Schedule of Accreditation

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North Bristol NHS Trust

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS:	Biochemistry examination activities for the purpose of clinical diagnosis:	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
	ACE	Colourimetric assay
	AFP (Tumour)	Sandwich principle
& Ascitic and Pleural Fluids	Albumin	Colourimetric assay
	ALP	Colourimetric assay
	ALT	Colourimetric assay
	Ammonia	Enzymatic with glutamate dehydrogenase
& Ascitic and Pleural 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd):	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	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
& Ascitic and Pleural luids	Cholesterol	Enzymatic colourimetric assay
	CK	Enzymatic colourimetric assay
	Cortisol	Competition principle
& Ascitic and Pleural 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
& Ascitic and Pleural Fluids/CSF	Glucose	UV enzymatic reference method with hexokinase
	HCG	Sandwich principle

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	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
& Ascitic and Pleural 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
Urine	Potassium	Ion selective electrode

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
& Urine	Sodium	Ion selective electrode
	SHBG	Competition principle
	Testosterone	Competition principle
	Theophylline	KIMS
	Total Bile Acids	KIMS
	Total Bilirubin	Colourimetric assay
& Ascitic and Pleural Fluids/CSF/ Urine	Total Protein	Colourimetric/Turbidimetric
& Ascitic and Pleural Fluids	Triglycerides	Enzymatic colourimetric assay
	Troponin T	Sandwich principle
	TSH	Sandwich principle
& Ascitic and Pleural 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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)	
	HbA1c	HA9210 Boron Affinity chromatography BS/CB/AUTO/MEN/1
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 deutrated methyl esters and in-house method: BS/CB/BIOGEN/GCMS/16

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)**:**	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	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 Hydroxybutryate	Roche C501 CE 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:	
	Cholinesterase activity	Roche c501 Colourimetric assay BS/CB/CIU/PHEN/5
	Determination of:	
	Cholinesterase phenotype	Lambda 25 spectrophotometer colourimetric assay BS/CB/CIU/PHEN/1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)**:**	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Serum/ Plasma unless otherwise specified (cont'd)	Newborn Screening:	
	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. Fluoroimmunometric assay BS/CB/NBS/GSP/6
Dried blood spot	Immunoreactive trypsin (IRT)	Perkin Elmer GSP. Fluoroimmunometric assay BS/CB/NBS/GSP/1
Dried blood spot	Thyroid Stimulating Hormone (TSH)	Perkin Elmer GSP. Fluoroimmunometric 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 Phenyalanine	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/AUTO/MAN/35
	<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)	Roche Cobas c501 KIMS 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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:
Vitreous humour	Beta-hydroxybutyrate	Roche Cobas c501 Colourimetric assay BS/CB/TOX/FT/20
	Sodium	Roche Cobas C8000 (C701) BS/CB/TOX/FT/20 Ion-Selective Electrode
	Urea	Kinetic test with urease and glutamate dehydrogenase
	Creatinine	Creatinase Enzymatic colourimetric assay
	Glucose	UV enzymatic reference method with hexokinase
	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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:
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	Quntitative 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) Lorazapam (20 ug/L)	Waters TQS Micro Tandem mass spectrometer Liquid extraction, LC-MS/MS BS/CB/TOX/FT/41

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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:
Whole blood, serum or plasma	Quantitation analysis of drugs: (LLOQ) Cocaine (0.01 mg/L) Benzoylecgonine (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) 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
Whole blood (plain femoral)	Mirtazapine (0.01mg/L)	Waters TQSmicro with I class uPLC and in-house method BS/CB/TOX/FT/42

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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> Quantitation analysis of drugs: (LLOQ)	Documented procedures & manufacturer's equipment instructions in conjunction with documented in-house procedures:
Whole blood (plain femoral)	Haloperidol (0.005mg/L) Chlorpromazine (0.005mg/L) Clozapine (0.005mg/L) Desmethylclozapine (0.005mg/L) Risperidone (0.005mg/L) 9OH risperidone (0.005mg/L) Quetapine 0.005mg/L)	Waters TQSmicro with I class uPLC and in-house method BS/CB/TOX/FT/2
Whole blood (plain femoral)	Paracetamol (5mg/L)	Waters TQSmicro with I class uPLC and in-house method BS/CB/TOX/FT/46
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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:
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 Ghromatograph 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 th '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