Schedule of Accreditation

United Kingdom Accreditation Service

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



9318

Accredited to ISO 15189:2012

East Suffolk & North Essex NHS Foundation Trust (ESNEFT)

Issue No: 007 Issue date: 02 July 2024

Biochemistry Department

Ipswich Hospital

Heath Road Ipswich Suffolk

IP4 5PD

Contact: Stephen Gee Tel: +44 (0)1473 704820

E-Mail: Stephen.Gee@esneft.nhs.uk Website: https://www.esneft.nhs.uk

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	General Biochemistry 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-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche c702
Serum, Li Heparin or EDTA plasma	Albumin	BIO-IPS-ADS-40 (Blood) Using bromcresol green
Urine- No Preservative.	Albumin/microalbumin	BIO-IPS-ADS-28 using Polyclonal anti-human albumin antibodies (sheep)
Blood Serum, Li Heparin or EDTA plasma	Alcohol (Ethanol)	BIO-IPS-ADS-96 using alcohol dehydrogenase
Serum or Li Heparin	Alkaline Phosphatase	BIO-IPS-ADS-92 using p- nitrophenyl phosphate
Serum, Li Heparin or EDTA plasma	Alpha 1 Antitrypsin	BIO-IPS-ADS-4 using - Anti-human α1-antitrypsin antibody (rabbit):
Serum, Li Heparin or EDTA plasma	ALT	BIO-IPS-ADS-37 using L-alanine and 2-oxoglutarate
EDTA plasma	Ammonia	BIO-IPS-ADS-98 using - + α- ketoglutarate + NADH

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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche c702
Blood- Serum or Li Heparin	Amylase	BIO-IPS-ADS-36 (Blood) Using 4,6-ethylidene-(G7) p- nitrophenyl-(G1)-α,D- maltoheptaoside (ethylidene- G7PNP)
Blood- Serum or Li Heparin	Angiotensin Converting enzyme	BIO-IPS-ADS-26 using synthetic substrate (FAPGG)
Serum, Li Heparin or EDTA plasma	Gentamycin	BIO-IPS-ADS-11 using KIMS
Serum, or EDTA plasma	Vancomycin	BIO-IPS-ADS-117 using - Vancomycin labelled with the enzyme glucose-6- phosphate dehydrogenase (G6PDH)
Serum, Li Heparin or EDTA plasma	AST	BIO-IPS-ADS-43 using - L- aspartate and 2-oxoglutarate
Serum or Li Heparin	Bicarbonate	BIO-IPS-ADS-78 using - phosphoenolpyruvate (PEP)
Serum or Li Heparin	Bile acids	BIO-IPS-ADS-47 using – Thio - Nicotinamide Adenine Dinucleotide
Serum or Li Heparin	Bilirubin (Conjugated)	BIO-IPS-ADS-5 using - diazotized sulfanilic acid
Serum or Li Heparin	Bilirubin (Total)	BIO-IPS-ADS-8 using diazonium ion
Serum or Li Heparin	Caeruloplasmin	BIO-IPS-ADS-8 using - Anticeruloplasmin T antiserum (rabbit)

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Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche c702
Blood- Serum or Li Heparin Urine- HCl preservative.	Calcium	BIO-IPS-ADS-89 (Blood) BIO-IPS-ADS-27 (Urine) Using - 5-nitro-5'-methyl-BAPTA (NM-BAPTA)
Serum, Li Heparin or EDTA plasma	Carbamazepine	BIO-IPS-ADS-70 using - Anti- carbamazepine antibody (mouse monoclonal)
Serum, Li Heparin or EDTA plasma	Cholesterol	BIO-IPS-ADS-38 using - phenol and 4-aminophenazone Non-calculated test
Serum, Li Heparin or EDTA plasma	CK (Creatine Kinase)	BIO-IPS-ADS-35using ADP
Serum, Li Heparin or EDTA plasma	Complement C3	BIO-IPS-ADS-6 using Anti-human C3 antibody (goat):
Serum, Li Heparin or EDTA plasma	Complement C4	BIO-IPS-ADS-9 using Anti-human C4 antibody (goat)
Serum, Li Heparin or EDTA plasma	C-Reactive Protein	BIO-IPS-ADS-83 using - Latex particles coated with anti-CRP (mouse
Serum, Li Heparin or EDTA plasma, Urine	Creatinine	BIO-IPS-ADS-94 (Blood) BIO-IPS-ADS-141 (Urine) Using 4-aminophenazone and HTIB ^a
CSF Fluoride EDTA or serum (<2 hours old)	Glucose	BIO-IPS-ADS-45 using Glucose-6- phosphate dehydrogenase oxidizes
CSF Fluoride EDTA	Protein	BIO-IPS-ADS-46 using copper in alkaline solution

