

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Accredited to
ISO 15189:2012

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Department of Blood Sciences
Newcastle upon Tyne Hospitals NHS
Foundation Trust
Freeman Hospital
Freeman Road, High Heaton
Newcastle upon Tyne
NE7 7DN

Contact: Dr J P Wallis Consultant Haematologist
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E-Mail: Jonathan.wallis@nuth.nhs.uk
Website: www.newcastle-hospitals.nhs.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 J P Wallis (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>Diabetics Centre Campus for ageing and vitality Westgate Road, Newcastle</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 metabolism • Maternal screening services • Neonatal screening services <p>Diabetic clinic - HbA1C only</p>	RVI DC



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



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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 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>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers instructions for	
Serum/Plasma unless otherwise stated	Quantitative determination of: Alpha 1- Antitrypsin Beta 2 Microglobulin ApoA1 ApoB100 C3 C4 Caeruloplasmin CRP (High sensitivity)	Roche Cobas 8000 c702 Module : Immunoturbidometric BS-SOP-OP-Biochem-17 BS-SOP-OP-Biochem-15 BS-SOP-OP-Biochem-112 BS-SOP-OP-Biochem-113 BS-SOP-OP-Biochem-66 BS-SOP-OP-Biochem-66 BS-SOP-OP-Biochem-8 BS-SOP-OP-Biochem-3	RVI
Serum only Serum only Serum only	Haptoglobin IgA IgG IgM	BS-SOP-OP-Biochem-133 BS-SOP-OP-Biochem-67	
CSF Urine Urine Urine	Lp(a) Rheumatoid Factor Transferrin Protein albumin Protein Sodium	BS-SOP-OP-Biochem-39 BS-SOP-OP-Biochem-63 BS-SOP-OP-Biochem-73 BS-SOP-OP-Biochem-62 BS-SOP-OP-Biochem-97 BS-SOP-OP-Biochem-62 BS-SOP-OP-Biochem-36	RVI RVI FH/RVI FH/RVI FH/RVI FH/RVI FH/RVI
Serum Only	ACE Albumin Alkaline Phosphatase ALT Amylase AST Bicarbonate Bile acids Bilirubin total	Roche Cobas 8000 c702 Module : Photometry BS-SOP-OP-Biochem-21 BS-SOP-OP-Biochem-98 BS-SOP-OP-Biochem-18 BS-SOP-OP-Biochem-22 BS-SOP-OP-Biochem-16 BS-SOP-OP-Biochem-23 BS-SOP-OP-Biochem-13 BS-SOP-OP-Biochem-12	RVI FH/RVI FH/RVI FH/RVI FH/RVI FH/RVI FH/RVI 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/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
	CRP	BS-SOP-OP-Biochem-29	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
FI-Oxalate Plasma only	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
	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
Urine	Uric Acid	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	Magnesium	BS-SOP-OP-Biochem-52	FH/RVI
Urine	Phosphate	BS-SOP-OP-Biochem-59	FH/RVI
Urine	Urate	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-SOP0OP-Biochem 50	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)	Roche Cobas 8000 c702 Module : Using WAKO Vanadate oxidation kit	
