

# Accreditation Certificate

## Galway University Hospital

Newcastle Rd Galway

### Testing Laboratory

Registration number: 255MT

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: 16:02:2010

Date of last renewal of accreditation: 16:02:2010

Expiry date of this certificate of accreditation: 16:02:2015

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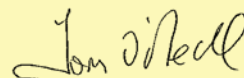
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr Adrienne Duff

Chairperson:



Mr Tom O'Neill

Issued on 16 February 2010

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 Immunology Department

### Medical Testing Laboratory

*Initial Registration Date :* 16-February-2010  
*Postal Address:* Newcastle Rd Galway  
*(Address of other locations as they apply)*  
*Telephone:* +353 (91) 544401  
*Fax:* +353 (91) 524216  
*E-mail:* immunology@hse.ie  
*Contact Name:* Ms Lorraine McDonagh  
*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 Immunology 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
1040 Immunology		
.01 Quantitative investigation of immunoglobulins G, A and M in body fluids	Investigation of immunoglobulin concentrations using the Dade Behring BNII System  Range of measurement: IgG: 1.4 - 46 (g/L) IgA: 0.06 - 8.00 (g/L) IgM: 0.05 - 6.4 (g/L)	IMG.SOP.IC.013 IMG.SOP.IC.014 Dade Behring BNII User's Guide
.03 Total IgE	Quantitative investigation of total IgE in serum using the Dade Behring BNII System  Range of measurement: IgE: 30 - 960 IU/mL	IMG.SOP.IC.013 IMG.SOP.IC.018 Dade Behring BNII User's Guide
.04 Allergen specific IgE	Investigation of serum samples for allergy testing.  Range of measurement: Specific IgE: 0-100 kU/l	IMG.SOP.AAL.020 IMG.SOP.AAL.003
.06 Investigation of complement	Quantitative investigation of the C3 and C4 components of the complement pathway in serum using the Dade Behring BNII System.	IMG.SOP.IC.013 IMG.SOP.IC.015 Dade Behring BNII User's Guide

# Scope of Accreditation



## Galway University Hospital Immunology 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
1040 Immunology  .06 Investigation of complement	Range of measurement: C3: 0.12 - 4.1 (g/L) C4: 0.06 -1.9 (g/L)  Evaluation of blood haemolytic complement activity by the classical and alternative pathways Range of measurement: Classical: 292 -1171 CH100 U/mL Alternative: 37 - 150 % normal activity	IMG.SOP.CEL.006 IMG.SOP.CEL.007 Alternative Haemolytic complement kit inserts.
.10 Rheumatoid factor - quantitative assays	Quantitative investigation of Rheumatoid Factor in serum using the Dade Behring BNII System  Range of measurement: RF: 10 - 640 IU/mL	IMG.SOP.IC.013 IMG.SOP.IC.008 Dade Behring BNII User's Guide

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1040 Immunology		
.12 Detection of autoantibodies	Investigation of serum samples for autoantibodies.  Range of measurement: ds DNA: 0 - 650 (WHO Units) Intrinsic Factor: 0-10 (B.I.) B-2 glycoprotein: 0-100 (U/ml) Cardiolipin (IgG): 0 - 120 (U/ml) Cardiolipin (IgM): 0 -80 (U/ml) Myeloperoxidase: 0 - 100 (U/ml) Proteinase-3: 0 - 100 (U/ml) TTG (IgG): 0 - 100 (U/ml) Centromere: 0 - 300 (U/ml) CCP: 0.4 -340 (EliA U/ml) TPO: 26 - 3340 (EliA U/ml) ENA Symphony: 0.7 -32 (Ratio) ENA Profile: 0 - 320 (EliA U/ml) GBM: 0.8 - 680 (EliA U/ml) TTG (IgA): 0.1 - 128 (EliA U/ml) GBM Quickcard:Qualitative	IMG.SOP.AAL.008 IMG.SOP.AAL.011 IMG.SOP.AAL.014 IMG.SOP.AAL.015 IMG.SOP.AAL.015 IMG.SOP.AAL.016 IMG.SOP.AAL.017 IMG.SOP.AAL.007 IMG.SOP.AAL.038 IMG.SOP.AAL.018 IMG.SOP.AAL.019 IMG.SOP.AAL.027 IMG.SOP.AAL.028 IMG.SOP.AAL. 034 IMG.SOP.AAL.026 IMG.SOP.AAL.004