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Blood (unless otherwise stated)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche c702
Serum, Li Heparin or EDTA plasma	Gamma Glutamyl Transferase	BIO-IPS-ADS-99 using - γ-glutamyl- 3-carboxy-4-nitroanilide + glycylglycine
Blood-Fluoride EDTA	Glucose	BIO-IPS-ADS-12 (Blood) BIO-IPS-ADS-24 (Pleura/ascitic fluid & dialysis fluid) Using Glucose-6-phosphate dehydrogenase oxidizes
Serum, Li Heparin or EDTA plasma	HDL	BIO-IPS-ADS-120 using PEG- cholesterol esterase
Serum, Li Heparin or EDTA plasma	IgA	BIO-IPS-ADS-7 using Anti-human IgA antibody (goat)
Serum, Li Heparin or EDTA plasma	IgG	BIO-IPS-ADS-122 using Anti- human IgG antibody (goat)
Serum, Li Heparin or EDTA plasma	IgM	BIO-IPS-ADS-123 using Anti- human IgM antibody (goat)
Serum, Li Heparin	Iron	BIO-IPS-ADS-124 using Transferrin-Fe-complex
Fluoride EDTA	Lactate	BIO-IPS-ADS-15 using enzyme lactate oxidase (LOD) & Peroxidase (POD)
Serum or Li Heparin	LD (Lactate Dehydrogenase)	BIO-IPS-ADS-2 (Blood) BIO-IPS-ADS-65 (Pleura/Ascitic fluid & Dialysis fluid) Using pyruvate
Serum	Lithium	BIO-IPS-ADS-44using Colorimetric test

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Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche c702
Blood- Serum or Li Heparin Urine- Hydrochloric acid Preservative	Magnesium	BIO-IPS-ADS-125 (Blood) BIO-IPS-ADS-148 (Urine) Using aminomethane & Xylidyl blue
Serum, Li Heparin or EDTA plasma	Paracetamol	BIO-IPS-ADS-118 using aryl acylamidase & o-cresol + ammoniacal copper sulphate
Serum, Li Heparin	Phenytoin	BIO-IPS-ADS-74 using KIMS
Blood- Serum, Li Heparin or EDTA plasma Urine- Random urine or 24 hour urine collection (collected into HCI	Phosphate	BIO-IPS-ADS-126 (Blood) BIO-IPS-ADS-147 (Urine) Using ammonium molybdate
preservative)		
Urine- No preservative	24hr Protein	BIO-IPS-ADS-27 using Benzethonium chloride
Serum, Li Heparin or EDTA plasma	Rheumatoid Factor	BIO-IPS-ADS-10 using Immunoturbidimetric assay
Serum or Li Heparin	Salicylate	BIO-IPS-ADS-81 using NADH & salicylate hydroxylase
Serum, Li Heparin or EDTA plasma	Theophylline	BIO-IPS-ADS-33 using KIMS
Blood- Serum, Li Heparin or EDTA plasma	Total Protein	BIO-IPS-ADS-105 (Blood) using copper in alkaline solution
Serum, Li Heparin	Transferrin	BIO-IPS-ADS-107 using Anti- human transferrin antibodies (rabbit)

