

Schedule of Accreditation



Organisation Name	Saolta University Health Care Group - Galway University Hospital - Clinical Biochemistry
Trading As	
INAB Reg No	246MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	27/10/2009
Scope Classification	Chemical pathology
Services available to the public ¹	

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Laboratory Medicine Directorate, Galway, H91 YR71

Scope of Accreditation

Head Office

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	24 Hour Inorganic Phosphjate	Urine	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
	24 Hour Urinary Amylase		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
	24 Hour Urinary Calcium		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
	24 Hour Urinary Chloride		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
	24 Hour Urinary Creatinine		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS

24 Hour Urinary Magnesium		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
24 Hour Urinary Potassium		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
24 Hour Urinary Sodium		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
24 Hour urinary Total Protein		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
24 Hour Urinary Urea		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
24 Hour Urinary Uric Acid		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Adjusted Calcium	Serum/Plasma	Calculated	Calculated	In house developed calculation	LP-GB-D-ADJCA
Alanine Amino Transferase (ALT)		IFCC (w/o PP activation)	Roche cobas 8000 5 U/L to 700 U/L	CE Marked	LP-GB-D-ALT
Albumin	Serum	Bromocresol Green	Roche cobas8000 2 g/L to 60 g/L	CE Marked	LP-GB-D-ALB
Alcohol Calculation (Units)		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Aldosterone	Plasma	Immunoassay	IDS i10 102.5 to 3656 pmol/L	CE	LP-GB-D-ALDO
Aldosterone/Renin Ratio	Serum	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Alkaline Phosphate (ALP)	Serum/Plasma	IFCC with PNPP	Roche cobas8000 5 U/L to 1200 U/L	CE Marked	LP-GB-D-ALP
Alpha Fetoprotein (AFP)		Immunoassay	Roche e800 0.908 ng/mL to 1210 ng/mL	CE Marked	LP-GB-D-AFP

Ammonia	EDTA Plasma	Enzymatic	Roche Cobas 8000 10 to 1000 µmol/L	CE	LP-GB-D-AMMO
Amylase	Serum/Urine	Enzymatic / IFCC	Roche cobas8000 Serum 3 U/L to 1500 U/L Urine 3 U/L to 1500 U/L	CE Marked	LP-GB-D-AMY
Amylase Creatinine Clearance Ratio	Urine	Calculated	Calculated	Based on standard method	LP-GB-D-ACCR
Anion Gap	Serum	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Asparate Amino Transferase (AST)	Serum/Plasma	IFCC (w/o PP activation)	Roche cobas8000 5 U/L to 700 U/L	CE Marked	LP-GB-D-AST
Beta-Hydroxybutrate	Serum	Enzymatic	Roche Cobas 8000 0.18 to 4.5 mmol/L	CE	LP-GB-D-BHB
Bicarbonate	Serum/Plasma	Enzymatic with PEP	Roche cobas8000 2.0 mmol/L to 50 mmol/L	CE Marked	LP-GB-D-HCO3
Bile Acids		Enzymatic	Roche cobas8000 1 µmol/L to 180 µmol/L	CE Marked	LP-GB-D-BILE
Bilirubin – Direct		Diazo	Roche cobas8000 1.5 µmol/L to 291 µmol/L	CE Marked	LP-GB-D-DBIL
Bilirubin – Total		Diazo	Roche cobas8000 2.5 µmol/L to 550 µmol/L	CE Marked	LP-GB-D-TBILI
Bioactive Prolactin		Serum	Calculation	Laboratory Information System	Based on Standard Method
C Reactive Protein (CRP)	Serum/Plasma	Immunoturbidimetric	Roche cobas8000 0.6 mg/L to 350 mg/L	CE Marked	LP-GB-D-CRP

