

Accreditation Certificate

University College Dublin National Virus Reference Laboratory

Belfield, Dublin 4.

Medical Testing Laboratory

Registration number: 326MT

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 15189:2012 3rd Edition**

“Medical laboratories -Requirements for quality and competence”

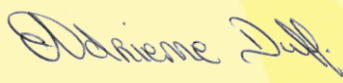
(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)


Date of award of accreditation: 09:09:2014

Date of last renewal of accreditation: n/a

Expiry date of this certificate of accreditation: 09:09:2019

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


Manager: _____
Dr Adrienne Duff


Chairperson: _____
Mr Tom O'Neill

Issued on 08 September 2015

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.

INAB is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, for Testing.

Schedule of Accreditation



(Annex to Accreditation Certificate)

Permanent Laboratory:
Category A

NATIONAL VIRUS REFERENCE LABORATORY.

Medical Testing Laboratory

Initial Registration Date : 9-September-2014
Postal Address: University College Dublin
(Address of other locations as they apply) Belfield
Dublin 4
Telephone: +353 (1) 7164401
Fax: +353 (1) 2697611
E-mail: eimear.malone@ucd.ie
Contact Name: Ms Eimear Malone
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 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



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Medical Testing Laboratory

Permanent Laboratory:
Category A

INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1016 General Serology of infection. .01	Anti-HCV	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HCV Ag	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HBsAg	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Anti-HBc II	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	CMV IgG	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	ToxolG	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Syphilis TP	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HAVAb-IgG	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HAVAb-IgM	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Anti-HBc IgM	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Anti-HBs	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HBeAg	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Anti-HBe	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	HIV Ag/Ab Combo	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	rHTLV-I/II	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	INNO-LIA HTLV I/II Score	Human Serum and Plasma	Immunoblot	AUTO-LIA	LP/VSER/016
	CMV IgM	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Rubella IgG	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
	Rubella IgM	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050
Toxo IgM	Human serum and plasma	CMIA	Architect i4000	LP/VSER/050	

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INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1016 General Serology of infection. .02	HIV screening	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	Genscreen Ultra HIV Ag/Ab	Human serum and plasma	EIA	Manual	LP/VSER/075
	INNO-LIA HIV I/11 Score	Human serum and plasma	Immunoblot	Auto-Lia	LP/VSER/016
	HAV IgM	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	Anti-HBc	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	Monolisa Anti-HBc	Human serum and plasma	EIA	Manual	LP/VSER/075
	Murex HBsAg	Human serum and plasma	EIA	Manual	LP/VSER/075
	Murex HBsAg Confirmatory	Human serum and plasma	EIA	Manual	LP/VSER/075
	Ortho HCV	Human serum and plasma	EIA	Manual	LP/VSER/075
	Monolisa HCV Ab	Human serum and plasma	EIA	Manual	LP/VSER/075
	Anti-HCV	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	INNO-LIA HCV Score	Human Serum and Plasma	Immunoblot	Auto-Lia	LP/VSER/016
	Vidas HIV 1 P24 11 Confirmatory	Human Serum and Plasma	ELFA	Vidas	LP/VSER/053
	Murex HTLV I/II	Human serum and plasma	EIA	Manual	LP/VSER/075
	CMV IgM	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	CMV IgG	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	Cytomegalovirus IgM	Human serum and plasma	EIA	Manual	LP/VSER/075
	Toxo IgG II	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	Toxo IgM	Human serum and plasma	ELFA	Vidas	LP/VSER/001

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INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1016 General Serology of infection. .02	Varicella Zoster IgG	Human serum and plasma	ELFA	Vidas	LP/VSER/001
	VZV IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	EBNA IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	EBV IgM	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	EBV VCA IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Measles IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Rubella IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Anti-HBs	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Measles IgM	Human serum and plasma and oral fluid	EIA	Manual	LP/VSER/075
	Mumps IgM	Oral Fluid, human serum and plasma	EIA	Manual	LP/VSER/075
	Mumps IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	RPR Reditest Syphilis	Human serum and plasma	Flocculation card test	Manual	LP/VSER/006
	Syphilis IgM	Human serum and plasma	EIA	Manual	LP/VSER/075
	Parvovirus B19 IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Parvovirus B19 IgM	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	Borrelia IgG	Human serum and plasma	CLIA	Diasorin Liaison XL	LP/VSER/077
	HSV 1 / 2 IgG	Human serum	CLIA	Diasorin Liaison XL	LP/VSER/077
	Herpes Select 1	Human serum	EIA	Manual	LP/VSER/075
	Herpes Select 2	Human serum	EIA	Manual	LP/VSER/075
	Leptospira IgM	Human serum	EIA	Manual	LP/VSER/075

