

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9862 Accredited to ISO 15189:2012	Leeds Teaching Hospitals NHS Trust	
	Issue No: 005 Issue date: 06 October 2020	
	Leeds General Infirmary Old Medical School Great George Street LS1 3EX	Contact: Dan Carless Tel: +44 (0)113 39 25697 E-Mail: Daniel.carless1@nhs.net Website: https://www.leedsth.nhs.uk/a-z-of-services/pathology/blood-sciences/

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 Blood Sciences Leeds General Infirmary Old Medical School Great George Street LS1 3EX	Biochemistry and Haematology laboratory service	LGI
Paediatric Clinic Leeds General Infirmary Old Medical School Great George Street LS1 3EX	Full blood count testing	B
Blood Sciences St James's University Hospital Chancellor Wing Beckett Street LS9 7TF	Biochemistry and Haematology laboratory service	SJUH
Oncology Clinic Ward J87 St James's University Hospital Bexley Wing Beckett Street LS9 7TF	Full blood count testing	D



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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>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSF2BSB054 (XPT) and BSF2BSB059 (Atellica). General Biochemistry:	
Serum, Plasma	Adjusted/corrected Calcium	By calculation	LGI SJUH
Serum, CSF	Angiotensin Converting Enzyme	Enzymatic kinetic assay	LGI
Serum, Plasma	Albumin	Colourimetric bromocresol purple (BCP) dye-binding	LGI SJUH
Serum, Plasma	Alanine amino-transferase ALT	Modified IFCC enzymatic assay	LGI SJUH
Serum, Plasma	Alkaline phosphatase ALP	IFCC standardised enzymatic assay	LGI SJUH
Plasma	Ammonia	GLDH Catalysis	LGI SJUH
Serum, Plasma	Amylase	Ethylidene Blocked-pNPG7	LGI SJUH
Serum, Plasma	Aspartate amino-transferase AST	Modified IFCC enzymatic assay	LGI SJUH
Serum, Plasma	Bicarbonate	Enzymatic kinetic assay	LGI SJUH
Serum	Bile Acid	Colourimetric enzymatic assay	LGI
Serum, Plasma	Bilirubin	Vanadate Oxidation	LGI SJUH
Serum, Plasma, Urine	Calcium	Arsenazo III colourimetric	LGI SJUH



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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>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSF2BSB054 (XPT) and BSF2BSB059 (Atellica). General Biochemistry: (cont'd)	
Serum, Plasma, Urine	Chloride	Ion selective electrode - diluted	LGI SJUH
Serum, Plasma	Cholesterol (total)	Enzymatic, Trinder endpoint	LGI SJUH
Serum, Plasma	Conjugated Bilirubin	Vanadate oxidation	LGI SJUH
Serum, Plasma	C-reactive Protein	Latex-enhanced immunoturbidimetric	LGI SJUH
Serum, Plasma	Creatine Kinase	NAC Activated, IFCC	LGI SJUH
Serum, Plasma, Urine	Creatinine	enzymatic	LGI SJUH
Serum, Plasma	eGFR	CKD-EPI Equation	LGI SJUH
Plasma	Ethanol	Enzyme Multiplied Immunoassay Technique (EMIT)	LGI SJUH
Serum, Plasma	Gamma GT	Modified IFCC enzymatic assay	LGI SJUH
Plasma	Glucose	Glucose Oxidase Trinder	LGI SJUH
Serum, Plasma	HDL-Cholesterol	Elimination/ catalase	LGI SJUH
Serum	Iron	Colourimetric	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSF2BSB054 (XPT) and BSF2BSB059 (Atellica). General Biochemistry: (cont'd)	
Plasma	Lactate	Lactate Oxidase, colourimetric	LGI SJUH
Serum, Plasma	Lactate Dehydrogenase LDH	Pyruvate/ Reduced NADH	LGI SJUH
Serum, Plasma	LDL	Friedwald Calculation	LGI SJUH
Serum, Plasma, Urine	Magnesium	Colourimetric, Xylidyl Blue	LGI SJUH
Serum, Plasma, Urine	Phosphate	Phosphomolybdate/UV	LGI SJUH
Serum, Plasma, Urine	Potassium	Ion selective electrode - diluted	LGI SJUH
Serum, Plasma	Protein (Total)	Biuret	LGI SJUH
Serum, Plasma	Salicylate	Enzymatic	LGI SJUH
Serum, Plasma, Urine	Sodium	Ion selective electrode - diluted	LGI SJUH
Serum	Total Iron Binding Capacity	Sequential release and uptake of iron, spectrophotometric	LGI SJUH
Serum, Plasma	Triglycerides	GPO-Trinder	LGI SJUH
Serum, Plasma, Urine	Urate	Enzymatic uricase/peroxidase	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSF2BSB054 (XPT) and BSF2BSB059 (Atellica). General Biochemistry: (cont'd)	
Serum, Plasma, Urine	Urea	Enzymatic urease with glutamate dehydrogenase (GLDH)	LGI SJUH
Urine	Microalbumin	Polyethyleneglycol (PEG)-enhanced	LGI SJUH
Urine	Protein	Immunoturbidimetric assay	LGI SJUH
