


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9063 Accredited to ISO 15189:2012	Manchester University NHS Foundation Trust	
	Issue No: 008 Issue date: 29 October 2020	
	Manchester University NHS Foundation Trust – Wythenshawe Site Biochemistry Department Wythenshawe Manchester M23 9LT	Contact: Mr Brian Keevil Tel: +44 (0) 161 291 2135 Fax: +44 (0) 161 291 2927 E-Mail: brian.keevil@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
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	A

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.	B
North West Lung Centre Wythenshawe site – as above Wythenshawe Manchester M23 9LT Local contact Michelle Miller	Point of Care Testing – Clinical Chemistry and Haematology	C



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



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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	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented in house procedure BI-S-AUTO-11 in conjunction with manufacturers instruction for analysis using Roche 8000 cobas c702/801	A
Serum	Quantification of: A1 Antitrypsin ACE Alkaline Phosphatase AST CK creatinine Glucose Lactate dehydrogenase Total bile acids	Turbidimetric assay Enzymatic assay	
Serum and urine Plasma and CSF Serum	Urea Salicylate		
Serum and urine	Glucose		
Serum and CSF	Protein	Colorimetric biuret	
Serum	Magnesium	Colorimetric	
Serum	Urea	Enzymatic	
Serum	Albumin	Colourimetric BCP	
	CRP	Immunoturbidimetric	
	IgA	I	
	IgG		
	IgM		
	Transferrin		
CSF	Rheumatoid factor		
Urine	CSF protein		
	Microalbumin		
serum	Gentamicin	CEDIA	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented in house procedure BI-S-AUTO-11 in conjunction with manufacturers instruction for analysis using Roche 8000 cobas c702/801	A
Serum and Urine	Quantification of: Chloride Potassium Sodium	Ion selective electrode	
Urine Serum and Urine Serum	24hr creatinine clearance Creatinine Direct bilirubin Total bilirubin HDL Cholesterol	Enzymatic Vanadate oxidation Colourimetric Diazomethod Homogenous enzymatic colorimetric test	
Serum	Tobramycin	Homegenous enzyme immunoassay	
Serum Urine Serum Serum and Urine serum Plasma	Macro Prolactin 24 hr protein Bicarbonate Calcium ALT Ammonia	PEG extraction and ECLIA Turbidimetry Phosphoenolpyruvate (PEP) Colourimetric (NM-BAPTA) Enzymatic (NADH) Enzymatic method with glutamate dehydrogenase	
Serum	Cholesterol Gamma GT Lipase Triglyceride Uric acid Magnesium	Enzymatic colourimetric	
Serum and urine Serum and urine		Colourimetric endpoint	
	<u>Toxicology examination activities for the purpose of clinical diagnosis</u>		
Plasma	Ethanol	Enzymatic assay with alcohol dehydrogenase	
Serum	Paracetamol	enzymatic	
Plasma Serum and urine	Iron lactate phosphate Total protein	colourimetric	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		A
Serum	<u>Therapeutic Drug Monitoring/Antibiotic</u> Amikacin Vancomycin Carbamezapine Phenytoin theophylline	Documented in house procedure BI-S-AUTO-11 in conjunction with manufacturers instruction for analysis using Roche 8000 cobas c702/801 Kinetic interaction of microparticles in solution (KIMS)	
Serum	Alpha Feto protein Anti TPO B12 Ca125 Ca19-9 CEA Digoxin Ferritin Folate Free T4 FSH FT3 High Sensitive Troponin T LH Oestradiol Progesterone Prolactin	Documented in house procedure BI-S-AUTO-11 in conjunction with manufacturers instruction for analysis using Roche cobas e801 Electrochemiluminescent Immunoassay (ECLIA)	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		A
Serum	Prostate specific antigen PTH SHBG HCG plus beta hCG TSH Thyroid peroxidase autoantibodies	Documented in house procedure BI-S-AUTO-11 in conjunction with manufacturers instruction for analysis using Roche cobas e801 Electrochemiluminescent Immunoassay (ECLIA)	
