# **Schedule of Accreditation**

issued by

# **United Kingdom Accreditation Service**

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



8601

Accredited to ISO 15189:2012

## **Northern Care Alliance NHS Foundation Trust**

Issue No: 007 Issue date: 03 December 2021

**Royal Oldham Hospital** 

**Pathology-Biochemisrty Department** 

**Rochdale Road** 

Oldham

OL1 2JH

Contact: Michelle Hurst Tel: +44 (0) 161 656 1679

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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: Biochemistry Department Royal Oldham Hospital Rochdale Road Oldham OL1 2JH United Kingdom	Local contact: Michelle Hurst	General Biochemistry Endocrinology Toxicology	A
Essential Services Laboratory Fairfield General Hospital Rochdale Old Road Bury BL9 7TD United Kingdom		General Biochemistry Endocrinology Toxicology	В
Essential Services Laboratory North Manchester General Hospital Delaunays Road Manchester M8 5RB United Kingdom		General Biochemistry Endocrinology Toxicology	С

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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	In house documented procedures based on equipment manuals and standard methods as specified below:	
	General chemistry	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum, Plasma	Albumin	using Bromocresol purple	A, C
	Alkaline phosphatase	using Paranitrophenyl phosphate	A, C
	Alpha 1 Antitrypsin	using immunoturbidimetry	А
Serum	Alpha feto protein	using chemiluminescence	А
Serum, Plasma	Alanine amino transferase	using NADH without P-5-P	A, C
Plasma	Ammonia	using Glutamate dehydrogenase	A, C
Plasma, Serum Urine	Amylase	using 2-Chloro-p-nitrophenyl-GD maltrioside	A, C A only
Serum, plasma	Aspartamine amino transferase	using NADH without P-5-P	A, C
Serum, plasma	Bicarbonate	using PEP carboxylase	A, C
	Bile Acids	using TBA enzyme cycling	А
	Bilirubin Conjugated	using Diazo colourimetry	A, C
	Bilirubin Total	using Diazo colourimetry	A, C
Serum, Plasma Urine	Calcium	using enzymatic arsenazo III	A, C A only
Serum, Urine	Chloride	using ICT chip method indirect	A, C A only

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

measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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:	
General chemistry	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Cholesterol	using enzymatic GOD PAP	A, C
Creatine Kinase	using NAC	A, C
Creatinine	using enzymatic methods	A, C A only
C-Reactive Protein (CRP)	using immunoturbidimetry	A, C
Ethanol	using enzymatic methods	A, C A only
Gamma GT	using IFCC standardised GGCN	A, C
Glucose	using hexokinase	A, C A only
Haptoglobin	using immunoturbidimetry	А
HDL Cholesterol	using accelerator selective DHE	A, C
IGA	using immunoturbidimetry	A
IGG		А
IGM		А
	measurement  Biochemical examination activities for the purposes of clinical diagnosis (cont'd)  General chemistry  Cholesterol Creatine Kinase Creatinine  C-Reactive Protein (CRP) Ethanol  Gamma GT Glucose  Haptoglobin  HDL Cholesterol  IGA  IGG	Biochemical examination activities for the purposes of clinical diagnosis (cont'd)  General chemistry  General chemistry  Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137  Cholesterol  Creatine Kinase  Creatinine  C-Reactive Protein (CRP)  Ethanol  Gamma GT  Glucose  Haptoglobin  HDL Cholesterol  In house documented procedures based on equipment manuals and standard methods as specified below:  In house documented procedures based on equipment manuals and standard methods as specified below:  Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137 Using enzymatic GOD PAP  using immunoturbidimetry using enzymatic methods  using IFCC standardised GGCN using hexokinase  Haptoglobin  HDL Cholesterol  IGA  using immunoturbidimetry  using accelerator selective DHE using immunoturbidimetry

