


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>8543</p> <p>Accredited to ISO 15189:2022</p>	The Newcastle upon Tyne Hospitals NHS Foundation Trust	
	Issue No: 020 Issue date: 03 February 2026	
	Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road High Heaton Newcastle upon Tyne NE7 7DN	Contact: Dr Andrew McGregor, Consultant Haematologist Tel: +44 (0) 191 2826234 E-Mail: akmcgregor@nhs.net Website: www.newcastle-hospitals.org.uk
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
<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 A McGregor (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 A McGregor (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 • Metabolic and Newborn screening • 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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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	
	Alpha 1- Antitrypsin	BS-SOP-OP-Biochem-131	RVI
	Beta 2 Microglobulin	BS-SOP-OP-Biochem-132	RVI
	ApoA1		RVI
	ApoB100		RVI
	C3		RVI
	C4		RVI
	Caeruloplasmin		RVI
	CRP (High sensitivity)		RVI
	CRP		FH/RVI
	Haptoglobin		RVI
Serum only	IgA		RVI
Serum only	IgG		
Serum only	IgM		
	Lp(a)		RVI
	Rheumatoid Factor		RVI
	Transferrin		FH
CSF	Protein		RVI
CSF	CSF IgG		RVI
Urine	albumin		FH/RVI
Urine	Protein		FH/RVI
		Roche Cobas 8000 c702 Module : Photometry	
Serum Only	ACE	BS-SOP-OP-Biochem-131	RVI
	Albumin	BS-SOP-OP-Biochem-132	FH/RVI
	Alkaline Phosphatase		FH/RVI
	ALT		FH/RVI
EDTA plasma	Ammonia		FH/RVI
Serum	Amylase		FH/RVI
	AST		FH/RVI
	Bicarbonate		FH/RVI
	Bile Acids		RVI
	Bilirubin total		FH/RVI
	Calcium		FH/RVI
	Cholesterol		FH/RVI
	CK		FH/RVI
	Creatinine		FH/RVI
	Ethanol		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 (cont'd)	Quantitative determination of: (cont'd)	Roche Cobas 8000 c702 Module : Photometry (cont'd)	
FI-Oxalate only	GGT Glucose HDL- Cholesterol Iron	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	FH/RVI FH/RVI FH/RVI FH/RVI
FI-oxalate only	Lactate LDH Lipase Magnesium Paracetamol Phosphate Salicylate Total Protein Triglyceride Urea Urate		FH/RVI FH/RVI FH FH/RVI RVI FH/RVI RVI FH/RVI FH/RVI FH/RVI FH/RVI FH/RVI
FI-oxalate CSF	Glucose		RVI
FI-oxalate CSF	Lactate		RVI
Urine	Calcium		FH/RVI
Urine	Creatinine		FH/RVI
Urine	Magnesium		RVI
Urine	Phosphate		FH/RVI
Urine	Uric Acid		FH/RVI
Urine	Urea		FH/RVI
	Methotrexate	Roche Cobas 8000 c702 Module : Using EMIT measurements: BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	RVI
		Roche Cobas 8000 c702 Module : Photometry	
Serum only	Lithium	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	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 (cont'd)	Quantitative determination of: (cont'd)	Roche Cobas 8000 c702 Module : Using WAKO Vanadate oxidation kit	
	Conjugated bilirubin	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	FH/RVI
	Carbamazepine Phenobarbitone Phenytoin Theophylline	Roche Cobas 8000 c702 Module : Using KIMS Immunoassay: BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	RVI RVI RVI RVI
	Chloride Potassium Sodium Chloride Potassium Sodium	Roche Cobas 8000 c702 Module : Using Indirect ISE: 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 FH/RVI FH/RVI RVI RVI/FH RVI/FH
Urine Urine Urine	Valproate	Roche Cobas 8000 c702 Module : Using EIA: BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	RVI
	Macroprolactin screen (inc. % recovery and bioactive monomeric prolactin)	Roche Cobas 8000 e602 Module : Using ECLIA and Calculation: BS-SOP-OP-Biochem-51	RVI
		Roche Cobas 8000 c702 Module : Using Buhlmann immunoturbidimetric assay:	
Faeces	Faecal Calprotectin	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	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 (cont'd)	Quantitative determination of: (cont'd)	Roche Cobas 8000 e602 Module : Using ECLIA:	
	Calcitonin	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	RVI
EDTA plasma only	Cortisol		RVI
	B-Ctx		RVI
	Digoxin		RVI
	Ferritin		RVI
	Folate		FH/RVI
	FSH		RVI
	fT3		RVI
	fT4		RVI
	hCG		RVI
Serum only	IgE		RVI
	LH		RVI
	NT-Pro BNP		RVI
	Oestradiol		RVI
	Progesterone		RVI
	Prolactin		RVI
EDTA plasma only	PTH		FH/RVI
	SHBG		RVI
	Testosterone		RVI
	Thyroglobulin antibody		RVI
	Thyroid peroxidase antibody		RVI
	Troponin-T		RVI
	TSH		RVI
	Vitamin B12		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 (cont'd)	Quantitative determination of: (cont'd)	Roche Cobas 8000 e801 Module : Using ECLIA:	
	AFP	BS-SOP-OP-Biochem-131 BS-SOP-OP-Biochem-132	FH
	CA125		FH
	CA15-3		FH
	CA19-9		FH
	CEA		FH
	Ferritin		FH
	fT3		FH
	fT4		FH
	hCG		FH
	PSA		FH
	Troponin T		FH
	TSH		FH
	Vitamin D		FH
Calculated equations	Calculated determination of:		
	Adjusted Calcium	BS-SOP-OP-Biochem-7	FH/RVI
	eGFR	CKD-EPI equation BS-SOP-OP-Biochem-2	FH/RVI
	LDL Cholesterol	Friedwald equation BS-SOP-OP-Biochem-5	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-Biochem-141	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-14	RVI



