

Accreditation Certificate

Connolly Hospital

Pathology Department, Blanchardstown, Dublin 15

Testing Laboratory

Registration number: 220MT


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)

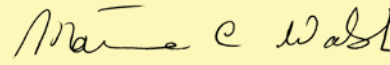
Date of award of accreditation: 17:02:2009

Date of last renewal of accreditation: 17:02:2009

Expiry date of this certificate of accreditation: 17:02:2014

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 17 February 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

CONNOLLY HOSPITAL

Medical Testing Laboratory

	Initial Registration Date
<i>Blood Transfusion Laboratory</i>	17-February-2009
<i>Histopathology Laboratory</i>	03-April-2012
<i>Postal Address:</i>	Connolly Hospital
<i>(Address of other locations as they apply)</i>	Blanchardstown Dublin 15
<i>Telephone:</i>	+353 (1) 6465302
<i>Fax:</i>	+353 (1) 8207747
<i>E-mail:</i>	joe.feely@hse.ie
<i>Contact Name:</i>	Mr Joe Feely
<i>Facilities:</i>	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.

Scope of Accreditation



Connolly Hospital

Blood Transfusion 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 and Rh(D)	ABO and RhD blood grouping <i>Red blood Cells</i>	LM-BT-0001 Manual method using DiaMed gels LM-BT-0001 Manual method using tubes
1020 Immunohaematology .03 Blood group antibody screen	Antibody screening <i>Plasma</i>	LM-BT-0002 Manual IAT method using DiaMed gels
1020 Immunohaematology .04 Identification of blood group antibodies	Antibody identification <i>Plasma</i>	LM-BT-0003 Manual method using DiaMed IAT and enzyme gel methods
1020 Immunohaematology .05 Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions	Compatability testing <i>Plasma</i>	LM-BT-0004 Manual method using DiaMed gels

Scope of Accreditation



Connolly Hospital

Blood Transfusion 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 .06 Red cell phenotyping	Antigen typing <i>Red blood cells</i>	LM-BT-0006 Manual methods using DiaMed and tube methods
1020 Immunohaematology .99 Miscellaneous tests -	Direct Antiglobulin Test <i>Red blood cells</i>	LM-BT-0005 Manual methods using DiaMed gels

Note: Connolly Hospital, Blood Transfusion Department, Blanchardstown, Dublin 15 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



Connolly Hospital

Histopathology 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
1051 Histopathology .01 Cut up	Biopsies & Surgical specimens for examination, description, dissection & block selection	LP-HIS-0001 LP-HIS-0002 LP-HIS-0031 LP-HIS-0062
.01 Tissue Processing	Programmed automated vacuum impregnation of Biopsies & Surgical specimens	LP-HIS-0003
.01 Embedding	Manual orientation of processed tissue sample in wax	LP-HIS-0007
.01 Microtomy	Cutting & selection of representative tissue sections	LP-HIS-0030 LP-HIS-0035
.01 Automated Haematoxylin & Eosin staining	Programmed automated application of reagents to tissue sections	LP-HIS-0004

Scope of Accreditation



Connolly Hospital

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 Histopathology .01 Special Stains <i>Acid Fast Bacteria</i> <i>Alcian Blue</i> <i>Alcian Blue / Periodic</i> <i>Acid Schiff /</i> <i>Haematoxylin</i> <i>Congo Red</i> <i>Gram</i> <i>Grocott Methenamine</i> <i>Silver</i> <i>Iron</i> <i>Massons Trichrome</i> <i>Periodic Acid Schiff</i> <i>Periodic Acid Schiff with</i> <i>Amylase Digestion</i> <i>Reticulin / Nuclear Fast</i> <i>Red</i> <i>Warthin-Starry</i> <i>Elastic</i>	Programmed automated application of reagents to tissue sections using Artisan	LP-HIS-0011
.01 Special Stains <i>Martius Scarlet Blue</i> <i>Van Gieson</i>	Manual application of reagents to tissue sections	LP-HIS-0052

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Histopathology 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
1051 Histopathology .01 Coverslipping	Application of coverslip to stained tissue section	LP-HIS-0004
.01 Diagnostic Pathology	Microscopic Examination	LP-HIS-0014 LP-HIS-0062
.02 Frozen section diagnostics	Rapid cutting & selection of snap-frozen tissue sections for urgent diagnoses	LP-HIS-0026
.03 Immunohistochemical investigation <i>34BE12</i> <i>Alk-1</i> <i>AE1/3 (MCK)</i> <i>AFP</i> <i>BCL2</i> <i>BCL6</i> <i>Ber-EP4</i> <i>CA125</i> <i>CA19.9</i> <i>Calcitonin</i> <i>Calretinin</i> <i>Cam 5.2</i> <i>CD3</i> <i>CD4</i> <i>CD5</i>	Programmed automated application of reagents to tissue sections using the BondMax	LP-HIS-0018

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Connolly Hospital

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 Histopathology .03 Immunohistochemical investigation <i>CD8</i> <i>CD10</i> <i>CD15</i> <i>CD20</i> <i>CD23</i> <i>CD30</i> <i>CD31</i> <i>CD34</i> <i>CD45 (CLA)</i> <i>CD68 (KP1)</i> <i>CD79a</i> <i>CD117 (C-kit)</i> <i>CD138</i> <i>CDX2</i> <i>CEA</i> <i>Chromogranin</i> <i>CK 5/6</i> <i>CK 7</i> <i>CK 20</i> <i>Cyclin D1</i> <i>Desmin</i> <i>DOG-1</i> <i>GCDFP-15</i> <i>Inhibin</i> <i>EMA</i>	Programmed automated application of reagents to tissue sections using the BondMax	LP-HIS-0018

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Histopathology 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
<p>1051 Histopathology</p> <p>.03 Immunohistochemical investigation</p> <p><i>HCG</i></p> <p><i>HMB 45</i></p> <p><i>Mib-1</i></p> <p><i>Mast Cell Tryptase</i></p> <p><i>Melan A</i></p> <p><i>MSA</i></p> <p><i>Mum-1</i></p> <p><i>Myeloperoxidase</i></p> <p><i>NSE</i></p> <p><i>Oestrogen Receptor</i></p> <p><i>p53</i></p> <p><i>p63</i></p> <p><i>Plap</i></p> <p><i>Progesterone Receptor</i></p> <p><i>PSA</i></p> <p><i>PSAP</i></p> <p><i>S100</i></p> <p><i>SMA</i></p> <p><i>Synaptophysin</i></p> <p><i>Thryoglobulin</i></p> <p><i>TTF-1</i></p> <p><i>Vimentin</i></p>	<p>Programmed automated application of reagents to tissue sections using the BondMax</p>	<p>LP-HIS-0018</p>

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Connolly Hospital

Cytopathology 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
1052 Cytopathology .02 Non-Gynae Exfoliative cytopathology	ThinPrep	LP-HIS-0021 LP-HIS-0038
.02 Non-Gynae fine needle aspiration	ThinPrep and Direct Smear	LP-HIS-0021 LP-HIS-0038