

Accreditation Certificate

Galway University Hospital

Newcastle Road

Medical Testing Laboratory

Registration number: 246MT

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 15189:2007 2nd Edition

"Medical laboratories - Particular requirements for quality and competence"

(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)

Date of award of accreditation: 27:10:2009

Date of last renewal of accreditation: 27:10:2009

Expiry date of this certificate of accreditation: 27:10:2014

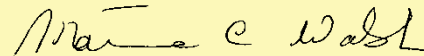
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr Adrienne Duff

Chairperson:



Dr Máire Walsh

Issued on 27 October 2009

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

Schedule of Accreditation



(Annex to Accreditation Certificate)

Permanent Laboratory:
Category A

GALWAY UNIVERSITY HOSPITAL Clinical Biochemistry Department

Medical Testing Laboratory

Initial Registration Date : 27-October-2009
Postal Address: Clinical Biochemistry Department
(Address of other locations as they apply) Newcastle Road
Galway
Telephone: +353 (91) 544499
Fax: +353 (91) 542456
E-mail: Anne.mannion@hse.ie
Contact Name: Anne Mannion
Facilities: Public testing service

Schedule of Accreditation



Permanent Laboratory:
 Category A

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category C:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
 - (b) a site laboratory
 - (c) a mobile laboratory or
 - (d) equipment from a mobile or site laboratory

Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

Glossary of Terms

Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will on request verify the status and scope.

Scope of Accreditation



Galway University Hospital
Medical Testing Laboratory

Permanent Laboratory:
 Category A

BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY	Alanine Amino Transferase (ALT)	Serum	IFCC (w/o PP activation)	Roche SWA	LP-GB-D-ALT
	Albumin	Serum	Bromocresol Green	Roche SWA	LP-GB-D-ALB
	Alcohol	Serum	Enzymatic	Roche SWA	LP-GB-D-ALCH
	Alkaline Phosphate (ALP)	Serum	IFCC with PNPP	Roche SWA	LP-GB-D-ALP
	Alpha Fetoprotein (AFP)	Serum	Immunoassay	Roche E170	LP-GB-D-AFP
	17-Alpha OH Progesterone	Serum	Radioimmunoassay	Wizard 1470 Gamma COUNTER	LP-GB-E-OHP
	Ammonia	Blood	Colorimetric	Arkray PocketChem A Ammonia meter	LP-GB-D-AMMO
	Amylase	Serum/Urine / Fluid	Enzymatic / IFCC	Roche SWA	LP-GB-D-AMY
	Amylase Creatinine Clearance Ratio		Calculated		LP-GB-D-ACCR
	Asparate Amino Transferase (AST)	Serum	IFCC (w/o PP activation)	Roche SWA	LP-GB-D-AST
	Base Excess		Calculated		LP-GB-P-DERIVEDBLOODG AS
	Bicarbonate	Serum	Enzymatic with PEP	Roche SWA	LP-GB-D-HCO3
	Bile Acids	Serum	Enzymatic	Roche SWA	LP-GB-D-BILE
	Bilirubin - Direct	Serum	Diazo	Roche SWA	LP-GB-D-DBIL
Bilirubin - Total	Serum	Diazo	Roche SWA	LP-GB-D-TBILI	