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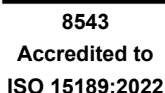
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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers instructions for	
Serum/plasma unless otherwise stated	Quantitative determination of:	UVIKON-XS Spectrophotometer : Using Spectrophotometry:	
CSF	Xanthochromia	BS-SOP-OP-Biochem-117	RVI
Urine	Porphobilinogen (PBG)	BS-SOP-OP-Biochem-129	RVI
		Tosoh G11 HPLC:	
EDTA or Fluoride Oxalate	HbA1c	BS-SOP-OP-Biochem-109	FH/RVI
		Advanced Micro-Osmometer:	
Serum/Urine/Faeces/plasma	Osmolality	BS-SOP-OP-Biochem-105	FH/RVI
		Alere Urine OBC Kit	
Urine	hCG	BS-SOP-OP-Biochem-127	FH/RVI
		Beckman Access II using Chemiluminescent immunoassay:	
Serum only	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	RVI
Serum only	Copeptin	BS-SOP-OP-Endo-29	RVI
		IDS iSYS using chemiluminescent immunoassay:	
	GH	BS-SOP-OP-Endo-10	RVI
	IGF-1	BS-SOP-OP-Endo-13	RVI
EDTA plasma	Aldosterone	BS-SOP-OP-Endo-02	RVI
EDTA plasma	Renin	BS-SOP-OP-Endo-17	RVI
		Mercodia ELISA:	
Lithium Heparin	Insulin	BS-SOP-OP-Endo-12	RVI
Plasma/serum/EDTA			
Lithium Heparin	C-Peptide	BS-SOP-OP-Endo-07	RVI
Plasma/serum/EDTA			



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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	
Blood/CSF in perchloric acid	Quantitative determination of intermediary metabolites:	BMG Flurostar Omega multi plate reader by enzymatically linked fluorometry:	
Blood/CSF in perchloric acid	3 OH Butyric acid	BS-SOP-OP-MNS-13	RVI
Blood/CSF in perchloric acid	Pyruvic acid, Lactate, Lactate/Pyruvate Ratio		
EDTA plasma/serum	Glucose		
EDTA plasma/serum	Non-esterified fatty acids	BS-SOP-OP-MNS-34	RVI
EDTA plasma, Li-Hep plasma, serum	Biotinidase	BS-SOP-OP-MNS-41	RVI
EDTA plasma, serum	Quantitative determination of sterols and acids:	GC Mass Spectrometry:	
EDTA plasma, serum	Campesterol	BS-SOP-OP-MNS-28	RVI
EDTA plasma, serum	Cholesterol		
EDTA plasma, serum	Cholestanol		
EDTA plasma, serum	7-Dehydrocholesterol		
EDTA plasma, serum	Lathosterol		
EDTA plasma, serum	Desmosterol		
EDTA plasma, serum	Sitosterol		
Urine	Methylmalonic acid	BS-SOP-OP-MNS-1	RVI
Urine	Organic acids	BS-SOP-OP-MNS-35	RVI
Urine	Orotic acid	BS-SOP-OP-MNS-2	RVI
	Very long chain fatty acids:	BS-SOP-OP-MNS-29	RVI
EDTA plasma, serum	C22:0 Behenic Acid		
EDTA plasma, serum	C24:0 Lignoceric Acid		
EDTA plasma, serum	C26:0 Cerotic Acid		
EDTA plasma, serum	Phytanic Acid		
EDTA plasma, serum	Pristanic Acid		



