Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8822

Accredited to ISO 15189:2012

Bedfordshire Hospitals NHS Foundation Trust

Issue No: 008 Issue date: 14 July 2021

Department of Clinical Biochemistry Bedfordshire Hospitals NHS Foundation Trust Kempston Road Bedford MK42 9DJ

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Testing provided 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	In house documented methods incorporating manufacturers' instructions as required
Serum/plasma	Sodium Potassium Chloride	Roche Cobas 8000 ISE Ion Selective Electrode BED-SOP-857
Serum/plasma	Bicarbonate	Roche Cobas 8000 c702 PEP enzymatic BED-SOP-857
	Creatinine GGT Urate Amylase Cholesterol HDL Cholesterol Triglyceride Lactate Paracetamol Alcohol "Ethanol"	Enzyme colorimetric assay BED-SOP-857
	Magnesium	CPZ 111 Colorimetric assay BED-SOP-857
	Lithium Calcium ALP	Colorimetric assay BED-SOP-857
	Iron	BED-SOP-857
	Bile Acids	Colorimetric assay (Alere reagent) BED-SOP-793

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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)	In house documented methods incorporating manufacturers' instructions as required
Serum/plasma	Total Bilirubin Conjugated Bilirubin	Roche Cobas 8000 c702 Diazo Colorimetric assay BED-SOP-857
	Total Protein	Biuret Colorimetric assay BED-SOP-857
	Albumin	BCP Colorimetric assay BED-SOP-857
	Glucose	Hexokinase colorimetric assay BED-SOP-857
	AST ALT Creatine Kinase LDH	NADH/NAD Kinetic assay BED-SOP-857
	Salicylate	Enzyme ADH assay BED-SOP-857
Serum/plasma	Vitamin D	Roche Cobas 8000 e602 Elecsys Competitive Binding BED-SOP-857
	Thyroid Stimulating Hormone IgE Ferritin Parathyroid Hormone Sex Hormone Binding Globulin Prostatic Surface Antigen Alpha-Fetoprotein (AFP) Beta HCG Troponin T Follicle Stimulating Hormone Luteinizing Hormone Prolactin	Elecsys Sandwich assay BED-SOP-903 BED-SOP-785 BED-SOP-857 BED-SOP-512 BED-SOP-857

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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/plasma	Carcinoembryonic Antigen (CEA) CA 125 CA 19-9 CA 15-3 NT-pro BNP	Roche Cobas 8000 e602 Elecsys Sandwich assay BED-SOP-517 BED-SOP-857
	Macroprolactin	Elecsys Sandwich assay/PEG BED-SOP-509
	Cortisol Free T4, Free T3 Vitamin B12 Serum Folate Testosterone Oestradiol Progesterone	Elecsys Competitive assay BED-SOP-511 BED-SOP-903 BED-SOP-857 BED-SOP-857
Serum/plasma	C Reactive Protein Transferrin Beta 2 Microglobulin	Roche Cobas 8000 c702 Turbidimetric assay BED-SOP-857 BED-SOP-857 BED-SOP-507
	eGFR ml/min/1.73m2	Calculation BED-SOP-857
Urine	Sodium Potassium Chloride	Roche Cobas 8000 ISE Ion Selective Electrode BED-SOP-857
Urine	Calcium	Roche Cobas 8000 c702 Colorimetric assay BED-SOP-857
	Urate Amylase	Enzymatic Colorimetric assay BED-SOP-857