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	SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
	Roche c702
Triglyceride	BIO-IPS-ADS-16 using - 4- aminophenazone + 4-chlorophenol 4-(p-benzoquinone-monoimino)- phenazone
Urate	BIO-IPS-ADS-30 (Urine) ADO229 (Blood) Using Uricase & 4-aminophenazone
Urea	BIO-IPS-ADS-13(Blood) ADO275 (Urine) using - urease and glutamate dehydrogenase
	Roche Cobas e801
AFP	BIO-IPS-ADS-112 Sandwich immunoassay (Monoclonal anti-AFP antibodies (mouse))
Anti-Thyroid peroxidase antibodies	BIO-IPS-ADS-135 using Competitive immunoassay (sheep antibody)
B12	BIO-IPS-ADS-132 Competitive immunoassay
BNP	BIO-IPS-ADS-88 Sandwich immunoassay (monoclonal mouse and monoclonal sheep antibodies)
CA125	BIO-IPS-ADS-136 Sandwich immunoassay (mouse antibody)
	measured/Range of measurement General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd) Triglyceride Urate Urea AFP Anti-Thyroid peroxidase antibodies B12 BNP

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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche Cobas e801
Serum, Li Heparin or EDTA plasma	CA153	BIO-IPS-ADS-137 Sandwich immunoassay (mouse antibody)
Serum, Li Heparin or EDTA plasma	CA19-9	BIO-IPS-ADS-84 Sandwich immunoassay (mouse antibody)
Serum, Li Heparin or EDTA plasma	CEA	BIO-IPS-ADS-72Sandwich immunoassay (mouse antibody)
Serum, Li Heparin or EDTA plasma	Cortisol	BIO-IPS-ADS-69 Competitive immunoassay (polyclonal anticortisol antibody (ovine))
Serum, Li Heparin or EDTA plasma	DHEAS	BIO-APS-ADS-138 Competitive immunoassay. Monoclonal rabbit antibody
Serum, Li Heparin or EDTA plasma	Digoxin	BIO-IPS-ADS-75 Competitive immunoassay (monoclonal mouse antibody).
Serum, Li Heparin or EDTA plasma	Ferritin	BIO-IPS-ADS-134 Sandwich Immunoassay. Monoclonal mouse antibody
Serum or Li Heparin	Folate	BIO-IPS-ADS-133 Competitive immunoassay
Serum, Li Heparin or EDTA plasma	FSH	BIO-IPS-ADS-66 Sandwich Immunoassay. Mouse antibody
Serum, Li Heparin or EDTA plasma	hCG	BIO-IPS-ADS-67 Sandwich immunoassay (monoclonal anti-hCG antibody, mouse)

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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche Cobas e801
Serum, Heparin or EDTA Plasma	IGF1	BIO-IPS-ADS-77 Sandwich immunoassay, Monoclonal mouse antibody
Serum, Li Heparin or EDTA plasma	PEG Precipitation pre-treatment for interfering antibodies to monoclonal proteins	BIO-IPS-LP-19 25% polyethylene glycol (PEG) solution precipitation
	Macroprolactin	
Serum, Li Heparin or EDTA plasma	LH	BIO-IPS-ADS-131 Sandwich Immunoassay. Monoclonal Mouse antibody.
Serum, Li Heparin or EDTA plasma	Oestradiol	BIO-IPS-ADS-71 Competitive immunoassay. Polyclonal Rabbit antibody.
Blood and serum	PLGF	BIO-IPS-ADS-61 Sandwich immunoassay Monoclonal mouse antibodies
Serum, Li Heparin or EDTA plasma	Procalcitonin	BIO-IPS-ADS-91Sandwich Immunoassay. Monoclonal anti PCT Antibodies (Mouse)
Serum, Li Heparin or EDTA plasma	Procollagen type 1 amino-terminal propeptide (P1NP)	BIO-IPS-ADS-121 Sandwich immunoassay (Monoclonal Mouse antibody)
Serum, Li Heparin or EDTA plasma	Progesterone	BIO-IPS-ADS-82 Competitive immunoassay. Monoclonal Mouse antibody.

