

# Accreditation Certificate

## Galway University Hospital

Newcastle Road, Galway.

**Medical Testing Laboratory**

Registration number: 239MT

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)*

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Date of award of accreditation: 15:09:2009

Date of last renewal of accreditation: 15:09:2009

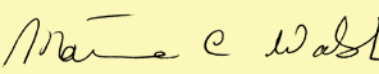
Expiry date of this certificate of accreditation: 15:09:2014

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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 15 September 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

## GALWAY UNIVERSITY HOSPITAL Haematology Laboratory

### Medical Testing Laboratory

**Initial Registration Date :** 15-September-2009  
**Postal Address:** Laboratory Medicine Directorate  
**(Address of other locations as they apply)** Newcastle Road  
Galway  
**Telephone:** +353 (91) 544419  
**Fax:** +353 (91) 542469  
**E-mail:** [mark.lyons@hse.ie](mailto:mark.lyons@hse.ie)  
**Contact Name:** Mr Mark Lyons  
**Facilities:** 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

## Galway University Hospital



### Medical Testing Laboratory

Permanent Laboratory:  
Category A

#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	SOP
1030 HAEMATOLOGY .01 BLOOD COUNTS	White Cell Count	Blood	Peroxidase/Basophil Flow Cytometry (FC)	FBC/SOP/001 FBC/SOP/007
	Red Cell Count	Blood	FC laser optic. Mie's theory	FBC/SOP/001 FBC/SOP/007
	Haemoglobin	Blood	CyanmethHB colorimetric method	FBC/SOP/001 FBC/SOP/007
	Haematocrit	Blood	Calculated from RBC and MCV	FBC/SOP/001 FBC/SOP/007
	Mean Cell Volume	Blood	Indirect measurement (mean of RBC vol)	FBC/SOP/001 FBC/SOP/007
	MCH	Blood	Calculation derived from HGB, RBC & MCV	FBC/SOP/001 FBC/SOP/007
	MCHC	Blood	FC laser optics. Utilizing RBC channel	FBC/SOP/001 FBC/SOP/007
	Platelet Count	Blood	FC laser optics. Utilizing RBC channel/Mie Map	FBC/SOP/001 FBC/SOP/007
.02 VISUAL EXAMINATION OF BLOOD FILMS	Includes Neutrophils	Blood		FBC/SOP/017
	Lymphocytes Monocytes	Blood	Staining/Microscopy	FBC/SOP/017
	Eosinophils, Basophils	Blood		FBC/SOP/017
	Red Cell Morphology	Blood		FBC/SOP/017
.03 ERYTHROCYTE SEDIMENTATION RATE	ESR (Automated)	Blood	Photo optical based on Westergren method	ESR/SOP/001
.05 AUTOMATED DIFFERENTIAL LEUCOCYTE COUNTS	Neutrophil Count	Blood	Optical FC-Cluster analysis	FBC/SOP/012
	Lymphocyte Count	Blood	Optical FC-Cluster analysis	FBC/SOP/012
	Monocyte Count	Blood	Optical FC-Cluster analysis	FBC/SOP/012
	Eosinophil Count	Blood	Optical FC-Cluster analysis	FBC/SOP/012
	Basophil Count	Blood	Optical FC-Cluster analysis	FBC/SOP/012
.06 AUTOMATED RETICULOCYTE COUNTS		Blood	Staining with Oxazine 750 and Optical FC	FBC/SOP/011

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## Galway University Hospital



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Category A

#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	SOP
1030 HAEMATOLOGY .08 BLOOD FILM EXAMINATIONS INVOLVING SPECIAL STAINING PROCEDURES	Iron Stain (Marrow and Urinary Haemosiderin)	Blood	Staining/Microscopy	SHaem/SOP/007
	Leucocyte Acid Phosphatase	Blood	Staining/Microscopy	SHaem/SOP/010
	Leucocyte Alkaline Phosphatase	Blood	Staining/Microscopy	SHaem/SOP/011
	Sudan Black B	Blood	Staining/Microscopy	SHaem/SOP/008
	Mixed Esterase Stain	Blood	Staining/Microscopy	SHaem/SOP/009
.09 EXAMINATION FOR MALARIAL PARASITES	Optimal Screening Test	Blood	Immuno-chromatographic Test	SHaem/SOP/004
	Blood film Examination	Blood	Staining/Microscopy	SHaem/SOP/005
.20 BONE MARROW EXAMINATION		Bone Marrow	Staining/Microscopy	SHaem/SOP/005
.25 PROGENITOR CELL TRANSPLANTATION PROCEDURE	CD34 Quantitation	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/030
.30 TESTS FOR HAEMOGLOBIN VARIANTS AND THALASSAEMIA	Haemoglobin A2	Blood	Reversed Phase Cation Exchange Chromatograph	SHaem/SOP/014
	Haemoglobin F	Blood	Reversed Phase Cation Exchange Chromatograph	SHaem/SOP/014
	Haemoglobin S	Blood	Reversed Phase Cation Exchange Chromatograph	SHaem/SOP/014
	Gel Electrophoresis	Blood	Agarose Gel Electrophoresis	SHaem/SOP/014
	Sickle Screen (Sickledex)	Blood	Qualitative Solubility Test	SHaem/SOP/015

