Irish National Accreditation Board

Accreditation Certificate

St Columcille's Hospital

Blood transfusion Laboratory, Loughlinstown, Co Dublin

Testing Laboratory

Registration number: **211MT**

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:_____ **Chairperson:** _____

Dr Adrienne Duff 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.

Wilton Park House, Wilton Place, Dublin 2, Ireland. Tel +353 1 607 3003 Fax +353 1 607 3109 E-mail inab@inab.ie Web www.inab.ie

Irish National Accreditation Board

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Schedule of Accreditation

ISO 15189 INAB ACCREDITED TESTING DETAILED IN SCOPE REG NO.211MT

(Annex to Accreditation Certificate)

Permanent Laboratory:

Category A

ST COLUMCILLE'S HOSPITAL

Blood Transfusion Testing Laboratory

Initial Registration Date :	**17-February-2009**
Postal Address:	Loughlinstown
(Address of other locations as they apply)	Co Dublin
Telephone:	+353 (1) 2215005
Fax:	+353 (1) 2821134
E-mail:	victor.shaw@hse.ie
Contact Name:	Mr Victor Shaw
Facilities:	Public testing service

Irish National Accreditation Board

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Schedule of Accreditation

ISO 15189
INAB
ACCREDITED
TESTING
DETAILED IN SCOPE REG NO.211MT

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

St Columcille's Hospital

Permanent Laboratory:

Category A

Blood Transfusion Testing Laboratory

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1020	**Immunohaematology**		
.01	Whole blood	Blood grouping (ABO & RhD Typing)	LM-BT-0002 LM-BT-0003 manual methods using tubes.
.03	*Serum*	Antibody Screening	LM-BT-0004 -manual method using gel
.04	*Serum*	Antibody Identification	LM-BT- 0005,6,7 manual method using Gel IAT and enzyme, and Tube method using IAT

Scope of Accreditation

St Columcille's Hospital

Permanent Laboratory:

Category A

Blood Transfusion Testing Laboratory

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1020	**Immunohaematology**		
.05	*Serum*	Crossmatch Testing	LM-BT 0011 Manual Method of Crossmatching in gels
.05	*Red Blood Cells*	Antigen Typing	LM-BT- 0009,0010 , Manual Method of Antigen Typing in tubes and Gel Cards
.05	*Red Blood Cells*	Direct Antiglobulin Testing	LM-BT 0012 , Manual Method of Direct Antiglobulin Testing by monospecific gel cards

Note: St Columcille's 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)