Serum	Lithium	Documented in house procedure in conjunction with manufacturers instruction for analysis using Roche 9180 Electrolyte Analyser and SOP BI-S-MISC-11 Ion selective electrode Documented in house procedure BI-S-LC-TPMT using LCMS/HPLC	
EDTA whole blood	TPMT	HPLC Chromatography PO-S-2 in conjunction with manufacturers instruction for analysis using Werfren Gem 4000	
Blood	Quantification of: Acid base balance	Ion selective electrode	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		A
Plasma	Aldosterone	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with : BI-S-LC-ALDO measurement by : LCMS	
serum	Androstenedione	BI-S-LCFTTEST measurement by : LCMS	
Serum and plasma	Cortisol	BI-S-LC-CORT measurement by : LCMS	
EDTA whole blood	Cyclosporin	BI-S-MS-14 measurement by : LCMS	
Serum	Dexamethasone	BI-S-LC-CYCTAC measurement by : LCMS	
	DHEAS Sulphate	BI-S-LC-DHEAS measurement by : LCMS	
Serum	Androgen profile: Testosterone Androstenedione 17-hydroxyprogesterone	BI-S-LC-FTEST measurement by : LCMS	
	Mycophenolic acid	BI-S-LC-MPA measurement by : LCMS	
	Oestradiol	BI-S-MS-2- measurement by: LCMS	
Plasma	Metanephrines: metanephrine, normetanephrine 3-methoxytyramine)	BI-S-LC-PMETS measurement by : LCMS	
Serum	Prednisolone	BI-S-LC-PRED measurement by : LCMS	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		A
Plasma	Renin	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with : BI-S-LC-RENIN measurement by : LCMS	
Serum	Vitamin D metabolites		
Serum and urine	5-HIAA	DOC32 (serum) BI-LC_5HIAAMS (urine)	
Serum	Vitamin A & E	Waters acquity UPLC BI-S-LC-VITSCHRO measurement by Chromsystems kit for HPLC	
Serum and heparin plasma	Vitamin D metabolites	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity with XEVO family in conjunction with :BI-S-LC-VITD23 measurement by : LCMS	
Saliva	Salivary Cortisol and cortisone	BI-S-LC_SFC measurement by : LCMS	
	Testosterone	BI-S-LC-STEST measurement by : LCMS	
Urine	Cystine	BI-S-LC-UCYST measurement by : LCMS	
	Cotinine	BI-S-LC-UCOT measurement by : LCMS ABSciex Citrine with Shimadzu Nexera HPLC	
EDTA whole blood	Tacrolimus Sirolimus	BI-S-MS-14	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Manufacturers instruction for analysis using LCMS/MS - Waters Acquity XEVO TQ-XS-LC-MS/MS	A
Serum	High sensitivity oestradiol	BI-S- MS-2	
	Testosterone	BI-S-LC_FTEST	
	Androstenedione	BI-S-LC_FTEST	
	17-hydroxyprogesterone	BI-S-LC_FTEST	
Serum and urine	5-HIAA	DOC32 (serum) BI-LC_5HIAAMS (urine)	
Heparinised plasma and serum	Teicoplanin	Waters Acquity UPLC Waters Acquity UPLC Thermo QE Focus and LC-MS/MS using Waters Xevo TQD2 and ABSciex Citrine with Shimadzu Nexera UPLC	
Serum	Voriconazole Itraconazole Posaconazole Hydroxitraconazole	BI-S-MS-194	
Serum and plasma	Testosterone	BI-S-LC-FTEST	
	Androstenedione		
	17-hydroxyprogesterone		
Saliva	Testosterone	Manufacturers instruction for analysis using Waters TQXS LC-MS-MS BS-S-LC_TEST	
Serum	Cortisol	Manufacturers instruction for analysis using Waters TQS Micro LC-MS-MS and TQS-LC-MS-MS BI-S-LC_CORT	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		A
Urine	Free cortisol	Manufacturers instruction for analysis using ABSciex Citrine MS/MS BI-S-LC_UFCOR	
	Oxalate	BI-S-MS-12	
	Citrate		
Urine	Bence Jones Protein	BI-S-PROT-UEPS measurement by electrophoresis	
Serum	Albumin , Alpha1, Alpha 2, Beta, Gamma	Manufacturers instruction for analysis using Sebia Cap 2 Flex serum protein electrophoresis, immunosubtraction and immunofixation) in conjunction with : BI-S-CAPILL-EPS BI-MISC-5	
	Calculated Parameter		
	Adjusted calcium Globulin Free androgen index AKI	Calculated using BI-S-LC-FTEST Calculated using BI-S-AUTO-G11and BI-F-10	
	Vitamin E/Cholesterol ratio Estimated GFR Urine creatinine clearance 24hr urine excretion calculation LDL and total cholesterol/HDL ratio		
Urine	Microalbumin/creatinine ratio		



