

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



25461

Accredited to
ISO 15189:2022

East Suffolk & North Essex NHS Foundation Trust (ESNEFT)

Issue No: 003 Issue date: 10 September 2024

Clinical Biochemistry
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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	<u>General Biochemistry</u> Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated)		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser Roche Cobas 702 module
Serum, Li-Heparin or Plasma	Albumin	BIO-COL-ADS-001 Colorimetric assay using bromocresol green (BCG),
Serum or Li-Heparin	Alkaline Phosphatase	BIO-COL-ADS-018 Colorimetric assay using p-nitrophenyl phosphate
Serum, Li-Heparin or K2-EDTA Plasma	ALT	BIO-COL-ADS-017 Colorimetric assay using L-alanine and 2-oxoglutarate
K2-EDTA Plasma	Ammonia (NH3)	BIO-COL-ADS-058 Enzymatic assay using Glutamate dehydrogenase (GLDH)
Serum, Li-Heparin or Plasma	Amylase	BIO-COL-ADS-019 Enzymatic colorimetric assay using 4,6-ethylidene-(G7)-p-nitrophenyl-(G1)- α ,D-maltoheptaoside (ethylidene-G7PNP)
Serum, Li-Heparin or K2-EDTA Plasma	AST	BIO-COL-ADS-020 Colorimetric assay using L-aspartate and 2-oxoglutarate



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of:	SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
Serum or Li-Heparin	Bicarbonate (CO ₂)	Roche Cobas 702 module
Serum, Li-Heparin or K ₂ -EDTA Plasma	Bile Acids	BIO-COL-ADS-002 Enzymatic assay using phosphoenolpyruvate carboxylase (PEPC)
Serum, Li-Heparin or Plasma	Calcium	BIO-COL-ADS-084 Colourmetric, 2 Point Kinetic using Thio-NAD
Serum, Li-Heparin or EDTA Plasma	Carbamazepine	BIO-COL-ADS-005 Colorimetric assay using 5-nitro-5'-methyl-BAPTA (NM-BAPTA)
Serum, Li-Heparin or K ₂ -EDTA Plasma	Cholesterol	BIO-COL-ADS-045 Microparticle agglutination immunoassay using Anti-carbamazepine antibody (mouse monoclonal)
Serum, Li-Heparin or K ₂ -EDTA Plasma	Conjugated Bilirubin	BIO-COL-ADS-024 Enzymatic assay using phenol and 4-aminophenazone
Serum, Li-Heparin or K ₂ -EDTA Plasma	Creatine Kinase (CK)	BIO-COL-ADS-003 Colorimetric assay using diazotized sulfanilic acid
Serum, Li-Heparin or K ₂ -EDTA Plasma	Creatinine Enzymatic	BIO-COL-ADS-021 UV Assay using ADP
Serum, Li-Heparin or K ₂ -EDTA Plasma	C-Reactive Protein (CRP)	BIO-COL-ADS-007 Enzymatic assay using 4-aminophenazone and HTIBa
Serum, Li-Heparin or K ₂ -EDTA Plasma		BIO-COL-ADS-008 Immunoturbidimetric assay using Latex particles coated with anti-CRP (mouse)



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
		Roche Cobas 702 module
Serum, Li-Heparin or K2-EDTA Plasma	Ethanol	BIO-COL-ADS-087 Enzymatic method with alcohol dehydrogenase
Serum or Li-Heparin	Gentamicin	BIO-COL-ADS-047 CEDIA Recombinant DNA technology: β -galactosidase
Serum, Li-Heparin or K2-EDTA Plasma	Gamma Glutamyl Transferase (GGT)	BIO-COL-ADS-022 Enzymatic colorimetric assay using L- γ -glutamyl-3-carboxy-4-nitroanilide
Fluoride Plasma	Glucose	BIO-COL-ADS-009 Enzymatic colorimetric assay using Hexokinase + ADP
CSF	Glucose CSF	BIO-COL-ADS-074 Enzymatic colorimetric assay using Hexokinase + ADP
Serum, Li-Heparin or K2-EDTA Plasma	HDL	BIO-COL-ADS-025 Enzymatic colorimetric assay using PEG-cholesterol esterase
Serum or Li-Heparin	Iron	BIO-COL-ADS-039 Colorimetric assay using Transferrin-Fe-complex
Fluoride Plasma	Lactate	BIO-COL-ADS-060 Colorimetric assay using lactate oxidase (LOD) & Peroxidase (POD)
CSF	Lactate CSF	BIO-COL-ADS-076 Colorimetric assay using lactate oxidase (LOD) & Peroxidase (POD)
Serum or Li-Heparin	Lactate Dehydrogenase (LDH)	BIO-COL-ADS-023 UV assay using L-Lactate + NAD