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Human body fluids (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:	
	General chemistry	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum, plasma	Iron	using colourimetric ferene	А
Plasma,	Lactate	using lactic acid-pyruvate enzymatic PAP	A, C
Plasma	Lactate Dehydrogenase	using IFCC 2002 lactic acid- pyruvate	A, C
Serum, plasma Urine	Magnesium	using enzymatic arsenazo III	A, C A only
Serum, plasma Urine	Phosphate	using phosphomolybdate	A, C A only
Serum, plasma	Paracetamol	using colourimetry	A, C
Serum, plasma Urine	Potassium	using ICT chip indirect method	A, C A only
Serum, plasma	Total Protein	using Biuret	A, C
Urine, CSF	Protein	using Benzemethonium chloride	А
Serum	Rheumatoid Factor	using immunoturbidimetry	А
Serum, plasma	Salicyclate	using colourimetry	A, C
Serum, Plasma, Urine	Sodium	using ICT chip indirect method	A, C A only

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Human body fluids (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:	
	General chemistry	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP 135 BC-SOP-137	
Serum	SARS CoV-2 IgG	Automated 2 step Chemiluminescent Microparticle Immunoassay	A
Serum, plasma	Transferrin	using immunoturbidimetry	А
Serum, plasma	Triglycerides	using GPO	A, C
Serum, plasma	Troponin I	using chemiluminescence	A, C
Serum, plasma, Urine	Urate	using Uricase	A, C A only
Serum Urine	Urea	using Urease	A, C A only
Serum, plasma	Vitamin D	using chemiluminescence	A
	General chemistry	Abbott Alinity by the following measurement principles using SOP's: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum, Plasma	Albumin	using Bromocresol purple	A, B
Serum, Plasma	Alkaline phosphatase	using Paranitrophenyl phosphate	А, В
Serum, Plasma	Alpha 1 Antitrypsin	using immunoturbidimetry	A
Serum	Alpha feto protein	using chemiluminescence	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 (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:	
Serum, Plasma	Alanine amino transferase	using NADH without P-5-P	A, B
Plasma	Ammonia	using Glutamate dehydrogenase	А, В
Serum, plasma	Amylase	using 2-Chloro-p-nitrophenyl-GD maltrioside	A, B
Urine		using CNPG3 substrate	Α
Serum, plasma	Aspartamine amino transferase	using NADH without P-5-P	A, B
Serum, plasma	Bicarbonate	using PEP carboxylase	A, B
Serum, plasma	Bile Acids	using TBA enzyme cycling	А
Serum, plasma	Bilirubin Conjugated	using Diazo colourimetry	А, В
Serum, plasma	Bilirubin Total	using Diazo colourimetry	А, В
Serum, plasma	CA 19-9	Using chemiluminescent microparticle Immunoassay (CMIA)	A
Serum, plasma Urine	Calcium	using enzymatic arsenazo III	A, B A
Serum, plasma	Carbamazepine	using particle enhanced turbidimetric inhibition immunoassay (PETINIA)	A
Serum Urine	Chloride	using ICT chip method indirect	A, B A
Serum, plasma	Cholesterol	using enzymatic GOD PAP	А, В
Serum, plasma	Creatine Kinase	using NAC	А, В
Serum Urine	Creatinine	using enzymatic methods	A, B A
Serum, plasma	C-Reactive Protein (CRP)	using immunoturbidimetry	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 (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:	
Serum, plasma	Ethanol	using enzymatic methods	А, В
Serum, plasma	Gamma GT	using IFCC standardised GGCN	А, В
Serum, plasma Urine	Glucose	using hexokinase	A, B A
Serum, plasma	Haptoglobin	using immunoturbidimetry	А
Serum, plasma	HDL Cholesterol	using accelerator selective DHE	А, В
Serum, plasma	IGA	using immunoturbidimetry	А
Serum, plasma	IGG	using immunoturbidimetry	А
Serum, plasma	IGM	using immunoturbidimetry	А
Serum, plasma	Iron	using colourimetric ferene	А, В
Plasma	Lactate	using lactic acid-pyruvate enzymatic PAP	A, B
Plasma	Lactate Dehydrogenase	using IFCC 2002 lactic acid- pyruvate	A, B
Serum, plasma Urine	Magnesium	using enzymatic arsenazo III	A, B A
Serum, plasma	NT pro-BNP	Using chemiluminescent microparticle Immunoassay (CMIA)	А
EDTA plasma	Parathyroid hormone	Using chemiluminescent microparticle Immunoassay (CMIA)	А
Serum, plasma Urine	Phosphate	using phosphomolybdate	A, B A
Serum, plasma	Paracetamol	using colourimetry	A, B
Serum, plasma Urine	Potassium	using ICT chip indirect method	A, B A