Serum	Alpha 1 Antitrypsin	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	C3	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	C4	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	Rheumatoid Factor	Latex-enhanced immunoturbidimetric	LGI
Serum	IgA	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	IgG	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	IgM	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSF2BSB054 (XPT) and BSF2BSB059 (Atellica). Therapeutic Drug Monitoring:	
Serum, Plasma	Carbamazepine	Enzyme Multiplied Immunoassay Technique (EMIT)	LGI
Serum	Digoxin	Latex-enhanced immunoturbidimetric	LGI SJUH
Serum, Plasma	Lithium	Colourimetric, endpoint	LGI SJUH
Serum, Plasma	Methotrexate	Enzyme immunoassay	LGI SJUH
Serum, Plasma	Paracetamol	Enzymatic	LGI SJUH
Serum, Plasma	Phenobarbitone	EMIT	LGI
Serum, Plasma	Phenytoin	EMIT	LGI
Serum	Theophylline	EMIT	LGI SJUH
Serum, Plasma	Valproate	EMIT	LGI
Serum, Plasma	Gentamicin	EMIT	LGI SJUH
Serum, Plasma	Tobramycin	EMIT	LGI SJUH
Serum, Plasma	Vancomycin	EMIT	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated		Siemens Immulite XPi using suppliers' methods unless otherwise stated and SOP: BSF2BSI042 Immunoassay	
EDTA Plasma	ACTH	Solid phase two-site sequential chemiluminescent immunometric assay	LGI
Serum	Growth Hormone	Solid phase two-site sequential chemiluminescent immunometric assay	LGI
Serum	IGF-1	Solid phase enzyme labelled chemiluminescent immunometric assay	LGI
Plasma	NT-Pro BNP	Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI041 (Centaur XPT), BSF2BSB059 (Atellica). Immunoassay:	LGI SJUH
Serum	AFP	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	CA15-3	Chemiluminescent two-step sandwich immunoassay	LGI SJUH
Serum	CA19-9	Chemiluminescent two-step sandwich immunoassay	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Immulite XPi (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI042 (Immulite), BSF2BSB059 (Atellica). Immunoassay	
Serum	CA125	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	CEA	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum unless otherwise stated		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI041 (Centaur XPT); BSF2BSB059 (Atellica). Immunoassay:	
Serum	25OH Vitamin D	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Cortisol	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	ELF Score (enhanced liver fibrosis score)	By calculation	LGI SJUH
Serum	Ferritin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Folate	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Free T4	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	FSH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Immulite XPi (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI042 (Immulite), BSF2BSB059 (Atellica). Immunoassay	
Serum	HCG (total) for the purposes of pregnancy marker only	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Hyaluronic Acid (HA)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	LH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Oestradiol	Chemiluminescent competitive immunoassay	LGI SJUH
Serum unless otherwise stated (cont'd)		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI041 (Centaur XPT); BSF2BSB059 (Atellica). Immunoassay:	
Serum	Parathyroid Hormone	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Procalcitonin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Pro collagen type III	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Progesterone	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Prolactin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI041 (Centaur XPT); BSF2BSB059 (Atellica). Immunoassay:	
Serum	Prostate Specific Antigen (PSA)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	SHBG	Chemiluminescent two-site sandwich immunoassay	LGI
Serum	Testosterone	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Tissue inhibitor of matrix metalloproteinase (TIMP-1)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Thyroid Peroxidase Ab (TPO)	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Total T3	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Troponin I	High-sensitivity Chemiluminescent three-site sandwich immunoassay	LGI SJUH