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
Serum	Lithium	Roche Cobas 702 module
Serum or Li-Heparin	Magnesium	BIO-COL-ADS-048 Colorimetric assay using substituted porphyrin compound
Urine – no preservative	Microalbumin (ALBT2)	BIO-COL-ADS-010 Colorimetric assay using Tris(hydroxymethyl)-aminomethane & Xylidyl blue
Serum, Li-Heparin or K2-EDTA Plasma	Paracetamol (ACET)	BIO-COL-ADS-065 Immunoturbidimetric assay using Polyclonal anti-human albumin antibodies (sheep)
Serum, Li-Heparin or K2-EDTA Plasma	Phenytoin	BIO-COL-ADS-049 Enzymatic colorimetric assay using Arylacylamidase + o-cresol
Serum, Li-Heparin or K2-EDTA Plasma	Phosphate	BIO-COL-ADS-050 Microparticle agglutination immunoassay using Anti- Phenytoin antibody (mouse monoclonal)
CSF	Protein CSF	BIO-COL-ADS-011 UV Assay using ammonium molybdate
Serum, Li-Heparin or K2-EDTA Plasma	Salicylate	BIO-COL-ADS-075 Immunoturbidimetric assay using Polyclonal anti-human albumin antibodies (sheep)
Serum, Li-Heparin or K2-EDTA Plasma	Theophylline	BIO-COL-ADS-051 UV Assay using NADH & salicylate hydroxylase
		BIO-COL-ADS-052 Microparticle agglutination immunoassay using Anti- Theophylline antibody (mouse monoclonal)



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	
		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
		Roche Cobas 702 module
Serum, Li-Heparin or K2-EDTA Plasma	Total Bilirubin	BIO-COL-ADS-004 Colorimetric assay using 3,5-Dichlorophenyl diazonium (DPD)
Serum, Li-Heparin or K2-EDTA Plasma	Total Protein	BIO-COL-ADS-014 Colorimetric assay using copper in alkaline solution
Serum or Li-Heparin	Transferrin	BIO-COL-ADS-040 Immunoturbidimetric assay using Anti-human transferrin antibodies (rabbit)
Serum, Li-Heparin or K2-EDTA Plasma	Triglyceride	BIO-COL-ADS-026 Enzymatic colorimetric test using lipoprotein lipase (LPL) & 4-aminophenazone
Serum, Li-Heparin or K2-EDTA Plasma	Urate	BIO-COL-ADS-016 Enzymatic colorimetric test using Uricase & 4-aminophenazone
Serum, Li-Heparin or K2-EDTA Plasma	Urea	BIO-COL-ADS-015 Kinetic Assay using urease and glutamate dehydrogenase
Urine HCL Preservative	Urine Calcium	BIO-COL-ADS-068 Colorimetric assay using 5-nitro-5'-methyl-BAPTA (NM-BAPTA)
Urine Plain or HCL Preservative	Urine Creatinine	BIO-COL-ADS-067 Enzymatic assay using 4-aminophenazone and HTIBa
Urine HCL Preservative	Urine Phosphate	BIO-COL-ADS-069 UV Assay using ammonium molybdate



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Blood (unless otherwise stated)		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser Roche Cobas 702 module
Urine Plain Preservative	Urine Total Protein	BIO-COL-ADS-066 Immunoturbidimetric assay using Polyclonal anti-human albumin antibodies (sheep)
Urine HCL Preservative	Urine Urate	BIO-COL-ADS-072 Enzymatic colorimetric test using Uricase & 4-aminophenazone
Urine Plain Preservative	Urine Urea	BIO-COL-ADS-073 Kinetic Assay using urease and glutamate dehydrogenase
Serum, Li-Heparin or K2-EDTA Plasma	Vancomycin	BIO-COL-ADS-053 Microparticle agglutination immunoassay using Anti- Vancomycin antibody (mouse monoclonal) Roche Cobas 801 module
Serum, Li-Heparin Plasma or K2-EDTA Plasma	AFP (alpha feto protein)	BIO-COL-ADS-054 Sandwich Assay using Monoclonal anti-AFP antibodies (mouse)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	B12	BIO-COL-ADS-027 Competitive Assay using intrinsic factor specific for vitamin B12
Serum, Li-Heparin Plasma or K2-EDTA Plasma	BNP (NT Pro)	BIO-COL-ADS-027 Sandwich Assay using monoclonal mouse and monoclonal sheep antibodies
Serum, Li-Heparin Plasma or K2-EDTA Plasma	CA125	BIO-COL-ADS-055 Sandwich Assay using Monoclonal CA 125-specific antibody (mouse antibody)