	Conjugated bilirubin	BS-SOP-OP-Biochem 11	FH/RVI
	Carbamazepine Phenobarbitone Phenytoin Theophylline	Roche Cobas 8000 c702 Module : Using KIMS Immunoassay: BS-SOP-OP-Biochem-6 BS-SOP-OP-Biochem-57 BS-SOP-OP-Biochem-58 BS-SOP-OP-Biochem-70	RVI
	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	FH/RVI
Urine Urine	Chloride Potassium	BS-SOP-OP-Biochem-36 BS-SOP-OP-Biochem-36	RVI RVI/FH
	Valproate	Roche Cobas 8000 c702 Module : Using EIA: BS-SOP-OP-Biochem-79	RVI
	Macroprolactin screen (inc. % recovery and biometric monoactive prolactin)	Roche Cobas 8000 e602 Module : Using ECLIA and Calculation: BS-SOP-OP-Biochem-51	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 plasma unless otherwise stated	Quantitative determination of: (cont'd)	Roche Cobas 8000 e602 Module : Using ECLIA:	
EDTA plasma only	Calcitonin B-Ctx Thyroglobulin antibody DHEAS Ferritin FSH fT4 IgE LH	BS-SOP-OP-Endo-4 BS-SOP-OP-Biochem-14 BS-SOP-OP-Biochem-71 BS-SOP-OP-Biochem-30 BS-SOP-OP-Biochem-44 BS-SOP-OP-Biochem-31 BS-SOP-OP-Biochem-33 BS-SOP-OP-Biochem-121 BS-SOP-OP-Biochem-38	RVI RVI RVI RVI FH/RVI RVI FH/RVI RVI RVI
Serum only			
Serum or Li-Hep plasma unless otherwise stated	NT-Pro BNP Oestradiol Progesterone Prolactin SHBG Testosterone Thyroid peroxidase antibody Troponin-T TSH	Roche Cobas 8000 e602 Module : Using ECLIA: (cont'd) BS-SOP-OP-Biochem-54 BS-SOP-OP-Biochem-55 BS-SOP-OP-Biochem-60 BS-SOP-OP-Biochem-61 BS-SOP-OP-Biochem-41 BS-SOP-OP-Biochem-69 BS-SOP-OP-Biochem-72 BS-SOP-OP-Biochem-75 BS-SOP-OP-Biochem-42	RVI RVI RVI RVI RVI RVI RVI RVI FH/RVI FH/RVI
EDTA plasma only	PTH Cortisol Digoxin Folate fT3 hCG Vitamin B12	Roche Cobas 8000 E602 and E170 Module : Using ECLIA: BS-SOP-OP-Biochem-47 BS-SOP-OP-Biochem-4 BS-SOP-OP-Biochem-43 BS-SOP-OP-Biochem-135 BS-SOP-OP-Biochem-32 BS-SOP-OP-Biochem-35 BS-SOP-OP-Biochem-136	FH/RVI RVI RVI FH/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: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
Serum or Li-Hep plasma unless otherwise stated	Quantitative determination of:	Roche Cobas 8000 E170 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
	PSA	BS-SOP-OP-Biochem-40	FH
	Vitamin D	BS-SOP-OP-Biochem-65	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	
	Transferrin saturation	BS-SOP-OP-Biochem-5	FH/RVI
	Free testosterone	BS-SOP-OP-Biochem-48	FH/RVI
		Wu formula	RVI
		BS-SOP-OP-Biochem-69	
EDTA Plasma Serum only	Quantitative determination of:	Siemens Immulite 2000 : Using Chemiluminescence:	
	ACTH	BS-SOP-OP-Biochem-99	RVI
	Androstenedione	BS-SOP-OP-Biochem-100	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	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	
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 Capillary Li-Hep (at DC)	HbA1c	Tosoh G8 HPLC: BS-SOP-OP-Biochem-109	FH/RVI/ DC
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



