Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9063

Accredited to ISO 15189:2022

Manchester University NHS Foundation Trust

Issue No: 016 Issue date: 06 May 2025

Clinical Biochemistry
Clinical Sciences Building
Manchester Royal Infirmary

Oxford Road

Manchester M13 9WL Contact: Ms Michelle Miller Tel: +44 (0) 161 701 1201

E-Mail: michelle.miller@mft.nhs.uk

Website: www.mft.nhs.uk

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 Clinical Biochemistry Clinical Sciences Building Oxford Road Campus Manchester Royal Infirmary Oxford Road Manchester M13 9WL	Local contact Michelle Miller	Diagnostic testing	A
Address Clinical Biochemistry Trafford Hospital Division Moorside Road Manchester M41 5SL	Local contact Michelle Miller	Diagnostic testing	В
Address Essential Services Laboratory, North Manchester General Hospital, Delaunays Road, Manchester M8 5RB United Kingdom	Local contact Michelle Miller	Diagnostic testing	С
Biochemistry Department. Manchester University NHS Foundation Trust – Wythenshawe Site Wythenshawe Manchester M23 9LT	Local contact Michelle Miller Biochemistry Laboratory Manager and POCT Manager E-mail: michelle.miller@mft.nhs.uk Tel: 0161 291 4783	Biochemistry Management of Point of Care Testing Provision – Clinical Chemistry and Haematology	D

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Site activities performed away from the locations listed above:

Location details		Activity	Location code
Hospital Wards, Clinics and Outpatients Wythenshawe site - as above	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology.	E
North West Lung Centre Wythenshawe site – as above Wythenshawe Manchester M23 9LT	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	F
North West Heart Centre Wythenshawe site – as above Wythenshawe Manchester M23 9LT	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	G
Withington Community Hospital Nell Lane Manchester M20 2LR	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	Н
Opal House Wythenshawe site – as above Wythenshawe Manchester M23 9LT	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	I
Ability House Altrincham Road Sharston Manchester M22 4NY	Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	J

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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	Biochemistry examination activities for the purpose of clinical diagnosis	Roche Cobas c702 (location A) and Roche Cobas c505 (location B) Roche Cobas c503 (location C) Roche Cobas c702/ (location D)	
	Quantification of:		
Serum/Plasma	Alpha-1-Antitrypsin	Turbidometric BC-AUTO-S-37	A,D
Serum	ACE	Enzymatic assay - BC-AUTO-S-37	D
Serum/Plasma	Alanine Transaminase (ALT)	Colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Albumin	Colorimetric BCP BC-AUTO-S-37	A, B, C, D
Urine	MicroAlbumin	Immunoturbidimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Alkaline Phosphatase	Colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Bilirubin	Colorimetric diazomethod BC-AUTO-S-37	A, B, C, D
Serum/Plasma, Urine	Calcium	Colorimetric (NM-BAPTA)BC-AUTO- S-37	A, B, C, D
Serum/Plasma, Urine	Chloride	ISE BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Cholesterol	Enymaticcolorimetric BC-AUTO-S-37	A, B, C,
Serum/Plasma	C Reactive Protein	Particle enhanced Immunoturbidimetric BC-AUTO-S-37	A, B, C, D
Serum /Plasma	Creatinine Kinase	Enzymatic Assay BC-AUTO-S-37	A, B, C, D
Serum/plasma	Creatinine	Enzymaticcolorimetric BC-AUTO-S-37	A, B, C, D
Urine	Creatinine	Jaffe Kinetic BC-AUTO-S-37	A, B, C, D