Calcium	Serum/Plasma/Urine	NM-BAPTA	Roche cobas8000 Serum 0.20 mmol/L to 5.00 mmol/L Urine 0.20 mmol/L to 7.50 mmol/L	CE Marked	LP-GB-D-CA
Calcium Excretion	Urine	Calculated	Calculated	Based on standard method	LP-GB-D-CAE
Calcium/Creatinine Molar Ratio		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Calcium:Creatinine Clearance Ratio		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Chloride	Serum/Plasma/Urine	Indirect ISE	Roche cobas8000 Serum/Plasma: 60 mmol/L to 140 mmol/L Urine: 60 mmol/L to 350 mmol/L	CE Marked	LP-GB-D-ISE
Cholesterol	Serum/Plasma	CHOP-PAP	Roche cobas8000 0.1 mmol/L to 20.7 mmol/L	CE Marked	LP-GB-D-CHOL
Cholesterol/HDL Ratio		Calculated	Calculated	Based on standard method	LP-GB-D-CHDL
Creatine Kinase (CK)		IFCC	Roche cobas8000 7 U/L to 2000 U/L	CE Marked	LP-GB-D-CK
Creatinine	Serum/Plasma/Urine	Enzymatic	Roche cobas8000 Serum: 5 µmol/L to 2700 µmol/L Urine: 100 µmol/L to 54,000 µmol/L	CE Marked	LP-GB-D-CREAT
Creatinine Clearance	Serum, Urine	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Estimated Glomerular Filtration Rate (eGFR)	Serum/Plasma	Calculated	Calculated	Based on standard method	LP-GB-D-EGFR

Free:Total Prostate Specific Antigen Ratio	Serum	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Gamma Glutamyl Transferase (GGT)	Serum/Plasma	IFCC	Roche cobas 8000 3 U/L to 1200 U/L	CE Marked	LP-GB-D-GGT
Glucose	Serum/Plasma/CSF	Hexokinase	Roche cobas 8000 0.11 mmol/L to 41.6 mmol/L	CE Marked	LP-GB-D-GLU
Growth Hormone	Serum	Immunoassay	IDS i10 0.050 to 100 mg/L	CE	LP-GB-D-HGH
High Density Lipoprotein (HDL)	Serum/Plasma	Enzymatic Colourimetric	Roche cobas 8000 0.08 mmol/L to 3.88 mmol/L	CE Marked	LP-GB-D-HDL
Homocysteine	Plasma	Immunoassay	Abbott Architect i2000sr 1.0 µmol/L to 50 µmol/L	CE Marked	LP-GB-D-HYC
Insulin Like Growth Factor 1 (IGF-1)	Serum	Immunoassay	IDS i10 10 to 1200 mg/L	CE	LP-GB-D-IGH1
Lactate Dehydrogenase (LDH)	Serum/Plasma	IFCC	Roche cobas 8000 10 U/L to 1000 U/L	CE Marked	LP-GB-D-LDH
Low Density Lipoprotein (LDL)		Calculated	Calculated	Based on standard method	LP-GB-D-LDL
Magnesium	Serum/Plasma/Urine	Colorimetric	Roche cobas 8000 Serum: 0.1 mmol/L to 2.00 mmol/L Urine: 0.56 mmol/L to 11.00 mmol/L	CE Marked	LP-GB-D-MG
Osmolality	Serum/Urine	Freezing Point Depression	Advanced Micro-Osmometer (Model 3320) 0 mmol/kg H ₂ O to 2000 mmol/kg H ₂ O	CE Marked	LP-GB-D-OSMO
Phosphate – inorganic	Serum/Plasma/Urine	Ammonium Molybdate	Roche cobas 8000 Serum 0.1 mmol/L to 6.46 mmol/L	CE Marked	LP-GB-D-PHOS

			Urine 1.1 mmol/L to 92 mmol/L		
Potassium	Serum/Urine/Plasma	Indirect ISE	Roche cobas 8000 Serum/Plasma: 0.5 mmol/L to 10 mmol/L Urine: 3.00 mmol/L to 100 mmol/L	CE Marked	LP-GB-D-ISE
Protein/Creatinine Ratio	Urine	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
		Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Protein-Total	Urine/CSF	Benzethonium Chloride	Roche cobas 8000 0.04 g/L to 2.00 g/L	CE Marked	LP-GB-D-UPROT LP-GB-D-CSF
Protein-Total	Serum	Biuret	Roche cobas 8000 2.0 g/L to 120 g/L	CE Marked	LP-GB-D-TP
Renin	Plasma	Immunoassay	IDS i10 1.8 to 550 mIU/L	CE	LP-GB-D-DIRECTRENIN
Sodium	Serum/Urine	Indirect ISE	Roche cobas 8000 Serum: 80 mmol/L to 180 mmol/L Urine: 60 mmol/L to 350 mmol/L	CE Marked	LP-GB-D-ISE
Transferrin Saturation	Serum	Calculation	Laboratory Information System	Based on Standard Method	MP-GB-LIS
Triglycerides	Serum/plasma	GPO-PAP	Roche cobas 8000 0.1 mmol/L to 10.0 mmol/L	CE Marked	LP-GB-D-TRIG
Troponin T high sensitivity		Immunoassay	Roche e801 3 ng/L to 10,000 ng/L	CE Marked	LP-GB-D-TNTHS

