

Schedule of Accreditation



Organisation Name	National Virus Reference Laboratory
Trading As	
INAB Reg No	326MT
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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)	Range of measurement	Std. ref & SOP
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Innotest HCV	Serum/Plasma	ELISA	CE Marked Commercial	Negative (≤ 0.7999), Equivocal ($\geq 0.800 - \leq 1.099$), Weak Positive (1.100 - ≤ 2.999), Positive (≥ 3.000)	LP/VSER/075
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Aptima Human Papilloma Virus (HPV) Assay	ThinPrep liquid cytology specimens	In vitro nucleic amplification test specific for HPV RNA. Run on the Genprobe Panther System	CE	Positive/Negative	The manufacturer's direction circular and the NVRL procedure LP/MVIR/186 Operation and Maintenance of the Panther System
	BioFire Filmarray Respiratory Panel	Respiratory Aspirates, BALS, Respiratory Swabs	Biofire Filmarray Instrument	CE Marked Commercial	Qualitative	LP/MVIR/183
	CMV DNA	Human serum and plasma	Taqman 7500 analyser	CE marked with validated modification	Plasma-Quantitative range 500-1 x 10 ⁷ Copies/ml	LP/MVIR/085
	CT/NG	Urine and swabs	Panther	CE	Not Detected RLU < 85 Equivocal 85-250 Detected 250- <4500	LP/MVIR/186
	Detection of Adenovirus using the Altona RealStar Adenovirus PCR Kit 1.0	Serum/Plasma	PSH, Magnapure 96, Qiagility, Taqman 7500 FAST	CE Marked Commercial	10 ³ - 10 ⁸ copies/ml	LP/MVIR/200
	Detection of Viral Infections in the Central Nervous System including herpes viruses (HSV 1,	CSF	Taqman 7500 analyser	in-house developed	Detected cT < 34 Refer to Alg MVIR 021 for cT	LP/MVIR/064 and LP/MVIR/134

HSV 2, VZV, Enterovirus, Parechovirus and HHV6)				Detected > 34	
EBV DNA	Human serum and plasma Whole Blood	Taqman 7500 analyser	CE marked with validated modification	Plasma-Quantitative range 500 -50 X 10 ⁷ Copies/ml	LP/MVIR/089
Fast-Track Diagnostics Pneumocystis jirovrcii	Respiratory Secretions and Respiratory Swabs	Easymag, Taqman 7500 FAST	CE Marked Commercial	Qualitative	LP/MVIR/194
Gastroenteritis screen including: Astrovirus, Sapovirus, Adenovirus type F, Rotavirus, Norovirus (Genogroup 1&2)	Faecal	Taqman 7500 analyser and ViiA 7	in-house developed	Detected cT ≤35	LP/MVIR/153
HCV Genotype 1 antiviral resistance testing (including Q80K polymorphism analysis) –NS3 gene	Serum and Plasma samples	Genetic Analyser 3500 Dx	in-house developed	> 10,000 copies/ml	LP/MVIR/187
HCV II Genotyping	Human serum and plasma	Abbott real time assay	CE	> 500 IU/ml Required for Genotyping	LP/MVIR/128
HCV RNA		Abbott real time assay	CE	Quantitative Range 12-10 ⁸ IU/ml	LP/MVIR/125
Hepatitis B Virus		Abbott real time assay	CE	Quantitative Range 10-10 ⁹ IU/ml	LP/MVIR/135
HIV-1 genotypic antiviral resistance testing (pol region)	Plasma samples	Genetic Analyser 3500 Dx	in-house developed	> 500 Copies/m	LP/MVIR/176
HPV (Roche System)	Hologic Thin Prep LBC	Roche Cobas 4800 system	CE Marked Commercial	High Risk HPV Types Positive/Negative and Partical Genotyping 16/18	LP/MVIR/209
Immunodeficiency virus type 1	Human serum and plasma	Abbott real time assay	CE	Quantitative Range 40-10 ⁷ Copies/ml	LP/MVIR/120
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	cT < 36- DETECTED cT > 36 Detected at low level	LP/MVIR/114
Parvovirus	Human serum and plasma	Taqman 7500 analyser	CE marked with validated modification	200-108 IU/ml - Quantitative value reported	LP/MVIR/101
Real-Time PCR for Adenovirus DNA	Swabs, Stool	Taqman 7500 analyser and/or ViiA 7	in-house developed	cT < 35 DETECTED cT 35-38 DETECTED at low level cT > 38, repeat	LP/MVIR/107