Serum	TSH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Vitamin B12	Chemiluminescent competitive immunoassay	LGI SJUH
Serum, Plasma, Urine	Osmolality	Advanced Instruments Osmometer 2020, freezing point depression using suppliers' methods unless otherwise stated and SOP BSF2BSIT015	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSF2BSI041 (Centaur XPT); BSF2BSB059 (Atellica). Immunoassay:	
EDTA Whole Blood	Haemoglobin HbA1c	TOSOH G8 HPLC using suppliers' methods unless otherwise stated and SOP BSF2BSIT027	LGI
Serum unless otherwise stated		Beckman Access II using suppliers' methods unless otherwise stated and SOP BSF2BSIT047. Immunoassay:	
Serum	Erythropoietin	Two-site immunoenzymatic ("sandwich") assay	LGI
Serum	Intrinsic Factor Antibody	Competitive binding immunoenzymatic assay	LGI
Serum	Thyroglobulin	Simultaneous one-step immunoenzymatic ("sandwich") assay	LGI
Serum	Thyroglobulin Antibody II	Sequential two-step immunoenzymatic ("sandwich") assay	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA Whole Blood	Full Blood Count (Red Blood Cells, White Blood Cells, Haemoglobin, MCV, MPV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Monocytes, Platelets, Reticulocytes)	Siemens Advia 2120i Cytochemical flow cell technology using suppliers' methods unless otherwise stated and SOP BSF2BSH001	LGI SJUH
EDTA Whole Blood	Detection of normal and abnormal morphologies with WBC differential count where indicated	Blood film assessment (peripheral) with microscopic analysis Advia Autoslide Siemens Hematek Staining Unit for: <ul style="list-style-type: none"> • Preparation and staining of adult samples • Staining only of paediatric/low volume adult samples that have been prepared manually Manual film preparation and staining - requesting, prep and staining [SOP BSF2BSH027] How to Report a Blood Film [SOP BSF2BSH032] Blood Film Selection criteria and referral guidance [SOP BSF2BSH015]	LGI LGI & SJUH
EDTA Whole Blood	Infectious Mononucleosis screen (detection of infectious mononucleosis heterophile antibodies)	Accusay Mono IM kit [SOP BSF2BSH006]	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA Whole Blood	Detection of malarial parasites: Parasite detected/not detected. Speciated from morphology: P. falciparum, P. vivax, P. ovale, P. malariae, P. knowlesi	Manual thick (field stain A and B) and thin (Giemsa stain) blood film examination using light I microscopy [SOP BSF2BSH031]	LGI SJUH
EDTA Whole Blood	Detection of Plasmodium spp. DNA	Alethia Malaria molecular assay using the Alethia Incubator/reader. Amplification and detection of a specific region of the plasmodium genome via loop-mediated amplification (LAMP) technology, [SOP BSF2BSH037]	LGI SJUH
EDTA Whole Blood	Sickle cell solubility	Sickle Check Kit (detection of haemoglobin S) BSF2BSH028	LGI SJUH
Citrated Plasma	APTT	Werfen TOP BSF2BSC005 Turbidimetric endpoint detection	LGI SJUH
Citrated Plasma	Clauss Fibrinogen		LGI SJUH
Citrated Plasma	DDimer level		LGI SJUH
Citrated Plasma	Derived Fibrinogen		LGI SJUH
Citrated Plasma	INR		LGI SJUH
Citrated Plasma	LMW Heparin (Anti Xa)		LGI SJUH
Citrated Plasma	Prothrombin Time		LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Citrated Plasma	Thrombin Time		LGI <u>SJUH</u>
Citrated Plasma	Reptilase		LGI
EDTA Plasma	Plasma Viscosity	Benson Viscometer (distance travelled using constant pressure / time) using suppliers' methods unless otherwise stated and SOP BSF2BSH002	LGI <u>SJUH</u>
EDTA Plasma	Erythrocyte Sedimentation Rate	Starrsed auto compact infrared absorption readings of red cell sedimentation using suppliers' methods unless otherwise stated and SOP BSF2BSH020	LGI
EDTA Plasma	Glucose-6-Phosphate Dehydrogenase (G6PD)	Glucose-6-Phosphate Dehydrogenase (G6PD) assay. Spectrophotometric assay, absorbance at 345 nm using suppliers' methods unless otherwise stated and SOP BSF2BSH023	SJUH
EDTA Whole Blood	Full Blood Count (Red Blood Cells, White Blood Cells, Haemoglobin, MCV, MPV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Monocytes, Platelets, Reticulocytes)	ADVIA 2120i Cytochemical flow cell technology using suppliers' methods unless otherwise stated and SOP BSF2BSH001	B D
END			