


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>8071</b> Accredited to ISO 15189:2022</p>	<p align="center"><b>North Bristol NHS Trust</b></p> <p align="center"><b>Issue No: 011 Issue date:22 May 2025</b></p>	
	<p><b>Department of Biochemistry</b> <b>Southmead Hospital</b> <b>Southmead Road</b> <b>Westbury on Trym</b> <b>Bristol</b> <b>BS10 5NB</b></p>	<p><b>Contact: Lesley Morgan</b> <b>Tel: +44 (0) 117 4148428</b> <b>E-Mail: lesley.morgan@nbt.nhs.uk</b> <b>Website: www.nbt.nhs.uk</b></p>
<p align="center"><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY FLUIDS:</b></p> <p>Serum/ Plasma unless otherwise specified</p> <p>&amp; Ascitic and Pleural Fluids</p> <p>Plasma EDTA only</p> <p>&amp; Ascitic and Pleural Fluids/urine</p> <p>&amp; Urine</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Quantification of:</p> <p>ACE</p> <p>AFP (Tumour)</p> <p>Albumin</p> <p>ALP</p> <p>ALT</p> <p>AMH (anti Mullerian hormone)</p> <p>Ammonia</p> <p>Amylase</p> <p>AST</p> <p>B12</p> <p>Bicarbonate</p> <p>Ca-125</p> <p>Ca15-3</p> <p>Ca19-9</p> <p>Calcium</p>	<p>Documented procedures &amp; manufacturer's instructions for Beckman AU5800 / DXI8000 BS/CB/AUTO/BECK/12</p> <p>Photometric</p> <p>Sandwich</p> <p>Colourimetric assay (serum/plasma) Turbidimetric assay (Urine/CSF</p> <p>Kinetic Colour</p> <p>Kinetic UV</p> <p>Sandwich Immunoassay</p> <p>Direct Enzyme</p> <p>Enzymatic colourimetric</p> <p>Kinetic UV</p> <p>Competitive immunoassay</p> <p>Enzymatic</p> <p>Sandwich immunoassay</p> <p>Sandwich immunoassay</p> <p>Sandwich immunoassay</p> <p>Photometric</p>



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for Beckman AU5800 / DXI8000 and BS/CB/AUTO/BECK/12
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	Carbamazepine	Enzyme immunoassay
	CEA	Sandwich immunoassay
& Urine	Chloride	Indirect ISE
& Ascitic and Pleural fluids	Cholesterol	Enzymatic colourimetric
	CK	Kinetic UV
	Cortisol	Sandwich immunoassay
& Ascitic and Pleural Fluids/ Urine	Creatinine	Enzymatic colourimetric
	CRP	Immunoturbidometric
	Digoxin	Immunoinhibition
	Direct Bilirubin	Photometric
	Ethanol	Enzymatic
	Erythropoietin	Competitive immunoassay
	Ferritin	Sandwich immunoassay
	Folate	Competitive binding receptor
	Free T3	Competitive immunoassay
	Free T4	Two step enzymatic
	FSH	Sandwich principle Sandwich immunoassay
	Gamma GT	Enzymatic colourimetric
& Ascitic and Pleural Fluids/CSF	Glucose	Enzymatic UV
	HCG	Two Step enzymatic



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for Beckman AU5800 / DXI800 and BS/CB/AUTO/BECK/12
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	HDL Cholesterol	Enzymatic colourimetric
	Intrinsic Factor antibodies (IFAB)	Competitive Immunoassay
	Iron	Photometric
Plasma & CSF	Lactate	Enzymatic Colourimetric
& Ascitic and Pleural Fluids	LDH	Kinetic UV
	LH	Sandwich Immunassay
	Lipase	Kinetic colourimetric
	Lithium	Spectrophotometric
	Macroprolactin	PEG precipitation BS/CB/AUTO/MAN/4
& Urine	Magnesium	Photometric colour
Urine	Microalbumin	Turbidimetric
	Oestradiol	Competitive immunoassay
	Paracetamol	Enzyme immunoassay
Plasma EDTA only	Parathyroid hormone	Sandwich immunoassay
	Phenobarbitone	Enzymatic immunoassay
	Phenytoin	Enzymatic immunoassay
& Urine	Phosphate	Photometric UV
& Urine	Potassium	Indirect ISE



