


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8543 Accredited to ISO 15189:2012	The Newcastle upon Tyne Hospitals NHS Foundation Trust	
	Issue No: 015 Issue date: 30 January 2023	
	Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Contact: Dr Helen Bourne, Consultant Immunologist Tel: +44 (0) 191 2336161 E-Mail: helen.bourne2@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
Address Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road, High Heaton Newcastle upon Tyne NE7 7DN	Local contact Dr H Bourne (as above)	<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
Address Department of Blood Sciences Newcastle upon Tyne Hospitals NHS Foundation Trust Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Local contact Dr H Bourne (as above)	<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-17	RVI
	Beta 2 Microglobulin	BS-SOP-OP-Biochem-15	RVI
	ApoA1	BS-SOP-OP-Biochem-112	RVI
	ApoB100	BS-SOP-OP-Biochem-113	RVI
	C3	BS-SOP-OP-Biochem-66	RVI
	C4	BS-SOP-OP-Biochem-66	RVI
	Caeruloplasmin	BS-SOP-OP-Biochem-8	RVI
	CRP (High sensitivity)	BS-SOP-OP-Biochem-3	RVI
	CRP	BS-SOP-OP Biochem-29	FH/RVI
	Haptoglobin	BS-SOP-OP-Biochem-133	RVI
Serum only	IgA	BS-SOP-OP-Biochem-67	RVI
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
EDTA plasma	Bilirubin total	BS-SOP-OP-Biochem-10	FH/RVI
Serum			



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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	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)	<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 : 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 RVI RVI RVI
Urine	Chloride	Roche Cobas 8000 c702 Module : Using Indirect ISE:	FH/RVI
Urine	Potassium	BS-SOP-OP-Biochem-36	FH/RVI
Urine	Sodium	BS-SOP-OP-Biochem-36	FH/RVI
	Chloride	BS-SOP-OP-Biochem-36	RVI
	Potassium	BS-SOP-OP-Biochem-36	RVI/FH
	Sodium	BS-SOP-OP-Biochem-36	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 immunoturbidmetric 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	BS-SOP-OP-Endo-4	RVI
	Cortisol	BS-SOP-OP-Biochem-4	RVI
	B-Ctx	BS-SOP-OP-Biochem-14	RVI
	Digoxin	BS-SOP-OP-Biochem-43	RVI
	Ferritin	BS-SOP-OP-Biochem-44	RVI
	Folate	BS-SOP-OP-Biochem-135	FH/RVI
	FSH	BS-SOP-OP-Biochem-31	RVI
	fT3	BS-SOP-OP-Biochem-32	RVI
	fT4	BS-SOP-OP-Biochem-33	RVI
	hCG	BS-SOP-OP-Biochem-35	RVI
Serum only	IgE	BS-SOP-OP-Biochem-121	RVI
	LH	BS-SOP-OP-Biochem-38	RVI
	NT-Pro BNP	BS-SOP-OP-Biochem-54	RVI
	Oestradiol	BS-SOP-OP-Biochem-55	RVI
	Progesterone	BS-SOP-OP-Biochem-60	RVI
	Prolactin	BS-SOP-OP-Biochem-61	RVI
EDTA plasma only	PTH	BS-SOP-OP-Biochem-47	FH/RVI
	SHBG	BS-SOP-OP-Biochem-41	RVI
	Testosterone	BS-SOP-OP-Biochem-69	RVI
	Thyroglobulin antibody	BS-SOP-OP-Biochem-71	RVI
	Thyroid peroxidase antibody	BS-SOP-OP-Biochem-72	RVI
	Troponin-T	BS-SOP-OP-Biochem-75	RVI
	TSH	BS-SOP-OP-Biochem-42	RVI
	Vitamin B12	BS-SOP-OP-Biochem-136	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-5	FH/RVI
	Free testosterone	BS-SOP-OP-Biochem-48	FH/RVI
		Wu formula	RVI
		BS-SOP-OP-Biochem-69	
	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-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:	UVIKON-XS Spectrophotometer : Using Spectrophotometry:	
CSF	Xanthochromia	BS-SOP-OP-Biochem-117	RVI
Urine	PBG	BS-SOP-OP-Biochem-129	RVI
		Tosoh G8 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
		Thermofisher Trace ISQ GC-MS:	
Urine	Urine Free Cortisol	BS-SOP-OP-Endo-22	RVI
		Tandem mass Spectrometry	
Urine/EDTA Plasma/Dry Blood Spot	Acylcarnitine Analysis	BS-SOP-OP-Paeds-31 BS-SOP-OP-Paeds-29 BS-SOP-OP-Paeds-28 BS-SOP-OP-Paeds 21	RVI
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



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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:	
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:	
EDTA plasma	GH	BS-SOP-OP-Endo-10	RVI
EDTA plasma	IGF-1	BS-SOP-OP-Endo-13	RVI
	Aldosterone	BS-SOP-OP-Endo-02	RVI
	Renin	BS-SOP-OP-Endo-17	RVI
		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)	Biochrom 30+ Amino Acid Analyser using Ion exchange chromatography:	
	Amino Acids to include:	BS-SOP-OP-MNS-8	RVI
	Alanine Arginine Asparagine Aspartic Acid Citrulline Cystine Glutamic Acid Glutamine Glycine Histidine Isoleucine Leucine Lysine Methionine Ornithine Proline Serine Taurine Threonine Tryptophan Valine		