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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)	Beckman RIA:	
	17OHP	BS-SOP-OP-Endo-01	RVI
	Thyroglobulin	Beckman Access II using Chemiluminescent immunoassay: BS-SOP-OP-Endo-20	RVI
Serum Only Serum only Serum only	TRAb Chromogranin A Copeptin	Brahms Kryptor using fluorescent immunoassay: BS-SOP-OP-Endo-25 BS-SOP-OP-Endo-27 BS-SOP-OP-Endo-29	RVI
		IDI iSYS using chemiluminescent immunoassay:	
EDTA Plasma EDTA plasma	GH IGF-1 Aldosterone Renin	BS-SOP-OP-Endo-10 BS-SOP-OP-Endo-13 BS-SOP-OP-Endo-02 BS-SOP-OP-Endo-17	RVI
Serum only	P3NP	Orion RIA: BS-SOP-OP-Endo-28	RVI
	AMH	Beckman ELISA: BS-SOP-OP-Endo-18 Mercodia ELISA:	RVI
Lithium Heparin Plasma/serum/EDTA	Insulin	BS-SOP-OP-Endo-12	RVI
Lithium Heparin Plasma/serum/EDTA	C-Peptide	BS-SOP-OP-Endo-07	



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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 Citrilline Cystine Glutamic Acid Glutamine Glycine Histidine Histidine 1-methyl Histidine 3-methyl Isoleucine Leucine Lysine Methionine Ornithine Proline Serine Taurine Threonine Valine	Biochrom Amino Acid Analyser using HPLC: BS-SOP-OP-PaedS-01	RVI
Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA Blood/CSF and PCA EDTA plasma/serum plasma	Quantitative determination of intermediary metabolites: 3 OH Butyric acid Alanine Glycerol Pyruvic acid Glucose NEFA Biotinidase	BMG Flurostar Omega multi plate reader by enzymatically linked fluorometry: BS-SOP-OP-PaedS-15 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: (cont'd)</u>	Documented in house methods and manufacturers instructions for	
EDTA plasma	Quantitative determination of sterols and acids:	GC Mass Spectrometry:	
EDTA plasma	Cholesterol	BS-SOP-OP-Paeds-19	RVI
EDTA plasma	Cholestanol		
EDTA plasma	7-Dehydrocholesterol		
EDTA plasma	Lathosterol		
EDTA plasma	Demosterol		
EDTA plasma	Sitosterol		
Urine	Methylmalonic acid	BS-SOP-OP-Paeds-11	RVI
Urine	Hexanoylglycine	BS-SOP-OP-Paeds-22	
Urine	Organic acids	BS-SOP-OP-Paeds-23	
Urine	Orotic acid	BS-SOP-OP-Paeds-25	
EDTA plasma	Very long chain acids:		
EDTA plasma	C22:0 Behenic Acid	BS-SOP-OP-Paeds-26	
EDTA plasma	C24:0 Lignoceric Acid		
EDTA plasma	C26:0 Cerotic Acid		
EDTA plasma	Phytanic Acid		
EDTA plasma	Pristanic Acid		
Sweat	Quantitative determination of:	Sherwood Scientific MK II Chloride Analyser 962 S: Collection and analysis	
	Chloride	BS-SOP-OP-Paeds-33 BS-SOP-OP-Paeds-34	RVI
Bloodspot	TSH	Perkin Elmer AutoDELFIA using Fluoro immunoassay:	
	IRT	BS-SOP-OP-NNS-7	RVI
	17OHP	BS-SOP-OP-NNS-6	
		BS-SOP-OP-NNS-3	
		BS-SOP-OP-NNS-1	
Urine	Normetadrenaline	HPLC Electrochemical Detection:	
	Metadrenaline	BS-SOP-OP-SpecChem-22	FH
	3-Methoxytyramine		



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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	Quantitative determination of: (cont'd)	Perkin Elmer ICP Mass Spectrometry:	
Serum/Urine	Zinc	BS-SOP-OP-SpecChem-42	FH
Serum	Copper	BS-SOP-OP-SpecChem-8	
Serum/water	Selenium	BS-SOP-OP-SpecChem-46	
EDTA Whole blood	Aluminium	BS-SOP-OP-SpecChem-43	
EDTA Whole Blood	Chromium	BS-SOP-OP-SpecChem-44	
EDTA Whole Blood	Cobalt	BS-SOP-OP-SpecChem-44	
	Manganese	BS-SOP-OP-SpecChem-49	
EDTA Whole Blood	Ciclosporin	Tandem Mass Spectrometry:	
	Sirolimus	BS-SOP-OP-SpecChem-7	FH
	Tacrolimus	BS-SOP-OP-SpecChem-19	
		BS-SOP-OP-SpecChem-20	
EDTA Plasma	Plasma Free Metanephrine	BS-SOP-OP-SpecChem-16	
	Plasma free non metanephrine		
	3 Methoxytyramine		
Serum	Paraproteins	Sebia CapillaryS using capillary electrophoresis in free solution followed by immunotyping:	
		BS-SOP-OP-Prot-28	RVI
Urine	Paraproteins	Sebia Hydrasys using hydra gel protein kits:	
		BS-SOP-OP-Prot-20	RVI
Serum	Free light chains	Binding Site SPA+ using turbidometric methods:	
	IgG subsets	BS-SOP-OP-Prot-27	RVI
		BS-SOP-OP-Prot-36	



