## **Schedule of Accreditation**

issued by

# **United Kingdom Accreditation Service**

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



8549

Accredited to ISO 15189:2012

## **Lancashire Teaching Hospitals NHS Foundation Trust**

Issue No: 012 Issue date: 14 February 2024

**Department of Clinical Biochemistry** 

**Royal Preston Hospital** 

**Sharoe Green Lane** 

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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 Clinical Biochemistry Royal Preston Hospital Sharoe Green Lane Fulwood Preston PR2 9HT United Kingdom	Local contact Amanda Southworth	General Biochemistry Immunoassay Metabolic Biochemistry Molecular Haematology	A
Biochemistry Department Chorley & South Ribble Hospital Preston Road Chorley PR7 1PP United Kingdom		General Biochemistry	В

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# United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

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Issue No: 012 Issue date: TBC

Testing performed by the Organisation at the locations specified

#### **DETAIL OF ACCREDITATION**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (as stated)	Biochemical examination activities for the purposes of clinical diagnosis.  General Biochemistry	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Quantification of:	SOPs using Roche Cobas 8000 (Site A; consists of tracked ISE, c702 & e801 modules across two lines) and Roche Cobas PURE (Site B: consists of modules 303, 801, across two instruments), all with Roche modular pre-analytical systems and with specific reference to:	
Serum	ACE	SBI-125 (by colourimetry)	А
Serum	Albumin	SBI-126 (by colourimetry)	A & B
Urine	Albumin Creatine Ratio	SBI-14 (calculated)	А
Urine	Albumin	SBI-170 (by immunoturbidimetry)	А
Serum	Amikacin	SBI-300 (by KIMS)	А
Plasma	Ammonia	SBI-129 (by colourimetry)	A & B
Serum & Urine	Amylase	SBI-131 (by colourimetry)	A & B (urine at A only)
Serum	ALP	SBI-127 (by colourimetry)	A & B
Serum	ALT	SBI-128 (by colourimetry)	A & B
Serum	AST	SBI-132 (by colourimetry)	А
Urine	Benzodiazepines	SBI-286 (by KIMS)	А
Urine	Cannabinoids	SBI-287 (by KIMS)	А
Serum	Beta Hydroxy Butyrate Dehydrogenase (BHBD)	SBI-248 (by colourimetry)	А
Serum	Bicarbonate	SBI-134 (by colourimetry)	A & B
Serum	Bile Acids	SBI-135 (by spectrophotometry)	Α

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HUMAN BODY FLUIDS (cont'd) (as stated)	Biochemical examination activities for the purposes of clinical diagnosis.  General Biochemistry	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Quantification of: (cont'd)	SOPs using Roche Cobas 8000 (Site A; consists of tracked ISE, c702 & e801 modules across two lines) and Roche Cobas PURE (Site B: consists of modules 303, 801, across two instruments), all with Roche modular pre-analytical systems and with specific reference to:	
Serum	Caeruloplasmin	SBI-230 (by colourimetry)	А
Urine	Cannabis	SBI-25 (by KIMS)	А
Serum	Carbamazepine	SBI-138 (by KIMS)	А
Serum & Urine	Chloride	SBI-152 (by ISE)	A & B (urine at A only)
Serum	Conjugated Bilirubin	SBI-145 (by spectrophotometry)	A
Serum	Corrected Calcium	SBI-14 (calculated)	A & B
Serum & Urine	Creatinine	SBI-142 (by colourimetry)	A & B (urine at A only)
Urine	Creatinine clearance	SBI-14 (calculated)	А
Urine	Creatinine excretion	SBI-14 (calculated)	A
Serum	Creatinine Kinase	SBI-140 (by colourimetry)	A & B
Serum	CRP	SBI-143 (by immunoturbidimetry)	A & B
Serum	c-Peptide	SBI-296 (by ECLIA)	А
Serum	Estimated GFR	SBI-14 (calculated)	A & B
Plasma & Urine	Ethanol	SBI-146 (by colourimetry)	Α
Serum	Gentamicin	SBI-238 (by spectrophotometry CEDIA)	A & B

