


# 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	<b>University Hospitals of North Midlands NHS Trust</b>	
	Issue No: 010 Issue date: 28 January 2022	
	<b>Biochemistry Department</b> University Hospitals of North Midlands NHS Trust Leighton Hospital Middlewich Road Crewe CW1 4QJ United Kingdom	<b>Contact: Jane Clarke</b> Tel: +44 (0)1270612345 Fax: +44 (0)1270250639 E-Mail: jane.clarke@mcht.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  <b>Local contact</b> Jane E Clarke	Biochemistry activities to assist with clinical diagnosis	A
Macclesfield District General Hospital Victoria Road Macclesfield SK10 3BL United Kingdom  <b>Local contact</b> Jane E Clarke	Biochemistry activities to assist with clinical diagnosis	B

#### Site activities performed away from the locations listed above:

Location details	Activity	Location code
Krishnan Chandran Children's centre Middlewich Road Crewe CW1 4QJ United Kingdom	Sweat test sample using wescor macroduct sweat collection system	KCC



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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  Serum / Plasma (unless otherwise stated)	<u>General Biochemistry</u>  Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In-house documented procedures based on equipment manuals and standard methods as specified:  SOP CBAU 001 using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) with the following kits and measurement principles:	
	Albumin	Glenbio BCP reagent – BCP (Bromocresol Purple) method.	A, B
	Alcohol	Microgenics DRI reagent – enzymatic method.	A
	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 <sub>2</sub> / NIST PEP method.	A, B
	Bile Acids	Sentinel Diagnostics reagent - enzymatic colourimetric (formazan dye) method.	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. Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) with the following kits and measurement principles:	
	Carbamazepine	Beckman reagent -enzymatic spectrophotometric method.	B
Urine also	Calcium	Beckman reagent - Calcium / Arsenazo III method.	A, B
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
	γGT	Beckman reagent - IFCC 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. Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) with the following kits and measurement principles:	
CSF also	Glucose	Beckman reagent - hexokinase method.	A, B
	HDL-Cholesterol	Beckman reagent - enzymatic method.	A, B
	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	Magnesium	Beckman reagent - Xylidyl blue method.	A, B
Urine also			
Urine only	Microalbimin	Beckman reagent - Turbidimetric method.	A, B
	Paracetamol	SOP CBPCMIFU using Cambridge Life Science Enzymatic Assay	A, B
	Phenytoin	Beckman reagent - Enzymatic spectrophotometric method.	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)	SOP CBAU 001 using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) with the following kits and measurement principles:	
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
	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



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HUMAN BODY FLUIDS (cont'd)	<u>General Biochemistry (cont'd)</u>		
Serum/Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis		
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
Serum / Plasma (unless otherwise stated) (cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of: (cont'd)	SOP CBAU 001 using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) with the following kits and measurement principles:	
Urine also	Urea	Beckman reagent - kinetic UV method.	A, B
Urine also	Uric Acid (Urate)	Beckman reagent – Trinders method.	A, B
	Valproic Acid	Beckman reagent - enzymatic immunoassay method.	B
	Vancomycin	Thermo Scientific QMS Reagent – Immunoturbidimetric method.	B
Urine only	Drugs of abuse screening: Cocaine Cannabis Methadone Benzodiazepine Amphetamines Opiates	Documented in-house procedure CBGEN 017 using Alere Drugs of Abuse kit	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. Quantification of: (cont'd)	In-house documented procedures based on equipment manuals and standard methods as specified:	
Arterial Whole Blood	Blood Gas Analysis: pH pCO <sub>2</sub> pO <sub>2</sub> O <sub>2</sub> -HbO <sub>2</sub> saturation (sO <sub>2</sub> ) Lactate Carboxyhaemoglobin (CO-Hb) Methaemoglobin (Meth -Hb) Standard Bicarbonate (calculated) (HCO <sub>3</sub> ) Base excess (calculated)	Documented in-house procedure SOP CBGEN 002 in conjunction with manufacturers instructions for analysis using IL GEM 5000 analyser by Blood Gase & Co-Oximetry	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 II Flex Piercing Analyser	, 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	, B
Plasma, Serum & Urine	Osmolality	Documented in-house procedure CBGEN 003 001 in conjunction with manufacturers instructions for analysis using Vitech Scientific Freezing Point Depression	A
Sweat	Sweat chloride concentration	Documented in-house procedure SOP CBGEN004 in conjunction with manufacturers instructions for analysis by conductivity using ChloroCheck 3400 Chloridimeter	A



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum / Plasma (unless otherwise stated) (cont'd)</p> <p>CSF only</p>	<p><u>General Biochemistry</u> (cont'd)</p> <p>Biochemical examination activities for the purposes of clinical diagnosis. Quantification of: (cont'd)</p> <p>Xanthochromia</p>	<p>In-house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Documented in-house procedure SOPs CBGEN007 in conjunctions with manufacturers instructions for analysis using Cecil Spectrophotometer</p>	<p>A, B</p>





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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Serum / Plasma (unless otherwise stated)	<u>Immunoassay</u>	In-house documented procedures based on equipment manuals and standard methods as specified:  SOP CBIA 001 using Beckman Coulter Dxl 800 Access chemiluminescent immunoassay kits  SOP CBIA 001 using Beckman Coulter Dxl and Alere two-site immunoenzymatic sandwich assay  Using Beckman sensitive Oestradiol assay	
	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:		
	AFP		A
	BNP		B
	CA-119		A
	CA-125		A
	CEA		A, B
	Cortisol		A, B
	Ferritin		A, B
	Folate		A, B
	FSH		A, B
	FT3		A, B
	FT4		A, B
	hCG		A, B
	LH		A, B
	Oestradiol		A
	Progesterone		A
Prolactin	A		
PSA	A, B		
PTH	A		



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Serum / Plasma (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	In-house documented procedures based on equipment manuals and standard methods as specified:  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 <sup>rd</sup> IS) reagent	A, B
	Vitamin B12		A, B
	Vitamin D 25 OH Vitamin D		B
	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	Calculation from generated results using using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (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	
Urine Total protein (24 hours)	By calculation	A, B	



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	Biochemical examination activities for the purposes of clinical diagnosis. Quantification of:	Calculation from generated results using using Beckman Coulter AU580 (A) SOP CBAU 002 using Beckman Coulter AU680 (B) unless otherwise stated	
	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 (Beckman Dxl 800)	A
	Fluid osmolarity	By calculation (Vitech Scientific Freezing Point Depression)	A
	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
	Osmolarity	By calculation (Vitech Scientific Freezing Point Depression)	A
	Total/HDL cholesterol ratio	By calculation	A, B
	Transferin saturation	By calculation	A, B



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	Urine Albumin/Creatinine ratio	By calculation	A, B
	Urine osmolarity	By calculation (Vitech Scientific Freezing Point Depression)	A
	Urine Protein/Creatinine ratio	By calculation	A, B
	Urine Urate/Creatinine ratio	By calculation	A, B
END			