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Roche Cobas c702 (location A) and Roche Cobas c505 (location B) Roche Cobas c503 (location C) Roche Cobas c702 (location D)	
Urine	24hr Creatinine Clearance	Enzymatic BC-AUTO-S-37	D
Serum/Plasma	Gamma-Glutamyl transpeptidase	Enzymatic colorimetric BC-AUTO-S-37	A, B, C, D
Plasma , CSF	Glucose	Enzymatic Assay BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Direct LDL Cholesterol	Enzymatic BC-AUTO-S-37	A, B, C, D
Serum/Plasma	High Density Cholesterol	Homogeneous enzymatic colorimetricBC-AUTO-S-37	A, B, C, D
Serum/Plasma	Iron	Colorimetric BC-AUTO-S-37	A, B, C, D
Serum,	Lactate	Colorimetric BC-AUTO-S-37	A, B, C
CSF	Lactate	Enzymatic BC-AUTO-S-37	С
Serum/Plasma	Lactate dehydrogenase	Enzymatic BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Lipase	Enzymaticcolorimetric BC-AUTO-S-37	A, B, C, D
Serum	Lithium	Colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma, urine	Phosphate	Colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma, urine	Potassium	ISE BC-AUTO-S-37	A, B, C, D
Serum/Plasma,, urine	Sodium	ISE BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Total Protein	Colorimetric BC-AUTO-S-37	A, B, C, D

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Roche Cobas c702 (location A) and Roche Cobas c505 (location B) Roche Cobas c503 (location C) Roche Cobas c702 (location D)	
Serum/Urine		BI-S-AUTO-11	D
Serum/CSF	Protein	Colorimetric biuret BI-S-AUTO-11	D
Urine, CSF	Total Protein	Colorimetric - AUTOCBImmunoturbidimetric -CBAUTO-PRO 140	A, B, D C,
Urine	24hr Protein	BC-AUTO-S-37	B, D
Serum/Plasma	Transferrin	Immunoturbidometric BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Triglycerides	Enzymatic colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma, Urine	Urate (Uric Acid)	End point colorimetric BC-AUTO-S-37	A, B, C, D
Serum/Plasma, Urine	Urea	Enzymatic BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Conjugated/Direct Bilirubin	End point colorimetric BC-AUTO-S-37	A,B,C,D
Serum/Plasma, Urine	Magnesium	End point colorimetric BC-AUTO-S-37	A, B, C, D
Serum	Ammonia	Enzymatic method, with glutamate dehydrogenase CB-AUTO-PRO-026	A, C, D
Plasma	Ammonia	Enzymatic method, with glutamate dehydrogenase CB-AUTO-PRO-026	С
Serum/Plasma	Asparatate Transaminase (AST)	Kinetic colorimetric BC-AUTO-S-37	A, C, D
Serum	Beta Hydroxybutyrate	Enzymatic colorimetric CB-AUTO-PRO-0108 (Randox)	А
Serum/Plasma	Bicarbonate	Phosphoenolpyruvate (PEP) BC-AUTO-S-37	A, B, C, D

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Roche Cobas c702 (location A) and Roche Cobas c505 (location B) Roche Cobas c503 (location C) Roche Cobas c702 (location D)	
Bile Acids	End point colorimetric (Diazyme) BC-AUTO-S-37	A, D
Caeruloplasmin	Immunoturbidometric BC-AUTO-S-37	А
Cystatin C	Immunoturbidometric CB-AUTO-PRO-01	А
Ethanol	Enzymatic method with alcohol dehydrogenase	A, C, D
Paracetamol	EnzymaticBC-AUTO-S-37	A, B, C, D
Salicylate	Enzymatic BC-AUTO-S-37	A, B, C, D
Cystatin C	Immunoturbidometric BC-AUTO-S-37	А
Free Fatty Acids	End point colorimetric Randox) BC-AUTO-S-37	А
Orosomucoid	Immunoturbidometric BC-AUTO-S-37	А
PIVKA	Electrochemiluminescence (ECLIA) BC-AUTO-S-61	А
GAAD score (using patients' gender, age, AFP and PIVKA)	Calculated parameter BC-auto-S-61	А
Macroprolactin	PEP extraction and electrochemiluminescence immunoassay ECLI CB-AUTO-PRO-130 , BC-AUTO-S-37	В
Macroprolactin	Calculated Test	С
	measured/Range of measurement Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Bile Acids Caeruloplasmin Cystatin C Ethanol Paracetamol Salicylate Cystatin C Free Fatty Acids Orosomucoid PIVKA GAAD score (using patients' gender, age, AFP and PIVKA) Macroprolactin	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Roche Cobas c505 (location A) and Roche Cobas c503 (location C) Roche Cobas c503 (location C) Roche Cobas c702 (location D) Roche Cobas c503 (location C) Roche Cobas c702 (location D) Roche Cobas c503 (location C) Roche Cobas c503 (location D) Roche Cobas