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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	
Serum/plasma	Quantitative determination of: (cont'd) Creatinine GGT Glucose Total protein Urea Nitrogen Albumin Alkaline Phosphatae Total Bilirubin	Abaxis Piccolo biochromatic measurement and absorbance utilises reagent discs: POCT-proc-15	RVI
Serum only	Sodium Potassium Chloride	Siemens Rapidpoint 500R1 BGA using Direct ISE: POCT-proc-16	RVI
	<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 D Positive A D Negative AB D Negative B D Negative D Negative O positive O negative	Column Technology: Ortho Vision automation. Manual BioVue system: BS-SOP-OP-BT-2201 BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2214	FH RVI



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EDTA Whole Blood	Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, c, e, f, C ^w , K, k, Kp ^a , Kp ^b , Fy ^a , Fy ^a , Jk ^a , Jk ^b , Le ^a , Le ^b , S, s, M, N, P ₁ , Lu ^a , Lu ^b		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 plasma	3 cell Antibody Screen	BS-SOP-OP-BT-2201 BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2214	FH RVI
EDTA Whole packed red cell	Specific Antigen Phenotype RhD Type Investigation	Column Technology: Ortho Vision automation. Manual BioVue system: BS-SOP-OP-BT-2711 BS-SOP-OP-BT-2219 BS-SOP-OP-BT-2222	FH RVI
EDTA Whole blood	Blood Group	MD multiscard (Manual) using lateral flow principles: BS-SOP-OP-BT-2221	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	FMH Screen	Complement activity. Manual Slide/Staining BS-SOP-OP-BT-2204 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 <u>Haematological examinations for the purpose of clinical diagnosis</u>	BS-SOP-OP-BT-2209	FH/RVI
EDTA Whole Blood	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	Sysmex XN9000 automated analysers, XT, XS and pOCHI Blood counters. Hb measurement by laurel sulphate conversion and colorimetry BS-SOP-OP-Haem-6020 BS-SOP-OP-Haem-4001 BS-SOP-OP-Haem-4002 BS-SOP-OP-Haem-6016	FH RVI



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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

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>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: Sysmex XN9000, XT and XS Blood Cell Counters. Hb Measurement by laural sulphate conversion and colorimetry. Light Microscopy	
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
Blood	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	CareStart commercial kit Chromatographic immunoassay BS-SOP-OP-Haem-4028 Light Microscopy:	FH RVI
Blood Bone marrow	Blood / bone marrow film analysis	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 IL ACL 700/Light transmission/Chromogenic/clotting end-point. Turbidometric	FH RVI FH RVI



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The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

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>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
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 Protein S Anti-thrombin 3 Activated Protein C resistance Homocysteine	BS-SOP-OP-HStasis-3023	FH
Citrated Plasma		BS-SOP-OP-HStasis-6048	
		Werfen ACL Acustar/Chemiluminescence	RVI
	Von Willebrand Antigen	BS-SOP-OP-HStasis-6034	
	Ristocetin Co-Factor	BS-SOP-OP-HStasis-3005	
	HIT Screening Assay	BS-SOP-OP-HStasis-6057	
		BS-SOP-OP-HStasis-6055	



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Schedule of Accreditation

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United Kingdom Accreditation Service

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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: ELISA	
Citrated Plasma/Serum	Anti-cardiolipin assay Anti- β 2 Glycoprotein 1 assay	BS-SOP-OP-HStasis-6001 BS-SOP-OP-HStasis-6005	FH
Citrated Plasma	ADAMTS 13 assay	BS-SOP-OP-HStasis-6039	
EDTA Plasma	Intrinsic Factor Antibodies (IFA)	BS-SOP-OP-HStasis-6003	
EDTA Plasma	Erythropoietin (EPO)	BS-SOP-OP-HStasis-6004	
Serum	Heparin Induced Thrombocytopenia (HIT)	BS-SOP-OP-HStasis-6002	
Blood	Blood Film Morphology	Light Microscopy, Modified Wrights stain 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
Citrated white cells	Detection of genetic mutation: Factor II mutation Factor V Leiden mutation	PCR using Roche Light cyclers BS-SOP-OP-Prot-13 and 14 BS-SOP-OP-Prot-31	RVI