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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-MNS-37 BS-SOP-OP-MNS-38 Tandem Mass Spectrometry using Waters Xevo TQD UPLC Mass Spectrometer	RVI RVI RVI
Dry Blood Spot	Acylcarnitines	BS-SOP-OP-MNS-20	RVI
ETDA plasma	Total Carnitine	BS-SOP-OP-MNS-22	RVI
EDTA plasma, Serum, Urine, Lithium Heparin plasma accepted	Free Carnitine		RVI
EDTA plasma, Serum, Urine, Lithium Heparin plasma accepted	Phenylalanine	BS-SOP-OP-MNS-22	RVI
Dry Blood Spot	Tyrosine	BS-SOP-OP-MNS-33	RVI
Dry Blood Spot			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	
Dried Blood Spot	Detection of T-cell Receptor Excision Circles (TRECs) from DNA	Newborn Screening for Severe Combined ImmunoDeficiency (SCID) Immuno-IVD TREC screening kit, DBS PerkinElmer Puncher, Applied Biosystems ProFlex Thermal cycler and Quantstudio 5 Dx Real-time PCR analyser (Measurement principle – time resolved fluorescence resonance energy transfer detection). BS-SOP-OP-MNS-5	RVI
		Tandem Mass Spectrometry using Shimadzu LCMS-8050 Electrospray Triple Quadrupole Tandem Mass Spectrometer	RVI
Dry Blood Spot	Acylcarnitines	BS-SOP-OP-MNS-20	RVI
ETDA plasma	Total Carnitine	BS-SOP-OP-MNS-43	RVI
EDTA plasma, Serum, Urine, Lithium Heparin plasma accepted		BS-SOP-OP-MNS-20	RVI
EDTA plasma, Serum, Urine, Lithium Heparin plasma accepted	Free Carnitine	BS-SOP-OP-MNS-43	RVI
		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"	RVI
		Perkin Elmer AutoDELFIA using Fluoro immunoassay:	
Bloodspot	TSH	BS-SOP-OP-MNS-25	RVI
Bloodspot	IRT	BS-SOP-OP-MNS-3	RVI
Bloodspot	17OHP	BS-SOP-OP-MNS-31	RVI
		BS-SOP-OP-MNS-24	RVI
Serum	Inhibin A	BS-SOP-OP-MSS-16	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
	<u>Maternal screening services 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:	
Serum only	fbhCG	Fluoro Immunoassay:	RVI
Serum only	PAPPA	BS-SOP-OP-MSS-10	RVI
Serum only	AFP	BS-SOP-OP-MSS-11	RVI
Serum only	hCG	BS-SOP-OP-MSS-8	RVI
Serum only	uE3	BS-SOP-OP-MSS-7	RVI
		BS-SOP-OP-MSS-9	RVI
Serum	Quantitative determination of:	Perkin Elmer ICP Mass Spectrometry:	
Serum/Urine	Zinc	BS-SOP-OP-SpecChem-45	FH
Serum	Copper	BS-SOP-OP-SpecChem-48	FH
EDTA Whole blood	Selenium	BS-SOP-OP-SpecChem-46	FH
EDTA Whole Blood	Chromium	BS-SOP-OP-SpecChem-44	FH
EDTA Whole Blood	Cobalt	BS-SOP-OP-SpecChem-44	FH
EDTA Whole blood	Manganese	BS-SOP-OP-SpecChem-49	FH
	Lead	BS-SOP-OP-SpecChem-54	FH
		Tandem Mass Spectrometry:	
EDTA Whole Blood	Ciclosporin	BS-SOP-OP-SpecChem-60	FH
	Sirolimus	BS-SOP-OP-SpecChem-60	FH
	Tacrolimus	BS-SOP-OP-SpecChem-60	FH
EDTA Plasma	Plasma Free Metanephrine	BS-SOP-OP-SpecChem-58	FH
	Plasma free normetanephrine		
	3 Methoxytyramine		
		Waters Acquity Arc HPLC system using HPLC.	FH
Serum, EDTA or LiHEP Plasma	Vitamin A	BS-SOP-OP-SpecChem-50	FH
Serum, EDTA or LiHEP Plasma	Vitamin E	BS-SOP-OP-SpecChem-50	FH