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Roche Cobas c702 (location A) and Roche Cobas c505 (location B) Roche Cobas c503 (location C) Roche Cobas c702 (location D)	
		Roche Cobas e801 electrochemiluminescence immunoassay ECLIA	
Serum/Plasma	Alpha-feto Protein (AFP)	BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Anti-Mullerian Hormone_AMH	BC-AUTO-S-37	А
Serum	Vitamin B12	BC-AUTO-S-37	A, B, C, D
Serum/Plasma	CA-125	BC-AUTO-S-37	A, B, C, D
Serum	CA19-9	BC-AUTO-S-37	D
Serum	Carcinoembryonic Antigen CEA	BC-AUTO-S-37	B, C, D
Serum/Plasma	Cortisol	BC-AUTO-S-37	A, B, C, D
Serum	Ferritin	BC-AUTO-S-37	A, B, C, D
Serum	Folate	BC-AUTO-S-37	A, B, C, D
Serum/Plasma	Folicle Stimulating Hormone (FSH)	BC-AUTO-S-37	A, B, C, D
Serum	Free T4	BC-AUTO-S-37	A, B, C, D
Serum	Human Chorionic Gonadotrophin (Beta hCG)	BC-AUTO-S-37	A, B, C, D

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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	Biochemistry examination activities for the purpose of clinical diagnosis	Roche Cobas e801 electrochemiluminescence immunoassay ECLIA	
Serum	Luteinising hormone (LH)	BC-AUTO-S-37	A, B, C, D
Serum/plasma	NT-ProBNP	BC-AUTO-S-37	A
Serum	Oestradiol	BC-AUTO-S-37	A, B, C, D
Serum/plasma	Placental growth Factor (PIGF)	BC-AUTO-S-37	A,
Serum/plasma	Progesterone	BC-AUTO-S-37	A, B, C, D
Serum/plasma	sFlt-1 (Solublefms-like tyrosine kinase-1)	BC-AUTO-S-37	А
Serum/plasma	sFlt-1/ PIGF ratio		A
Serum	Prolactin	BC-AUTO-S-37	A, B, C, D
Serum/plasma	Parathyroid Hormone (PTH)	BC-AUTO-S-37	A, B, C, D
Serum/plasma	Prostate Specific Antigen (PSA)	BC-AUTO-S-37	A, B, C, D
Serum/ plasma	Sex Hormone Binding Globulin	BC-AUTO-S-37	A, B, C, D
Serum & plasma	Testosterone	BC-AUTO-S-37	A, B, C, D
Serum & plasma	Thyroid Stimulating Hormone (TSH)	BC-AUTO-S-37	A, B, C, D
Serum	Thyroid Peroxidase Autoantibodies (Anti-TPO)	BC-AUTO-S-37	A, D
Serum & plasma	Procalcitonin	BC-AUTO-S-37	A, D
Serum & plasma	Troponin-T	BC-AUTO-S-37	A
Serum & plasma	Free T3	BC-AUTO-S-37	A, D