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for Beckman AU5800 / DXI800 BS/CB/AUTO/BECK/12
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	Progesterone	Sandwich immunoassay
	Prolactin	Sandwich immunoassay
Serum	Prostate Specific Antigen (PSA)	Sandwich immunoassay
	Salicylate	Enzymatic immunoassay
& Urine	Sodium	Indirect ISE
	SHBG	Sandwich immunoassay
	Testosterone	Competitive immunoassay
	Theophylline	Enzyme immunoassay
	Total Bile Acids	Enzyme immunoassay
	Total Bilirubin	Photometric Colour
& Ascitic and Pleural Fluids/CSF/ Urine	Total Protein	Turbidimetric
	TPO (Anti-thyroid peroxidase antibodies)	Sandwich Immunoassay
& Ascitic and Pleural Fluids	Triglycerides	Enzymatic colourimetric
	Troponin T	Sandwich immunoassay
	TSH	Sandwich immunoassay
& Ascitic and Pleural Fluids/Urine	Urea	Kinetic UV
& Urine	Uric Acid	Enzymatic colourimetric
	Transferrin Saturation	Immunoturbidimetric
	NT Pro BNP	Manufacturers instructions for Biomerieux Vidas Immunoassay (ELFA) BS/CB/AUTO/BECK/14



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
CSF	Haem pigments	Lambda 25 spectrophotometer BS/CB/AUTO/MAN/5
& Urine	Osmolality	Advanced Micro-Osmometer model 3320 and freezing point depression BS/CB/AUTO/MAN/16
	<u>Biochemical Genetics</u>	
Urine	Organic Acids	Thermo Scientific GC-MS BS/CB/BIOGEN/GCMS/23
	7-Dehydrocholesterol	Shimadzu 2010 Ultra GC/MS extraction, saponification and derivitisation and in house method: BS/CB/BIOGEN/GCMS/17
Urine	Galactitol	Shimadzu 2010 Ultra GC/MS Formation of hexa-acetate and in-house method: BS/CB/BIOGEN/GCMS/18
Urine	Methylmalonic Acid	Shimadzu 2010 Ultra GC/MS solvent extraction and in-house method: BS/CB/BIOGEN/GCMS/19
	Very long chain fatty acids C22.0 C24.0 C26.0 Pristanate Phytanate	Shimadzu 2010 Ultra GC/MS extraction of deuterated methyl esters and in-house method: BS/CB/BIOGEN/GCMS/16



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
Whole blood/Dried blood spot	Galactosaemia screen	Manual Fluorimetric reduction assay and in-house method BS/CB/BioGen/Manual/2
Whole Blood	Galactose -1-Phosphate (G-1-P)	Waters Acquity TQD HPLC-MS/MS and in-house method BS/CB/BIOGEN/MS/7
Whole blood lithium heparin-washed red blood cells	Galactose-1-Phosphate Uridyl Transferase	Waters TQD Acquity Tandem Mass Spectrometer with Waters Acquity HPLC system (HPLC MS-MS) (TMS)
	Galactose-1-Phosphate Uridyl Transferase	BS/CB/BIOGEN/MS/3
Whole blood lithium heparin-washed red blood cells	Galactokinase	BS/CB/BIOGEN/MS/5
Serum/Plasma	Free fatty acids and Hydroxybutyrate	Beckman AU5800 Kinetic reduction method and in-house method: BS/CB/BioGen/Manual/1
& Dried blood spot	Acylcarnitine	Waters Acquity TQD TMS Extraction of butyl ester derivatives BS/CB/BIOGEN/MS/1
Plasma/Urine/CSF	Quantitation of amino acids	Biochrom 30+ HPLC ion exchange chromatography BS/CB/BIOGEN/CHROMATOGRAPHY/4
	Quantitation of:	
Serum and plasma (heparin and EDTA)	Cholinesterase activity	Beckman AU5800 Colourimetric BS/CB/CIU/PHEN/5
	Determination of:	
	Cholinesterase phenotype	Lambda 25 spectrophotometer colourimetric assay BS/CB/CIU/PHEN/1



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)	<u>Newborn Screening:</u>  Detection of:	Documented -in-house methods to meet the requirements of the Newborn blood spot screening programme as defined in the July 2018 'NHS Newborn Blood Spot Screening Programme: laboratory QA evidence requirements'
Dried blood spot	17-OH Progesterone	Perkin Elmer GSP. Fluoroimmunoassay BS/CB/NBS/GSP/6
Dried blood spot	Immunoreactive trypsin (IRT)	Perkin Elmer GSP. Fluoroimmunoassay BS/CB/NBS/GSP/1
Dried blood spot	Thyroid Stimulating Hormone (TSH)	Perkin Elmer GSP. Fluoroimmunoassay BS/CB/NBS/GSP/2
Dried blood spot	Sickle Cell Haemoglobin	Bio-Rad Variant HPLC cation exchange BS/CB/NBS/HPLC/2
Dried blood spot	Leucine	Waters Xevo TMS Micro electrospray ionisation Deuterated stds ratios BS/CB/NBS/MS/7
Dried blood spot	Methionine	BS/CB/NBS/MS/7
Dried Blood spot	Isovaleryl Carnitine	BS/CB/NBS/MS/7
Dried Blood spot	Glutaryl Carnitine (C5DC)	BS/CB/NBS/MS/7
Dried blood spot	Tyrosine	BS/CB/NBS/MS/7



