

# Accreditation Certificate

## Galway University Hospital Galway

Laboratory Medicine Directorate

Testing Laboratory

Registration number: 223MT

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: 07:04:2009

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

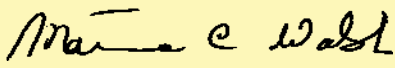
Expiry date of this certificate of accreditation: 07:04:2014

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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 Maire Walsh

Issued on 7 April 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 Laboratory Medicine Directorate Galway

### Clinical Microbiology Testing Laboratory

*Initial Registration Date :* 7-April-2009  
*Postal Address:* Newcastle Road  
*(Address of other locations as they apply)* Galway  
*Telephone:* +353 (91) 544429  
*Fax:* +353 (91) 544899  
*E-mail:* [frances.higgins@hse.ie](mailto:frances.higgins@hse.ie)  
*Contact Name:* Ms Frances Higgins  
*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 Clinical Microbiology 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
<b>1011 Bacteriology</b>		
.01 Preparation of films for microscopic examination	Investigation of Blood Cultures using the Becton Dickinson BACTEC 9240 Blood Culture system	MICSOP009  National Standard Methods, Health Protection Agency, UK  -Becton Dickinson BACTEC 9240 User's Guide
.02 Inoculation of cultures		
.03 Microscopic examination of Clinical Specimens		
.04 Identification of organisms including antibiotic sensitivity testing		
.06 Detection of bacterial antigens		
.07 Specialised antibiotic procedures		
.08 Detection and characterisation of microbial DNA/RNA		
.99 Miscellaneous tests		
Specimen Type: Blood		

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
<b>1011 Bacteriology</b>  .01 Preparation of films for microscopic examination .02 Inoculation of cultures .03 Microscopic examination of Clinical Specimens .04 Identification of organisms including antibiotic sensitivity testing .06 Detection of bacterial antigens .07 Specialised antibiotic procedures .08 Detection and characterisation of microbial DNA/RNA .99 Miscellaneous tests  Specimen Type: Urines	Investigation of Urine specimens- Microscopy and culture and sensitivity	MICSOP025  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



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Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<p><b>1011 Bacteriology</b></p> <p>.01 Preparation of films for microscopic examination</p> <p>.02 Inoculation of cultures</p> <p>.03 Microscopic examination of Clinical Specimens</p> <p>.04 Identification of organisms including antibiotic sensitivity testing</p> <p>.06 Detection of bacterial antigens</p> <p>.07 Specialised antibiotic procedures</p> <p>.08 Detection and characterisation of microbial DNA/RNA</p> <p>.99 Miscellaneous tests</p> <p>Specimens: Swabs other than genital tract and associated specimens Pus Catheter tips</p>	<p>Investigation of superficial and deep seated wound infections, intravascular cannulae and fluids from normally sterile body sites</p>	<p>MICSOP010 MICSOP011 MICSOP014 MICSOP015</p> <p>National Standard Methods, Health Protection Agency, UK</p>

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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><b>1011 Bacteriology</b></p> <p>.99 Miscellaneous tests</p> <p>Specimens:</p> <ul style="list-style-type: none"> <li>Bile</li> <li>Fluids</li> <li>Tissues</li> <li>Bone</li> <li>Biopsies</li> <li>CSFs</li> <li>Corneal lens and intraocular fluids</li> <li>Corneal lens</li> <li>Prosthetic devices</li> <li>Products of conception</li> </ul>	<p>Investigation of superficial and deep seated wound infections, intravascular cannulae and fluids from normally sterile body sites</p>	<p>MICSOP010 MICSOP011 MICSOP014 MICSOP015</p> <p>National Standard Methods, Health Protection Agency, UK</p>

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
<b>1011 Bacteriology</b>		
.01 Preparation of films for microscopic examination	Investigation of genital tract and associated specimens	MICSOP010 MICSOP013
.02 Inoculation of cultures		National Standard Methods, Health Protection Agency, UK
.03 Microscopic examination of Clinical Specimens		
.04 Identification of organisms including antibiotic sensitivity testing		
.06 Detection of bacterial antigens		
.07 Specialised antibiotic procedures		
.08 Detection and characterisation of microbial DNA/RNA		
.99 .99 Miscellaneous tests		
Specimens: Vaginal swabs, Vulval / Labial swabs Endocervical/cervical swabs Penile swabs		

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
1011 Bacteriology  .99 Miscellaneous tests Specimens: Urethral swabs Rectal swabs Bartholins gland aspirate Products of conception IUD Fallopian tube aspirate	Investigation of genital tract and associated specimens	MICSOP010 MICSOP013  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



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Permanent Laboratory:  
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1011 Bacteriology</b> .01 Preparation of films for microscopic examination .02 Inoculation of cultures .03 Microscopic examination of Clinical Specimens .04 Identification of organisms including antibiotic sensitivity testing .06 Detection of bacterial antigens .07 Specialised antibiotic procedures .08 Detection and characterisation of microbial DNA/RNA .99 Miscellaneous tests Specimens: Sputum Bronchial Lavage/Brushings/aspirates/washings Pleural Fluids Cough swabs Nasopharyngeal aspirates	Investigation of respiratory specimens for bacterial pathogens other than Mycobacteria	MICSOP009  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