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Roche Cobas e801 electrochemiluminescence immunoassay ECLIA	
Serum & plasma	N-Terminal of the Prohormone Brain Natriuretic Peptide	BC-AUTO-S-37	A
Serum & plasma	Digoxin	BC-AUTO-S-37	A, B,C,D
CSF	b-Amyloid (1-42) Phospho-Tau Total-Tau	BC-AUTO-S-37 BC-AUTO-S-37 BC-AUTO-S-37	C C C
	Therapeutic Drug Monitoring/Antibiotic	Roche e801 Roche c702 Roche e503	A, C, D A, D D
Serum	Amikacin	Kinetic interaction of microparticles in solution (KIMS) BC-AUTO-S-37	A, D
	Gentamicin	Enzyme Immunoassay CEDIA BC-AUTO-S-37	A, C, D
	Methotrexate	Immunoassay CB-AUTO-PRO-101 ARK/Alpha labs kit	A
	Tobramycin	Homogeneous enzyme Immunoassay CB-AUTO-PRO-095 BC-AUTO-S-37	A D
	Vancomycin	Kinetic interaction of microparticles in solution (KIMS) BC-AUTO-S-37	A, C, D
	Carbamezapine	Kinetic interaction of microparticles in solution (KIMS) BC-AUTO-S-37	A, D
	Phenobarbitone	Kinetic interaction of microparticles in solution (KIMS) BC-AUTO-S-37	A
	Phenytoin	Kinetic interaction of microparticles in solution (KIMS) BC-AUTO-S-37	A, D

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
	Therapeutic Drug Monitoring/Antibiotic (cont'd)	Roche e801 Roche c702 Roche e503	A, C, D A, D D
Serum	Valproate	Homogeneous enzyme Immunoassay BC-AUTO-S-37	А
	Quantification of:	Agilent HPLC system	
	Thiopental	HPLC fractionation BC-SP-S-66	А
		Finnegan Surveyor HPLC with PDA plus detector	
Whole blood (EDTA)	Thiopurine metabolites:		
	Thioguanine nucleotides (6GTN)	BC-SP-S-106	А
	Methylmercaptopurine nucleotides (6MMPN)		А
		Dionex ultimate 3000 UHPLC with thermo scientific Q Exactive High Resolution Accurate MS	
Whole blood	ТРМТ	CB-SPEC-PRO-137	A
Whole blood	Cyclosporin Sirolimus Tacrolimus	Waters xevo TQD LC-MS/MS BC-SP-S-61	А
Serum/plasma	25 hydroxy vitamin D2/D3	BC-SP-S-134	А
Serum/plasma	Vitamin A	BC-SP-S-109	А
	Vitamin E		Α

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Serum	1,25-Dihydroxy Vitamin D	Absciex 6500+ LC-MS/MS System BC-SP-S-98	А
Serum/Plasma	Androgen profile: Testosterone Androstenedione 17-hydroxyprogesterone	B0-01 -0-90	
Serum/Plasma	Busulphan	Waters TQD LC-MS/MS BC-SP-S-133	А
	Calculated parameter Busulphan pharmacokinetics	By calculation BC-SP-S-79	А
		Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with :	
Serum/Plasma	Aldosterone (D7 Aldosterone Internal Standard)	BC-SP-S-5 measurement by : LCMS	D
Serum and plasma	Cortisol	BC-SP-S-6 measurement by : LCMS	D
EDTA whole blood	Cyclosporin	BC-SP-S-27measurement by : LCMS	D
Serum	Dexamethasone	BC-SP-S-129 measurement by : LCMS	D
Serum	Androgen profile: Testosterone Androstenedione 17-hydroxyprogesterone	BC-SP-S-7 measurement by : LCMS	D
Plasma	Metanephrines: metanephrine, normetanephrine 3-methoxytyramine)	BC-SP-S-128 measurement by : LCMS	D
	o monoxytyramine)	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with :	
Plasma	Renin	BC-SP-S-10 measurement by : LCMS	D
Serum and urine	5-HIAA	BC-AUTO-S12 (serum) BC-SP-S-4 (urine)	D

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Serum and heparin plasma	Vitamin D metabolites	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with :BC-SP-S-18 measurement by : LCMS	D
Saliva	Salivary Cortisol and cortisone	BC-SP-S-11 measurement by : LCMS	D
	Testosterone	BC-SPS-12 measurement by : LCMS	D
Urine	Cystine	BC-SP-S-16 measurement by : LCMS	D
		Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO TQD 2 TQD 3 measurement by: LCMS	
Serum	25-hydroxyvitamin D2 and D3	BI-S-LC_VITD3 R14	D
Whole blood mitra collection device	Creatinine		D
Urine	Cotinine	Waters TQD LC-MS/MS BC-SP-S-15	D
		Analysis using LCMS/MS - Waters Acquity XEVO TQ-XS-LC-MS/MS	
Serum	High sensitivity oestradiol	BC-SP-S-22	D
		Waters AcquityLC-MS/MS using Waters Xevo TQD2 and ABSciex Citrine with Shimadzu Nexera UPLC	
Serum	Voriconazole Itraconazole Posaconazole Isavuconazole	BC-SP-S-29	D