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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated) (cont'd)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche Cobas e801
Serum, Li Heparin or EDTA plasma	Prolactin	BIO-IPS-ADS-76 Sandwich immunoassay. Monoclonal Mouse antibody
Serum, Li Heparin or EDTA plasma	PSA (Total)	BIO-IPS-ADS-139 Sandwich immunoassay. Monoclonal mouse antibody.
EDTA plasma	PTH	BIO-IPS-ADS-39Sandwich immunoassay. Monoclonal mouse antibody.
Blood or serum	SFLT-1	BIO-IPS-ADS-62 Sandwich immunoassay Monoclonal mouse antibodies
Serum, Li-Heparin plasma	Vitamin D	BIO-IPS-ADS-1 Competitive immunoassay
Serum, Li Heparin	SHBG	BIO-IPS-ADS-32 Sandwich immunoassay. Monoclonal mouse antibody.
Serum, Li Heparin or EDTA plasma	T3 (Free)	BIO-IPS-ADS-115 Competitive Immunoassay. Monoclonal Sheep antibody.
Serum, Li Heparin or EDTA plasma	T4 (Free)	BIO-IPS-ADS-68 Competitive immunoassay. Monoclonal rabbit antibody.
Serum, Li Heparin or EDTA plasma	Testosterone	BIO-IPS-ADS-73 Competitive immunoassay. Monoclonal sheep antibody.

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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd) Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Blood (unless otherwise stated)		SOP BIO-IPS-LP-18 using Roche Cobas 8000 analyser (ISE, e801 and c702)
		Roche Cobas e801
Serum	Troponin T	BIO-IPS-ADS-90 Sandwich immunoassay (mouse antibody)
Serum, Li Heparin or EDTA plasma	TSH	BIO-IPS-ADS-85 Sandwich immunoassay. Monoclonal mouse antibody.
Blood- Serum or Li Heparin	Chloride	BIO-IPS-ADS-93 (Blood)
Urine- No Preservative		ADO247 (Urine) Ion-Selective Electrode (ISE)
Blood, Serum or Li Heparin	Potassium	BIO-IPS-ADS-86 (Blood) BIO-IPS-ADS-145 (Urine)
Urine No Preservative		Ion-Selective Electrode (ISE)
Blood, Serum or Li Heparin Urine No Preservative	Sodium	BIO-IPS-ADS-97 (Blood) ADO273 (Urine) Ion-Selective Electrode (ISE)
		BIO-IPS-CP-2 using Roche Cobas e411 analyser
EDTA whole blood	Ciclosporin	BIO-IPS-ADS-34 using Competitive immunoassay. Monoclonal mouse antibody
Serum	Thyroid Receptor Antibody (TRAB)	BIO-IPS-ADS-3 using Competitive immunoassay. Monoclonal mouse antibody

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	Blood gas analysis:	Radiometer ABL 825 Flex BIO-IPS-LP-8
Blood- Li Heparin whole blood Pleural fluid- Li Heparin Whole blood- Li Heparin	p.CO2 TCO2 (Bicarbonate) p.O2 Ionized Calcium Sodium Potassium Chloride Lactate Carboxyhaemoglobin MetHb	BIO-IPS-ADS-49 (Blood) BIO-IPS-ADS-140 (Pleural Fluid) Using pH electrode BIO-IPS-ADS-49
		Diasorin Liaison XL LP0060
Faeces	Calprotectin	BIO-IPS-ADS-42 using chemiluminescent Immunoassay technology
Faeces	Elastase	BIO-IPS-ADS-029 using chemiluminescent Immunoassay technology
Blood (Unless otherwise specified) Serum	Protein electrophoresis assays:	SP 60 Helena SAS Protein electrophoresis Gel, CZE, and CZE Immunodisplacement Using SOP LP089, BIO-IPS-LP-9, BIO-IPS-LP-17
Serum	Cryoglobulin	
Serum	Paraprotein Quantitation	