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### Medical Testing Laboratory

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#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	SOP
1030 HAEMATOLOGY .31 TESTS FOR FOETAL HB	Kleihauer Test	Blood	Semi-Quantative Acid Elution/Microscopy	SHaem/SOP/001
.35 TESTS TO INVESTIGATE HAEMOLYSIS	Hams Test	Blood	Incubation with acidified fresh serum	SHaem/SOP/012
.36 SCREENING TESTS FOR G6PD DEFICIENCY	Glucose 6 Phosphate Dehydrogenase (G6PD) Screen	Blood	Qualitative Visual Fluorescence	SHaem/SOP/002
.40 LIMITED HAEMOSTASIS RELATED TESTS	Activated Protein C Resistance	Blood	Photo-Optical Technology	SCoag/SOP/006
	Anti Factor Xa level (LMWH)	Blood	Photo-Optical Technology	SCoag/SOP/008
	Antithrombin	Blood	Photo-Optical Technology	SCoag/SOP/005
	Free Protein S	Blood	Photo-Optical Technology	SCoag/SOP/006
	Fibrinogen Degradation Products	Blood	Latex Particle Agglutination	RCoag/SOP/016
	Lupus Anticoagulant	Blood	Photo-Optical Technology	SCoag/SOP/007
	Protein C	Blood	Photo-Optical Technology	SCoag/SOP/005
	Von Willibrand Factor Antigen	Blood	Photo-Optical Technology	SCoag/SOP/004
	Ristocetin Co-Factor (RiCOF)	Blood	Optical Impedance	SCoag/SOP/003

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#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	SOP
1030 HAEMATOLOGY .40 LIMITED HAEMOSTASIS RELATED TESTS	Coagulation Factor Assays			
	FII	Blood	Photo-Optical Technology	SCoag/SOP/010
	FV	Blood	Photo-Optical Technology	SCoag/SOP/011
	FVII	Blood	Photo-Optical Technology	SCoag/SOP/012
	FVIII	Blood	Photo-Optical Technology	SCoag/SOP/013
	FIX	Blood	Photo-Optical Technology	RCoag/SOP/014
	FX	Blood	Photo-Optical Technology	SCoag/SOP/015
	FXI	Blood	Photo-Optical Technology	SCoag/SOP/016
	FXII	Blood	Photo-Optical Technology	SCoag/SOP/017
.41 GENERAL HAEMOSTASIS RELATED TESTS	Prothrombin Time (PT)	Blood	Photo-Optical Technology	RCoag/SOP/004
	International Normalised Ratio (INR)	Blood	Ratio Calculation	RCoag/SOP/004
	Activated Partial Thromboplastin Time (APTT)	Blood	Photo-Optical Technology	RCoag/SOP/007
	Fibrinogen	Blood	Derived Calculation from PT	RCoag/SOP/010
	Fibrinogen (Clauss)	Blood	Photo-Optical Technology	RCoag/SOP/012
	D-Dimer	Blood	Photo-Optical Technology	RCoag/SOP/014
.45 TESTS OF PLATELET FXN	Platelet Aggregation Studies	Blood	Optical Impedance	SCoag/SOP/002
.55 IRON STUDIES	Ferritin	Blood	Immunoassay Technology	Haematinics/SOP/002

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#### HAEMATOLOGY DEPARTMENT

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	SOP
1030 HAEMATOLOGY .58 VITAMIN B12 AND FOLATE (SERUM AND RED CELL)	Vitamin B12	Blood	Immunoassay Technology	Haematinics/SOP/002
	Serum Folate	Blood	Immunoassay Technology	Haematinics/SOP/002
	Red Cell Folate	Blood	Immunoassay Technology	Haematinics/SOP/003
.62 PLASMA VISCOSITY		Blood	Capillary Viscometer	SHaem/SOP/003
.70 IMMUNOPHENOTYPING	Primary Acute Leukaemia Panel	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/026
	Secondary Acute Leukaemia Panel	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/028
	Lymphoproliferative Panel	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/024
	Surface IgG Marker Panel	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/025
	Intracellular Cytoplasmic Markers	Blood/Bone Marrow	Flow Cytometry	SHaem/SOP/027
.99 MISCELLANEOUS TESTS	Meth-Haemoglobin	Blood	Visible Absorption Spectroscopy	SHaem/SOP/017