

Schedule of Accreditation



Organisation Name	National Virus Reference Laboratory
INAB Reg No	326MT
Contact Name	Eimear Malone
Address	University College Dublin, Belfield, Dublin
Contact Phone No	01-7161319
Email	eimear.malone@ucd.ie
Website	
Accreditation Standard	ISO 15189
Date Initially Awarded	09/09/2014
Scope Classification	Microbiology and virology
Services available to the public ¹	No

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered	
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)	
Name	Address
1 Head Office	University College Dublin, Belfield, Dublin, D4

Scope of Accreditation

Head Office

Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .05 Immunofluorescence	Bartels Viral	Respiratory secretions	Manual/IF	CE
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Abbott RealTime High Risk Human Papilloma Virus (HPV) Assay	ThinPrep liquid cytology specimens	RealTime PCR based assay detectin HPV HR DNA. Run on the Abbott m2000.	CE
	Aptima Human Papilloma Virus (HPV) Assay		In vitro nucleic amplification test specific for HPV RNA. Run on the Genprobe TIGRIS DTS and Panther System	CE
	Aptima Trichomonas vaginalis (TV) assay	Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab Specimens: Aptima Urine Collection Kit for Male and Female Urine Specimens: Aptima Vaginal Swab Specimen Collection Kit	In vitro qualitative nucleic acid amplification test for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis using the TIGRIS DTS system	CE
	CMV DNA	Human serum and plasma	Taqman 7500 analyser	CE marked with validated modification
	CT/NG	Urine and swabs	Tigris and Panther	CE
	Detection of Viral Infections in the Central Nervous System including herpes viruses (HSV 1, HSV 2, VZV, Enterovirus, Parechovirus and HHV6)	CSF	Taqman 7500 analyser	in-house developed

	EBV DNA	Human serum and plasma Whole Blood	Taqman 7500 analyser	CE marked with validated modification
	Gastroenteritis screen including: Astrovirus, Sapovirus, Adenovirus type F, Rotavirus, Norovirus (Genogroup 1&2)	Faecal	Taqman 7500 analyser and ViiA 7	in-house developed
	HCV Genotype 1 antiviral resistance testing (including Q80K polymorphism analysis) –NS3 gene	Serum and Plasma samples	Genetic Analyser 3500 Dx	in-house developed
	HCV II Genotyping	Human serum and plasma	Abbott real time assay	CE
	HCV RNA		Abbott real time assay	CE
	Hepatitis B Virus		Abbott real time assay	CE
	HIV-1 genotypic antiviral resistance testing (pol region)	Plasma samples	Genetic Analyser 3500 Dx	in-house developed
	Immunodeficiency virus type 1	Human serum and plasma	Abbott real time assay	CE
	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	Taqman 7500 analyser and ViiA 7	in-house developed
	Parvovirus	Human serum and plasma	Taqman 7500 analyser	CE marked with validated modification
	Real-Time PCR for Adenovirus DNA	Swabs, Stool	Taqman 7500 analyser and/or ViiA 7	in-house developed
	Real-Time PCR for BK virus DNA (Quantitative)	Serum, Plasma, and Urine samples	Taqman 7500	CE
	Real-Time PCR for Hepatitis A virus RNA	Serum	Taqman 7500	CE marked with validated modification
	Real-Time PCR for Hepatitis E Virus		Taqman 7500	CE marked with validated modification
	Real-time PCR for Herpes Simplex 1 and 2 virus DNA	Swabs,	Taqman 7500 analyser and ViiA 7	in-house developed
	Real-time PCR for JC Virus DNA	CSF, Serum, Urine and Plasma	Taqman 7500	CE
	Real-Time PCR for Varicella Zoster DNA	Swabs,	Taqman 7500 analyser and ViiA 7	in-house developed
	Real-Time RT-PCR for Enterovirus and Parechovirus RNA	Stool, Swab	Taqman 7500	in-house developed
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques -	TP-PA	Human serum and plasma	Manual	CE