	Urea	Serum/plasma/Urine/Fluid	Urease	Roche cobas 8000 Serum 0.5 mmol/L to 40 mmol/L Urine 1.0 mmol/L to 2000 mmol/L	CE Marked	LP-GB-D-UREA
	Uric Acid	Serum/Urine/Plasma	Uricase	Roche cobas 8000 Serum 11.9 µmol/L to 1487 µmol/L Urine 131 µmol/L to 16362 µmol/L	CE Marked	LP-GB-D-UA
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine	Serum/Plasma	KIMS	Roche cobas c702 2 mg/L to 20 mg/L	CE Marked	LP-GB-D-CARB
	Cyclosporin	EDTA Whole Blood	CMIA	Abbott Architect 30 to 1500 ng/mL	CE	LP-GB-D-CYC
	Digoxin	Serum/Plasma	Immunoassay	Roche cobas e801 0.2 ng/mL to 5.0 ng/mL	CE Marked	LP-GB-D-DIG
	Gentamicin		CEDIA	Roche cobas 8000 0.24 mg/L to 12 mg/L	CE Marked	LP-GB-D-GENT
	Lithium	Serum	Colorimetric	Roche cobas c702 0.05 mmol/L to 3.00 mmol/L	CE Marked	LP-GB-D-LI
	Methotrexate		CMIA	Abbott Architect i2000sr 0.04 µmol/L to 1.50 µmol/L	CE Marked	LP-GB-D-MTX
	Phenobarbitone		KIMS	Roche cobas c702 2.4 mg/L to 60 mg/L	CE Marked	LP-GB-D-PBARB
	Phenytoin		KIMS	Roche cobas c702 0.8 mg/L to 40 mg/L	CE Marked	LP-GB-D-PTOIN
Tacrolimus	Plasma	MEIA	Abbott Architect i2000sr 2.0 µg/L to 30 µg/L	CE Marked	LP-GB-D-TACRO	

	Theophylline	Serum/Plasma	KIMS	Roche cobas c702 0.80 mg/L to 40 mg/L	CE Marked	LP-GB-D-THEO
	Valproate	Serum/Plasma	Immunoassay	Roche cobas c702 2.8 µg/mL to 150 µg/mL	CE Marked	LP-GB-D-VALP
	Vancomycin		KIMS	COBAS 8000	CE	LP-GB-D-VANC
1061 Clinical Chemistry - .14 Alcohol for non- legal purposes	Alcohol	Serum	Enzymatic	Roche cobas 8000 10.1 mg/dL to 498 mg/dL	CE Marked	LP-GB-D-ALCH
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol		Colourimetric	Roche cobas 8000 1.2 µg/mL to 500 µg/mL	CE Marked	LP-GB-D-PARAC
	Salicylate		Ferric Nitrate	Roche cobas 8000 3.0 µg/mL to 700 µg/mL	CE Marked	LP-GB-D-SALIC
1061 Clinical Chemistry - .20 Hormones	Adrenocorticotrophic hormone (ACTH)	Plasma	Sandwich principle	Roche Cobas 8000 1.5 ng/L to 2000 ng/L	CE Marked	LP-GB-D-ACTH
	C Peptide	Serum/Plasma	Immunoassay	Roche cobas e801 7.0 pmol/L to 13,300 pmol/L	CE Marked	LP-GB-D-CPEP
	Cortisol		Immunoassay	Roche cobas e801 1.5 nmol/L to 1750 nmol/L	CE Marked	LP-GB-D-CORT
	Follicle Stimulating Hormone (FSH)		Immunoassay	Roche cobas e801 0.300 mIU/mL to 200.0 mIU/mL	CE Marked	LP-GB-D-FSH
	Human Chorionic Gonadotropin (HCG) - Total		Immunoassay	Roche cobas e801 0.20 U/L to 10000 U/L	CE Marked	LP-GB-D-HCG
	Insulin	Plasma	Immunoassay	Roche cobas e801 2.78 pmol/L to 6945 pmol/L	CE Marked	LP-GB-D-INS
	Leuteinising Hormone (LH)	Serum	Immunoassay	Roche cobas e801 0.30 mIU/mL to 200 mIU/mL	CE Marked	LP-GB-D-LH