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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 (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:	
Serum, plasma	Procalcitonin	Using chemiluminescent microparticle Immunoassay (CMIA)	А
Serum, plasma Urine CSF	Total Protein	using Biuret using immunoturbidimetry using immunoturbidimetry	A, B A A
Serum	Rheumatoid Factor	using immunoturbidimetry	Α
Serum, plasma	Salicyclate	using colourimetry	A, B
Serum, plasma Urine	Sodium	using ICT chip indirect method	A, B A
Serum, plasma	Transferrin	using immunoturbidimetry	A, B
Serum, plasma	Triglycerides	using GPO	A, B
Serum, plasma	Troponin I	using chemiluminescence	A, B
Serum, plasma Urine	Urate	using Uricase	A, B A
Serum	Urea	using Urease	A, B
Serum, plasma	Vitamin D	using chemiluminescence	А
	Therapeutic Drug Monitoring	Abbott Architect by the following measurement principles using SOPs BC-SOP-7, BC-SOP-74, BC-SOP-75	
Serum & plasma	Carbamazepine	using enzyme immunoassay	А
Serum & plasma	Digoxin	using particle-enhanced turbidimetric inhibition	А
Serum & plasma	Gentamicin	immunoassay	A, C
Serum & plasma	Lithium	using turbidimetry	А
		using colurimetry	

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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 (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:	
	Therapeutic Drug Monitoring	Abbott Architect by the following measurement principles using SOPs BC-SOP-7, BC-SOP-74, BC-SOP-75	
Serum & plasma	Phenytoin	using enzyme immunoassay	А
Serum & plasma	Sodium Valproate	using turbidimetry	A
Serum & plasma	Theophyilline	using enzyme immunoassay	А
Serum & plasma	Vancomycin	using particle enhanced turbidimetric inhibition immunoassay	A, C
Serum & plasma	Digoxin	using particle-enhanced turbidimetric inhibition immunoassay	A
Serum & plasma	Gentamicin	using turbidimetry	A, B
Serum & plasma	Lithium	using colurimetry	Α
Serum & plasma	Phenytoin	using enzyme immunoassay	А
Serum & plasma	Sodium Valproate	using turbidimetry	Α
Serum & plasma	Theophyilline	using enzyme immunoassay	А
Serum & plasma	Vancomycin	using particle enhanced turbidimetric inhibition immunoassay	A, B

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Human body fluids (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:	
	Tumour Markers	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum & plasma	CA-125	by chemiluminescence	A
Serum & plasma	CEA		A
Serum & plasma	PSA		A, C
		Roche Cobas e411 by chemiluminescence using SOP BC-SOP-53	
Serum & plasma	CA-153	001 20 001 00	A
Serum & plasma	CA-199		
Serum & plasma	HCG Total		
Serum & plasma	NT Pro BNP		
	Tumour Markers	Abbott Alinity by the following measurement principles using SOP's: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum & plasma	CA-125	by chemiluminescence	А
Serum & plasma	CEA		А
Serum & plasma	PSA		А, В