.01 Particle agglutination, using CE marked commercial systems				
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Anti-HBc		Vidas	CE
	Anti-HCV		Vidas	CE
	CMV IgM		Vidas	CE
	Cytomegalovirus IgM		Manual	CE
	Diasorin Enzyme Immunoassay for Qualitative determination of Total antibodies to Hepatitis Delta antigen (anti- D)	Human serum	Manual	CE
	Fortress HEV IgG	Human serum and plasma	Manual	CE
	Fortress HEV-IgM		Manual	CE
	Genscreen Ultra HIV Ag/Ab		Manual	CE
	HAV IgM		Vidas	CE
	Herpes Select 1	Human serum	Manual	CE
	Herpes Select 2		Manual	CE
	HIV screening	Human serum and plasma	Vidas	CE
	Leptospira IgM	Human serum	Manual	CE
	Liaison XL Anti-HBc assay	Serum/Plasma	Chemiluminescence immunoassay (CLIA) technology for the qualitative determination of total antibodies to hepatitis B core antigen (anti-HBc) in human serum or plasma samples	CE
	Measles IgM	Human serum and plasma and oral fluid	Manual	CE
	Monolisa Anti-HBc	Human serum and plasma	Manual	CE
	Monolisa HCV Ab		Manual	CE
	Mumps IgG		Diasorin Liaison XL	CE
	Mumps IgM	Human serum and plasma and oral fluid	Manual	CE
	Murex HBsAg	Human serum and plasma	Manual	CE
Murex HBsAg Confirmatory	Manual		CE	
Murex HTLV I/II	Manual		CE	
Ortho HCV	Manual		CE	
Syphilis IgM	Manual		CE	

	Toxo IgG II		Vidas	CE
	Toxo IgM		Vidas	CE
	Vidas HIV 1 P24 11 Confirmatory		Vidas	CE
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .04 Line immunoassay, using CE marked commercial systems	INNO-LIA HCV Score		AUTO-LIA	CE
	INNO-LIA HIV I/II		Immunoblot	CE
	INNO-LIA HTLV I/II Score		AUTO-LIA	CE
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Anti-HBc IgM		Architect i4000	CE
	Anti-HBc II		Architect i4000	CE
	Anti-HBe		Architect i4000	CE
	Anti-HBs		Architect i4000	CE
	Anti-HCV		Diasorin Liaison XL	CE
	Borrelia IgG		Architect i4000	CE
	CMV IgG		Diasorin Liaison XL	CE
	CMV IgM		Architect i4000	CE
	EBNA IgG		Architect i4000	CE
	EBV IgM		Diasorin Liaison XL	CE
	EBV VCA IgG		Diasorin Liaison XL	CE
	HAVAb-IgG		Architect i4000	CE
	HAVAb-IgM		Architect i4000	CE
	HBeAg		Architect i4000	CE
	HBsAg		Architect i4000	CE
	HCV Ag		Architect i4000	CE
	HIV Ag/Ab Combo		Architect i4000	CE
	HSV 1 / 2 IgG	Human serum	Diasorin Liaison XL	CE
	Liaison XL Murex recHTLV-I/II assay	Serum/Plasma	Chemiluminescence immunoassay (CLIA) technology for the qualitative determination of specific antibodies to Human T-cell Lymphotropic Virus (HTLV) Type I and Type II (anti-HTLV I and anti-HTLV II) in human serum and	CE

			plasma samples	
	Measles IgG	Human serum and plasma	Diasorin Liaison XL	CE
	Parvovirus B19 IgG		Diasorin Liaison XL	CE
	Parvovirus B19 IgM		Diasorin Liaison XL	CE
	Platelia Mycoplasma pneumonia IgM ELISA	Serum	Detection of anti-mycoplasma pneumonia IgM in human serum by enzyme immunoassay.	CE
	rHTLV-I/II	Human serum and plasma	Architect i4000	CE
	Rubella IgG		Architect i4000	CE
			Diasorin Liaison XL	CE
	Rubella IgM		Architect i4000	CE
	Syphilis TP		Architect i4000	CE
	Toxo IgM		Architect i4000	CE
	ToxoIgG		Architect i4000	CE
	VZV IgG		Diasorin Liaison XL	CE
1029 Miscellaneous - .99 Miscellaneous tests	RPR Reditest Syphilis		Manual	CE