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HUMAN BODY FLUIDS (cont'd) (as stated)	Biochemical examination activities for the purposes of clinical diagnosis.  General Biochemistry	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Quantification of: (cont'd)	SOPs using Roche Cobas 8000 (Site A; consists of tracked ISE, c702 & e801 modules across two lines) and Roche Cobas PURE (Site B: consists of modules 303, 801, across two instruments), all with Roche modular pre-analytical systems and with specific reference to:	
Plasma, Urine & CSF	Glucose	SBI-149 (by colourimetry)	A & B
Serum	γGT	SBI-147 (by colourimetry)	A & B
Serum	HDL	SBI-150 (by colourimetry)	A
Serum & Urine	Inorganic Phosphate	SBI-162 (by colourimetry)	A & B (Urine at A only)
Serum	IL-6	SBI-293 (by ECLIA)	Α
Serum	Insulin	SBI-295 (by ECLIA)	А
Serum & CSF	Lactate	SBI-153 (by colourimetry)	A & B (CSF at A only)
Serum	LDH	SBI-154 (by colourimetry)	Α
	LDL	SBI-14 (calculated)	Α
Serum	Lipid Risk Ratio	SBI-14 (calculated)	А
Serum	Lithium	SBI-83 (by colourimetry)	А
Serum	Magnesium	SBI-155 (by colourimetry)	A & B
Serum	Paracetamol	SBI-158 (by colourimetry)	A & B
Serum	Phenobarbitone	SBI-160 (by KIMS)	A
Serum	Phenytoin	SBI-161 (by KIMS)	А
Urine	Phosphate excretion	SBI-14 (calculated)	А

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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) (as stated)	Biochemical examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified below:	
	General Biochemistry		
	Quantification of: (cont'd)	SOPs using Roche Cobas 8000 (Site A; consists of tracked ISE, c702 & e801 modules across two lines) and Roche Cobas PURE (Site B: consists of modules 303, 801, across two instruments), all with Roche modular pre-analytical systems and with specific reference to:	
Serum & Urine	Potassium	SBI-152 (by ISE)	A & B (urine at A only)
Urine	Potassium excretion	SBI-14 (calculated)	А
Serum	Procalcitonin	SBI-290 (by ECLIA)	А
Serum	Salicyclate	SBI-250 (by colourimetry)	A & B
Serum & Urine	Sodium	SBI-152 (by ISE)	A & B (urine at A only)
Urine	Sodium Excretion	SBI-14 (calculated)	А
Serum	Theophylline	SBI-165 (by KIMS)	А
Serum	TIBC	SBI-14 (calculated)	A
Serum	Total Bilirubin	SBI-166 (by colourimetry)	A & B
Serum & Urine	Total Calcium	SBI-136 (by colourimetry)	A & B (urine at A only)
Serum	Total Cholesterol	SBI-139 (by colourimetry)	А
Serum	Total Iron	SBI-151 (by colourimetry)	А
Serum	Total immunoglobulins A, M & G	SBI-235 (by immunoturbidimetry)	А
Serum	Total Protein	SBI-167 (by colourimetry)	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) (as stated)	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 below:	
	General Biochemistry		
	Quantification of: (cont'd)	SOPs using Roche Cobas 8000 (Site A; consists of tracked ISE, c702 & e801 modules across two lines) and Roche Cobas PURE (Site B: consists of modules 303, 801, across two instruments), all with Roche modular pre-analytical systems and with specific reference to:	
Urine & CSF	Total Protein	SBI-172 (by immunoturbidimetry)	А
Serum	Transferrin	SBI-168 (by colourimetry)	A
Serum	Triglyceride	SBI-169 (by colourimetry)	А
Serum	Urate	SBI-173 (by colourimetry)	A
Urine	Urate excretion	SBI-14 (calculated)	A
Serum & Urine	Urea	SBI-174 (by colourimetry)	A & B (Urine at A only)
Urine	Urea excretion	SBI-14 (calculated)	А
Serum	Unconjugated Bilirubin	SBI-14 (calculated)	А
Serum	Vancomycin	SBI-239 (by colourimetry)	A & B

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#### Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Human serum 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 below:	
	<u>Immunoassay</u>		
	Quantification of:	By ECLIA using Roche Cobas 8000 (consists of tracked ISE, c702 & e801 modules) with specific reference to SOPs:	A
	AFP	SBI-26	
Serum or Plasma (LiHep)	Anti Mullerian Hormone	SBI E170 (602/801 module)	
	Ca 125	SBI-27	
	Ca 19-9	SBI-28	
	CEA	SBI-29	
	Cortisol	SBI-30	
	Digoxin	SBI-31	
	Ferritin	SBI-32	
	Folate	SBI-33	
	Free T4	SBI-36	
	Free T3	SBI-35	
	FSH	SBI-34	
	HCG (total)	SBI-47	
	LH	SBI-38	
	NT pro BNP	SBI-227	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Human serum 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 below:	
	<u>Immunoassay</u>		
	Quantification of:	By ECLIA using Roche Cobas 8000 (consists of tracked ISE, c702 & e801 modules) with specific reference to SOPs:	
	Oestradiol	SBI-40	А
	Progesterone	SBI-41	А
	Prolactin	SBI-42	А
	PSA	SBI-43	А
	PTH	SBI-44	А
	SBHG	SBI-45	А
	Testosterone	SBI-46	А
	Troponin T	SBI-48	A & B
	TSH	SBI-49	А
	Vitamin B12	SBI-50	А
	Vitamin D	SBI-201	А
	Cystatin C	SBI-279	А
	Placental Growth Factor (PIGF)	S BI PIGF 19_1	А
	Soluble fms-like tyrosine kinase-1 (sFlt-1)	S BI-sFIT-1 19_1	А
	sFlt-1/PIGF ratio	S BI PIGF 19_1	А

