


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	University Hospitals of North Midlands NHS Trust Issue No: 018 Issue date: 11 November 2024	
	Biochemistry Department University Hospitals of North Midlands NHS Trust Leighton Hospital Middlewich Road Crewe CW1 4QJ United Kingdom	Contact: Laura Kinghorn-Perry, Pathology Quality Manager Tel: +44 (0)1782 679664 E-Mail: laura.kinghorn-perry@uhnm.nhs.uk Website: www.uhnm.nhs.uk

Testing performed by the Organization at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Leighton Hospital Middlewich Road Crewe CW1 4QJ United Kingdom Local contact As above	Biochemistry activities to assist with clinical diagnosis	A
Macclesfield District General Hospital Victoria Road Macclesfield SK10 3BL United Kingdom Local contact As above	Biochemistry activities to assist with clinical diagnosis	B



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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>General Biochemistry</u>		
Serum / Plasma (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis.	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of:	SOP CBAU 001 using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) with the following kits and measurement principles:	
	Albumin	Glenbio BCP reagent – BCP (Bromocresol Purple) method.	A, B
	Alkaline-Phosphatase	Beckman Reagent - ALP / Beckman calibrator P-NPP IFCC method.	A, B
	ALT	Beckman reagent - ALT/ IFCC 2-oxoglutarate method.	A, B
	Ammonia	Thermo Scientific Infinity reagent - Direct Enzymatic method.	A, B
Urine also	Amylase	Beckman reagent - Amylase/IFCC with alpha-glucosidase method.	A, B
	AST	Beckman reagent - AST/ IFCC 2-oxoglutarate method.	A
	β -2 Microglobulin	Beckman reagent – immunoturbidimetric method.	A
	Bicarbonate	Beckman reagent - CO ₂ / NIST PEP method.	A, B
	Bile Acids	Sentinel Diagnostics reagent - enzymatic colourimetric (formazan dye) method.	B
Urine also	Calcium	Beckman reagent - Calcium / Arsenazo III method.	A, B



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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>General Biochemistry</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis.(cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) with the following kits and measurement principles:	
Serum/Plasma	Chloride	Beckman reagent - Indirect ISE method.	A, B
Urine also	Cholesterol	Beckman reagent - NIST homogenous method.	A, B
Urine also	Creatinine	Beckman reagent – enzymatic method.	A, B
	Creatinine Kinase	Beckman reagent - IFCC 6GP method.	A, B
	CRP	Beckman reagent - IFCC method.	A, B
	Digoxin	Beckman reagent – Immunoturbidimetric method	A, B
Serum/Plasma	Direct Bilirubin	Beckman reagent - DPD azobilirubin – accel method.	A, B
Urine also	Gentamicin	Beckman reagent – enzyme immunoassay method.	A, B
	YGT	Beckman reagent - IFCC enzymatic method.	A, B
CSF also	Glucose	Beckman reagent - hexokinase method.	A, B
	HDL-Cholesterol	Beckman reagent - enzymatic method.	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>General Biochemistry</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman Coulter DxC 700 AU (B) with the following kits and measurement principles:	
	Immunoglobulins (IgA, IgG, IgM)	Beckman reagents - Immunoturbidimetric method.	B
	Iron	Beckman reagent – TPTZ colorimetric method.	A, B
Plasma only	Lactate	Beckma reagent - Lactate to pyruvate method	A, B
	LDH	Beckman reagent - IFCC Pyruvate to lactate method.	A, B
	Lithium	Thermo Scientific Infinity reagent - Porphyrin spectrophotometric method.	A, B
Serum, Plasma, urine	Magnesium	Beckman reagent - Xylidyl blue method.	A, B
Urine only	Microalbumin	Beckman reagent - Turbidimetric method.	A, B
	Paracetamol	SOP CBPCMIFU using Cambridge Life Science Enzymatic Assay	A, B
Urine also	Phosphate	Beckman reagent – Molybdate method.	A, B
Urine also	Potassium	Beckman - Indirect ISE method.	A, B
	Rheumatoid Factor	Beckman reagent – Immuno-Turbidimetric method.	A



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HUMAN BODY FLUIDS (cont'd)	<u>General Biochemistry</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) with the following kits and measurement principles:	
	Salicyclate	Siemens Enzymatic reagent – enzymatic reagent.	A, B
Urine also	Sodium	Beckman reagent - Indirect ISE method.	A, B
	Theophylline	Beckman reagent - Enzymatic immunoassay method.	A, B
	Tobramycin	SOP CBTOBIFU using Siemens Enzymatic Assay	A
	Total Bilirubin	Beckman reagent - DPD azobilirubin + accel method.	A, B
Also Urine, CSF	Total Protein	Beckman reagent - Pyrogallol Red method	A, B
	Transferrin	Beckman reagent – Immunoturbidimetric method	A, B
	Triglycerides	Beckman reagent – enzymatic method IDMS traceable	A, B
Urine also	Urea	Beckman reagent - kinetic UV method.	A, B
Urine also	Uric Acid (Urate)	Beckman reagent – Trinders method.	A, B
	Vancomycin	Beckman reagent – enzyme immunoassay method	A,B



