

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)

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:  Chairperson: 
Dr Adrienne Duff Dr Máire 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
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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
1011 Bacteriology		
.01 Preparation of films for microscopic examination	Investigation of Blood Cultures using the Becton Dickinson BACTEC FX Blood Culture system	MICSOP009
.02 Inoculation of cultures		National Standard Methods, Health Protection Agency, UK
.03 Microscopic examination of Clinical Specimens		Becton Dickinson BACTEC FX User's Guide
.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
1011 Bacteriology		
.01 Preparation of films for microscopic examination	Investigation of Urine specimens- Microscopy and culture and sensitivity	MICSOP025 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		
Specimen Type: Urines		

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		
.01 Preparation of films for microscopic examination	Investigation of superficial and deep seated wound infections, intravascular cannulae and fluids from normally sterile body sites	MICSOP010
.02 Inoculation of cultures		MICSOP011
.03 Microscopic examination of Clinical Specimens		MICSOP014
.04 Identification of organisms including antibiotic sensitivity testing		MICSOP015
.06 Detection of bacterial antigens		National Standard Methods, Health Protection Agency, UK
.07 Specialised antibiotic procedures		
.08 Detection and characterisation of microbial DNA/RNA		
.99 Miscellaneous tests		
Specimens: Swabs other than genital tract and associated specimens Pus Catheter tips		

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: Bile Fluids Tissues Bone Biopsies CSFs Corneal lens and intraocular fluids Corneal lens Prosthetic devices Products of conception	Investigation of superficial and deep seated wound infections, intravascular cannulae and fluids from normally sterile body sites	MICSOP010 MICSOP011 MICSOP014 MICSOP015 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
1011 Bacteriology		
.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		

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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>1011 Bacteriology</p> <p>.99 Miscellaneous tests Specimens: Urethral swabs Rectal swabs Bartholins gland aspirate Products of conception IUD Fallopian tube aspirate</p>	<p>Investigation of genital tract and associated specimens</p>	<p>MICSOP010 MICSOP013</p> <p>National Standard Methods, Health Protection Agency, UK</p>

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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		
.01 Preparation of films for microscopic examination	Investigation of respiratory specimens for bacterial pathogens other than Mycobacteria	MICSOP011
.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 Miscellaneous tests Specimens: Sputum Bronchial Lavage/Brushings/ aspirates/washings Pleural Fluids Cough swabs Nasopharyngeal aspirates		

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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
1011 Bacteriology		
.01 Preparation of films for microscopic examination	Investigation of faeces specimens for bacterial pathogens	MICSOP022
.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	Detection of Helicobacter pylori antigen detection in faeces	MICSOP053
.07 Specialised antibiotic procedures		Coris Bioconcept Immunostat Meridian
.08 Detection and characterisation of microbial DNA/RNA	Identification and characterisation of Clostridium difficile using GeneXpert system from Cepheid	GeneXpert System Operator manual Xpert C.difficile Assay Instructions
.09 Helicobacter pylori antigen detection		
.99 Miscellaneous tests		
Specimens: Faeces Rectal swabs		

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1011 Bacteriology .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

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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
1011 Bacteriology		
.01 Preparation of films for microscopic examination	Screening of specimens for Vancomycin Resistant Enterococci (VRE)	MICSOP017
.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 Miscellaneous tests		
Specimens: Rectal swabs Stoma site swab Swabs from other sites as clinically indicated		

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1011 Bacteriology		
.01 Preparation of films for microscopic examination	Screening of specimens for Extended Spectrum Beta lactamases (ESBL)	MICSOP018 National Standard Methods, Health Protection Agency, UK
.02 Inoculation of cultures .03 Microscopic examination of Clinical Specimens	Screening of specimens for Carbapenem Resistant Enterobacteriaceae	MICL0153 Laboratory Protocol for detection of Carbapenem-Resistant or Carbapenemase-Producing, Klebsiella spp. and Ecoli from Rectal Swabs - CDC Atlanta.
.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		