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Blood (unless otherwise stated)		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser Roche Cobas 801 module
Serum, Li-Heparin Plasma or K2-EDTA Plasma	CA199	BIO-COL-ADS-056 Sandwich Assay using monoclonal CA 19-9-specific antibody (mouse antibody)
Serum or Li-Heparin Plasma	CEA	BIO-COL-ADS-077 Competitive Immunoassay using (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Cortisol	BIO-COL-ADS-041 Sandwich Assay using (polyclonal anti-cortisol antibody (ovine))
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Digoxin	BIO-COL-ADS-046 Competitive Assay using digoxin-specific ruthenium-labelled antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Ferritin	BIO-COL-ADS-037 Sandwich Assay using monoclonal ferritin-specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Folate III	BIO-COL-ADS-038 Competitive Assay using labelled folate binding protein (Human)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	FSH	BIO-COL-ADS-029 Sandwich Assay using monoclonal FSH-specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	FT3	BIO-COL-ADS-079 Competitive Assay using T3-specific antibody (sheep)



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	
		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
		Roche Cobas 801 module
Serum, Li-Heparin Plasma or K2-EDTA Plasma	FT4	BIO-COL-ADS-042 Competitive Assay using T4-specific antibody (sheep)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	HCG+β	BIO-COL-ADS-030 Sandwich Assay using monoclonal hCG-specific antibodies(mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	LH	BIO-COL-ADS-031 Sandwich Assay using monoclonal LH-specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Oestradiol	BIO-COL-ADS-032 Competitive Assay: two Estradiol-specific biotinylated antibodies (rabbit)
Serum	PLGF	BIO-COL-ADS-061 Sandwich Assay using monoclonal PIGF specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Procalcitonin	BIO-COL-ADS-062 Sandwich immunoassay using Monoclonal anti-PCT antibodies (mouse)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Progesterone	BIO-COL-ADS-033 Competitive Assay using progesterone specific biotinylated antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Prolactin	BIO-COL-ADS-034 Sandwich immunoassay using monoclonal Prolactin specific antibody (mouse antibody)



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Blood (unless otherwise stated)		SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser Roche Cobas 801 module
Serum, Li-Heparin Plasma or K2-EDTA Plasma	PSA	BIO-COL-ADS-057 Sandwich immunoassay using monoclonal PSA-specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	PTH	BIO-COL-ADS-043 Sandwich immunoassay using monoclonal PTH specific antibody (mouse antibody)
Serum	SFLT	BIO-COL-ADS-064 Sandwich immunoassay using monoclonal sFlt 1 specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Testosterone	BIO-COL-ADS-035 Competitive Assay using monoclonal testosterone-specific antibody (sheep)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	Troponin T	BIO-COL-ADS-028 Sandwich immunoassay using monoclonal cardiac troponin T specific antibody (mouse antibody)
Serum, Li-Heparin Plasma or K2-EDTA Plasma	TSH	BIO-COL-ADS-044 Sandwich immunoassay using monoclonal TSH-specific antibody (mouse antibody)
Serum or Li-Heparin	Vitamin D	BIO-COL-ADS-063 Competitive Immunoassay



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Blood (unless otherwise stated)	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	SOP BIO-COL-GP-002 using Roche Cobas 8000 analyser
		Roche Cobas ISE module
Serum or Li-Heparin Plasma	Chloride	BIO-COL-ADS-006 An Ion-Selective Electrode (ISE)
Serum or Li-Heparin Plasma	Potassium	BIO-COL-ADS-012 An Ion-Selective Electrode (ISE)
Serum or Li-Heparin Plasma	Sodium	BIO-COL-ADS-013 An Ion-Selective Electrode (ISE)
Urine – no preservative	Urine Potassium	BIO-COL-ADS-070 An Ion-Selective Electrode (ISE)
Urine – no preservative	Urine Sodium	BIO-COL-ADS-071 An Ion-Selective Electrode (ISE)
	Blood gas analysis:	BIO-COL-LP-005 using Radiometer 800 Flex Blood Gas Analyser
Whole Blood: Li-Heparin Plasma	pH pCO ₂ pO ₂ Haemoglobin Carboxyhaemoglobin Methaemoglobin	BIO-COL-LP-005
Serum or Li-Heparin Plasma	Osmolality	BIO-COL-LP-002 Advanced Micro-Osmometer Model 3320 Depression of freezing point
Urine – No preservative	Urine Osmolality	BIO-COL-LP-002 Advanced Micro-Osmometer Model 3320 Depression of freezing point
Serum or Li-Heparin Plasma	Sodium (Direct ISE)	BIO-COL-LP-003 Roche 9180 Ion Selective Electrode (ISE)



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CSF	Xanthochromia	BIO-COL-LP-004 Spectrophotometric analysis using NorthStar BIO-UV Spectrophotometer
Pleural Fluid	Pleural Fluid pH	BIO-COL-LP-005 Radiometer 800 Flex Blood Gas Analyser
END		