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Schedule of Accreditation
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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

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Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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:	RVI
EDTA Whole Blood	Lymphocyte subsets: T Cells B Cells NK Cells CD4 T Cells CD8 T Cells CD4:CD8 ratio Activated T Cells 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	BD Canto II Flowcytometer, antibodies conjugated to fluorescent molecules: BS-SOP-OP-FLOW-24 BS-SOP-OP-FLOW-20 BS-SOP-OP-FLOW-02	



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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: 007 Issue date: 18 November 2018

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
<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</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, antibodies conjugated to fluorescent molecules:</p> <p>BS-SOP-OP-FLOW-06</p>	<p>RVI</p>



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Schedule of Accreditation
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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>EDTA Blood Bone Marrow CSF & Various body fluids</p> <p>Preservative free Heparinised Whole Blood EDTA Whole Blood</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Lymphoproliferative panel to include:</p> <p>FMC7 CD23 CD15 CD5 APC CD103 CD22 CD20 CD10 APC CD45 APC H7 CD79b FITC CD38 PE CD19 Per CP cy5.5 CD110 APC CD2 FITC Lamda PE Kappa APC</p> <p>Plasma Cells: CD138 FITC CD56 PE</p> <p>Intracellular proteins: FOXP3 Btk SAP Perforin CGD Proteins</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</p> <p>BS-SOP-OP-FLOW-06</p> <p>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</p>	<p>RVI</p>



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Schedule of Accreditation

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United Kingdom Accreditation Service

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

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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>JRH</p>



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Schedule of Accreditation
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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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: Flow cytometry using antibodies conjugated to fluorescent molecules:	
Preservative free heparinised Whole Blood	CD40 Ligand Expression	BS-SOP-OP-FLOW-34	RVI
EDTA Whole Blood	Screen for Toll like receptors	BS-SOP-OP-FLOW-18	
	NK Cell degradation	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 Neytrophils stimulated with PMA and colour changes to NBT assessed on cytopsin 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 Miltenyi automacs- magnetic bead separation:	RVI
	T,B,CD15 cell seperation	BS-SOP-OP-FLOW-33	RVI



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Schedule of Accreditation
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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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	T Cell proliferation	Parkin Elmer Beta counter. Tritiated thymidine incorporation into dividing cells: BS-SOP-OP-FLOW-22 Flow cytometry (see above for measurement principle)	RVI
EDTA Whole Blood EDTA Bone marrow EDTA Apherisis Product	CD34 Stem cell enumeration	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>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Serum only Serum only Serum only Serum only Serum only	fbhCG PAPPA AFP hCG uE3	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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The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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:	
Serum only unless otherwise stated	ANA Pattern Gastric Parietal Cell antibody Anti Nuclear antibody Anti mitochondrial Ab Anti smooth muscle Ab Anti Ribosomal Ab	Hamilton Dilutor, Slide Trays and immunofluorescence microscope BS-SOP-OP-AIMM-1 BS-SOP-OP-AIMM-5 BS-SOP-OP-AIMM-20	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	Bioplex 2200 analyser. Multiplexing bead based flow cytometric principles: BS-SOP-OP-AIMM-71	RVI
	Anti-RNP 68 Ab Anti-Scl-70 Ab Anti-Jo-1 Ab Anti-Centromere Ab		
	Anti-MPO Ab Anti PR3 Ab Anti GBM Ab	BS-SOP-OP-AIMM-70	
	Anti-CCP Ab	BS-SOP-OP-AIMM-72	
	IgA Anti-TTG Ab	BS-SOP-OP-AIMM-73	



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Schedule of Accreditation
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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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	ENA Sci-70 Antibody	Hamilton dilutor, rocking platform immunoblot BS-SOP-OP-AIMM-8	RVI
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	
Serum	Myeloperoxidase Antibodies Proteinase 3 Antibodies Glomerular basement membrane Antibodies:	Organtec Alegria ELISA : BS-SOP-OP-AIMM-2	RVI
Serum	ENA Sci-70 Antibody Mitochondrial M2 Anti Liver-Kidney Mic. Ab Liver Cytosol Ab Soluble Liver Antigen Ab	Hamilton dilutor, rocking platform immunoblot BS-SOP-OP-AIMM-8 BS-SOP-OP-AIMM-14	RVI