Macroprolactin	Serum/Plasma	PEG pptte	Roche cobas e801 2 mIU/L to 10,000 mIU/L	CE Marked	LP-GB-D-MPRL
N-Terminal pro B-Type Natriuretic Peptide (NT-pro BNP)	Serum	Immunoassay	Roche cobas e801 5 ng/L to 35000 ng/L	CE Marked	LP-GB-D-PROBNPII
Oestradiol	Serum/Plasma	Immunoassay	Roche cobas e801 18.4 pmol/L to 11010 pmol/L	CE Marked	LP-GB-D-OEST
Parathyroid Hormone (PTH)		Immunoassay	Roche cobas e801 1.20 ng/L to 5000 ng/L	CE Marked	LP-GB-D-PTH
Progesterone		Immunoassay	Roche cobas e801 0.159 nmol/L to 191 nmol/L	CE Marked	LP-GB-D-PROG
Prolactin	Serum	Immunoassay	Roche cobas e801 2 mIU/L to 10,000 mIU/L	CE Marked	LP-GB-D-PRL
Prostate Specific Antigen (PSA) – Total		Immunoassay	Roche cobas e801 0.006 µg/L to 100.00 µg/L	CE Marked	LP-GB-D-PSA
Sex Hormone Binding Globulin (SHBG)		Immunoassay	Roche cobas e801 0.8 nmol/L to 200 nmol/L	CE Marked	LP-GB-D-SHBG
Testosterone	Serum/Plasma	Immunoassay	Roche cobas e801 0.087 nmol/L to 52.00 nmol/L	CE Marked	LP-GB-D-TESTO
Testosterone (Free)		Calculated	Calculated	Based on standard method	LP-GB-D-FT
Thyroid Stimulating Hormone (TSH)		Chemiluminescent Microparticle	Abbott Architect i2000sr 0.0025 µIU/mL to 100 µIU/mL	CE Marked	LP-GB-D- ABBOTTTSH
		Immunoassay	Roche cobas e801 0.005 mIU/L to 100.0 mIU/L	CE Marked	LP-GB-D-TSH

	Thyroxine (T4) - Free		Immunoassay	Roche cobas e801 0.5 pmol/L to 100 pmol/L	CE Marked	LP-GB-D-FT4
	Thyroxine (T4) – Free		Chemiluminescent Microparticle	Abbott Architect i2000sr 5.15 pmol/L to 64.35 pmol/L	CE Marked	LP-GB-D-ABBOTTFT4
	Triiodothyronine (T3) – Total	Serum	Immunoassay	Roche cobas e801 0.30 nmol/L to 10 nmol/L	CE Marked	LP-GB-D-TT3
1061 Clinical Chemistry - .30 Sweat electrolytes	Sweat Test	Sweat	Indirect ISE	Chorning Chloride Meter Sweat Conductivity: 0 mmol/L to 150 mmol.L Sweat Chloride: 10 mmol/L to 160 mmol>l	CE Marked	LP-GB-D-SWTCL LP-GB-D-SWTCON
1061 Clinical Chemistry - .40 Iron studies	Iron	Serum	Ferrazine	Roche cobas 8000 0.90 µmol/L to179 µmol/L	CE Marked	LP-GB-D-IRON
	Total Iron Binding Capacity (TIBC)	Serum/Plasma	Calculated	Calculated	Based on Standard Method	LP-GB-D-TIBC
	Transferrin		Immunoturbidimetric	Roche cobas 8000 0.1 g/L to 5.2 g/L	CE Marked	LP-GB-D-TRF
	Transferrin Saturation		Calculated	Calculated	Based on standard method	LP-GB-D-TSAT
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D	Serum	Electrochemiluminescence	Roche e801/ 7.5 nmol/L to 300 nmol/L	CE Marked	LP-GB-VITD
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	CA 125		Immunoassay	Roche cobas e801 0.600 U/mL to 5000 U/mL	CE Marked	LP-GB-D-CA125
	CA 15-3		Immunoassay	Roche cobas e801 1.5 U/mL to 300 U/mL	CE Marked	LP-GB-D-CA153

	CA 19-9	Serum/Plasma	Immunoassay	Roche cobas e801 2 U/mL to1000 U/mL	CE Marked	LP-GB-D-CA199
	Carcinoembryonic Antigen (CEA)		Immunoassay	Roche cobas c801 0.200 ng/ml to 1000 ng/ml	CE Marked	LP-GB-D-CEA
1061 Clinical Chemistry - .60 Glycohaemoglobins	Haemoglobin A1c (HbA1c)	EDTA Whole Blood	HPLC	Arkray H8190 0 mmol/M to151 mmol/M	CE Marked	LP-GB-HBA1C