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
		Manufacturers instruction for analysis using Waters TQS Micro LC-MS-MS and TQS-LC-MS-MS	
Serum	Cortisol	BC-SP-S-6	D
Serum and plasma	Dehydroepiandrosterone (DHEAS)	Waters TQS-Micro mass spectrometer and Acquity I-Class UPLC.	D
Serum and Plasma	Oestradiol		D
Serum and heparinsed plasma	Teicoplanin	Teicoplanin by LC-MS/MS	
Serum/plasma	7-alpha-hydroxy-	Waters TQS LC-MS/MS	D
	cholestenone	CC-VAL-BC-15	
		Manufacturers instruction for analysis using ABSciex Citrine MS/MS	D
Urine	Free cortisol	BC-SP-S-17	D
	Oxalate	BC-SP-S-26	D
	Citrate		D
Plasma	Mycophenolic Acid	BC-SP-S-8	D
Serum& Plasma	Prednisolone	BC-SP-S-9	D
	Calculated Parameters:	By calculation	D
Serum/Plasma	AKI		A, B
Serum/Plasma	Adjusted calcium Globulin Free androgen index	Calculated using BC-SP-S-7	A, B, D D D

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Serum	AKI	Calculated using BC-IT-INS-1	A, B, D
Serum/plasma	Estimated GFR		A, B, D
Serum/Plasma	Estimated GFR (children)		A, B, D
Urine	Creatinine clearance		A, B, D
Urine	24hr urine excretion calculation		D
Urine	Microalbumin/creatinine ratio		D
Serum/Plasma	Transferrin saturation		A, B, D
Serum/Plasma	Total cholesterol/HDL ratio		A, B, D
Serum/Plasma	TmP/GFR		A
Serum/Plasma	Trans-tubular potassium gradient		A
Serum/Plasma	CKD-EPI Cystatin C		A
Serum/Plasma	Free Androgen Index		A, B, D
Urine	Urine albumin creatinine ratio		A, B, D
	Urine calcium/creatinine clearance ratio		A, B, D
	Urine fractional excretion of sodium		A
	Urine protein/creatinine ratio		A, B, D
	Urine urate/creatinine ratio		A, B, D
Urine	Urine HMMA/creatinine ratio		Α
	Urine HVA/creatinine ratio		A
	Urine noradrenaline/creatinine ratio		A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	activities for the purpose of incorporating manufacturers'	
	Urine calcium/creatinine ratio	ine calcium/creatinine ratio	
Urine	Dopamine/creatinine ratio		А
Faeces	Elastase	Roche Cobas c702 Particle enhanced turbidimetric immunoassay (PETIA) BC-AUTO-S-64	D
Sweat	Sweat Analysis	Documented in-house procedure BC-SP-S-48 and BC-SP-S-38 for analysis using Sherwood 926S chloride analyser. Measurement by Colourimetric titration	D
CSF	Xanthochromia	Spectrophotometry using Thermo Scientific Evolution 300 spectrophotometer with OptLab-SPX software and Bilirubin application routine. BC-SP-S-40	D
Renal calculi	Determination of the composition of renal calculi	Reflectance Spectroscopy using Nicolet iS5 with Omnic software BC-SP-S-42 In house documented methods incorporating manufacturers' instructions as required	D
Blood		IDS iSYS Automated Analyser	
Serum	Insulin Like Growth factor 1	Chemiluminescent Immunoassay BC-NBS-S-20	A
	Growth Hormone	Chemiluminescent Immunoassay BC-NBS-S-21	А
	Procollagen N Peptide type 1	Chemiluminescent Immunoassay BCNBS-S-14	А
Serum	Renin	Chemiluminescent Immunoassay BC-NBS-S-16	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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Serum	IGF-BP3	Chemiluminescent Immunoassay BC-NBS-S-19	A
Whole Blood	СТх	Chemiluminescent Immunoassay BC-NBS-S-32	A
Serum	C-Peptide	ELISA assay using Mercodia kit and manual method or Tecan robot BC-NBS-S-9	A
	Insulin (normal)	BC-NBS-S-11	А
	Insulin (Ultrasensitive)	BC-NBS-S-12	А
	Insulin to C peptide ratio	Calculated parameter	А
Serum, urine	Osmolality	Advanced Instruments Micro Osmometer using freezing point depression BC-AUTO-S-13 BC-AUTO-S-6	A, C B D
	Calculated parameter: Osmolar gap		A, C
		Gem 5000 blood gas analyser CB-BC-AUTO-S-54	В
Blood	Actual bicarbonate, calculated	Calculation	
	Base Excess	Calculation	
	O2 content	Calculation	
	HCO3-Std	Calculation	
	Carboxyhaemoglobin	Cooximetry	
	Haemoglobin (Total)	Cooximetry	
	Oxy Haemoglobin	Cooximetry	
	Oxygen saturation	Cooximetry	