	TP-PA	Human serum and plasma	Particle agglutination	Manual	LP/VSER/008
	Fortress HEV-IgM	Human serum and plasma	EIA	Manual	LP/VSER/075
	Fortress HEV IgG	Human Serum and Plasma	EIA	Manual	LP/VSER/075
	Diasorin Enzyme Immunoassay for Qualitative determination of Total antibodies to Hepatitis Delta antigen (anti- D)	Serum samples	EIA	Manual	LP/VSER/075

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INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1013.4 Detection and characterisation of viral DNA/RNA	Immunodeficiency virus type 1	Human serum and plasma	PCR	Abbott real time assay	LP/MVIR/120
	HCV RNA	Human serum and plasma	PCR	Abbott real time assay	LP/MVIR/125
	Hepatitis B Virus	Human serum and plasma	PCR	Abbott real time assay	LP/MVIR/135
	CMV DNA	Human serum and plasma	PCR	Taqman 7500 analyser	LP/MVIR/085
	EBV DNA	Human serum and plasma Whole Blood	PCR	Taqman 7500 analyser	LP/MVIR/089
	HBV genotypes A to H	Human serum and plasma	PCR	Auto-Lipa	LP/MVIR/091
	Parvovirus	Human serum and plasma	PCR	Taqman 7500 analyser	LP/MVIR/101
	HCV II Genotyping	Human serum and plasma	PCR	Abbott real time assay	LP/MVIR/128
	CT/NG	Urine and swabs	PCR	Tigris and Panther	LP/MVIR/097 and LP/MVIR/186

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INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1013.4 Detection and characterisation of viral DNA/RNA	Influenza viruses A and B, Respiratory Syncytial virus, Human Metapneumovirus, Adenovirus, Parainfluenza viruses 1,2,3,4 (P1,2,3,4)	Swabs/Respiratory samples/Aspirates	PCR	Taqman 7500 analyser and ViiA 7	LP/MVIR/114
	Gastroenteritis screen including: Astrovirus, Sapovirus, Adenovirus type F, Rotavirus, Norovirus (Genogroup 1&2)	Faecal	PCR	Taqman 7500 analyser and ViiA 7	LP/MVIR/153
	Detection of Viral Infections in the Central Nervous System including herpes viruses (HSV 1, HSV 2, VZV, Enterovirus, Parechovirus and HHV6)	CSF	PCR	Taqman 7500 analyser	LP/MVIR/064 and LP/MVIR/134
	Real-time PCR for Herpes Simplex 1 and 2 virus DNA	Swabs,	PCR	Taqman 7500 analyser and ViiA 7	LP/MVIR/107
	Real-Time PCR for Varicella Zoster DNA	Swabs	PCR	Taqman 7500 analyser/or ViiA 7	LP/MVIR/107
	Real-Time PCR for Adenovirus DNA	Swabs, Stool,	PCR	Taqman 7500 analyser and/or ViiA 7	LP/MVIR/107
	Real-Time PCR for Hepatitis E Virus	Serum	PCR	Taqman 7500	LP/MVIR/160
	Real-Time PCR for Hepatitis A virus RNA	Serum	PCR	Taqman 7500	LP/MVIR/161

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INAB Classification Number (P9)	Test / Assay Name	Specimen Type	Method	Equipment	SOP
1013.4 Detection and characterisation of viral DNA/RNA	Real-time PCR for JC Virus DNA	CSF, Serum, Urine and Plasma	PCR	Taqman 7500	LP/MVIR/152
	Real-Time PCR for BK virus DNA (Quantitative)	Serum, Plasma, and Urine samples	PCR	Taqman 7500	LP/MVIR/177
	HIV-1 genotypic antiviral resistance testing (pol region)	Plasma samples	PCR	Genetic Analyser 3500 Dx	LP/MVIR/176
	Real-Time RT-PCR for Enterovirus and Parechovirus RNA	Stool, Swab,	PCR	Taqman 7500	LP/MVIR/134
	HCV Genotype 1 antiviral resistance testing (including Q80K polymorphism analysis) -NS3 gene	Serum and Plasma samples	PCR	Genetic Analyser 3500 Dx	LP/MVIR/187
1013.01 Non-cultural methods of detection	Bartels Viral	Respiratory secretions	Immunofluorescence	Manual/IF	LP/VIR/044
	Imagen Respiratory Syncytial Virus	Respiratory secretions	Immunofluorescence	Manual/IF	LP/VIR/044
	Imagen human metapneumovirus (hMPV)	Nasal Pharyngeal Aspirates (NPA) and other Respiratory Secretary samples	Immunofluorescence	Manual/IF	LP/VIR/044