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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) as stated	Biochemical examination activities for the purposes of clinical diagnosis: Other Biochemistry	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Quantification of:	SOPs using IDS Isys with specific reference to:	А
	GH	SBI-71	
	IGF1	SBI-72	
Plasma	Renin	SBI-270	
Plasma	Aldosterone	SBI-271	
EDTA Whole Blood	Therapeutic drug monitoring Cyclosporin Tacrolimus	SOP SBI-267 using LCMSMS Waters Aquity UHPLC with Xevo TQD (Mass Spectrometry)	А
Urine	Drugs of Abuse: Morphine Codeine 6MAM Acetyl codeine DHC BZE Cocaine Methadone EDDP Amphetamine Metamphetamine MDA MDMA Ketamine Buprenorphine Norbuprenorphine	SOP SBI-277 using Waters Xevo TQS micro (Mass Spectrometry)	A
Urine	Detection of Cortisol	SOP SBI-268 Urine Cortisol on Xevo TQD using LCMSMS Waters Aquity UHPLC with Xevo TQD	А
Serum	Testosterone & Androstenedione	SOP SBI-285 using Waters Xevo TQS micro (Mass Spectrometry)	А
Whole blood	HbA1c	SOP SBI-69 using TOSOH G11	А

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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) as stated	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Other Biochemistry (cont')		
Serum and urine	Osmolality	SOP SB1-101 using Vitech Osmometer	А
Urine	5HIAA Metadrenaline & Normatadrenaline	SOPs SBI-255 by LCMSMS Waters Aquity UHPLC with detection by Xevo TQS micro	A
CSF	Xanthochromia	SOPs SBI-20 & 237 using UVIKON XS spectrophotometer	А
Serum	Trace metals – Copper & Zinc	SOPs SBI-181 & 182 using Perkin Elmer PinAAcle 500 Atomic Absorption Spectrophotometer	A
Sweat	Sweat tests / Sweat Chloride	SOP SBI-185 using Sherwood 926 Chloride meter	A
Urine	Porphobilinogen screen	SOP SBI-105 using Uvikon XS Spectrophotometer with RECIPE Inc. Clineasy columns PBG kit	A
Faeces	Calprotectin	SOP SBI-253 using Phadia 250 and Phadi EliA Calpro 2 kit	A
Faeces	Faecal Haemoglobin	SOP SBI-269 Faecal Immunochemical Test (FIT) using latex agglutination on the MAST OC Sensor Pledia analyser	A

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HUMAN BODY FLUIDS (cont'd) as stated	Biochemical examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
	Other Biochemistry (cont')		
Whole blood	Blood Gases:  pH (calculated) pO2 pCO2 %OXYGEN saturation Carboxyhaemoglobin Haemoglobin (Hb) Methaemoglobin Sodium (Direct ISE) Potassium (Direct ISE) Chloride (Direct ISE)	SOP SBI-263 using Radiometer ABL 90 Flex + Blood Gas Analyser	A & B (Hb at A only)
EDTA Whole Blood	HFE genotyping	SOP SBI-275 Automated Extraction of DNA using the MagNA Pure 24 system SOP SBI-274PCR for HFE genotyping on Roche Light Cycler 2.0 using the TIB Molbiol LightMix kit	A
EDTA Whole Blood	Detection of Factor 5 Leiden mutation	SOP SBI-63 Alkaline Extraction of Genomic DNA SOP-56 PCR using the cobas Factor II & Factor V duplex kit on the Cobas z480 analyser	А
EDTA Whole Blood	Detection of Prothrombin G20210A mutation	SOP SBI-63 Alkaline Extraction of Genomic DNA SOP-56 PCR using the cobas Factor II & Factor V duplex kit on the Cobas z480 analyser	A
END			

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