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
		Gem 5000 blood gas analyser CB- TRAF-PROC-28	В
Blood (cont'd)	Met Haemoglobin	Cooximetry	
	pCO2	Potentiometric	
	рН	Potentiometric	
	pO2	Amperometric	
	Sodium	Potentiometric	
	Potassium	Potentiometric	
	Chloride	Potentiometric	
	Calcium	Potentiometric	
	Lactate	Amperometric	
	Glucose	Amperometric	
	New Born Screening Biochemistry exmaniation activities for the purposes of clinical diagnosis	Documented in-house methods to meet the requirements of the Newborn blood spot screening programme (NBS) as defined in laboratory QA evidence requirements.'	
		Biorad Variant HPLC and Panthera sample puncher	А
Dried blood spot	Haemoglobinopathy	BC-NBS-S-1, BC-NBS-S-17	Α
		Waters TQS Micro LC-MS/MS and SpOtOn Clinical Diagnostics Kit BC-NBS-S-42	A
		Perkin Elmer GSP , time resolved fluorescence and Panthera sample puncher	A
	Immuno-reactive trypsin	BC-NBS-S-26	

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Dried blood spot	TSH	BC-NBS-S-26	A
	17-Hydroxy Progesterone	Waters TQS micro LC-MS/MS and Panthera sample puncher BC-NBS-S-39	A
Dried Blood spot	T-cell Receptor Excision Circles (TRECs) SCID	Using EnLite™ Neonatal TREC kit, thermal cyclers and VICTOR EnLite instrument (time resolved fluorescence resonance energy transfer detection) BC-NBS-S-30	A
Serum/Plasma	Alkaline phosphatase ISO enzymes		А
		Hydrasys 2 System sebia Electrophoresis	
Serum	Androstenedione DHEA-S Testosterone 17-Hydroxy Progesterone	Dionex Ultimate 3000 UHPLC with Thermo Scientific Exactive Plus MS,BC-SP-S-90 CB-NBS-PRO-46	A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required Dionex Ultimate 3000 UHPLC with Thermo Scientific Q Exactive MS	
Urine	Antihypertensive drug screen – metabolites of: Enalapril Enalaprilat Lisinopril Perindoprilat Ramiprilat Quianpril Quinaprilat Trandolaprilat Trandolaprilat Candesartan Irbesartan Valsartan Losartan Telmisartan Olmesartan Atenolol Metoprolol Propranolol Labetalol Bisoprolol Nebivolol Amloodipine Delodipine Lercanidipine Lacidipine Diltiazem Verapamil Norverapamil Nifedipine Bendoflumethiazide Hydrochlorothiazide Indapamide Chlorthalidone Bumetanide Furosemide	BC-SP-S-103	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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
	Antihypertensive drug screen – metabolites of	Dionex Ultimate 3000 UHPLC with Thermo Scientific Q Exactive MS, BC-SP-S-103	А
Urine (cont'd)	Eplerenone Canrenone Amiloride Hydralazine Doxazosin Prazosin Aliskiren Moxonidine Methyldopa		
	Detection of Drugs of Abuse screen:	BC-SP-S-101	А
Urine	Morphine Codiene 6-MAM Norcodeine Acetylcodeine Dihydrocodeine Tramadol Fentanyl Methadone EDDP		
	Detection of Drugs of Abuse screen:	Dionex Ultimate 3000 UHPLC with Thermo Scientific Q Exactive MS CB-SPEC-PRO-123	А
Urine	Buprenorphine norbuprenorphine Amphetamine Benzoylecgonine Tetrahydrocannabinol carboxylic acid Ketamine Alprazolam Bromazepam Clonazepam Diazepam Flunitrazepam Flurazepam Lorazepam Lorazepam	OD OF EO-FRO-120	

