

# Accreditation Certificate

## Galway University Hospital Galway

Laboratory Medicine Directorate  
Newcastle Road, Galway

Testing Laboratory  
Registration number: 266MT

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: 01:06:2010

Date of last renewal of accreditation: 01:06:2010

Expiry date of this certificate of accreditation: 01:06:2015

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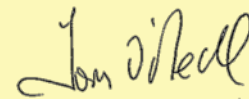
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager: \_\_\_\_\_



Dr Adrienne Duff

Chairperson: \_\_\_\_\_



Mr Tom O'Neill

Issued on 07 September 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 Laboratory Medicine Directorate Galway

### Virology Laboratory

*Initial Registration Date :* 7-September-2010  
*Postal Address:* Newcastle Road  
*(Address of other locations as they apply)* Galway  
*Telephone:* +353 (91) 544575  
*Fax:* +353 (91) 542238  
*E-mail:* colette.faherty@hse.ie  
*Contact Name:* Ms Colette Faherty  
*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
- portable test equipment
  - a site laboratory
  - a mobile laboratory or
  - 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

Permanent Laboratory:

Category A

### Virology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1013 Virology  .04	Detection of Influenza A virus RNA, in nose and throat swabs, using in-house real-time RT-PCR. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/019 Detection of Influenza A RNA; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500
.04	Detection of swine-lineage Influenza A virus (H1N1) RNA, in nose and throat swabs, using in-house real-time RT-PCR. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/068 Detection of swine-lineage Influenza A (H1N1) RNA; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500
.04	H1 and H3 subtyping, of seasonal Influenza A virus, in nose and throat swabs. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/067 H1 and H3 subtyping of seasonal Influenza A strains; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500
.04	Detection of Influenza B virus RNA, in nose and throat swabs, using in-house real-time RT-PCR. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/020 Detection of Influenza B RNA; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500

# Scope of Accreditation



## Galway University Hospital

Permanent Laboratory:

Category A

### Virology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1013 Virology  .04	Detection of Respiratory Syncytial Virus A virus RNA, in nose and throat swabs, using in-house real-time RT-PCR. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/069 Detection of RSV A RNA; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500
.02	Detection of Respiratory Syncytial Virus B virus RNA, in nose and throat swabs, using in-house real-time RT-PCR. Nucleic acid extraction is performed using the BioMerieux EasyMag instrument and real-time PCR is performed using the AB7500 real-time PCR instrument	VIR/SOP/070 Detection of RSV B RNA; VIR/SOP/045 Operation of the EasyMag; VIR/SOP/051 Operation of the AB7500
1016 Serology of Infection  .02	Qualitative detection of Hepatitis B virus Surface Antigen in human serum and plasma, using the Abbott Architect HBsAg Qualitative assay, and Chemiluminescent Microparticle Immunoassay (CMIA) technology.	VIR/SOP/066 Detection of HBsAg using the Architect HBsAg Qualitative assay
.02	Confirmation of the presence of Hepatitis B virus Surface Antigen, in human serum and plasma, using the Abbott Architect HBsAg Qualitative Confirmatory assay and CMIA technology.	VIR/SOP/055 Confirmation of the presence of HBsAg using the Abbott Architect HBsAg Qualitative Confirmatory assay.

# Scope of Accreditation



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Category A

### Virology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 Serology of Infection .02	Qualitative detection of Hepatitis B Core Antibody, in human serum and plasma, using the Abbott Architect Anti-HBc II assay and CMIA technology.	VIR/SOP/034 Detection of anti-HBc using the Abbott Architect Anti-HBc II assay
.02	Qualitative detection of Hepatitis B virus Core Antibody, in human serum and plasma, using the Biomerieux VIDAS Anti-HBc Total II assay	VIR/SOP/048 Detection of anti-HBc using the Biomerieux VIDAS Anti-HBc Total II assay
.02	Semi-quantitative detection of Hepatitis B virus Surface Antibody, in human serum and plasma, using the Abbott Architect Anti-HBs assay and CMIA technology.	VIR/SOP/031 Detection of anti-HBs using the Abbott Architect Anti-HBs assay
.02	Qualitative detection of Hepatitis B virus e antigen, in human serum and plasma, using the Biomerieux VIDAS HBe/Anti-HBe assay	VIR/SOP/047 Detection of Hepatitis Be antigen using the Biomerieux VIDAS HBe/Anti-HBe assay
.02	Qualitative detection of antibody to Hepatitis C virus, in human serum and plasma, using the Abbott Architect Anti-HCV assay, and CMIA technology.	VIR/SOP/029 Detection of anti-HCV using the Abbott Architect Anti-HCV assay