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented -in-house methods to meet the requirements of the Newborn blood spot screening programme as defined in the July 2018 'NHS Newborn Blood Spot Screening Programme: laboratory QA evidence requirements'
Serum/ Plasma unless otherwise specified (cont'd)		
Dried blood spot	Octanoylcarnitine (C8)	BS/CB/NBS/MS/7
Dried blood spot	Phenylalanine	BS/CB/NBS/MS/7
Dried Blood spot	Decanoyl carnitine (C10)	BS/CB/NBS/MS/7
Dried Blood spot	Diet Phenylalanine	BS/CB/NBS/MS/8
Dried Blood spot	Diet Tyrosine	BS/CB/NBS/MS/8
	AMH	Beckman Access 2 paramagnetic particle Chemiluminescent immunoassay IMMICSOP026
	Vitamin D	Beckman DXI800 two-step competitive binding immunoassay BS/CB/AUTO/BECK/14
	<u>Toxicology</u>	
Urine	Presumptive screening for the presence of Drugs of Abuse (cut off) : Amphetamines (1000 ug/L) Barbiturates (200 ug/L) Benzodiazepines (200 ug/L) Cannabinoids (50 ug/L) Cocaine metabolite (300 ug/L) Methadone (300 ug/L) Methadone Metabolite (EDDP) (100ug/L) Opiates (300 ug/L)	Beckman AU5800 Enzyme immunoassay BS/CB/TOX/CT/2
Plain, EDTA, fluoride and heparinised whole blood	Paracetamol (LLOQ 10mg/L)	Roche Cobas c501 Colourimetric assay BS/CB/TOX/FT/20





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HUMAN BODY FLUIDS (cont'd)  Serum/ Plasma unless otherwise specified (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:  Beckman AU5800 and in house method BS/CB/TOX/FT/43
Vitreous humour	Beta-hydroxybutyrate	Kinetic
	Sodium Urea Creatinine Glucose	Indirect ISE Kinetic UV Enzymatic colourimetric Enzymatic UV
	Quantification of:	
Whole blood	Cyclosporin (LLOQ 20 ug/L)	Waters TQD Tandem Mass Spectrometer TMS BS/CB/TOX/CT/8
Whole blood	Tacrolimus (LLOQ 0.5 ug/L)	Waters TQD Tandem Mass Spectrometer TMS BS/CB/TOX/CT/8
Whole blood	Sirolimus (LLOQ 2.0 ug/L)	Waters TQD Tandem Mass Spectrometer TMS BS/CB/TOX/CT/8
Serum	Iohexol Glomerular Filtration Rate (calculated parameter)	Waters TQD Tandem Mass Spectrometer TMS BS/CB/TOX/CT/55



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)		
Urine	Confirmation (Qualitative) analysis above specified cut off limits for drugs of abuse (Cut off limit) Amphetamine confirmation: Amphetamine (10 ug/L) Methamphetamine (10 ug/L) MDMA (10 ug/L) MDA (10 ug/L) Ketamine (10 ug/L)	Waters Xevo TQS Micro Tandem Mass Spectrometer  BS/CB/TOX/CT/56
Urine	Opioid Confirmation: Morphine (10 ug/L) Codeine (10 ug/L) Dihydrocodeine (10 ug/L) Methadone (10 ug/L) Methadone metabolite (EDDP) (10 ug/L) 6-monoacetyl morphine (10 ug/L) Tramadol (25 ug/L) Desmethyltramadol (25 ug/L)	BS/CB/TOX/CT/54
Whole blood, serum or plasma	Quantitative analysis of drugs (LLOQ):  Amphetamine (0.05mg/L) Methamphetamine (0.05 mg/L) MDMA (0.05 mg/L) MDA (0.05 mg/L) Ketamine (0.05 mg/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS SOP BS/CB/TOX/FT/16
Whole blood, serum or plasma	  Diazepam (20 ug/L) Desmethyldiazepam (20 ug/L) Temazepam (20 ug/L) Chlordiazepoxide (20 ug/L) Oxazepam (20 ug/L) Nitrazepam (20 ug/L) Midazolam (20 ug/L) Lorazepam (20 ug/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS BS/CB/TOX/FT/41



