

Accreditation Certificate

Midland Regional Hospital Tullamore

Pathology Laboratory

Testing Laboratory

Registration number: 221MT


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: 07:04:2009

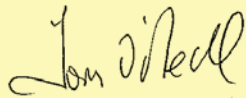
Date of last renewal of accreditation: 07:04:2009

Expiry date of this certificate of accreditation: 07:04:2014

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: 

Mr Tom O'Neill

Issued on 15 February 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

MIDLAND REGIONAL HOSPITAL TULLAMORE

Blood Transfusion Testing Laboratory

	Blood Transfusion Laboratory	Histopathology/Haematology
<i>Initial Registration Date :</i>	7-April-2009	5 - April - 2011
<i>Postal Address:</i>	Arden Road	
<i>(Address of other locations as they apply)</i>	Tullamore Co Offaly	
<i>Telephone:</i>	+353 (57) 9357752	
<i>Fax:</i>	+353 (57) 9359395	
<i>E-mail:</i>	seamus.conroy@hse.ie	
<i>Contact Name:</i>	Mr Shay Conroy	
<i>Facilities:</i>	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



Midland Regional Hospital Tullamore Blood Transfusion Testing Laboratory

Permanent Laboratory:
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1020 Immunohaematology		
.01 Blood grouping including ABO, Rh(D)	Red blood cells	T/BTL/LP/003 Manual Method using tube and Gel cards
.03 Blood group antibody screen	Plasma	T/BTL/LP/003 Manual method using Gel cards
.04 Identification of blood group antibodies	Plasma	T/BTL/LP/005 Manual method using Gel IAT and enzyme
.05 Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions	Crossmatch testing, plasma	T/BTL/LP/004 Manual Method using gel cards
	Antigen typing, red blood cells	T/BTL/LP/009 Manual Method using gel cards
	Direct coombs testing, red blood cells	T/BTL/LP/010 Manual Method using gel cards
	Monospecific coombs test, red blood cells	T/BTL/LP/010 Manual method using gel cards

Note: Tullamore Midland Regional Hospital has been assessed and is competent to comply with articles 14 and 15 of the EU Directive 2002/98/EC (S.I.No. 360 of 2005 and S.I. No. 547 of 2006)

Scope of Accreditation



Midland Regional Hospital Tullamore

Permanent Laboratory:

Histopathology Laboratory

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 Histopathology .01 General	Cut Up Tissue Processing Embedding Microtomy Automated Haematoxylin & Eosin Staining Coverslipping Frozen section cryotomy and staining	T/HIS/LP/002 T/HIS/EQ/003, T/HIS/EQ/004 T/HIS/LP/033 T/HIS/LP/038 T/HIS/LP/015 T/HIS/EQ/016 T/HIS/LP/010 T/HIS/EQ/039
.01 Special stains	Warthin and Starry Perls Prussian Blue Reticulin Nuclear Fast Red PAS Stain PAP (Papanicolou stain) May Grunwald Giemsa Diastase PAS stain Gram Twort Grocott Methenamine Silver Massons Trichrome Verhoeff Elastic Stain Ziehl Neelsen Alcian Blue / PAS stain Alcian Blue Congo Red Toulidine Blue Masson Fontana Haematoxylin Van Gieson Martius Scarlett Blue	T/HIS/LP/043, T/HIS/EQ/034 T/HIS/LP/048, T/HIS/EQ/034 T/HIS/LP/049, T/HIS/EQ/034 T/HIS/LP/045, T/HIS/EQ/034 T/HIS/LP/030 T/HIS/LP/029 T/HIS/LP/046, T/HIS/EQ/034 T/HIS/LP/052 T/HIS/LP/062, T/HIS/EQ/034 T/HIS/LP/050, T/HIS/EQ/034 T/HIS/LP/053, T/HIS/EQ/034 T/HIS/LP/054, T/HIS/EQ/034 T/HIS/LP/047 T/HIS/LP/066 T/HIS/LP/055, T/HIS/EQ/034 T/HIS/LP/057 T/HIS/LP/058 T/HIS/LP/051 T/HIS/LP/060

Scope of Accreditation



Midland Regional Hospital Tullamore Histopathology Laboratory

Permanent Laboratory:
Category A

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 .03	Histopathology Immunohistochemistry	Automated Immunohistochemistry Staining	T/HIS/LP/022, T/HIS/EQ/027 t/HIS/EQ/028, T/HIS/LP/024
.03		34BE12 antibody Smooth Muscle Actin Alk-1 Ber-Ep4 Calponin CD117 (cKit) Carcinoembryonic Antigen Desmin Epithelial membrane Antigen (EMA) Oestrogen receptor (ER) Progesterone Receptor (PR) S100 Antigen HMB45 Melan A MIB-1 thyroglobulin TTF-1 Prostate Specific Antigen P63 Cyclin D1 CD4 CD8 CD56 CK5/6 CD31	T/HIS/EQ/028, T/HIS/LP/022 T/HIS/EQ/27

