acid Phytanic Acid Pristanic Acid	BS-SOP-OP-Paeds-26	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Sweat	Quantitative determination of: Chloride	Sherwood Scientific MK II Chloride Analyser 962 S: Collection and analysis BS-SOP-OP-Paeds-33 BS-SOP-OP-Paeds-34	RVI
	Antenatal & Newborn Screening	Documented in-house methods to meet the requirements of the Newborn blood spot screening programme as defined in the July 2018 "Newborn blood spot screening laboratory QA evidence requirements"	RVI
Bloodspot	TSH IRT 17OHP	Documented in-house methods to meet the requirements of the Fetal anomaly screening programme as defined in the July 2018 "Fetal anomaly screening laboratory QA evidence requirements" Perkin Elmer AutoDELFLIA using Fluoro immunoassay:	RVI
Serum	Inhibin A	BS-SOP-OP-NNS-7 BS-SOP-OP-NNS-6 BS-SOP-OP-MNS-3 BS-SOP-OP-NNS-1 BS-SOP-OP-MSS-16	RVI
Urine	Normetadrenaline Metadrenaline 3-Methoxytyramine	HPLC Electrochemical Detection: BS-SOP-OP-SpecChem-22	FH



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
	Quantitative determination of: (cont'd)	Perkin Elmer ICP Mass Spectrometry:	
Serum	Zinc	BS-SOP-OP-SpecChem-42	FH
Serum/Urine	Copper	BS-SOP-OP-SpecChem-8	
Serum	Selenium	BS-SOP-OP-SpecChem-46	
Serum/water	Aluminium	BS-SOP-OP-SpecChem-43	
EDTA Whole blood	Chromium	BS-SOP-OP-SpecChem-44	
EDTA Whole Blood	Cobalt	BS-SOP-OP-SpecChem-44	
EDTA Whole Blood	Manganese	BS-SOP-OP-SpecChem-49	
EDTA Whole blood	Lead	BS-SOP-OP-SpecChem-49	
		Tandem Mass Spectrometry:	
EDTA Whole Blood	Ciclosporin	BS-SOP-OP-SpecChem-7	FH
	Sirolimus	BS-SOP-OP-SpecChem-19	
	Tacrolimus	BS-SOP-OP-SpecChem-20	
EDTA Plasma	Plasma Free Metanephrine Plasma free non metanephrine 3 Methoxytyramine	BS-SOP-OP-SpecChem-16	FH



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
	<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:	
EDTA Packed red cells	Blood Group by detection and identification of antigens: A D Positive AB D Positive B D Positive O D Positive A D Negative AB D Negative B D Negative O D Negative	Column Technology: Ortho Visionx1 and Ortho Vision Max x1 automation or Manual BioVue system: BS-SOP-OP-BT-2201 BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2214 BS-SOP-OP-BT-2213	FH/RVI
EDTA plasma	3 cell Antibody Screen	BS-SOP-OP-BT-2201 BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2214 BS-SOP-OP-BT-2213	FH/RVI
EDTA Plasma	Antibody Investigation by detection of antibodies to: Rh which includes anti-C, D, E, c, e, f, C ^w K, k, Kp ^a Fy ^a , Fy ^a , Jk ^a , Jk ^b Le ^a , Le ^b S, s, M, N P ₁ Lu ^a	Column Technology: Ortho Vision x1 and ortho vision Max x1 automation or Manual BioVue system: BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2203 BS-SOP-OP-BT-2216 BS-SOP-OP-BT-2218	FH/RVI
EDTA Packed red cells	Confirmation of Phenotype by detection of antigens	BS-SOP-OP-BT-2219	FH/RVI
EDTA Plasma	Compatibility testing of patients plasma with donor cells	BS-SOP-OP-BT-2202 BS-SOP-OP-BT-2711	FH/RVI
EDTA packed red cell	Direct Antiglobulin Test (DAT)	BS-SOP-OP-BT-2217	FH/RVI



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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:	
EDTA Whole blood	Blood Group: A D Positive AB D Positive B D Positive O D Positive A D Negative AB D Negative B D Negative O D Negative	MD multiscard (Manual) using lateral flow principles: BS-SOP-OP-BT-2221	RVI
EDTA Whole blood	Foetal Cells	Manual Slide/Staining using 1% Eosin BS-SOP-OP-BT-2212 Quantitative titre of Anti-A and anti-B by testing against red blood cells using manual tube agglutination and ortho Biovue cassettes	RVI
EDTA Plasma	Isohaemagglutinins	BS-SOP-OP-BT-2209	FH/RVI