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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 (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:	
	Blood Gases		
Whole blood	Quantitation of: Bicarbonate Actual Bicarbonate Std - calculated Base Excess - calculated Carboxyhaemoglobin Haemoglobin Methaemoglobin Oxygen Saturation - calculated Oxyhaemoglobin PCO2, PH, PO2	In house documented procedures BC-SOP-98 based on equipment manuals and standard methods using Instrumentation Laboratories GEM 4000	A, B, C
	Endocrinology	Abbott Architect by the following measurement principles using SOPs: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum & plasma	FSH FT3 FT4 HCG Pregnancy LH Progesterone Prolactin (macroprolactin) Testosterone TSH Oestradiol Sex hormone binding globulin		A A, C A, C A A A A, C A
Serum, plasma, Urine	Cortisol		A, C A only
Serum, plasma	Parathyroid	Roche e411 using electochemiluminescence BC-SOP-53	A

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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 (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:	
	Endocrinology	Abbott Alinity by the following measurement principles using SOP's: BC-SOP-74 BC-SOP-75 BC-SOP-135 BC-SOP-137	
Serum & plasma	FSH		А
Serum & plasma	FT3		А
Serum & plasma	FT4		A, B
Serum & plasma	HCG Pregnancy		A, B
Serum & plasma	LH		А
Serum & plasma	Progesterone		А
Serum & plasma	Prolactin (macroprolactin)		А
Serum & plasma	Testosterone		А
Serum & plasma	TSH		A, B
Serum & plasma	Oestradiol		А
Serum & plasma	Sex hormone binding globulin		А
Serum & plasma	Cortisol		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 (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:	
	Electrophoresis		
Serum	Detection of normal & abnormal protein electrophoretic patterns	SOP by capillary electrophoresis using BC-SOP- 46 Sebia Capillarys 2	A
Serum, urine	Detection of monoclonal components	SOP BC-SOP-45 BC-SOP-46 by gel electrophoresis using Sebia Hydrasys 2	A
Urine	Quantification of Bence Jones Protein	SOP BC-SOP-45, BC-SOP-46 by gel electrophoresis using Sebia Capillarys 2 /Hydrasys 2	A
Serum	Paraprotein quantitation	SOP BC-SOP-45, BC-SOP-46 by capillary and gel electrophoresis using Sebia Capillarys 2 /Hydrasys 2	A
Serum, urine	Osmolality	SOP BC-SOP-38 by freezing point depression using Vitech Osmometer	A, B, C
Whole blood	HbA1c	SOP BC-SOP-9 by HPLC using TOSOH G11 (x4)	А
CSF	Xanthochromia screening	SOP BC-SOP-4 by spectrophotometry using Northstar Scientific	A

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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 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:		
Sweat	Conductivity	SOP BC-SOP-18 using WESCOR system and conductance meter	А	
Sweat	Measurement of Sweat chloride	WESCOR Chlorochek Chloride meter using SOP: BC-SOP-18	А	
Urine	Urine volume	Weighing on calibrated balance using SOP: BC-SOP-37	A, B, C	
Faeces	Quantitation of haemoglobin	HM-JACKarc Faecal Immunochemical Testing (FIT) Detection System by Kyowa Medex Co. Ltd. Integrated Sphere Latex Turbidimetry Method. Using BC- SOP-139	А	
Plasma, Serum	Calculated values  Acute Kidney Injury (AKI)	Abbott Architect and Abbott Alinity using the same calculation programme Using SOP: BC-REC-4	A, B, C	
	Corrected Calcium Cholesterol/HDL ratio Serum LDL Cholesterol Non-HDL Cholesterol EGFR			
Plasma, Serum, Urine	Creatinine Clearance Calcium/creatinine ratio Hammersmith		A A A	
Plasma, Serum	Free Androgen Index Prolactin Recovery Transferrin Saturation		A A A and B	
Urine	24 hour urines Protein /Creatinine ratio Albumin/Creatinine ratio Calcium/Creatinine ratio		A A A	
END				

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