Scope of Accreditation



Galway University Hospital Medical Testing Laboratory

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Category A

BIOCHEMISTRY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY	CA 125	Serum	Immunoassay	Roche E170	LP-GB-D-CA125
	CA 15-3	Serum	Immunoassay	Roche E170	LP-GB-D-CA153
	CA 19-9	Serum	Immunoassay	Roche E170	LP-GB-D-CA199
	Calcium	Serum/Urine	O-Cresolphthalein	Roche SWA	LP-GB-D-CA
	Calcium - ionized	Heparin Blood	Direct ISE-Potentiometric	ABL800x	LP-GB-P-IONCA
	Adjusted Calcium		Calculated		LP-GB-D-ADJCA
	Calcium Excretion		Calculated		LP-GB-D-CAE
	Carbamazepine	Serum	KIMS	Roche SWA	LP-GB-D-CARB
	Carboxyhaemoglobin	Blood	Cooximetry	ABL800x	LP-GB-P-COOX
	CEA	Serum	Immunoassay	Roche E170	LP-GB-D-CEA
	Chloride	Serum/Urine	Indirect ISE	Roche SWA	LP-GB-D-ISE
	Cholesterol	Serum/Fluid	CHOP-PAP	Roche SWA	LP-GB-D-CHOL
	Cholesterol/HDL Ratio		Calculated		LP-GB-D-CHDL
	Copper	Serum	Atomic Absorption Spectrophotometry	AAAnalyst 800	LP-GB-S-CUZN
	Cortisol	Serum	Immunoassay	Roche E170	LP-GB-D-CORT
	C Peptide	Serum	Immunoassay	Roche E170	LP-GB-D-CPEP
	Creatine Kinase (CK)	Serum	IFCC	Roche SWA	LP-GB-D-CK
	Creatinine	Serum/Urine /Fluid	Jaffe	Roche SWA	LP-GB-D-CREAT
	C Reactive Protein (CRP)	Serum	Immunoturbidimetric	Roche SWA	LP-GB-D-CRP
	Digoxin	Serum	Immunoassay	Roche E170	LP-GB-D-DIG

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INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY	eGFR		Calculated		LP-GB-D-eGFR
	Follicle Stimulating Hormone (FSH)	Serum	Immunoassay	Roche E170	LP-GB-D-FSH
	Gamma Glutamyl Transferase (GGT)	Serum	IFCC	Roche SWA	LP-GB-D-GGT
	Gentamicin	Serum	Immunoassay	Roche SWA	LP-GB-D-GENT
	Glucose	Serum/Plasma /CSF/Fluid	Hexokinase	Roche SWA	LP-GB-D-GLU
	Growth Hormone	Serum	Immunometric	Immulite 2000	LP-GB-E-HGH
	Haemoglobin A _{1c}	EDTA Blood	HPLC	Menarini HA8160	LP-GB-S-HBA1C
	HCG - Total	Serum	Immunoassay	Roche E170	LP-GB-D-HCG
	HCO ₃		Calculated		LP-GB-P-DERIVEDBLOODG AS
	High Density Lipoprotein (HDL)	Serum	Enzymatic	Roche SWA	LP-GB-D-HDL
	Homocysteine	Plasma	Immunoassay	Abbott Architect	LP-GB-E-HYC
	Insulin	Serum	Immunoassay	Roche E170	LP-GB-D-INS
	Insulin Like Growth Factor 1 (IgF1)	Serum	Immunometric assay	Immulite 2000	LP-GB-E-IGF1
	Iron	Serum	Ferrazine	Roche SWA	LP-GB-D-IRON
	Lactate	Blood	Amperometric	ABL800x	LP-GB-P-LACT
	Lactate Dehydrogenase (LDH)	Serum/Fluid	IFCC	Roche SWA	LP-GB-D-LDH
	LH	Serum	Immunoassay	Roche E170	LP-GB-D-LH
	Lithium	Serum	Colorimetric	Roche SWA	LP-GB-D-LI
	Low Density Lipoprotein (LDL)		Calculated		LP-GB-D-LDL