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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
1011 Bacteriology .04 Identification of organisms including antibiotic sensitivity testing .07 Specialised antibiotic procedures .99 Miscellaneous tests Specimen type: Bacterial cultures	Antimicrobial resistance testing using disk diffusion and Vitek Compact from Biomerieux	MICSOP002 -Performance standards for Antimicrobial Susceptibility Testing, using EUCAST and Clinical and Laboratory Standards Institute (CLSI), U.S. - Guidance notes, HPA, UK - Vitek Compact User's Guide
1011 Bacteriology .06 Specialised Antibiotic Procedures Bacterial cultures	Rapid detection of B-lactamase producing bacteria Determination of Minimum inhibitory concentrations using Etest	Remel Nitrocefin disk kit insert MICSOP002 E Test Procedure, Biomerieux
1011 Bacteriology .08 Detection and Characterisation of microbial DNA/RNA	Real - Time PCR for CoA in S.aureus Real-Time PCR for Group A Streptococci	MICSOP061 MICSOP060 VIR/LD/086 Applied Biosystems Real-Time PCR System plus/minus Assay Getting Started guide

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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
1012 Parasitology .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
1013 Virology .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

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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
1014 Mycology		
.01 Microscopic examination of Clinical Specimens	Investigation of specimens for superficial mycoses	MICSOP002 MICSOP048 MICSOP032
.02 Culture of Specimens		National Standard Methods, Health Protection Agency, UK
.03 Limited identification of isolates		
.04 Definitive identification of isolates		Clinical Laboratory Standards Institute (CLSI) and
.05 Antifungal susceptibility testing using Vitek 2		EUCAST susceptibility testing methodologies Vitek 2 User Manual, Biomerieux
.99 Miscellaneous tests		
Skin Hair Nail		

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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
1015 Mycobacteriology .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 using the MGIT 960 from Becton Dickinson Identification of <i>M. tuberculosis</i> Complex using Becton Dickinson (BD) MGIT Tbc identification test Identification and susceptibility testing of Mycobacteria using the Genotype MTBDRplus assay from HAIN Gmbh Molecular detection of <i>M. tuberculosis</i> Complex and Rifampicin resistance using GeneXpert (Cepheid)	MICSOP007 MICSOP008 MICSOP057 MICSOP062 National Standard Methods, Health Protection Agency, UK Becton Dickinson MGIT 960 User's Guide Becton Dickinson MGIT Tbc identification test kit insert Hain kit insert GeneXpert System Operator Manual GeneXpert MTB/RIF Assay instructions

Scope of Accreditation



Galway University Hospital

National Salmonella Shigella & Listeria Reference Laboratory (NSSLRL)

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 .06	Bacteriology Detection of Bacterial Antigens	Serotyping of Salmonella species and Identification and typing of Typhoidal salmonella
.05	Bacteriology Identification of organisms including antibiotic sensitivity testing	Biochemical differentiation of Salmonella subspecies and Susceptibility testing using the Sensititre from TREK diagnostic and the EUCAST Disk diffusion methods
.08	Bacteriology Detection and characterisation of microbial DNA/RNA	Phage typing of Salmonella Typhimurium/S. Enteritidis and Molecular Subtyping of non-typhoidal Salmonella serotypes and Shigella sonnei by Pulsed Field Gel Electrophoresis (PFGE) and S. Typhimurium MLVA and Multiplex PCR protocols for Salmonella and Shigella species
.06	Bacteriology Detection of Bacterial Antigens and Bacteriology Identification of organisms including antibiotic sensitivity testing	Identification and typing of Shigella spp and Susceptibility testing using the Sensititre from TREK diagnostic And the EUCAST disk diffusion methods
.08	Bacteriology Detection and characterisation of microbial DNA/RNA	Molecular Subtyping of Listeria monocytogenes by Pulse-Field Gel Electrophoresis (PFGE)