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u>	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)		
Whole blood, serum or plasma	Quantitation analysis of drugs: (LLOQ)  Cocaine (0.01 mg/L) Benzoylcegonine (0.01 mg/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS SOP BS/CB/TOX/FT/19
Whole blood, serum or plasma	Morphine (0.01 mg/L) Codeine (0.01 mg/L) Dihydrocodeine (0.01 mg/L) Methadone (0.01 mg/L) EDDP (0.01 mg/L) Tramadol (0.01 mg/L) Desmethytramadol (0.01 mg/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS SOP BS/CB/TOX/FT/14
Whole blood, serum or plasma	Citalopram (0.02 mg/L) Norcitalopram (0.02 mg/L) Fluoxetine (0.02 mg/L) Venlafaxine (0.02 mg/L) Desmethylvenlafaxine (0.02 mg/L) Sertraline (0.02 mg/L) Paroxetine (0.05 mg/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS BS/CB/TOX/FT/17
Whole blood, serum or plasma	Amitriptyline (0.02 mg/L) Nortriptyline (0.02 mg/L) Dothiepin (0.02 mg/L)	BS/CB/TOX/FT/4
Whole blood (plain femoral)	Mirtazapine (0.01mg/L)	Waters TQSmicro with I class uPLC and in-house method BS/CB/TOX/FT/42
Whole blood or serum	Haloperidol (0.002mg/L) Chlorpromazine (0.002mg/L) Clozapine (0.002mg/L) Desmethylozapine (0.002mg/L) Risperidone (0.002mg/L) 9OH risperidone (0.002mg/L) Quetapine 0.002mg/L)	Waters TQS micro with I class uPLC and in-house method BS/CB/TOX/FT/2
Whole blood (plain femoral)	Paracetamol (5mg/L)	Waters TQS micro with I class uPLC and in-house method BS/CB/TOX/FT/46



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HUMAN BODY FLUIDS (cont'd)  Serum/ Plasma unless otherwise specified (cont'd)          Whole Blood (post mortem)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u>  Qualitative analysis of targeted analytes (LOD)  Amphetamine (0.01mg/L) Ketamine (0.01mg/L) MDA (0.01mg/L) MDMA (0.01mg/L) Methamphetamine (0.01mg/L) Chlorpromazine (0.01mg/L) Clozapine (0.01mg/L) Haloperidol (0.01mg/L) Mirtazapine (0.01mg/L) Quetiapine (0.01mg/L) Risperidone (0.02mg/L) Alprazolam (0.01mg/L) Chlordiazepoxide (0.01mg/L) Clonazepam (0.02mg/L) Desmethyldiazepam (0.02mg/L) Diazepam (0.01mg/L) Lorazepam (0.1mg/L) Midazolam (0.01mg/L) Nitrazepam (0.01mg/L) Oxazepam (0.02mg/L) Temazepam (0.02mg/L) Benzoyllecgonine (0.01mg/L) Cocaine (0.01mg/L) Ecgonine methyl ester (0.01mg/L) 6-monoacetylmorphine (0.01mg/L) Codeine (0.01mg/L) Dihydrocodeine (0.01mg/L) EDDP (0.01mg/L) Methadone (0.01mg/L) Morphine (0.01mg/L) Tramadol (0.01mg/L) Citalopram (0.01mg/L) Desmethylvenlafaxine (0.01mg/L) Fluoxetine (0.01mg/L) Paroxetine (0.01mg/L) Sertraline (0.01mg/L) Venlafaxine (0.01mg/L) Amitriptyline (0.01mg/L) Nortriptyline (0.01mg/L)	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:          Waters TQS Micro with I class uPLC and in house method BS/CB/TOX/FT/44



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Serum/ Plasma unless otherwise specified (cont'd)		
Plasma	Aluminium	Agilent 7700 ICP-MS Inductively coupled plasma mass spectroscopy and in-house method: BS/CB/TOX/CT/42
Whole Blood	Lead	BS/CB/TOX/CT/41
Serum /Plasma	Copper	BS/CB/TOX/CT/40
Serum/Plasma	Zinc	BS/CB/TOX/CT/40
Serum/Plasma	Selenium	BS/CB/TOX/CT/40
Whole Blood	Cobalt	BS/CB/TOX/CT/46
Whole Blood	Chromium	BS/CB/TOX/CT/46
Plasma /Whole Blood	Ethylene Glycol (LLOQ 50 mg/L)	Thermo Scientific 1310 Trace Gas Liquid Chromatograph and TRIRSH Autosampler, automated headspace gas liquid chromatography and in-house method: BS/CB/TOX/CT/44
Urine, whole blood, serum	Ethanol (LLOQ 10 mg/100ml)	BS/CB/TOX/CT/45
Plasma/Whole blood	Methanol (LLOQ 50 mg/L)	BS/CB/TOX/CT/43
		Documented in-house methods to meet the requirements as defined in the 'NHS Fetal Anomaly Screening Programme: laboratory QA evidence requirements'
Serum	PAPP-A	BS/CB/TOX/DOWN/1 &4 ThermoFisher Brahms Kryptor Immunoassay
Serum	free bHCG	BS/CB/TOX/DOWN/1&4 ThermoFisher Brahms Kryptor Immunoassay
END		