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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)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
	Detection of Drugs of Abuse screen: (cont'd)	Dionex Ultimate 3000 UHPLC with Thermo Scientific Q Exactive MS CB-SPEC-PRO-123	А
Urine (cont'd)	Lormetazepam Midazolam Nitrazepream Nordiazepam Oxazepam Phenazepam Temazepam		
		Dionex Ultimate 3000 UHPLC with Thermo Scientific Exactive Plus MS, BC-SP-S-101	А
Urine	Gabapentin Pregabalin	20 01 0 101	
CSF	Bilirubin	Uvikon XL Spectrophotometer CB-BC-SP-S-62	A
Urine	Catecholamines as below:	Agilent 1100 UPLC ECD BC-SP-S-049	А
	HMMA HVA	CB-SPEC-PRO-027	
		Agilent 7850 ICP-MS	A
Whole blood	Chromium	BC-SP-S-72	A
	Cobalt	BC-SP-S-72	A
Serum	Copper	BC-SP-S- 67	A
	Selenium		A
	Zinc		A
Urine	Copper	BC-SP-S-71	A
	Chloride	BC-SP-S-104	A
Sweat	Chloride	CB-SPEC-PRO-127	A
	Sodium	BC-SP-S-104	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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Whole Blood (EDTA)	Glycated haemoglobin	Biorad D-100 HPLC, BC-SP-S-5 BC-SP-S-60	B A
EDTA Whole blood	HbA1c-IFCC	Manufacturers instruction for analysis using Biorad D-100 in conjunction with BC-SP-S-43 BC-AUTO-S-57	D C
Blood	Pro Collagen Type 3	Packard Cobra 2 RIA, using Orion kit and BC-SP-S-54	A
Faeces	Calprotectin	DS2 Immunoassay CB-SPEC-PRO-086	A
Pleural fluid	pН	iStat G3	А
Faeces	Faecal immunochemical testing (FIT)	Intergrate sphere latex turbidimetry using the OC-Sensor Pledia analyser BC-SP-S-142	A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)				
	Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following:	Nova Statstrip POCT analyser			
Whole blood	Glucose	Electrochemical biosensor technology and SOP PO-S-4	E,F,G,H,I ,J		
Whole blood	Ketones	Electrochemical biosensor technology and SOP PO-S-4	E		
		HemoCue 201DM Hb POCT analyser	Е		
Whole blood	Haemoglobin	Azidemethoglobin reaction and SOP PO-S-5	E		
Whole blood		Werfen Gem 5000 POCT analyser			
	pH, pCO ₂ and pO ₂ Electrolytes: Na+,K+,Ca2+,Cl-	Potentiometric measurement and SOP PO-S-8	E,F,G		
	Co-oximetry: oxyhaemoglobin,carboxyhaemo globin Methaemoglobin	Optical measurement and SOP PO-S-8	E,F,G		
Whole blood	pO ₂ , Glucose, lactate	Amperometric measurement and SOP PO-S-8	E,F,G		
	haematocrit, total Haemoglobin, reduced haemoglobin	Conductivity measurement and SOP PO-S-8	E,F,G		
	nacmoglobin	Abbot I-stat POCT analyser			
Arterial and venous whole blood	Creatinine	Electrochemical biosensor technology and SOP PO-S-6	E		
(See Appendix	(See Appendix 1 for details of accredited examinations at location types E - J)				

