

Accreditation Certificate

Galway University Hospital
Division of Anatomic Pathology
Newcastle Road, Galway

Medical Testing Laboratory
Registration number: 274MT

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: 07:12:2010

Date of last renewal of accreditation: 07:12:2010

Expiry date of this certificate of accreditation: 07:12:2015

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: 

Mr Tom O'Neill

Issued on 07 December 2010

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 Division of Anatomic Pathology

Medical Testing Laboratory

Initial Registration Date : 7-December-2010
Postal Address: Newcastle Road
(Address of other locations as they apply) Galway
Telephone: +353 (91) 544078
Fax: +353 (91) 544902
E-mail: terri.muldoon@hse.ie
Contact Name: Ms Terri Muldoon
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
Division of Anatomic Pathology
Medical Testing Laboratory

Permanent Laboratory:
 Category A

INAB Classification number (P9) Materials or products tested/calibrated	Type of test/calibration or properties measured and Range of measurement	Relevant standard or documented procedure used
1051	Histopathology (General)	
.01	Histopathology Tissue samples	HSOP015, HSOP121, HSOP029 HSOP125, HSOP030, HSOP151 HSOP094, HSOP152, HSOP111 HSOP113, HSOP173, HSOP091 HSOP079, HSOP187, HSOP251, HSOP287 HSOP115 HSOP011, HSOP256 HSOP034 to HSOP055 HSOP077, HSOP084, HSOP140 HSOP116, HSOP076, HSOP120 HSOP153 HSOP116, HSOP076, HSOP120 HSOP153 HSOP117 HSOP listed below HSOP023, HSOP024, HSOP025 HSOP056 HSOP268
	Diagnostic Histopathology Diagnostic Specialised Pathology	
	Dermapathology	HSOP290 HSOP265
	Cutaneous neoplastic Cutaneous non-neoplastic	

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INAB Classification number (P9) Materials or products tested/calibrated	Type of test/calibration or properties measured and Range of measurement	Relevant standard or documented procedure used
1051 .01 Histopathology Histopathology Tissue samples Breast Pathology	Breast Tissue	HSOP212, HSOP213, HSOP214 HSOP215, HSOP216, HSOP226
Gynaecologic Pathology	Cervical Tissue Uterine tract tissue Ovarian Tissue	HSOP028 HSOP173, HSOP080, HSOP081 HSOP082 HSOP189
Urological Pathology	Prostatic tissue Urinary tract tissue Urinary bladder tissue	HSOP182, HSOP287, HSOP183 HSOP180 HSOP179
Gastrointestinal/ Hepatopancreaticobiliary	Gastrointestinal tissue, Upper and Lower tract Hepatopancreaticobiliary tissue	HSOP151, HSOP093, HSOP096 HSOP127, HSOP017, HSOP086 HSOP152, HSOP095, HSOP086
Endocrine Pathology	Thyroid, Parathyroid and Adrenal Tissue	HSOP027, HSOP298 HSOP190
Head and Neck Pathology	Head and Neck tissue	HSOP147, HSOP146, HSOP150 HSOP148, HSOP149, HSOP154
Haematolymphoid Pathology	Haematolymphoid tissue	HSOP188, HSOP300
Respiratory	Respiratory tissue	HSOP138

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INAB Classification number (P9) Materials or products tested/calibrated	Type of test/calibration or properties measured and Range of measurement	Relevant standard or documented procedure used
1051 .02	Histopathology Immediate frozen section diagnosis Tissue selection, cryomicrotomy, rapid H&E staining; Smear & touch preparation Flow cytometry preparation	HSOP016 HSOP263 HSOP259
.03	Immunohistochemical investigation Automated Immunocytochemical Staining Ag/Ab reaction Section cutting 34BE12 BCL2 BCL6 Calretinin CD3 CD4 CD5 CD8 CD20 CD23 CD30 CD31 CD34	HSOP120, HSOP116 HSOP035, HSOP077 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116 HSOP120, HSOP116

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1051 .03	Histopathology Immunohistochemical investigation	
	CD43	HSOP120, HSOP116
	CD45	HSOP120, HSOP116
	CD56	HSOP120, HSOP116
	CD68	HSOP120, HSOP116
	CD79A	HSOP120, HSOP116
	CD117 (C-Kit)	HSOP120, HSOP116
	CD138	HSOP120, HSOP116
	CEA	HSOP120, HSOP116
	Chromogranin	HSOP120, HSOP116
	CK5/6	HSOP120, HSOP116
	CK7	HSOP120, HSOP116
	CD10	HSOP120
	CD15	HSOP120
	CK20	HSOP120, HSOP116
	Cyclin D1	HSOP120, HSOP116
	Cytokeratin	HSOP120, HSOP116
	Desmin	HSOP120, HSOP116
	EMA	HSOP120, HSOP116
	Estrogen (Oestrogen, ER)	HSOP120, HSOP116
	HCG	HSOP120, HSOP116
	HER-2	HSOP120, HSOP116, HSOP076
	HMB45	HSOP120, HSOP116

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
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1051 .01	Histopathology Special Stains	Section cutting Alcian Blue Alcian Blue/PAS Congo red EVG Gordon & Sweet's Reticulin GRAM Grocott's Grimelius HVG Masson's trichrome MF/MF bleach MSB PAS PAS Diastase Perl's Prussian Blue Reticulin Shikata Orcein ZN	SOP037 HSOP297 HSOP117, HSOP297 HSOP117, HSOP024 HSOP117 HSOP117, HSOP235 HSOP117 HSOP117 HSOP097 HSOP269 HSOP117 HSOP236 HSOP088 HSOP117 HSOP117 HSOP117, HSOP233 HSOP117, HSOP235 HSOP100 HSOP117
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INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1040 .12	Immunology Detection of autoantibodies in body fluids and biopsy material Immunofluorescent staining	Skin Direct Immunofluorescence Tissue selection and preparation C3 Fibrin IgA IgG IgM Kappa Lambda Fluorescent microscopy	HSOP114
1052 .02	Cytopathology Non-gynaecological	Specimen Reception Preparation of Direct Smears Preparation of Cytospins Preparation agar blocks Preparation tissue blocks Automated staining Automated coverslipping FNA procurement, preparation and interpretation	DCSOP/Fluids/001 DCSOP/Fluids/005 DCSOP/Fluids/005 DCSOP/Fluids/013 DCSOP/Fluids/013 DCSOP/Fluids/003 DCSOP/Fluids/004 DCSOP/FNA/002

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1059	Molecular Techniques		
	In Situ Hybridisation		
.01	Tissue sections	HER2 FISH on formalin fixed paraffin embedded tissue sections	DCSOP/FISH/001
		Fluorescent microscopic determination of HER2 (Spectrum orange) to CEP17 (Spectrum green) ratio in FISH slides	DCSOP/FISH/001
.02	Synovial fluid	Preparation and microscopy	DCSOP/SYN/001