Scope of Accreditation



Midland Regional Hospital Tullamore

Permanent Laboratory:

Histopathology Laboratory

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 .03 Histopathology Immunohistochemistry	CD34 Cd45 (CLA) CD79a Chromogranin CK7 CK20 CMV P504S Synaptophysin Vimentin Vs38 (Plasma Cell) TdT MUM-1 MLH-1 MSH-2 MSH-6 PMS-2 HEP PAR CD5 E-Cadherin Pan Cytokeratin AE1/AE3 BCL2 BCL6 Calretinin Cam 5.2 CD 10 CD15 CD20 CD23 CD3	

Scope of Accreditation



Midland Regional Hospital Tullamore Histopathology Laboratory

Permanent Laboratory:
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
	CD30 CD68	
.01 Diagnosis	Skin Pathology tissue dissection	T/HIS/LP/070, T/HIS/LP/092
.01	Skin Pathology Microscopic examination and reporting	T/HIS/LP/070, T/HIS/LP/092 T/HIS/LP/093, T/HIS/LP/094
.01	Gastrointestinal Pathology tissue dissection	T/HIS/LP/070, T/HIS/LP/071 T/HIS/LP/079, T/HIS/LP/080 T/HIS/LP/082, T/HIS/LP/083 T/HIS/LP/090, T/HIS/LP/091
.01	Gastrointestinal Pathology Microscopic examination and reporting	T/HIS/LP/093, T/HIS/LP/094 T/HIS/LP/070, T/HIS/LP/071 T/HIS/LP/079, T/HIS/LP/080 T/HIS/LP/082, T/HIS/LP/083 T/HIS/LP/090, T/HIS/LP/091

Scope of Accreditation



Midland Regional Hospital Tullamore

Permanent Laboratory:

Histopathology Laboratory

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1052 Diagnostic cytology .02	Bronchial Cytology Sample Preparation and description Non Bronchial Cytology Sample Preparation and description	T/HIS/LP/011, T/HIS/LP/036, T/HIS/LP/030, T/HIS/LP/029 T/HIS/LP/011, T/HIS/LP/030 T/HIS/LP/029, T/HIS/LP/004 T/HIS/LP/006, T/HIS/LP/007
.02	Microscopic examination and reporting of non gynae cytology	T/HIS/LP/098
.03 Fine Needle aspiration cytology	FNA Sample preparation and description	T/HIS/LP/005
.03	FNA Sample preparation and description	T/HIS/LP/098

Scope of Accreditation



Midland Regional Hospital Tullamore

Permanent Laboratory:

Haematology Laboratory

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1030 Haematology .01 Blood counts	Full Blood Count including White Cell Count red Cell Count Haemoglobin Mean Cell Volume Platelet Count	Automated on Advia 2120i Analyser using Flow Cytometry and CN-Free Colourimetric methods T/HAE/EQ/001 T/HAE/EQ/002 T/HAE/EQ/003 T/HAE/EQ/004
.02 Visual examination of blood films	Manual WBC Differential and Blood Film review	Manual Method/Microscopy/ Staining using Wescor Stainer T/HAE/EQ/007 T/HAE/EQ/015
.05 Automated differential leucocyte counts	Automated WBC Differential including Neutrophils, Lymphocytes, Monocytes, Eosinohils and Basophils	Automated on Advia 2120i Analyser using Flow Cytometry T/HAE/EQ/001 T/HAE/EQ/002 T/HAE/EQ/003 T/HAE/EQ/004
.06 Automated reticulocyte counts	Automated Reticulocyte Count	Automated on Advia 2120i Analyser using Flow Cytometry T/HAE/EQ/001 T/HAE/EQ/002 T/HAE/EQ/003 T/HAE/EQ/004

Scope of Accreditation



Midland Regional Hospital Tullamore

Permanent Laboratory:

Haematology Laboratory

Category A

INAB Classification number (P9)	Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
.09	Examination for malarial parasites	Malaria Parasites Detection using Malaria rapid test Immuno assay and thick and thin Morphology (Field Stain)	Detection of Parasitic Antigens using a qualitative antigen test for pLDH T/HAE/LP/011 T/HAE/LP/012 T/HAE/LP/013
.30	Erythrocyte sedimentation rate	Sickle Cell Screening test for HbS heterozygotes/homozygotes	QUalitative Solubility Test T/HAE/LP/009
.41	Plasma	Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Derived Fib) Fibrogen (Claus Fib) International Normalised Ratio D-Dimer (D-D)	Automated methods on IL ACL 9000 Haemostasis Analyser T/HAE/EQ/005 T/HAE/EQ/006 T/HAE/EQ/007 T/HAE/EQ/008 T/HAE/EQ/009, T/HAE/EQ/010
.57	Plasma	Epson Barr Virus (Monospot) Screening Test for Infectious mononucleosis	Latex Agglutination Immunoassay Test kit (BioKit) T/HAE/LP/011