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>		
Faeces	Elastase	Manufacturers instruction for analysis using the Schebo manual Eliza with Thermo Multiskan FC Plate Reader with SkanIt software in conjunction with : BI-S-MISC 7	
Sweat and urine	Osmolality	Vitech osmometer. Depression of freezing point using BI-S-OSMOMETER	
Sweat	Sweat Conductivity Analysis	Documented in-house procedure BI-S-SWMD and BI-S-MISC-2 for analysis using Sherwood 926S chloride analyser. Measurement by Colourimetric titration	
EDTA Whole blood	HbA1c-IFCC	Manufacturers instruction for analysis using Biorad D-100 in conjunction with BI-MISC-10	
Urine	Pregnancy test - HCG	Chromatographic immunoassay using Siemens Clinitek in conjunction with BI-S-MISC-8	
CSF	Xanthochromia	Spectrophotometry using Thermo Scientific Evolution 300 spectrophotometer with OptLab-SPX software and Bilirubin application routine. BI-S-MISC-6	
Renal calculi	Determination of the composition of renal calculi	Reflectance Spectroscopy using Nicolet iS5 with Omnic software BI-S-MISC-9	



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> <u>Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following:</u>		
Whole blood	Glucose	Nova Statstrip POCT analyser Electrochemical biosensor technology and SOP PO-S-4	B,C,D,E, F,G
Whole blood	Ketones	Electrochemical biosensor technology and SOP PO-S-4 HemoCue 201DM Hb POCT analyser	B
Whole blood	Haemoglobin	Azidemethoglobin reaction and SOP PO-S-5	B
Whole blood		Werfen Gem 5000 POCT analyser	
	pH, pCO ₂ and pO ₂ Electrolytes: Na ⁺ ,K ⁺ ,Ca ²⁺ ,Cl ⁻	Potentiometric measurement and SOP PO-S-8	B,C,D
	Co-oximetry: oxyhaemoglobin,carboxyhaemoglobin Methaemoglobin	Optical measurement and SOP PO-S-8	B,C,D
Whole blood	pO ₂ , Glucose, lactate	Amperometric measurement and SOP PO-S-8	B,C,D
	haematocrit, total Haemoglobin, reduced haemoglobin	Conductivity measurement and SOP PO-S-8 Abbot I-stat POCT analyser	B,C,D
Arterial and venous whole blood	Creatinine	Electrochemical biosensor technology and SOP PO-S-6	B

(See Appendix 1 for details of accredited examinations at location types B - G)

END



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B: 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
AMRU	X				
A&E	X	X		1	
ACUTE WARDS A1	X				
A2	X				
A3	X				
A4	X				
A5	X				
A6	X				
A7	X				
A8	X				
A9	X				
A10	X	X		1	
Coronary care	X				
Admissions unit	X				
Acute ITU	X	X		1	
Burns unit	X			1	
Cardiac rehab	X				
Maternity wards C1	X				
Maternity wards C2	X			1	
Maternity wards C3	X				
Acute theatres	X		X	1	
Cecilia unit	X				
Transplant unit	X				
Treatment Day case unit	X			1	
Treatment Day case Recovery	X				
Delivery suite	X	X	X	2	
Discharge lounge	X				
Endoscopy pre ass	X				
Endoscopy recovery	X				
ENT	X				
F block theatre	X		X		
F1 N/S	X				
NWVU	X			2	
F12	X	X			
F14	X				
F15	X				



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B: 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				
F2 Cardio	X				
F2 lung	X				
F3	X				
F4	X				
F5	X				
F6	X				
F7	X				
F8 HDU	X				
F8 STARLIGHT	X	X		1	
F9	X				
Allergy	X				
Paeds obs Assessment unit (POAU)	X				
JQ cardiac ward	X				
PITU - F11	X				
POU Oncology	X				
Acute XRAY	X				
F Block Theatre	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				
Diabetes Centre	X				
ANC	X				
ANC DCU	X				
Resus ERC	X				
Vanguard theatres	X		X		



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C: North West Lung Centre	Glucose	Testing using (Gem 5000) (see below – key)
Bronchoscopy	X	
Doyle ward (respiratory)	X	
Wilson Ward	X	1
Pearce CF ward	X	2
Charles Blakely unit	X	
CF OPD	X	
Lung function ward		2
North West Chest Clinic	X	

D: North West Heart Centre	Glucose	Testing using (Gem 5000) (see below – key)
Cardiac Theatre	X	1
Cardio clinic	X	
Catheter laboratory	X	
CICU TXU	X	
CT CCU zone 1		1
CT CCU zone 2		1
CT CCU zone 3		1
CT CCU zone 4		1

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

F: Opal House	Glucose
Opal House – frailty care	X

G: Ability House	Glucose
Ability Centre	X



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Testing undertaken on Gem 5000

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