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EDTA Whole Blood	<p><u>Haematological examinations for the purpose of clinical diagnosis</u></p> <p>Full Blood Count (FBC) analysis of the following parameters:</p> <p>WBC RBC ESR HGB HCT MCH MCHC PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count RET-He</p>	<p>Sysmex XN9000 automated analysers, XT, XS and pOCHI Blood counters. Hb measurement by laural sulphate conversion and colorimetry</p> <p>BS-SOP-OP-Haem-6020 BS-SOP-OP-Haem-4001 BS-SOP-OP-Haem-4002 BS-SOP-OP-Haem-6016</p> <p>Sysmex XN9000, XT and XS Blood Cell Counters. Hb Measurement by laural sulphate conversion and colorimetry. Light Microscopy</p>	FH/RVI
CSF Ascitic Fluid PD fluid	Body Fluid Analysis/ Cell Counting	BS-SOP-OP-Haem-4013 BS-SOP-OP-Haem-4035 BS-SOP-OP-Haem-4021	FH/RVI
EDTA Plasma	Infectious Mononucleosis Screen	Clearview IM II commercial kit, latex micro particle immunoassay BS-SOP-OP-Haem-4015	FH/RVI



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Blood	<p><u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Malarial antigens of:</p> <p><i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i>, <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i></p>	<p>CareStart commercial kit Chromatographic immunoassay</p> <p>BS-SOP-OP-Haem-4028</p> <p>Light Microscopy:</p>	FH/RVI
Blood Bone marrow	Blood / bone marrow film analysis	<p>BS-SOP-OP-Haem-5033 BS-SOP-OP-Haem-4008 BS-SOP-OP-Haem-4009 BS-SOP-OP-Haem-4006 BS-SOP-OP-Haem-4520</p>	FH/RVI



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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:	FH RVI
Citrate Plasma	Routine Coagulation testing for: Prothrombin Time (PT) INR Activated Partial Thromboplastin Time (APTT) Actin FS APTT PT derived Fibrinogen Fibrinogen (Clauss) Thrombin Time (TT) Lupus Anticoagulant Screen D Dimer Factor II Factor V Factor VII Factor X Factor VIII Factor IX Factor XI Factor VIII Refacto AF Chromogenic Factor VIII Anti-IIa	IL ACL 700/Light transmission/Chromogenic/clotting end-point. Turbidometric BS-SOP-OP-HStasis-6042 BS-SOP-OP-HStasis-6043 BS-SOP-OP-HStasis-3000 BS-SOP-OP-HStasis-6044 BS-SOP-OP-HStasis-6045 BS-SOP-OP-HStasis-6046 BS-SOP-OP-HStasis-3001 BS-SOP-OP-HStasis-6047 BS-SOP-OP-HStasis-3021 BS-SOP-OP-HStasis-3020 BS-SOP-OP-HStasis-3004 BS-SOP-OP-HStasis-6049 BS-SOP-OP-HStasis-3002 BS-SOP-OP-HStasis-3003	
Citrate Plasma	Factor VIII Inhibitor screen Inhibitor Titre	Spectrophotometer/Chromogenic BS-SOP-OP-HStasis-3009 IL ACL 700/Light transmission/clotting end-point. 1 stage factor assay BS-SOP-OP-HStasis-3010 BS-SOP-OP-HStasis-3011	



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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:	
Citrate Plasma	Rivaroxaban	IL ACL 700/Light transmission/Chromogenic/clotting end-point.	FH/RVI
	Dabigatran	BS-SOP-OP-HStasis-6051	
	Anti-Xa Low Molecular Weight Heparin	BS-SOP-OP-HStasis-6040	
	Protein C	BS-SOP-OP-HStasis-3023	
	Protein S	BS-SOP-OP-HStasis-6048	FH
	Anti-thrombin 3		
	Activated Protein C resistance	BS-SOP-OP-HStasis-6034	
	Homocysteine		
Citrated Plasma		Werfen ACL Acustar/Chemiluminescence	RVI
	Von Willebrand Antigen	BS-SOP-OP-HStasis-3005	
	Ristocetin Co-Factor	BS-SOP-OP-HStasis-6057	
	HIT Screening Assay	BS-SOP-OP-HStasis-6055	