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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	
	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		
Blood/CSF in perchloric acid	Glucose		
EDTA plasma/serum	Non-esterified fatty acids	BS-SOP-OP-Paeds-16	RVI
EDTA plasma, Li-Hep	Biotinidase	BS-SOP-OP-Paeds-32	RVI
plasma, serum			
	Quantitative determination of sterols and acids:	GC Mass Spectrometry:	
EDTA plasma, serum	Campesterol	BS-SOP-OP-Paeds-19	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	Hexanoylglycine	BS-SOP-OP-MNS-12	RVI
Urine	Organic acids	BS-SOP-OP-Paeds-23	RVI
Urine	Orotic acid	BS-SOP-OP-MNS-2	RVI
	Very long chain fatty acids:		
EDTA plasma, serum	C22:0 Behenic Acid	BS-SOP-OP-Paeds-26	RVI
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 Antenatal & Newborn Screening	Sherwood Scientific MK II Chloride Analyser 962 S: Collection and analysis BS-SOP-OP-Paeds-33 BS-SOP-OP-Paeds-34 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" 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 AutoDELFIA using Fluoro immunoassay:	RVI RVI RVI RVI
Bloodspot Bloodspot Bloodspot	TSH IRT 17OHP	BS-SOP-OP-NNS-7 BS-SOP-OP-NNS-6 BS-SOP-OP-MNS-3 BS-SOP-OP-NNS-1	RVI RVI RVI RVI
Serum	Inhibin A	BS-SOP-OP-MSS-16 HPLC Electrochemical Detection:	RVI
Urine	Normetadrenaline Metadrenaline 3-Methoxytyramine	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	FH
Serum	Selenium	BS-SOP-OP-SpecChem-46	FH
Serum/water	Aluminium	BS-SOP-OP-SpecChem-43	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
EDTA Whole blood	Lead	BS-SOP-OP-SpecChem-49	FH
		Tandem Mass Spectrometry:	
EDTA Whole Blood	Ciclosporin	BS-SOP-OP-SpecChem-7	FH
	Sirolimus	BS-SOP-OP-SpecChem-19	FH
	Tacrolimus	BS-SOP-OP-SpecChem-20	FH
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	RVI
EDTA Plasma	Isohaemagglutinins	Quantitative titre of Anti-A and anti-B by testing against red blood cells using manual tube agglutination BS-SOP-OP-BT-2209	FH/RVI



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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, 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 Sysmex XN9000, XT and XS 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-4013 BS-SOP-OP-Haem-4035 BS-SOP-OP-Haem-4021	FH/RVI FH/RVI FH/RVI
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



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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	FH/RVI 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	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	
		BS-SOP-OP-HStasis-3023	
	Protein C	BS-SOP-OP-HStasis-6048	FH
	Protein S		
	Anti-thrombin 3		
	Activated Protein C resistance	BS-SOP-OP-HStasis-6034	FH
	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	
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



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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 (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	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	Flow Cytometry Platelet Count (CD61)	BS-SOP-OP-FLOW-03	RVI
EDTA Whole Blood	CD3	BS-SOP-OP-FLOW-11	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;	RVI
EDTA Bone Marrow	CD2	BS-SOP-OP-FLOW-06	RVI
CSF	CD3	BS-SOP-OP-FLOW-39	RVI
Other Fluids	cCD3	BS-SOP-OP-FLOW-37	RVI
	CD4		
	CD5		
	CD7		
	CD8		
	CD10		
	CD11c		
	CD13		
	CD14		
	CD15		
	CD16 + 56		
	CD19		
	CD20		
	CD22		
	CD23		
	CD33		
	CD34		
	CD38		
	CD41a		
	CD45		
	CD56		
	CD64		
	cCD79a		
	CD79b		
	CD103		
	CD117		
	CD138		
	CD235a		
	HLA-DR		
	FMC7		
	sKappa		
	sLambda		
	nTDT		
	cMPO		



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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
T,B,CD15 cell separation	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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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: 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"	
	<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



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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 Anti-RNP 68 Ab Anti-Scl-70 Ab Anti-Jo-1 Ab Anti-Centromere Ab	Bioplex 2200 analyser. Multiplexing bead based flow cytometric principles: BS-SOP-OP-AIMM-71	RVI
	Anti-MPO Ab Anti PR3 Ab Anti GBM Ab	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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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
Serum	Pemphigoid Ab Pemphigus Ab Adrenal Ab Islet Cell Ab Purkinje Cell Ab Anti Neuronal Nuc. Ab	Hamilton Dilutor, Slide Trays, Moisture Chamber and immunofluorescence microscope: 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)	<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	<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>BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77</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:	RVI
Serum (cont'd)	<p>Specific IgE Antibodies to include: (cont'd)</p> <p>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</p>	<p>BS-SOP-OP-AIMM-69 BS-SOP-OP-AIMM-76 BS-SOP-OP-AIMM-77</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:	RVI
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	



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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 Weed mix 3	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>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:	
Serum	Paraproteins	Sebia CapillaryS using capillary electrophoresis in free solution followed by immunotyping	RVI
Urine	Paraproteins	Sebia Hydrasys using hydra gel protein kits BS-SOP-OP-Prot-8 BS-SOP-OP-Prot-20	RVI
Blood	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants:	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"	
	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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Dried Blood Spots	Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants:	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
	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	
Serum	Quantitative determination of:	Binding site RID Plates immunoassay::	RVI
	Complement: Comp I Comp H AP100	BS-SOP-OP-Prot-22 BS-SOP-OP-Prot-22 BS-SOP-OP-Prot-21	
Serum	C3 Nephritic Factor	Sebia Hydrasys using immunofixation:	RVI
		BS-SOP-OP-Prot-29	
		Sebia Hydrasys & kit using immunofixation and enzymes:	RVI
CSF	Oligoclonal banding	BS-SOP-OP-Prot-12	
END			