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HUMAN BODY FLUIDS (cont'd)	<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 ^b 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
EDTA Whole blood	Foetal Cells	Manual Slide/Staining using 1% Eosin	



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	BS-SOP-OP-BT-2212 Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Quantitative titre of Anti-A and anti-B by testing against red blood cells using manual tube agglutination	RVI
EDTA Plasma	Isohaemagglutinins	BS-SOP-OP-BT-2209	FH/RVI
EDTA Whole Blood	<u>Haematological examinations for the purpose of clinical diagnosis</u> Full Blood Count (FBC) analysis of the following parameters: WBC RBC ESR HGB HCT MCH MCHC PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count RET-He	Sysmex XN9000 automated analysers, and pocH-100i Blood counters. Hb measurement by laural sulphate conversion and colorimetry BS-SOP-OP-Haem-6020 BS-SOP-OP-Haem-6016 Sysmex XN9000 Blood Cell Counters. Hb Measurement by laural sulphate conversion and colorimetry. Light Microscopy	FH/RVI
CSF Ascitic Fluid PD fluid	Body Fluid Analysis/ Cell Counting	BS-SOP-OP-Haem-4035 BS-SOP-OP-Haem-4021	FH/RVI FH/RVI FH/RVI



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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>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:	
EDTA Plasma	Infectious Mononucleosis Screen	Clearview IM II commercial kit, latex micro particle immunoassay BS-SOP-OP-Haem-4015	FH/RVI
Blood Bone marrow	Blood / bone marrow film analysis	Light Microscopy: 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	FH/RVI FH/RVI FH/RVI FH/RVI FH/RVI
Citrate Plasma	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u> 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 Chromogenic Factor VIII Factor XIII	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 Spectrophotometer/Chromogenic BS-SOP-OP-HStasis-3009	FH/RVI



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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	Inhibitor screen Inhibitor Titre	IL ACL 700/Light transmission/clotting end-point. 1 stage factor assay BS-SOP-OP-HStasis-3010 BS-SOP-OP-HStasis-3011	FH/RVI FH/RVI
Citrate Plasma	Rivaroxaban Dabigatran Anti-Xa Low Molecular Weight Heparin	IL ACL 700/Light transmission/Chromogenic/clotting end-point. BS-SOP-OP-HStasis-6051 BS-SOP-OP-HStasis-6040 BS-SOP-OP-HStasis-3023	FH/RVI
	Protein C Protein S Anti-thrombin 3 Activated Protein C resistance Homocysteine	BS-SOP-OP-HStasis-6048 BS-SOP-OP-HStasis-6034	FH FH
Citrated Plasma	Von Willebrand Antigen Ristocetin Co-Factor HIT Screening Assay	Werfen ACL Acustar/Chemiluminescence BS-SOP-OP-HStasis-3005 BS-SOP-OP-HStasis-6057 BS-SOP-OP-HStasis-6055 ELISA	RVI
Citrated Plasma	ADAMTS 13 assay	BS-SOP-OP-HStasis-6039	FH
EDTA Plasma	Erythropoietin (EPO)	BS-SOP-OP-HStasis-6004	