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HUMAN BODY FLUIDS (cont'd)	<u>General Biochemistry</u> (cont'd)		
Serum/Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
Whole Blood (EDTA)	HbA1c for Diabetic Monitoring	Documented in-house procedure SOP CBGEN 018 in conjunction with manufacturers instructions for analysis using TOSOH G11 HPLC analyser (Ion Exchange chromatography)	A, B
Urine only	Drugs of abuse screening: Cocaine Cannabis Methadone Benzodiazepine Amphetamines Opiates	Documented in-house procedure CBGEN 017 using Surestep Drugs of Abuse kit	A
Serum	Detection of normal and abnormal electrophoretic patterns and quantitation of Monoclonal paraprotein Bands	Documented in-house procedures SOPs CBGEN008, CBGEN 015 in conjunction with manufacturers instructions for analysis by capillary electrophoresis using Sebia Capillarys III Octa Analyser	B
Serum and Urine	Immunotyping	Documented in-house procedures SOPs CBGEN010, CBGEN016, CBP263 in conjunction with manufacturers instructions for analysis by capillary electrophoresis using Sebia Capillarys III OctaAnalyser	B
Serum and Urine	Detection of normal and abnormal electrophoretic patterns and quantitation of Monoclonal paraprotein Bands	Documented in-house procedures SOPs CBGEN009, CBGEN 015 in conjunction with manufacturers instructions for analysis by gel electrophoresis using Sebia Hydrasys 2	B



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HUMAN BODY FLUIDS (cont'd)	<u>General Biochemistry</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of: (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
Plasma, Serum & Urine	Osmolality	Documented in-house procedure CBGEN 003 001 in conjunction with manufacturers instructions for analysis using OSMO 1 Osmometer	A, B
Sweat	Sweat chloride concentration	Documented in-house procedure SOP CBGEN004 in conjunction with manufacturers instructions for analysis by conductivity using ChloroCheck 3400 Chloridometer	A
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of: (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
CSF only	Xanthochromia	Documented in-house procedure SOPs CBGEN007 in conjunctions with manufactuers instructions for analysis using NorthStar Bio-UV Spectrophotometer	A, B



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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>Immunoassay</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of: (cont'd)	SOP CBIA 001 using Beckman Coulter Dxl 800 Access chemiluminescent immunoassay kits	
	SHBG		A
	Testosterone		A
	TPO		A
	Troponin I	SOP CBTROPIFU using Beckman High Sensitivity Assay on the Beckman DXI Analyser -	A, B
	TSH	(using Beckman Access TSH (3 rd IS) reagent	A, B
	Vitamin B12		A, B
	Vitamin D 25 OH Vitamin D		B
	Quantification of:	Calculation from generated results using using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) unless otherwise stated	
	Urine Calcium (24 hours)	By calculation	A, B
	Urine Chloride (24 hours)	By calculation	A, B
	Urine Creatinine (24 hours)	By calculation	A, B
	Urine Potassium (24 hours)	By calculation	A, B
	Urine Magnesium (24 hours)	By calculation	A, B
	Urine Sodium (24 hours)	By calculation	A, B
	Urine Phosphate (24 hours)	By calculation	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Immunoassay</u> (cont'd)		
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
	Quantification of: (cont'd)	Calculation from generated results using using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) unless otherwise stated	
	Urine Total protein (24 hours)	By calculation	A, B
	Urine Urate (24 hours)	By calculation	A
	Urine Urea (24 hours)	By calculation	A, B
	Adjusted calcium	By calculation	A, B
	Anion Gap	By calculation	A, B
	AKI Warning stage	By calculation	A
	Aldesterone/Renin ratio	By calculation (from referred results)	A, B
	C-Peptide/Insulin ration	By calculation (from referred results)	A, B
	Creatinine clearance	By calculation	A, B
	Urine Amylase/Creatinine ratio	By calculation	A, B
	eGFR (CKD-EPI)	By calculation	A, B
	Free Androgen index	By calculation (Beckaman Dxl 800)	A
	Fluid osmolality	By calculation (OSMO 1)	A, B
	IGF-1/IGF-2 ratio	By calculation (from referred results)	A, B
	LDL Cholesterol	By calculation	A, B
	Non-HDL Cholesterol	By calculation	A, B



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HUMAN BODY FLUIDS (cont'd) Serum / Plasma (unless otherwise stated) (cont'd)	<u>Immunoassay</u> (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. (cont'd) Quantification of: (cont'd) Osmolarity Total/HDL cholesterol ratio Transferin saturation Urine Albumin/Creatinine ratio Urine osmolarity Urine Protein/Creatinine ratio Urine Urate/Creatinine ratio	In-house documented procedures based on equipment manuals and standard methods as specified: Calculation from generated results using using Beckman Coulter AU5800 (A) SOP CBAU 005 using Beckman DxC 700 AU (B) unless otherwise stated By calculation (OSMO 1)) By calculation By calculation By calculation By calculation (OSMO 1) By calculation By calculation	 A, B A, B A, B A, B A, B A, B A, B
END			