

Accreditation Certificate

Sligo General Hospital

Pathology Department, The Mall, Sligo, Ireland

Medical Testing Laboratory

Registration number: 291MT

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: 31:05:2011

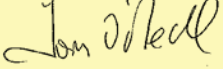
Date of last renewal of accreditation: 31:05:2011

Expiry date of this certificate of accreditation: 31:05:2016

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 31 May 2011

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

SLIGO GENERAL HOSPITAL

Medical Testing Laboratory Department: Pathology

Initial Registration Date : 1-January-2005
Postal Address: Histopathology/Cytology Laboratory
(Address of other locations as they apply) The Mall
Sligo, Ireland
Telephone: +353 (71) 9174564
Fax: +353 (71) 9174710
E-mail: sallybrowne@hse.ie
Contact Name: Ms Sally Browne
Facilities: Normally not available for Public testing

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.

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PATHOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1051 HISTOPATHOLOGY .01	Cut-up	Tissue Biopsies for Examination	Tissue description, dissection and block selection	Manual	TMH 04, 05, 24,25
	Tissue Processing	Tissue Sample	Vacuum impregnation	Vacuum Impregnation Processor x 2	TMH 06, EMOM 19, 20 QCHE 10,
	Embedding	Processed Tissue Sample	Manual tissue orientation in wax	Leica Embedding Console	TMH 7, 24,25 EMOM 8, QCHE12
	Microtomy	Paraffin Embedded Tissue Sample	Cutting and selection of representative tissue sections	Micromicrotomes	TMH 8, EMOM 15
	Automated Haematoxylin/ Eosin Staining	Tissue Section on glass slide	Programmed automated application of reagents	Sakura DRS 2000	TMH 10, EMOM 21, QCIM 21, QC 13, QC 1
	Automated Immunohistochemical Tissue Staining	Tissue section on glass slide	Programmed automated application of reagents	Ventana Benchmark XT	TMIHC 1-9, TMIHC 12-14, QC 13, QCIHC 1
	Mounting (Cover slipping)	Stained tissue section on glass slide	Application of coverslip to stained tissue section	Manual	TMH 10 QC 13
	Diagnostic Prostate Pathology	Prostate Tissue		Gross Descriptions, Dissections and Block Selection	Manual
Prostate Tissue			Immunohistochemistry	Ventana Benchmark XT	TMIHC 1-9, TMIHC 12-14 QCIHC 1, QC 13

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INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1051 HISTOPATHOLOGY (GENERAL) .01 Histopathology of biopsy material	Upper and Lower GIT Pathology	Stained Tissue Section	Microscopic Examination	Manual	TMH 24, TMH 25
		GIT biopsies and excisions	Gross description, Dissection Block selection	Manual	TMH 25
		GIT biopsies and excisions	Immunohistochemistry Special Stain Histochemistry	Ventana Benchmark XT Dako Artisan Manual	TMIHC 1-9, TMIHC 12-14 QCIHC 1, QC 13 TMHC 1-17, QCSS
.03 Immunohistochemical investigation	AE 1/3	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	BCI 2	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	BCI 6	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 3	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 5	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 10	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 15	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1

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1051 HISTOPATHOLOGY .03 Immunohistochemical investigation	CD 20	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 30	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 45	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD 117	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Chromogranin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CK 5/6	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CK 7	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CK 20	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Cyclin D1	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Desmin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	ER	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	F 8	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	HER 2	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	HMB 45	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Melan A	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	NSE	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	PSA	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	PR	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	S 100	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	TTF-1	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
Vimentin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1	

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1051 HISTOPATHOLOGY .03 Immunohistochemical investigation	Antibodies	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Actin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	AFP	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	BerEp4	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Ca19.9	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Ca125	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Cam 5.2	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD21	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD23	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD31	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD34	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD43	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD68	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD79a	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CD138	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CDx2	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CEA	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	34BE12	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	CK19	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Calretinin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
ECadherin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1	

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1051 HISTOPATHOLOGY .03 Immunohistochemical investigation	EGFR	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	EMA	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	HCG	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	HPL	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Ki67	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	PLAP	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	P53	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	P63	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1
	Thyroglobulin	Tissue Section	Ag/Ab reaction	Ventana Benchmark	TMIHC 1-9, TMIHC 12-14 QCIHC 1

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1051 HISTOPATHOLOGY .01 SPECIAL STAINS Histochemistry	Alcian Blue	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 4.1 QCSS 4.1
	Alcian Blue / PAS	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 4.2 QCSS 4.2
	PAS Pas + diastase	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 4.3 TMHC 4.4 QCSS 4.3, 4.4
	Gomori's Trichrome	Tissue Section	Application of Reagents	Manual	TMHC 6.1 QCSS 6.1
	Masson's Trichrome	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 6.7 QCSS 6.7
	Reticulin	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 6.2 QCSS 6.2
	Martius Scarlet Blue (MSB)	Tissue Section	Application of Reagents	Manual	TMHC 6.3 QCSS 6.3
	Elastic Stain	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 6.5 QCSS 6.5
	Weigert's van Gieson	Tissue Section	Application of Reagents	Manual	TMHC 6.8 QCSS 6.8
	Grimelius Silver	Tissue Section	Application of Reagents	Manual	TMHC 7.1 QCSS 7.1

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1051 HISTOPATHOLOGY SPECIAL STAINS Histochemistry	Giemsa	Tissue Section	Application of Reagents	Manual	TMHC 12.1 QCSS 12.1
	Gram Stain	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 12.2 QCSS 12.2
	Grocott's Silver stain	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 12.3 QCSS 12.3
	Shikata's Orcein	Tissue Section	Application of Reagents	Manual	TMHC 12.4 QCSS 12.4
	Ziehl Nielson stain	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 12.5 QCSS 12.5
	Perl's Iron stain	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 14.1 QCSS 14.1
	Masson Fontana	Tissue Section	Application of Reagents	Dako Artisan Manual	TMHC 17 TMHC 14.3 QCSS 14.3
	Highman's Congo Red	Tissue Section	Application of Reagents	Manual	TMHC 15.1 QCSS 15.1
1019 Andrology	Semen Analysis: Concentration, Motility, Morphology	Semen	Microscopy	Microscope	TMA 2
	Reporting				TMA 3
	Papanicolaou stain	Smear	Application of reagents	Tribune Stainer	TMHC 9.3 QCSS 9.3