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1040 Immunology		
.60 Simple slide tests for Immunology	Investigation of autoantibodies by indirect immunofluorescence.  ANA: 1/80 ANA Titre: 1/80 to 1/1280 ANCA: 1/20 Tissue screen: 1/40 Endomysial: 1/10 Mitochondrial: 1/100	IMG.SOP.AAL.031 IMG.SOP.AAL.033 IMG.SOP.AAL.022 IMG.SOP.AAL.025 IMG.SOP.AAL.023 IMG.SOP.AAL.024 IMG.SOP.AAL.021 IMG.SOP.AAL.005
.02 Tests of cellular immunity-quantitation of lymphocytes	Enumeration of lymphocyte subsets using the Beckman Coulter Epics XL-MCL flow cytometer	IMG.SOP.CEL.001 IMG.SOP.CEL.002 IMG.SOP.CEL.003 IMG.SOP.CEL.004

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1040 Immunology		
.99 Miscellaneous tests	Detection of oligoclonal IgG banding in CSF by isoelectric focussing. Range of measurement: Detection limit: > 0.031 mg/dL	IMG.SOP.IC.004
.61 b2-microglobulin	Quantitative determination of b2-microglobulin by means of immunonephelometry on the Dade Behring BNII System Range of measurement: B2-Microglobulin: 0.6 - 20 mg/L	IMG.SOP.IC.013 IMG.SOP.IC.020 Dade Behring BNII User's Guide

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Permanent Laboratory:  
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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1061 General Chemistry</b>		
.01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Analysis of urine by urinary electrophoresis using the Sebia Hydrasys system. Range of measurement:	IMG.SOP.IC.016 IMG.SOP.IC.017 IMG.SOP.IC.012
.02 Proteins, quantitative analysis	Quantitative determination of proteins in human serum by means of immunonephelometry on the Dade Behring BNII System  Range of measurement: Albumin: 0.011 - 52 (g/L) Al-1 antitrypsin: 0.16 - 5.2 (g/L) Caeroplasmin: 0.07- 2.2 (g/L) Haptoglobin: 0.26 - 8.3 (g/L) Transferrin: 0.31 - 5.0 (g/L) IgG Subclasses IgG1: 0.85 - 27.2 (g/L) IgG2: 0.18 - 5.8 (g/L) IgG3: 0.10 -3.1 (g/L) IgG4: 0.14 - 4.4 (g/L) Kappa free light chains: 5.9 -190 (mg/L) Lambda free light chains: 8.1 - 260 (mg/L)	IMG.SOP.IC.013 Dade Behring BNII User's Guide  IMG.SOP.IC.019 IMG.SOP.IC.005 IMG.SOP.IC.006 IMG.SOP.IC.007 IMG.SOP.IC.009 IMG.SOP.IC.022  IMG.SOP.IC.026 Binding Site Free Lite kit inserts

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1061 General Chemistry		
.02 Proteins, quantitative analysis	Detection and quantitation of monoclonal components to aid in the diagnosis and treatment of monoclonal gammopathies using Sebia Capillary2 and Hydrasys systems. Range of measurement: Capillary2: > 0.18g/L Hydrasys: > 0.18 g/L	IMG.SOP.IC.019 IMG.SOP.IC.002 IMG.SOP.IC.016 IMG.SOP.IC.012 IMG.SOP.IC.017 IMG.SOP.IC.010 Sebia Capillary2 User's Guide Sebia Hydrasys User's Guide
.51 C-1 esterase inhibitor	Quantitative determination of C-1 esterase inhibitor in human serum by immunonephelometry on the Dade Behring BNII System Range of measurement: C1- Inhibitor: 0.25 -8 g/L  Determination of C1-esterase inhibitor function by spectrophotometry using the TECHNOCHROME C1-INH kit.	IMG.SOP.IC.013 IMG.SOP.IC.023 Dade Behring BNII User's Guide  IMG.SOP.CEL.008 TECHNOCHROME C1-INH kit insert.