END

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ISO 15189:2022

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Testing performed by the Organisation at the locations specified

E: Wythenshawe site – as above Wards	Glucose Nova Statstrip	Ketone Nova Statstrip	Haemoglobin HemoCue 201DM Hb	Testing using (Gem 5000) (see below – key)	Creatinine Abbot I-Stat
SDEC	Χ				
A&E	Х	Χ		1	
ACUTE WARDS A1	Χ			1	
A2	Χ			1	
A3	Χ	Χ			
A4	X				
A5	X	X			
A6	X				
A7	Χ	X			
A8	Χ				
A9	Χ				
A10	Χ	Х		1	
Coronary care	Χ				
Admissions unit	Χ				
Acute ITU	Χ	Х		1	
Burns unit	Χ			1	
Cardaic rehab	Χ				
Maternity wards C1	Χ				
Maternity wards C2	Χ			1	
Maternity wards C3	Χ				
Acute theatres	Χ		X	1	
Cecilia unit	Χ				
F1 Sexton Suite	Χ				
Transplant unit	Χ				
Treatment Day case unit	Χ			1	
Treatment Day case Recovery	Χ				
Delivery suite	Χ	Х	Х	1	
Discharge lounge	Χ				
Endoscopy pre ass	Χ				
Endoscopy recovery	Χ				
ENT	Χ				
F block theatre	Χ		Х	1	
F1 SRU	Χ				
NWVU	Χ			2	
F12	Χ	Х			
F14	Χ				
F15	Χ				

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E: Wythenshawe site – as above Wards	Glucose Nova Statstrip	Ketone Nova Statstrip	Haemoglobin HemoCue 201DM Hb	Testing using (Gem 5000) (see below – key)	Creatine Abbot I-Stat
F16	X				
Cardiology theatres	X			1	
Catheter laboratory	X				
CF OPD	X				
F2 Cardio	X				
F2 lung	X				
F3	X				
F4	X				
F5	X				
F6	X				
F7	Х	Х			
F8 HDU	Х				
F8 STARLIGHT	Х	Χ		1	
F9	Х				
Allergy	X				
Paeds obs Assessment unit (POAU)	Х				
JQ cardiac ward	X				
F11	X				
POU Oncology	X				
Acute XRAY	X				
Nightingale centre	X				
Haem day unit	X				
Long-term ventilation				2	
SCBU	X			1	
Radiology					X
Ante natal clinic	X				
Transplant OPD	X				
Paediatric OPD	X				
OPD Clinic	X				
Pain clinic	X				
MaxFax OPD	X				
Pearce CF ward	X			2	
Diabetes Centre	X				
ANC	X				
ANC DCU	X				
Doyle (Gastro)	X				
Wilson (Gastro)	Х				

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F: North West Lung Centre		
	Glucose	Testing using
(Gem 5000)		
(see below – key)		
Bronchoscopy	Х	
Charles Blakely unit	Х	
Chest Clinic	X	
Lung function ward		2

G: North West Heart Centre	Glucose	Testing using (Gem 5000) (see below – key)	Creatinine Abbot - Istat Alinity
Heart Failure Clinic			X
Cardio clinic	X		
Cardiac Imaging			Χ
CT CCU zone 1	X	1	
CT CCU zone 2	X	1	
CT CCU zone 3	X	1	
CT CCU zone 4	X	1	
CICU TXU (pocu)	X	1	

H: Withington Community Hospital	
	Glucose
Resus team	X
Treatment centre	X
Ante Natal clinic	X
Dermatology	X
H: Withington Community	
Hospital	
Buccleagh Lodge	Χ

I: Opal House	Glucose
Opal House – frailty care	Χ

J: Ability House	Glucose
Ability Centre	Χ

Testing undertaken on Gem 5000

- 1: Blood gases, glucose, lactose, co-oximetry
- 2: Blood gases, co-oximetry

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