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HUMAN BODY FLUIDS (cont'd)	<u>Morphology and immunophenotyping 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	ADAMTS 13 assay	ELISA BS-SOP-OP-HStasis-6039	FH
EDTA Plasma	Erythropoietin (EPO)	BS-SOP-OP-HStasis-6004	
Serum	Heparin Induced Thrombocytopenia (HIT)	BS-SOP-OP-HStasis-6002 Light Microscopy, Modified Wrights stain	
Blood	Blood Film Morphology	BS-SOP-OP-Haem-6020 BS-SOP-OP-Haem-4008 BS-SOP-OP-Haem-4009 BS-SOP-OP-Haem-4006 BS-SOP-OP-Haem-4021 BS-SOP-OP-Haem-4520	FH/
Blood	Detection & speciation (thin films) of malaria parasites: All plasmodium species known to cause human disease	Preparation of thick and thin films, staining and light microscopy BS-SOP-OP-Haem-4028 BS-SOP-OP-Haem-4519	FH/RVI



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HUMAN BODY FLUIDS (cont'd) EDTA Whole Blood	<p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Lymphocyte subsets: T Cells B Cells NK Cells CD4 T Cells CD8 T Cells CD4:CD8 ratio Activated T Cells</p> <p>Additional Markers: Naïve T Cells B Cell phenotype T Cell receptor Double negative alpha/beta T regulatory cells Dendritic cell screen CD46 Adhesion molecules TCR VB repertoire</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>BD Canto II Flowcytometer, antibodies conjugated to fluorescent molecules:</p> <p>BS-SOP-OP-FLOW-24 BS-SOP-OP-FLOW-20</p> <p>BS-SOP-OP-FLOW-02</p>	RVI



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>EDTA Blood Bone Marrow CSF Various body fluids</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Acute Leukaemia antigen detection and quantification. Panel to include:</p> <p>CD5 CD10 CD19 CD34 CD45 CD7 CD33 CD2 PerCP Cy5.5 CD13 APC CD45 APC-Cy7 CD14 CD64 CD45 PerCP Cy5.5 CD235a APC CD15 CD117 HLA DR PerCP Cy5.5 CD41a APC CD15FITC CD117 PE CD45 APC-H7 CD19 PerCP Cy5.5 CD34 APC cCD3 nTDT cMPO cCD79a</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>BD FACS Canto II analyser, flow cytometry, antibodies conjugated to fluorescent molecules:</p> <p>BS-SOP-OP-FLOW-06</p>	<p>RVI</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
EDTA Blood Bone Marrow CSF & Various body fluids	Lymphoproliferative panel to include: FMC7 CD23 CD19 CD5 APC CD103 CD22 CD20 CD10 APC CD45 APC H7 CD79b FITC CD38 PE CD19 Per CP cy5.5 CD11a APC CD2 FITC Lambda PE Kappa APC Plasma Cells: CD138 FITC CD56 PE	BD FacsCanto II analyser, flow cytometry BS-SOP-OP-FLOW-06	RVI
Preservative free Heparinised Whole Blood EDTA Whole Blood	Intracellular proteins: FOXP3 Btk SAP Perforin CGD Proteins	BS-SOP-OP-FLOW-28 BS-SOP-OP-FLOW-27 BS-SOP-OP-FLOW-32 BS-SOP-OP-FLOW-16 BS-SOP-OP-FLOW-23 BS-SOP-OP-FLOW-15	RVI