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ISO 15189:2012

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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	Phemgoid Ab Phemphigus Ab Adrenal Ab Ovarian Ab Testes Ab Islet Cell Ab Cardiac Ab Skeletal/Striated muscle Ab Purkinjie Cell Ab Anti Neuronal Nuc. Ab GAD Antibody Manna Binding Lectin Levels Pneumococcal Ab Tetanus Ab Haemophilus B Antibodies	BS-SOP-OP-AIMM-18 BS-SOP-OP-AIMM-9 BS-SOP-OP-AIMM-11 Grifols Triturus ELISA processor: BS-SOP-OP-AIMM-21 BS-SOP-OP-AIMM-10 BS-SOP-OP-AIMM-15 BS-SOP-OP-AIMM-17 BS-SOP-OP-AIMM-19 BS-SOP-OP-AIMM-13 Phadia ImmunoCAP 250:	RVI
Serum	Serum Tryptase level	BS-SOP-OP-AIMM-67	RVI



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Schedule of Accreditation
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Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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	Specific IgE Antibodies to include: Pen G Pen V Succinyl choline (Suxameth) Amoxicilloyl 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 Cod Tuna Salmon Haddock Mackerel Crab Shrimp Scallop Mussel (Blue Mussel) Lobster	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI



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The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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) Squid Tropomyosin/Recombinant Shrimp 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	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	



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ISO 15189:2012

Schedule of Accreditation
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United Kingdom Accreditation Service
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The Newcastle upon Tyne Hospitals NHS Foundation Trust
Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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 Orange Lemon Apple Pear Melon Mango Strawberry Kiwi Banana Pineapple Blueberry Peach Apricot Plum Cherry Grape Avocado Pork Beef Lamb (mutton) Black pepper	BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77	RVI



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ISO 15189:2012

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

Testing performed by the Organisation at the locations specified

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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)	<p>Specific IgE Antibodies to include: (cont'd)</p> <p>Cacao (cocoa) Celery Chilli pepper Coffee Ginger Malt Mustard Yeast (bakers) Spice mix 1 Spice mix 2 Spice mix 3</p> <p>Timothy Grass Bee Wasp Mosquito spp. Latex Recomb. Latex rHEV B 8 Recomb. Latex rHEV B 5 Recomb. Latex rHEV B 1 Recomb. Latex rHEV B 6,02 Recomb. Latex rHEV B 6,01 Recomb. Latex rHEV B 3 Recomb. Latex rHEV B 9 Cladosporium Aspergillus Alternaria alternata Moulds mix Common silver Birch</p> <p>Recomb. Birch BET V 1 Recomb. Birch BET V 2 Palm (oil) pollen Tree mix 1 Rape pollen Weed mix 1</p>	<p>BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77</p>	RVI



Accredited to
ISO 15189:2012

Schedule of Accreditation

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 18 November 2018

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:	
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
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	Sebia CapillaryS Neonate, HPLC BS-SOP-OP-Prot-19 BS-SOP-OP-Prot-40	RVI
Serum	Quantitative determination of: Complement: Comp I Comp H C1E AP100 CH100	Binding site RID Plates immunoassay: BS-SOP-OP-Prot-22 BS-SOP-OP-Prot-21	RVI



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Issue No: 007 Issue date: 18 November 2018

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 (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Serum	CE1 functional	Technochrome ELISA kit: BS-SOP-Prot-24	RVI
Serum	C3 Nephritic Factor	Helena Kit: Sebia Hydrasys using immunofixation: BS-SOP-Prot-29	RVI RVI
CSF	Oligoclonal banding	Sebia Hydrasys & kit using immunofixation and enzymes: BS-SOP-OP-Prot-12	RVI
EDTA Whole Blood	Sickle cell solubility	Microgen Bioproducts commercial kit, modified Itano solubility technique: BS-SOP-OP-Prot-07	RVI

END