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Blood (Unless otherwise specified) Serum (cont'd)	Protein electrophoresis assays: (cont'd)	SP 60 Helena SAS Protein electrophoresis Gel, CZE, and CZE Immunodisplacement Using SOP LP089, BIO-IPS-LP-9, BIO-IPS-LP-17		
Serum	Protein electrophoresis Report paraprotein if present together with quantitation of paraprotein. Report the degree of immune paresis/background when a paraprotein is present. Report polyclonal increase in gamma globulins if present and decrease in the Gamma region if present.			
Serum	Protein immunodisplacement/Immunofixatio n Paraprotein classification IgA kappa or lambda IgM kappa or lambda IgG kappa or lambda IgD kappa or lambda IgE kappa or lambda Free Kappa or Free Lambda			
Urine- No Preservative	Electrophoresis Paraprotein quantification Immunofixation Lambda or Kappa free light chains			
Blood- EDTA Whole Blood	HbA1c	Using the TOSOH G11 HPLC BIO-IPS-LP-22		
Blood- Serum	Osmolality	Advanced instruments Osmometer model Osmo 1		
Urine- No Preservative		BIO-IPS-LP-26		

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CSF	Xanthochromia	In house procedure and Thermo electron corporation UV 500 Spectrophotometry BIO-IPS-LP-1
Sweat- Induced Sweat Sample	Sweat Chloride	Sherwood scientific Model 926S chloride analyser BIO-IPS-LP-16
Renal calculi	Renal calculi	Brucker Alpha FITR infra-red spectrophotometer with ATR attachment BIO-IPS-LP-24
Serum	Light Free chains	Binding site Optilite SOP BIO-IPS- LP-13
	Kappa Light Chain Assay	BIO-IPS-ADS-150 using determination of soluble antigen concentration by turbidimetric
Serum	Lambda Light Chains Assay	BIO-IPS-ADS-151 using determination of soluble antigen concentration by turbidimetric
Faeces	FIT Occult Blood	BIO-IPS-LP-27 using HM-JACKarc Analyser BIO-IPS-ADS-109 latex agglutination using Anti-human haemoglobin sheep antibody sensitised latex suspension
EDTA Whole Blood	DCA HbA1c	BIO-IPS-LP-11 Siemens DCA Advantage. BIO-IPS-ADS-53 using Latex Immunoagglutination Inhibition methodology

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Blood and Urine		Calculated tests using SOP BIO- IPS-GP-4
	Adjusted Calcium; CADJ	
	Albumin/ Creatinine Ratio; MAUC	
	Aldosterone/ Renin Ratio; ALDR	
	Anion Gap; AG	
	Creatinine clearance; CRC	
	Estimated Glomerular Filtration Rate (enzymatic); GFRE	
	Globulins; GLOB	
	LDL Cholesterol (calculated); LDL	
	Non-HDL cholesterol; NHDL	
	Free Androgen Index; FAI	
	Free Light Chain Ratio; KLR	
	Protein/ Creatinine Ratio; TPC	
	Total Cholesterol / HDL Cholesterol	
	Ratio; CHHR	
	Saturated Transferrin; SATR	
	Unconjugated Bilirubin; BITC	
	Urine Amylase 24h; AMYD	
	Urine Calcium 24h; CAD	
	Urine Chloride 24h; CLD	

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Blood and Urine (unless otherwise stated) (cont'd)		Calculated tests using SOP BIO- IPS-GP-4	
	Urine Creatinine 24h; CRD		
	Urine Magnesium 24h; MGD		
	Urine Paraprotein 24h; PPD		
	Urine Phosphate 24h; PO4D		
	Urine Potassium 24h; KD		
	Urine Protein 24h; TPD		
	Urine Sodium 24h; NAD		
	Urine Urate 24h; UAD		
	Urine Urea 24h; URD		
Serum	SFLT-1/PLGF Ratio	Calculated tests using SOP BIO- IPS-GP-4	
END			

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