Schedule of Accreditation

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8083

Accredited to ISO 15189:2022

University Hospitals of North Midlands NHS Trust

Issue No: 021 **Issue date:** 11 September 2025

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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

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
	Bicarbonate	Beckman reagent - CO2/ 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (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
	Gentamicin	Beckman reagent – enzyme immunoassay method.	A, B
	ɣGT	Beckman reagent - IFCC enzymatic method.	A, B
CSF also	Glucose	Beckman reagent - hexokinase method.	A, B
	HDL-Cholesterol	Beckman reagent - enzymatic method.	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (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 001using Beckman Coulter AU5800 (A) SOP CBAU 005using 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	Lactate	Beckman reagent - Lactate to pyruvate method	A, B
CSF	Lactate	Beckman reagent - Lactate to pyruvate method	A
	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (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
	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (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 015in conjunction with manufacturers instructions for analysis by gel electrophoresis using Sebia Hydrasys 2	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (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 Chloridemeter	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

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>		
Serum / Plasma (unless otherwise stated) (cont'd)	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 CBIA 001 using Beckman Coulter DxI 800 Access chemiluminscent immunoassay kits	
	PTH		A
	Cortisol		A, B
	Ferritin		A, B
	Folate		A, B
	FSH		A, B
	FT3		A, B
	FT4		A, B
	hCG		A, B
	LH		A, B
	Prolactin		A
	PSA		A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunoassay (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 DxI 800 Access chemiluminscent immunoassay kits	
	Troponin I	SOP CBTROPIFU using Beckman High Sensitivity Assay on the Beckman DXI Analyser -	A, B
	TSH	(using Beckman Access TSH (3rd IS) reagent	A, B
	Vitamin B12		A, B
	Vitamin D 25 OH Vitamin D		A, 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (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) from referred results	A
	Fluid osmolarity	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (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	
	Osmolarity	By calculation (OSMO 1))	A, B
	Total/HDL cholesterol ratio	By calculation	A, B
	Transferin saturation	By calculation	A, B
	Urine Albumin/Creatinine ratio	By calculation	A, B
	Urine osmolarity	By calculation (OSMO 1)	A, B
	Urine Protein/Creatinine ratio	By calculation	A, B
	Urine Urate/Creatinine ratio	By calculation	A, B
END			