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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: 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/RVI
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)	<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:	
EDTA Whole Blood	Lymphocyte subsets: T Cells B Cells NK Cells CD4 T Cells CD8 T Cells CD4:CD8 ratio Activated T Cells Naïve T Cells B Cell phenotype T Cell receptor Double negative alpha/beta T cells T regulatory cells Dendritic cell screen	BD FACS Canto II Flow Cytometry and antibodies conjugated to fluorescent molecules as per BS-SOP-OP-FLOW-28 and the following SOPs; BS-SOP-OP-FLOW-24	RVI RVI
EDTA Whole Blood	Adhesion molecules	BS-SOP-OP-FLOW-24	RVI
EDTA Whole Blood	CD46	BS-SOP-OP-FLOW-38	RVI
EDTA Whole Blood	TCR VB repertoire	BS-SOP-OP-FLOW-02	RVI
EDTA Whole Blood	BTK Assay	BS-SOP-OP-FLOW-32	RVI
EDTA Whole Blood	Screen for Toll like receptors	BS-SOP-OP-FLOW-18	RVI
EDTA Whole Blood	SAP	BS-SOP-OP-FLOW-16	RVI
EDTA Whole Blood	Perforin	BS-SOP-OP-FLOW-23	RVI
EDTA Whole Blood	NK Cell degranulation	BS-SOP-OP-FLOW-25	RVI
EDTA Whole Blood	CGD Proteins	BS-SOP-OP-FLOW-15	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:	
Preservative free heparinised Whole Blood	CD40 Ligand Expression	BD FACS Canto II Flow Cytometry and antibodies conjugated to fluorescent molecules as per BS-SOP-OP-FLOW-28 and the following SOPs;	RVI
Preservative free Heparinised Whole Blood	FOXP3	BS-SOP-OP-FLOW-34	RVI
EDTA Whole Blood	PNH screen	BS-SOP-OP-FLOW-27	RVI
EDTA Whole Blood	EMA test for hereditary spherocytosis	BS-SOP-OP-FLOW-08	RVI
EDTA Whole Blood	Quantification of FMH	BS-SOP-OP-FLOW-07	RVI
EDTA Whole Blood	CD3	BS-SOP-OP-FLOW-03	RVI
Citrated Whole Blood	Platelet glycoproteins	BS-SOP-OP-FLOW-14	RVI
EDTA Whole Blood EDTA Bone marrow EDTA Apheresis Product	CD34 Stem cell enumeration	BS-SOP-OP-FLOW-12	RVI
		BS-SOP-OP-FLOW-10	RVI



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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:	
EDTA Whole Blood	Detection and Quantification of Haematological Malignancies including the following antigens;	BD FACS Canto II Flow Cytometry and antibodies conjugated to fluorescent molecules as per BS-SOP-OP-FLOW-28 and the following SOPs;	
EDTA Whole Blood	Peripheral Blood Monocyte Panel (CD45, CD4, CD14, CD16, CD56)	Flow Cytometry using BD FACSCanto II. BD lyse Wash Assistant. BS-SOP-OP-FLOW-06	RVI
EDTA Bone Marrow	Bone Marrow Monocyte Panel BMMONO1 - (CD45, CD4, CD56, CD14, CD64) BMMONO2 - (CD45, CD34, CD117, HLA DR, CD2, CD16)	BS-SOP-OP-FLOW-06	RVI
EDTA Whole Blood	Platelet Count (CD61,CD41)	BS-SOP-OP-FLOW-11	RVI
EDTA Whole Blood, EDTA Bone Marrow	Lymphoproliferative Panel L1 - (CD19, CD5, FMC7, CD23, CD200) L2 - (CD45, CD20, CD22, CD10, CD25, CD103) L3 - (CD19, CD79b, CD38, CD11c) L4 - (CD19, CD3, Kappa, Lambda)	BS-SOP-OP-FLOW-06. BS-SOP-OP-FLOW-37	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Morphology and immunophenotyping 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 Whole Blood, EDTA Bone Marrow, EDTA CSF, CSF, Pleural Fluid, EDTA Pleural Fluid	Acute Leukaemia Panel/Acute Screening Tube <ul style="list-style-type: none"> ○ ALP1 - (CD45, CD34, CD10, CD19, CD5, CD117, HLA-DR) ○ ALP2 - (CD45, CD2, CD7, CD33, CD13, CD15, CD123) ○ ALP3 - (CD45, CD14, CD64, CD235a, CD41a) ○ ALP4 - (CD45, cCD3, cMPO, cCD79a, nTDT) 	Flow Cytometry Using BD FACSCanto II. BD Lyse Wash Assistant. BS-SOP-OP-FLOW-06 BS-SOP-OP-FLOW-37	RVI
EDTA Whole Blood, EDTA Bone Marrow	Plasma Cell Tube- Extracellular (CD38, CD138, CD45, CD56, CD19, CD117)	BS-SOP-OP-FLOW-39	RVI
EDTA Whole Blood, EDTA Bone Marrow, EDTA CSF, CSF, Pleural Fluid, EDTA Pleural Fluid	TC3 Cell Panel (CD10, CD3, CD8, TCR AB, TCR GD, CD25, CD45, CD57)	BS-SOP-OP-FLOW-06 BS-SOP-OP-FLOW-37	RVI
EDTA Whole Blood, EDTA Bone Marrow, EDTA CSF, CSF, Pleural Fluid, EDTA Pleural Fluid	TC2 Cell Panel (CD45, CD3, CD4, CD2, CD5, CD7, CD26)	BS-SOP-OP-FLOW-06 BS-SOP-OP-FLOW-37	
EDTA Whole Blood, EDTA Bone Marrow	Intracellular Plasma Cell Tube (CD20, CD27, CD81, VS38c, cLambda, cKappa, CD45)	BS-SOP-OP-FLOW-06 BS-SOP-OP-FLOW-39	RVI
EDTA Whole Blood	Lymphocyte Count (6 colour TBNK)	BS-SOP-OP-FLOW-06	RVI