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Permanent Laboratory:  
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1011 Bacteriology</b>		
.01 Preparation of films for microscopic examination	Investigation of faeces specimens for bacterial pathogens	MICSOP022  National Standard Methods, Health Protection Agency, UK
.02 Inoculation of cultures		
.03 Microscopic examination of Clinical Specimens		
.04 Identification of organisms including antibiotic sensitivity testing		
.06 Detection of bacterial antigens		
.07 Specialised antibiotic procedures		
.08 Detection and characterisation of microbial DNA/RNA		
.99 Miscellaneous tests		
Specimens: Faeces Rectal swabs		

# Scope of Accreditation



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Permanent Laboratory:  
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1011 Bacteriology</b> .01 Preparation of films for microscopic examination .02 Inoculation of cultures .03 Microscopic examination of Clinical Specimens .04 Identification of organisms including antibiotic sensitivity testing .06 Detection of bacterial antigens .07 Specialised antibiotic procedures Detection and characterisation of microbial DNA/RNA .99 Miscellaneous tests  Specimens: Nasal swabs Throat swabs Perineal swabs Wound swabs Swabs from other sites as clinically indicated	Screening of specimens for Methicillin Resistant Staph aureus (MRSA)	MICSOP016  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<p><b>1011 Bacteriology</b></p> <p>.01 Preparation of films for microscopic examination</p> <p>.02 Inoculation of cultures</p> <p>.03 Microscopic examination of Clinical Specimens</p> <p>.04 Identification of organisms including antibiotic sensitivity testing</p> <p>.06 Detection of bacterial antigens</p> <p>.07 Specialised antibiotic procedures</p> <p>.08 Detection and characterisation of microbial DNA/RNA</p> <p>.99 Miscellaneous tests</p> <p>Specimens: Rectal swabs Stoma site swab Swabs from other sites as clinically indicated</p>	<p>Screening of specimens for Vancomycin Resistant Enterococci (VRE)</p>	<p>MICSOP017</p> <p>National Standard Methods, Health Protection Agency, UK</p>

# Scope of Accreditation



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Permanent Laboratory:  
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1011 Bacteriology</b>  .01 Preparation of films for microscopic examination .02 Inoculation of cultures .03 Microscopic examination of Clinical Specimens .04 Identification of organisms including antibiotic sensitivity testing .06 Detection of bacterial antigens .07 Specialised antibiotic procedures .08 Detection and characterisation of microbial DNA/RNA .99 Miscellaneous tests  Specimens: Rectal swabs Swabs from other sites as clinically indicated	Screening of specimens for Extended Spectrum Beta lactamases (ESBL)	MICSOP018  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



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Permanent Laboratory:  
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<b>1011 Bacteriology</b>  .04 Identification of organisms including antibiotic sensitivity testing .07 Specialised antibiotic procedures .99 Miscellaneous tests  Specimen type: Bacterial cultures	Antimicrobial resistance testing using disc diffusion and Vitek Compact form Biomerieux	MICSOP002  -Performance standards for Antimicrobial Susceptibility Testing, Clinical and Laboratory Standards Institute (CLSI), U.S. - Guidance notes, HPA, UK - Vitek Compact User's Guide
<b>1011 Bacteriology</b> .06 Specialised Antibiotic Procedures  Bacterial cultures	Determination of Minimum inhibitory concentrations using Etest	MICSOP002  E Test Procedure, Biomerieux

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
<b>1012 Parasitology</b>  .01 Detection and provisional identification of parasites  .02 Definitive identification of parasites  .99 Miscellaneous tests  Specimens: Faeces Sellotape slides Duodenal/Jejunal aspirates Urine Liver/spleen aspirates BALs Blood	Detection and identification of parasites	MICSOP023 MICSOP024  National Standard Methods, Health Protection Agency, UK
<b>1013 Virology</b> .01 Non-cultural methods of detection Definitive identification of viruses Specimen: Faeces	Investigation of faeces specimens for rota and adenovirus using an Immunochromatographic test kit	MICSOP026  Kit insert

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
<b>1014 Mycology</b>  .01 Microscopic examination of Clinical Specimens .02 Culture of Specimens .03 Limited identification of isolates .04 Definitive identification of isolates .99 Miscellaneous tests  Skin Hair Nail	Investigation of specimens for superficial mycoses	MICSOP019  National Standard Methods, Health Protection Agency, UK

# Scope of Accreditation



## Galway University Hospital Clinical Microbiology 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
<b>1015 Mycobacteriology</b> .01 Microscopic examination of clinical specimens .02 Culture and isolation of mycobacteria .03 Limited detection of isolates .04 Definitive identification of isolates .05 Susceptibility testing .99 Miscellaneous tests  Specimen Types: Sputum Cough swabs Bronchial Lavage/Brushings CSFs Other body fluids Pus Pleural Fluids Sputum Tissue Early morning urine Blood Cultures	Investigation of specimens for Mycobacteria	MICSOP007 MICSOP008  -National Standard Methods, Health Protection Agency, UK -Becton Dickinson MGIT 960 User's Guide -Becton Dickinson Probetec User's Guide

# Scope of Accreditation



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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>1061    General Chemistry</p> <p>.00    Drugs for therapeutic monitoring</p> <p>Specimens: Serum/Plasma</p>	<p>Measurement of blood/serum levels of:</p> <p>Gentamicin(0.27ug/ml-10ug/ml) Amikacin(0.8ug/ml-50ug/ml)</p> <p>Tobramycin(0.18ug/ml-10ug/ml)</p> <p>Vancomycin(2.0ug/ml-100ug/ml)</p> <p>using the Abbott TDX FLX</p>	<p>MICSOP012</p> <p>Abbot TDxFLx User's Manual</p>