


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8071 Accredited to ISO 15189:2012</p>	<h3>North Bristol NHS Trust</h3> <p>Issue No: 005 Issue date: 29 June 2021</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS:	<u>Biochemistry examination activities for the purpose of clinical diagnosis:</u>	Documented procedures & manufacturer's instructions for Roche Cobas C8000
Serum/ Plasma unless otherwise specified	Quantification of:	Line 1 (c701,c710,e601,e601) Line 2 ((c701,c501,e601,e601) Line 3 ((c701,e601) analyser with specific reference to: BS/CB/AUTO/ROCHE/4
& Fluids	ACE	Colourimetric assay
	AFP (Tumour)	Sandwich principle
	Albumin	Colourimetric assay
	ALP	Colourimetric assay
	ALT	Colourimetric assay
	Ammonia	Enzymatic with glutamate dehydrogenase
& Fluids/urine	Amylase	Enzymatic colourimetric
	AST	Enzymatic colourimetric
	B12	Competition principle
	Bicarbonate	Colourimetric assay
	Ca-125	Sandwich principle
	Ca15-3	Sandwich principle
	Ca19-9	Sandwich principle
& Urine	Calcium	Colourimetric assay



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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 Roche Cobas C8000 (c501/e601/c701 modules) analyser in conjunction with in house documented procedures: BS/CB/AUTO/ROCHE/4
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	Carbamazepine	Homogeneous microparticle agglutination assay
	CEA	Sandwich principle
& Urine	Chloride	Ion selective electrode
& Fluids	Cholesterol	Enzymatic colourimetric assay
	CK	Enzymatic colourimetric assay
	Cortisol	Competition principle
& Fluids/ Urine	Creatinine	Enzymatic colourimetric assay
	CRP	Particle enhanced turbidimetry
	Digoxin	Competition principle
	Direct Bilirubin	Diazo method
	Ethanol	Enzymatic with alcohol dehydrogenase
	Ferritin	Sandwich principle
	Folate	Competition principle
	Free T3	Competition principle
	Free T4	Competition principle
	FSH	Sandwich principle
	gamma GT	Enzymatic colourimetric assay
& Fluids/CSF	Glucose	UV enzymatic reference method with hexokinase
	HCG	Sandwich principle



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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 Roche Cobas C8000 (c501/e601/c701 modules) analyser in conjunction with in house documented procedures: BS/CB/AUTO/ROCHE/4
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	HDL Cholesterol	Homogeneous enzymatic colourimetric assay
	Iron	Colourimetric assay
& CSF	Lactate	Colourimetric assay
& Fluids	LDH	UV assay
	LH	Sandwich principle
	Lipase	Enzymatic colourimetric assay
	Lithium	Colourimetric assay
	Macroprolactin	PEG precipitation BS/CB/AUTO/MAN/4
& Urine	Magnesium	Colourimetric endpoint assay
Urine	Microalbumin	Kinetic interaction of microparticles in solution (KIMS)
	Oestradiol	Competition principle
	Paracetamol	Colourimetric assay
	Parathyroid hormone	Sandwich principle
	Phenobarbitone	KIMS
	Phenytoin	KIMS
& Urine	Phosphate	Colourimetric endpoint with sample blanking
fluids/ Urine	Potassium	Ion selective electrode



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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 Roche Cobas C8000 (c501/e601/c701 modules) analyser in conjunction with in house documented procedures: BS/CB/AUTO/ROCHE/4
Serum/ Plasma unless otherwise specified (cont'd)	Quantification of: (cont'd)	
	Progesterone	Competition principle
	Prolactin	Sandwich principle
	Prostate Specific Antigen (PSA)	Sandwich principle
	Salicylate	Enzymatic colourimetric assay
& Fluids/ Urine	Sodium	Ion selective electrode
	SHBG	Competition principle
	Testosterone	Competition principle
	Theophylline	KIMS
	Total Bile Acids	KIMS
	Total Bilirubin	Colourimetric assay
& Fluids/CSF/ Urine	Total Protein	Colourimetric/Turbidimetric
& Fluids	Triglycerides	Enzymatic colourimetric assay
	Troponin T	Sandwich principle
	TSH	Sandwich principle
& Fluids/Urine	Urea	Kinetic assay with urease and glutamate dehydrogenase
& Urine	Uric Acid	Enzymatic colourimetric assay
	NT Pro BNP	Sandwich principle
	Unsaturated Iron Binding Capacity	Colourimetric assay



