

Accreditation Certificate

Health Services Executive, South East St. Luke's General Hospital

Pathology Laboratory, Freshford Road, Kilkenny

Testing Laboratory

Registration number: 228MT

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

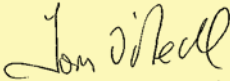
Date of last renewal of accreditation: 07:04:2009

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 05 April 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

Hse, South East

St. Luke's General Hospital

Medical Testing Laboratory

<i>Initial Registration Date :</i>	7-April-2009	5-April-2011
<i>Postal Address:</i>	Blood Transfusion Laboratory	Haematology Laboratory
<i>(Address of other locations as they apply)</i>	St. Luke's General Hospital Freshford Road, Kilkenny	
<i>Telephone:</i>	+353 (56) 7785483	
<i>Fax:</i>		
<i>E-mail:</i>	Helena.doheny@hse.ie	
<i>Contact Name:</i>	Ms. Helena Doheny	
<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

- 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



HSE South East, St. Luke's Hospital

Permanent Laboratory:

Medical Testing Laboratory

Category A

Blood Transfusion Department

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)	ABO and Rh D grouping of blood <i>Red Cells/plasma</i>	SLH-BT-LP-004 Manual ABO & RhD Grouping by Test Tube method SLH-BT-LP-006 Manual ABO and RhD Cell Grouping of Patient samples by test tube method SLH-BT-LP-054 Group confirmation of donor Red Cells
.03 Blood Group antibody screen	Antibody Screening <i>Plasma</i>	SLH-BT-LP-021 Manual Antibody Screening using Diamed Screen Cells SLH-BT-LP-025 manual Antibody Screening using Alba Bioscience Screen Cells
.04 Identification of blood group antibodies	Antibody Identification <i>Plasma</i>	SLH-BT-LP-023 manual Antibody Identification using Diamed Gel System

Scope of Accreditation



HSE South East, St. Luke's Hospital

Permanent Laboratory:

Medical Testing Laboratory

Category A

Blood Transfusion Department

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
.05 Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions	Compatibility testing <i>Red Cells/Plasma</i>	SLH-BT-LP-050 Manual Crossmatching Procedure, Diamed Gel System SLH-BT-LP-052 Crossmatching Red Cells for Neonatal Use, Diamed Gel System.
.06 Red cell phenotyping	Antigen typing <i>Red Cells</i>	SLH-BT-LP-011 Manual Red Cell Rhesus and Kell Antigen Typing Diamed Gell System SLH-BT-LP-013 Patient and Donor Red Cell Antigen Typing (Manual) Tube Method
.99 Miscellaneous Tests	Direct Coombs Test <i>Red Cells</i>	SLH-BT-LP-030 Manual Polyspecific DCT SLH-BT-LP-031 Diamed Gel System Manual monospecific DCT

Note: St. Luke's General Hospital, Blood Transfusion Laboratory, Freshford Road, Kilkenny 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



HSE South East, St. Luke's Hospital
 Medical Testing Laboratory

Permanent Laboratory:
 Category A

Haematology Department

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP	
1030 Haematology .01 Blood Counts	White Cell Count	Blood	Impedance Technology	Pentra DF120 and Pentra XL 80	SLH - HAE - LP - 005 Management of the Automated Analyser Pentra 120	
	Red Cell Count	Blood	Impedance Technology	Pentra DF120 and Pentra XL 80		
	Haemaglobin	Blood	Spectrophotometric	Pentra DF120 and Pentra XL 80	SLH - HAE - LP - 006 Management of the Automated Analyser Pentra 80	
	Haematocrit		Measures as a function of the numeric integration of FBC	Pentra DF120 and Pentra XL 80		
	Mean Cell Volume	Blood	Calculated Parameter	Pentra DF120 and Pentra XL 80		
	MCH	Blood	Calculated Parameter	Pentra DF120 and Pentra XL 80	SLH - HAE - LP - 009 FBC Authorisation & Interpretation	
	MCHC	Blood	Calculated Parameter	Pentra DF120 and Pentra XL 80		
	Platelet Count	Blood	Impedance Technology	Pentra DF120 and Pentra XL 80		
	.05 Automated Differential Leucocyte Counts	Neutrophil Count	Blood	Electronic Impedance and Staining	Pentra DF120 and Pentra XL 80	
		Lymphocyte Count	Blood	Electronic Impedance and Staining	Pentra DF120 and Pentra XL 80	

Scope of Accreditation



HSE South East, St. Luke's Hospital Medical Testing Laboratory

Permanent Laboratory:
Category A

Haematology Department

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
.05 Automated Differential Leucocyte Counts	Monocyte Count	Blood	Electronic Impedance and Staining	Pentra DF120 and Pentra XL 80	
	Eosinophil Count	Blood	Electronic Impedance and Staining	Pentra DF120 and Pentra XL 80	
	Basophil Count	Blood	Electronic Impedance and Staining	Pentra DF120 and Pentra XL 80	
.041 General Haemostasis Related Tests	Prothrombin Time (PT)	Blood	Photo-Optical Technology	Sysmex CA 1500	SLH - HAE - LP - 001 Management of Automated Coagulation Analyser SLH - HAE - LP - 002 Coagulation Testing on Automated Analyser SLH - HAE - LP - 003 Authorisation of Coagulation Screen Tests
	International Normalised Ratio (INR)	Blood	Photo-Optical Technology	Sysmex CA 1500	
	Activated Partial Thromboplastin Time (APTT)	Blood	Photo-Optical Technology	Sysmex CA 1500	
	D-Dimer	Blood	Photo-Optical Technology	Sysmex CA 1500	
.02 Visual examination of blood films	Visual examination of blood films	Blood	Microscopic Examination of Blood Films	Nikon eclipse 50i Asset No 2892	SLH-HAEM-LP-016
.03 Erythrocyte Sedimentation Rate	Erythrocyte Sedimentation Rate	Blood	Automatic Analyser Determination	Alifax Test 1 TH Esr Reader Asset No 22719	SLH-HAEM-LP-013
.57 Screening test for Infectious Mononucleosis	Screening test for Infectious Mononucleosis	Blood	Infectious Mononucleosis Screen	None, manual method	SLH-HAEM-LP-013