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INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY	Macroprolactin	Serum	PEG pptte	Roche E170	LP-GB-D-MPRL
	Magnesium	Serum/Urine	Colorimetric	Roche SWA	LP-GB-D-MG
	Methotrexate	Serum	FPIA	Abbott TD _x	LP-GB-S-MTX
	Oestradiol	Serum	Immunoassay	Roche E170	LP-GB-D-OEST
	Osmolality	Serum/Urine	Freezing Point Depression	Gonotec Osmomat 030	LP-GB-S-OSMO
	Paracetamol	Serum	Enzymatic	Roche SWA	LP-GB-D-PARAC
	pCO2	Heparin Blood	Potentiometric	ABL800x	LP-GB-P-PCO2
	pH	Heparin Blood/Fluid	Potentiometric	ABL800x	LP-GB-P-PH
	pH	Urine/Fluid	Potentiometric	PH Meter	LP-GB-S-PHMETER
	pO2	Heparin Blood	Amperometric	ABL800x	LP-GB-P-PO2
	Phenobarbitone	Serum	KIMS	Roche SWA	LP-GB-D-PBARB
	Phenytoin	Serum	KIMS	Roche SWA	LP-GB-D-PTOIN
	Phosphate - inorganic	Serum	Ammonium Molybdate	Roche SWA	LP-GB-D-PHOS
	Potassium	Serum/Urine	Indirect ISE	Roche SWA	LP-GB-D-ISE
	Pro-BNP	Serum	Immunoassay	Roche E170	LP-GB-E-PROBNPII
	Progesterone	Serum	Immunoassay	Roche E170	LP-GB-D-PROG
	Prolactin	Serum	Immunoassay	Roche E170	LP-GB-D-PRL
	Protein-Total	Serum/Fluid	Biuret	Roche SWA	LP-GB-D-TP
	Protein-Total	Urine/CSF	Benzethonium Chloride	Roche SWA	LP-GB-D-UCSF

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1061 GENERAL CHEMISTRY	PSA - Free	Serum	Immunoassay	Roche E170	LP-GB-D-FPSA
	PSA - Total	Serum	Immunoassay	Roche E170	LP-GB-D-PSA
	PTH	Serum/Plasma	Immunoassay	Roche E170	LP-GB-D-PTH
	Salicylate	Serum	Ferric Nitrate	Roche SWA	LP-GB-D-SALIC
	Sex Hormone Binding Globulin (SHBG)	Serum	Immunoassay	Roche E170	LP-GB-D-SHBG
	Sodium	Serum/Urine	Indirect ISE	Roche SWA	LP-GB-D-ISE
	Standard Bicarbonate	Blood	Calculated	ABL800x	LP-GB-P-DERIVEDBLOODG AS
	Sweat Test	Sweat	Conductivity/Chloride	Corning Chloride/Wescor Conductivity Analyser 923/Wescor Sweat-Chek 3120	LP-GB-S-SWTCL LP-GB-S-SWTCON
	T3 - Total	Serum	Immunoassay	E170	LP-GB-E-TT3
	Tacrolimus	Plasma	MEIA	Abbott Architect	LP-GB-S-TACRO
	Total CO2		Calculated		LP-GB-P-DERIVEDBLOODG AS
	Testosterone	Serum	Immunoassay	Roche E170	LP-GB-D-TEST
	Testosterone (Free)		Calculated		LP-GB-D-FT
	Theophylline	Serum	KIMS	Roche SWA	LP-GB-D-THEO
	Total Iron Binding Capacity (TIBC)		Calculated		LP-GB-D-TIBC

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INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY	T4 - Free	Serum	Immunoassay	Roche E170	LP-GB-D-FT4
	Triglycerides	Serum/Fluid	GPO-PAP	Roche SWA	LP-GB-D-TRIG
	Troponin T hs	Serum	Immunoassay	Roche E170	LP-GB-D-TNTHS
	Thyroid Stimulating Hormone (TSH)	Serum	Immunoassay	Roche E170	LP-GB-D-TSH
	Transferrin	Serum	Immunoassay	Roche E170	LP-GB-D-TRF
	Transferrin Saturation	Serum	Calculated	Roche SWA	LP-GB-D-TSAT
	Urea	Serum/Urine	Urease	Roche SWA	LP-GB-D-UREA
	Uric Acid	Serum/Urine	Uricase	Roche SWA	LP-GB-D-UA
	Valproate	Serum	Immunoassay	Roche SWA	LP-GB-D-VALP
	Vancomycin	Serum	Colorimetric	Roche E170	LP-GB-D-VANC
	Vitamin D	Serum/Plasma	Tandem Mass Spectrometry	Agilent 6400 series Triple Quad LC/MS	LP-GB-D-MSVD
	Zinc	Serum	Atomic Absorption	AAAnalyst 800 Flame Atomic Absorption	LP-GB-S-CUZN