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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
Urine	Protein Microalbumin	Roche Cobas 8000 c702 Turbidimetric assay BED-SOP-467 BED-SOP-480
Serum/plasmaUrine	Urea	Urease kinetic BED-SOP-857
	Phosphate	Molybdate endpoint BED-SOP-857
	Creatinine	Jaffe BED-SOP-857
Fluid	Creatinine	Jaffe BED-SOP-857
	Amylase Triglycerides	Enzymatic Colorimetric assay BED-SOP-857
	Albumin	BCG Colorimetric assay BED-SOP-857
	Glucose	Hexokinase colorimetric assay BED-SOP-857
	Total Protein	Biuret colorimetric assay SOP: BED-SOP-857
CSF	Glucose	Hexokinase colorimetric assay BED-SOP-504
	Lactate	Colorimetric assay BED-SOP-504
Serum/plasma	lgM IgA IgG	Immunoturbdimetric assay BED-SOP-857

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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/plasma	Phenytoin Phenobarbitone Carbamazepine Valproate Theophylline Gentamicin	Roche Cobas Integra 400 FPIA BED-SOP-752 BED-SOP-468
	Vancomycin Digoxin	KIMS Turbidometric BED-SOP-752
	Complement C3 Complement C4	Immunoturbdimetric assay BED-SOP-1082
	Ammonia	Enzyme colorimetric assay BED-SOP-857
CSF	Total Protein	Turbidimetric BED-SOP-504

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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 Urine	Osmolality	Vitech Osmometer 3320 Freezing Point Depression BED-SOP-464
Faeces	Total Porphyrin Coproporphyrin I Coproporphyrin III % Coproporphyrin III Dicarboxylate Porphyrin	Varian HPLC system HPLC fractionation BED-SOP-529
Urine	Uroporphyrin I Uroporphyrin III Total Uroporphyrin (I+III) Heptacarboxylate Porphyrin Coproporphyrin I Coproporphyrin III	Varian HPLC system HPLC fractionation BED-SOP-529
Urine	5-Aminolaevulinic acid (ALA) Porphobilinogen (PBG)	Recipe urine ALA and PBG (Ion exchange Chromatography) BED-SOP-525
Urine Faeces	Total Porphyrin	Spectrophotometer Absorbance scan BED-SOP-524
Blood	Red Cell Free Protoporphyrin Red Cell Zinc Protoporphyrin Red Cell HMBS	Luminiscence Spectrophotometer scan BED-SOP-527 BED-SOP-528
Urine	Benzodiazipine screen Amphetamine screen Cannabinoids screen Opiates screen Cocaine screen	Chirus XPress reader Chromatographic Membrane immunoassay BED-SOP-465

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions as required
	Sebia Hydrasys system
Serum paraprotein detection	Electrophoresis BED-SOP-475
Paraprotein type: IgG IgM IgA Kappa Lambda	Antigen/antibody reaction BED-SOP-476
Serum paraprotein quantitation	Electrophoresis scanner BED-SOP-475
	Radiometer ABL90 FLEX blood gas analyser BED-SOP-1062
pH pCO ₂ Sodium pO ₂ Carboxyhaemoglobin Methaemoglobin	Potentiometry Potentiometry Potentiometry Optical phosphorescence Co-oximetry
Actual bicarbonate Standard bicarbonate CO ₂ Content Base Excess Oxygen Saturation	Calculated from the above
	Provide a structure of measurement Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Serum paraprotein detection Paraprotein type: IgG IgM IgA Kappa Lambda Serum paraprotein quantitation PH pCO2 Sodium pO2 Carboxyhaemoglobin Methaemoglobin Actual bicarbonate Standard bicarbonate CO2 Content Base Excess

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HUMAN BODY FLUIDS (cont'd)	Serology examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions as required	
Serum	Detection of:	Roche Cobas 8000 e602 Elecsys Sandwich assay BED-SOP-857	
	Hepatitis B antibody (immunity) Hepatitis B core total antibody (HBcT) Hepatitis C /Antibody		
Serum	HBsAg* HIV-1&2 Antibody & HIV-1 p24 Antigen*	Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy Screening: laboratory QA evidence requirements (targets marked *) Roche Cobas 8000 e602 Elecsys Sandwich assay BED-SOP-873 BED-SOP-146	
	Syphilis IgG/IgM*	BED-SOP-874	
END			