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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</u></p> <p>Chronic Leukaemia antigen detection and quantification. Panel to include (cont'd):</p> <p>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 CD-57 CD-16 + 56 TCR-a/b TCR-g/d CD-56 CD-138 Cyt Kappa Cyt Lambda</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>BD FacsCanto II analyser, flow cytometry SOPs as above</p>	<p>RVI</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
Preservative free heparinised Whole Blood	CD40 Ligand Expression	Flow cytometry using antibodies conjugated to fluorescent molecules: BS-SOP-OP-FLOW-34	RVI
EDTA Whole Blood	Screen for Toll like receptors	BS-SOP-OP-FLOW-18	
	NK Cell degranulation	BS-SOP-OP-FLOW-25	
	PNH screen	BS-SOP-OP-FLOW-08	
	EMA test for hereditary spherocytosis	BS-SOP-OP-FLOW-07	
	Quantification of FMH	BS-SOP-OP-FLOW-03	
	CD61 platelet enumeration	BS-SOP-OP-FLOW-11	
Citrated Whole Blood	Platelet Ag typing (platelet glycoproteins)	BS-SOP-OP-FLOW-12	
		Neutrophils stimulated with PMA and colour changes to NBT assessed on cyto-spin by microscopy. Fluorescent changes are assessed by Flow Cytometry for DHR:	
EDTA Whole Blood	Neutrophil Oxidative burst	BS-SOP-OP-FLOW-04 BS-SOP-OP-FLOW-05	RVI
		Miltenyi automacs- magnetic bead separation:	
	T,B,CD15 cell separation	BS-SOP-OP-FLOW-33	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
Preservative Free heparinised whole blood	T Cell proliferation	Perkin Elmer Beta counter. Tritiated thymidine incorporation into dividing cells: BS-SOP-OP-FLOW-22	RVI
EDTA Whole Blood EDTA Bone marrow EDTA Apherisis Product	CD34 Stem cell enumeration	Flow cytometry (see above for measurement principle) BS-SOP-OP-FLOW-10	RVI
EDTA Whole Blood	CD3	BS-SOP-OP-FLOW-14	
	<u>Maternal screening services for the purpose of clinical diagnosis</u>	Documented in-house methods to meet the requirements of the Fetal anomaly screening programme as defined in the July 2018 "Fetal anomaly screening laboratory QA evidence requirements"	
Serum only Serum only Serum only Serum only Serum only	fbhCG PAPPA AFP hCG uE3	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Fluoro Immunoassay: BS-SOP-OP-MSS-10 BS-SOP-OP-MSS-11 BS-SOP-OP-MSS-8 BS-SOP-OP-MSS-7 BS-SOP-OP-MSS-9	RVI



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HUMAN BODY FLUIDS (cont'd) Serum only unless otherwise stated	<u>Immunological examinations for the purpose of clinical diagnosis</u> ANA Pattern Gastric Parietal Cell antibody Anti Nuclear antibody Anti mitochondrial Ab Anti smooth muscle Ab Anti Ribosomal Ab	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Hamilton Dilutor, Slide Trays and immunofluorescence microscope BS-SOP-OP-AIMM-1 BS-SOP-OP-AIMM-5 BS-SOP-OP-AIMM-20 Bioplex 2200 analyser. Multiplexing bead based flow cytometric principles:	RVI
	Anti-DNA Ab Anti-Chromatin Ab Anti-ribosomal P Ab Anti-Ro 52 Ab Anti-Ro 60 Ab Anti-La Ab Anti-Sm Ab Anti-RNP 68 Ab Anti-Scl-70 Ab Anti-Jo-1 Ab Anti-Centromere Ab Anti-MPO Ab Anti PR3 Ab Anti GBM Ab Anti-CCP Ab IgA Anti-TTG Ab	BS-SOP-OP-AIMM-71 BS-SOP-OP-AIMM-70 BS-SOP-OP-AIMM-72 BS-SOP-OP-AIMM-73	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
Serum	Perinuclear ANCA Cytoplasmic ANCA	Hamilton Dilutor, Slide trays and immunofluorescence microscope: BS-SOP-OP-AIMM-3 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11	RVI
Serum	IgA Endomysial Antibody IgG Endomysial Antibody	BS-SOP-OP-AIMM-7 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11 Hamilton dilutor, rocking platform immunoblot	
Serum	ENA Scl-70 Antibody Mitochondrial M2 Anti Liver-Kidney Mic. Ab Liver Cytosol Ab Soluble Liver Antigen Ab	BS-SOP-OP-AIMM-8 BS-SOP-OP-AIMM-14	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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: Hamilton Dilutor, Slide Trays, Moisture Chamber and immunofluorescence microscope:	
Serum	Pemphigoid Ab Pemphigus Ab Adrenal Ab Ovarian Ab Testes Ab Islet Cell Ab Cardiac Ab Skeletal/Striated muscle Ab Purkinje Cell Ab Anti Neuronal Nuc. Ab	BS-SOP-OP-AIMM-18 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11	RVI
Serum	Serum Tryptase level	Phadia ImmunoCAP 250: BS-SOP-OP-AIMM-67	RVI