# Scope of Accreditation



## Galway University Hospital

Permanent Laboratory:

### Virology Testing Laboratory

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 Serology of Infection .02	Qualitative detection of IgG antibody to Hepatitis A virus, in human serum and plasma, using the Abbott Architect HAVAb-IgG assay, and CMIA technology.	VIR/SOP/030a Detection of Hepatitis A IgG antibody using the Abbott Architect HAVAB-IgG assay
.02	Qualitative detection of IgM antibody to Hepatitis A virus, in human serum and plasma, using the Abbott Architect HAVAb-IgM assay, and CMIA technology.	VIR/SOP/030b Detection of Hepatitis A IgM antibody using the Abbott Architect HAVAB-IgM assay
.02	Qualitative detection of antibody to Treponema pallidum, in human serum and plasma, using the Abbott Architect Syphilis TP assay, and CMIA technology.	VIR/SOP/033 Detection of antibody to Treponema pallidum using the Abbott Architect Syphilis TP assay.
.02	Qualitative detection of HIV p24 antigen, HIV-1 antibody and HIV-2 antibody, in human serum and plasma, using the Abbott Architect HIV Ag/Ab Combo assay, and CMIA technology.	VIR/SOP/027 HIV type 1 and HIV type 2 Ag/Ab detection using the Architect HIV Ag/Ab Combo assay
.02	Qualitative detection of HIV p24 antigen, HIV-1 antibody and HIV-2 antibody, in human serum and plasma, using the BioMerieux VIDAS HIV DUO Ultra assay	VIR/SOP/050 Detection of HIV p24 antigen, HIV-1 antibody and HIV-2 antibody, using the BioMerieux VIDAS HIV DUO Ultra assay

# Scope of Accreditation



## Galway University Hospital

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Category A

### Virology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 Serology of Infection .02	Semi-quantitative detection of infectious mononucleosis heterophile antibodies, in human serum and plasma, using the Meridian Monospot Latex agglutination test.	VIR/SOP/057 Monospot latex agglutination test.
.02	Semi-quantitative detection of infectious mononucleosis heterophile antibodies, in human serum and plasma (outside of normal working hours by the on-call staff), using the Meridian Monospot Latex agglutination test.	VIR/SOP/056 Monospot latex agglutination test (outside of normal working hours by the on-call staff).
.02	Semi-quantitative detection of antistreptolysin-O antibodies, in human serum, using the Biokit rheumajet ASO Latex agglutination test.	VIR/SOP/053 Antistreptolysin-O latex agglutination test
.02	Qualitative detection of antibodies to Treponema pallidum in human serum or plasma, using the Serodia-TP-PA particle agglutination test.	VIR/SOP/063 Detection of antibodies to Treponema pallidum using the Serodia-TP-PA particle agglutination test.
.02	Semi-quantitative detection of anti-cardiolipin antibodies, in human serum, using the BD RPR Card Antigen flocculation test	VIR/SOP/064 RPR Card test
.02	Semi-quantitative detection of Rubella virus IgG with the Abbott Architect Rubella IgG assay and CMIA technology	Vir/SOP/032 Rubella IgG detection using the Abbott Architect Rubella IgG assay

# Scope of Accreditation



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Permanent Laboratory:

Category A

## Virology Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1011 Bacteriology .08	Detection of Chlamydia trachomatis DNA in endocervical, urethral, conjunctival and rectal swabs using the Roche Cobas 48 real-time PCR system	VIR/SOP/059 C. trachomatis DNA detection using the Cobas 48