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HUMAN BODY FLUIDS (cont'd): Serum/ Plasma unless otherwise specified (cont'd) CSF & Urine	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> Quantification of: (cont'd) HbA1c Haem pigments Osmolality	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures: HA9210 Boron Affinity chromatography BS/CB/AUTO/MEN/1 Lambda 25 spectrophotometer BS/CB/AUTO/MAN/5 Advanced Micro-Osmometer model 3320 and freezing point depression BS/CB/AUTO/MAN/16
Urine Urine Urine	<u>Biochemical Genetics</u> Organic Acids 7-Dehydrocholesterol Galactitol Methylmalonic Acid	Thermo Scientific GC-MS BS/CB/BIOGEN/GCMS/23 Shimadzu 2010 Ultra GC/MS extraction, saponification and derivitisation and in house method: BS/CB/BIOGEN/GCMS/17 Shimadzu 2010 Ultra GC/MS Formation of hexa-acetate and in-house method: BS/CB/BIOGEN/GCMS/18 Shimadzu 2010 Ultra GC/MS solvent extraction and in-house method: BS/CB/BIOGEN/GCMS/19



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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> Quantification of: (cont'd) Very long chain fatty acids C22.0 C24.0 C26.0 Pristanate Phytanate	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures: Shimadzu 2010 Ultra GC/MS extraction of deuterated methyl esters and in-house method: BS/CB/BIOGEN/GCMS/16
Whole blood/Dried blood spot	Galactosaemia screen	Manual Fluorimetric reduction assay and in-house method BS/CB/BioGen/Manual/2
Serum/Plasma & Dried blood spot	Free fatty acids and Hydroxybutyrate Acylcarnitine	Roche C501 CE Kinetic reduction method and in-house method: BS/CB/BioGen/Manual/1 Waters Acquity TQD TMS Extraction of butyl ester derivatives BS/CB/BIOGEN/MS/1
Plasma/Urine/CSF	Quantitation of amino acids Quantitation of: Cholinesterase activity Determination of: Cholinesterase phenotype	Biochrom 30+ HPLC ion exchange chromatography BS/CB/BIOGEN/CHROMATOGRAPHY/4 Roche c501 Colourimetric assay BS/CB/CIU/PHEN/5 Lambda 25 spectrophotometer colourimetric assay BS/CB/CIU/PHEN/1



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HUMAN BODY FLUIDS (cont'd): Serum/ Plasma unless otherwise specified (cont'd) Serum/ Plasma unless otherwise specified (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> Newborn Screening: Detection of:	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures: 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. Fluoroimmuno-metric assay BS/CB/NBS/GSP/6
Dried blood spot	Immunoreactive trypsin (IRT)	Perkin Elmer GSP. Fluoroimmuno-metric assay BS/CB/NBS/GSP/1
Dried blood spot	Thyroid Stimulating Hormone (TSH)	Perkin Elmer GSP. Fluoroimmuno-metric assay 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): Serum/ Plasma unless otherwise specified (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'
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 Access 2 two-step competitive binding immunoassay BS/CB/TOX/CT/30
Urine	Toxicology 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)	Roche Cobas c501 KIMS BS/CB/TOX/CT/2
Plain, EDTA, fluoride and heparinised whole blood	Paracetamol (LLOQ 10mg/L) Salicylate (LLOQ 30mg/L)	Roche Cobas c501 Colourimetric assay BS/CB/TOX/FT/20 BS/CB/TOX/FT/20



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HUMAN BODY FLUIDS (cont'd) Serum/ Plasma unless otherwise specified (cont'd) Vitreous humour	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u> Beta-hydroxybutyrate Sodium Urea Creatinine Glucose Quantification of:	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures: Roche Cobas c501 Colourimetric assay BS/CB/TOX/FT/20 Roche Cobas C8000 (C701) BS/CB/TOX/FT/20 Ion-Selective Electrode Kinetic test with urease and glutamate dehydrogenase Creatinase Enzymatic colourimetric assay UV enzymatic reference method with hexokinase
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
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



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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) Serum/ Plasma unless otherwise specified (cont'd) Whole blood, serum or plasma	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u> Cocaine (0.01 mg/L) Benzoylcegonine (0.01 mg/L)	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures: 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) Desmethyltramadol (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
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



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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)		
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 of the Newborn blood spot screening programme as defined in the July 2018 'NHS Fetal Anomaly Screening Programme: laboratory QA evidence requirements'
	PAPP-A	Roche e601 Sandwich assay BS/CB/TOX/DOWN/1,4
	free bHCG	Roche e601 Sandwich assay BS/CB/TOX/DOWN/1,4
END		