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HUMAN BODY FLUIDS (cont'd) Serum	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Specific IgE Antibodies to include:</p> <p>Pen G Pen V Succinyl choline (Suxameth) House dust mite D.Farinae Cat Horse Dog Guinea pig Rabbit Hamster Rat Feathers (farm fowl) Feathers (Domestic fowl) Milk Casein Lactoalbumin Lactoglobulin Cheddar Blue Cheese Egg Egg white Egg yolk Ovalbumin Ovomucoid Cod Tuna Salmon Haddock Mackerel Crab Shrimp Scallop Mussel (Blue Mussel) Lobster Squid rCor a 9 Recombinant Hazelnut rCor a 14 Recombinant Hazelnut</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77</p>	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	RVI
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd) Wheat Omega-5-Gliadin Gluten Rye Barley Oat Corn Rice Peanut Recomb.Peanut ARA H 1 Recomb.Peanut ARA H 2 Recomb.Peanut ARA H 3 Recomb.Peanut ARA H 8 Recomb.Peanut ARA H 9 Hazelnut Brazil nut Almond Coconut Pecan Cashew Pistachio Walnut Chestnut Macadamia Nut Recomb. Hazelnut rCOR A 8 Recomb. Hazelnut rCOR A 1 Sesame seed Sunflower seed Poppy seed Lupin seed Pumpkin seed Linseed Pea rAna o 3 Recomb. Cashew rJug r 1 Recomb. Walnut rBer e 1 Recomb. Brazil nut rJug r3 Recomb. Walnut Chlorhexidine Trout Tilapia	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd) Soya White bean Lentil Chick Pea Kidney bean Tomato Carrot Lettuce Cucumber Potato (white) Paprika/Sweet pepper Garlic Onion Mushroom rPru p 3 Recomb. Peach Orange Lemon Apple Pear Melon Mango Strawberry Kiwi Banana Pineapple Blueberry Peach Apricot Plum Cherry Grape Avocado Pork Beef Chicken Lamb (mutton) Black pepper rApi m 1 phospholipase A2 Honey Bee rVes v 5 Recomb. Wasp	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological 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:	
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd)		
	Cacao (cocoa) Celery Chilli pepper Coffee Ginger Malt Mustard Yeast (bakers) Spice mix 1 Spice mix 2 Spice mix 3 rVes v1 phospholipase A1 Wasp Timothy Grass Grass Mix 1 Bee Wasp Mosquito spp. Latex Recomb. Latex rHEV B 5 Cladosporium Aspergillus Alternaria alternata Moulds mix Common silver Birch Recomb. Birch BET V 1 Recomb. Birch BET V 2 Palm (oil) pollen Tree mix 10 Rape pollen	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI
	Weed mix 3	Sebia CapillaryS using capillary electrophoresis in free solution followed by immunotyping	
Serum	Paraproteins	Sebia Hydrasys using hydra gel protein kits BS-SOP-OP-Prot-8	RVI



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

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 014 Issue date: 21 January 2022

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 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 Sickle Cell and Thalassaemia screening programme as defined in the July 2018 "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 Hb E Hb O Barts Leopore	TOSOH G8, HPLC: BS-SOP-OP-Prot-33 BS-SOP-OP-Prot-39 BS-SOP-OP-Prot-30 BS-SOP-OP-Prot-38	RVI



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Dried Blood Spots	Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb F Hb S Hb C Hb D Hb E Hb O Barts	Documented in-house methods to meet the requirements of the Newborn blood spot screening programme as defined in the July 2018 "Newborn blood spot screening laboratory QA evidence requirements" Sebia CapillaryS Neonate, HPLC BS-SOP-OP-Prot-19 BS-SOP-OP-Prot-40	RVI
EDTA Whole Blood	Sickle Cell solubility	Microgen Bioproducts commercial kit, modified Itano solubility technique: BS-SOP-OP-Prot-07	RVI
Serum	Quantitative determination of: Complement: Comp I Comp H AP100	Binding site RID Plates immunoassay: BS-SOP-OP-Prot-22 BS-SOP-OP-Prot-21	RVI



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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:	
Serum	C3 Nephritic Factor	Sebia Hydrasys using immunofixation: BS-SOP-OP-Prot-29	RVI
CSF	Oligoclonal banding	Sebia Hydrasys & kit using immunofixation and enzymes: BS-SOP-OP-Prot-12	RVI
END			