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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	T Cell proliferation	Tritiated thymidine incorporation into dividing cells then assessed by Perkin Elmer Beta counter BS-SOP-OP-FLOW-22	RVI
EDTA Whole Blood	T,B,CD15 cell separation	Magnetic bead separation using Miltenyi automacs, quality assessed by BD FACS Canto II Flow Cytometry and antibodies conjugated to fluorescent molecules BS-SOP-OP-FLOW-33	RVI
EDTA Whole Blood	NBT	Neutrophils stimulated with PMA and colour changes to NBT assessed on cytopsin by microscopy BS-SOP-OP-FLOW-05	RVI
EDTA Whole Blood	Neutrophil Respiratory Burst	Neutrophils stimulated with PMA and labelled with DHR, fluorescent changes are assessed by BD FACS Canto II BS-SOP-OP-FLOW-04	RVI



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



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum only unless otherwise stated</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u></p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p>	RVI
	<p>Perinuclear ANCA Cytoplasmic ANCA</p>	<p>Hamilton Dilutor, Slide trays and immunofluorescence microscope:</p> <p>BS-SOP-OP-AIMM-3 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11</p>	
	<p>IgA Endomysial Antibody IgG Endomysial Antibody</p>	<p>BS-SOP-OP-AIMM-7 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11</p> <p>Hamilton dilutor, rocking platform immunoblot</p>	
	<p>ENA Scl-70 Antibody</p>	<p>BS-SOP-OP-AIMM-8</p>	RVI
	<p>Mitochondrial M2 Anti Liver-Kidney Mic. Ab Liver Cytosol Ab Soluble Liver Antigen Ab</p>	<p>BS-SOP-OP-AIMM-14</p> <p>Hamilton Dilutor, Slide Trays, Moisture Chamber and immunofluorescence microscope:</p>	RVI
	<p>Pemphigoid Ab Pemphigus Ab Adrenal Ab Islet Cell Ab Purkinje Cell Ab Anti Neuronal Nuc. Ab</p>	<p>BS-SOP-OP-AIMM-18 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11</p>	
	<p>Serum Tryptase level</p>	<p>Phadia ImmunoCAP 250: BS-SOP-OP-AIMM-67</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: BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI
Serum	Specific IgE Antibodies to include: 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		



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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: BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd) rCor a 14 Recombinant Hazelnut 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		



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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: BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd) rJug r3 Recomb. Walnut Chlorhexidine Trout Tilapia 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		



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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: BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI
Serum (cont'd)	Specific IgE Antibodies to include: (cont'd) Chicken Lamb (mutton) Black pepper rApi m 1 phospholipase A2 Honey Bee rVes v 5 Recomb. Wasp 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 Weed mix 3		



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood</p>	<p><u>Haemoglobinopathy examinations for the purpose of clinical diagnosis</u></p> <p>Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants:</p> <p>Hb A Hb A2 Hb F Hb S Hb C Hb D Hb E Hb O Barts Leopore</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>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"</p> <p>TOSOH G8, HPLC:</p> <p>BS-SOP-OP-Prot-33 BS-SOP-OP-Prot-39 BS-SOP-OP-Prot-30 BS-SOP-OP-Prot-38</p>	RVI
Dried Blood Spots	<p>Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants:</p> <p>Hb A Hb F Hb S Hb C Hb D Hb E Hb O Barts</p>	<p>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"</p> <p>Sebia CapillaryS Neonate, HPLC</p> <p>BS-SOP-OP-Prot-19 BS-SOP-OP-Prot-40</p>	RVI



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u>	Sebia CAP3 using capillary electrophoresis in free solution followed by immunotyping Sebia Hydrasys using hydra gel protein kits	
Serum	Paraproteins	BS-SOP-OP-Prot-23 BS-SOP-OP-Prot-46 BS-SOP-OP-Prot-47	RVI
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 Binding Site OptiLite using Turbidimetry.	RVI
Serum Serum Serum Serum	C1 Esterase Inhibitor IgG Subclasses Free Light Chains CH50	BS-SOP-OP-Prot-48 BS-SOP-OP-Prot-36 BS-SOP-OP-Prot-27 BS-SOP-OP-Prot-49	RVI RVI RVI RVI
END			