	Real-Time PCR for BK virus DNA (Quantitative)	Serum, Plasma, and Urine samples	Taqman 7500	CE	Quantitative range 1000- 10 ⁹ Copies/ml	LP/MVIR/177
	Real-Time PCR for Hepatitis A virus RNA	Serum	Taqman 7500	CE marked with validated modification	Detected, Not Detected Inhibitory(IC cT 34)	LP/MVIR/161
	Real-Time PCR for Hepatitis E Virus		Taqman 7500	CE marked with validated modification	Detected, Not Detected Inhibitory(IC cT 34)	LP/MVIR/160
	Real-time PCR for Herpes Simplex 1 and 2 virus DNA	Swabs,	Taqman 7500 analyser and ViiA 7	in-house developed	cT < 35 DETECTED cT 35-38 DETECTED at low level cT > 38, repeat	LP/MVIR/107
	Real-time PCR for JC Virus DNA	CSF, Serum, Urine and Plasma	Taqman 7500	CE	Detected, Not Detected Inhibitory(IC cT 30)	LP/MVIR/152
	Real-Time PCR for Varicella Zoster DNA	Swabs,	Taqman 7500 analyser and ViiA 7	in-house developed	cT < 35 DETECTED cT 35-38 DETECTED at low level cT > 38, repeat	LP/MVIR/107
	Real-Time RT-PCR for Enterovirus and Parechovirus RNA	Stool, Swab	Taqman 7500	in-house developed	Detected cT < 38	0 LP/MVIR/134
	Trichomonas vaginalis on the Panther	Aptima Collection Device	Panther System	CE Marked Commercial	Qualitative	LP/MVIR/097
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays	One-Step Real-Time RT-PCR for the Detection of Mumps Virus	Oral Fluid, CSF, other sample types are tested with an NVRL comment	Qiagen, Taqman 7500 FAST	In House	Qualitative	LP/MVIR/112
	Rubella Virus Real-Time RT-PCR	Throat Swab, Oral Fluid, Serum	Taqman 7500 FAST	In House	Qualitative	LP/MVIR/166
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis	Genotypic Assay for HIV-1 Integrase Inhibitor Antiretroviral Resistance	Serum/Plasma	Manual Qiagen, RT-PCR (nested), Sanger sequencing (ABI 3500Dx)	In House	>500 copies/ml	LP/MVIR/176
	HBV Genotyping/Resistance		Manual Qiagen, RT-PCR (nested), Sanger sequencing (ABI 3500Dx)	In House	>=log 3 IU/ml	LP/MVIR/193
	HCV Genotyping by Sanger Sequencing		Manual Qiagen, RT-PCR (nested), Sanger sequencing (ABI 3500Dx)	In House	>=log 4 IU/ml	LP/MVIR/197

1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	TP-PA	Human serum and plasma	Manual	CE	Negative Indeterminate Pos 1:80, 1:160, 1:320, 1:640, 1:1280	LP/VSER/008
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	Negative ≥ 1.4 Equivocal ≥ 1 to < 1.4 Positive < 1	LP/VSER/001
	Anti-HCV		Vidas	CE	Negative < 0.999 Positive ≥ 1.00	LP/VSER/001
	CMV IgM		Vidas	CE	Negative < 0.7 Equivocal ≥ 0.7 to < 0.9 Positive ≥ 0.9	LP/VSER/001
	Cytomegalovirus IgM		Manual	CE	$<$ Cut-off (CO) Negative Lower CO to Upper CO Equivocal \geq Upper CO Positive	LP/VSER/075
	Diasorin Enzyme Immunoassay for Qualitative determination of Total antibodies to Hepatitis Delta antigen (anti- D)	Human serum	Manual	CE	≤ 0.899 Negative 0.900- 0.999 Equivocal 1.000 – 1.099 Weak Positive ≥ 1.100 Positive	LP/VSER/075
	Fortress HEV IgG	Human serum and plasma	Manual	CE	≤ 0.899 Negative 0.9-1.099 Equivocal 1.100-2.999 Weak Positive ≥ 3.000 Positive	LP/VSER/075
	Fortress HEV-IgM		Manual	CE	≤ 0.899 Negative 0.9-1.099 Equivocal 1.100-2.999 Weak Positive ≥ 3.000 Positive	LP/VSER/075
Genscreen Ultra HIV Ag/Ab		Manual	CE	≤ 0.899 Negative 0.900-1.000 Equivocal 1.001-2.999 Weak Positive ≥ 3.00 Positive	LP/VSER/075	

HAV IgM		Vidas	CE	Negative <0.4 Equivocal ≥0.4 to <0.499 Positive ≥0.500	LP/VSER/001
Herpes Select 1	Human serum	Manual	CE	<0.9 Negative ≥0.900-≤1.100 Equivocal N/A Weak Positive ≥1.1 Positive	LP/VSER/075
Herpes Select 2		Manual	CE	<0.9 Negative ≥0.900-≤1.100 Equivocal N/A Weak Positive ≥1.1 Positive	LP/VSER/075
HIV screening	Human serum and plasma	Vidas	CE	Negative Ab <0.25 Negative Ag<0.25 Positive Ab ≥0.25 Positive Ag ≥0.25	LP/VSER/001
Leptospira IgM	Human serum	Manual	CE	≤0.899 Negative 0.900-1.100 Equivocal 1.101-1.999 Weak Positive ≥2.000 Positive	LP/VSER/075
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	Samples with anti-HBc levels between an index value of >/=0.300-0.900 are graded weak positive. Samples with an index value of 0.300 are graded positive	The manufacturer's direction circular and the NVRL procedure LP/VSER/077 Operation and Maintenance of the Diasorin Liaison XL
Measles IgM	Human serum and plasma and oral fluid	Manual	CE	Oral Fluid ≤0.799 Negative 0.800-1.000 Equivocal 1.001-1.999 Weak Positive ≥2.000 Positive Serum ≤0.899 Negative 0.900-1.099 Equivocal 1.100-1.999 Weak Positive ≥2.000 Positive	LP/VSER/075
Monolisa Anti-HBc	Human serum and plasma	Manual	CE	≤0.899 Negative 0.900-1.000 Equivocal 1.001-2.999	LP/VSER/075

					Weak Positive ≥3.000 Positive	
Monolisa HCV Ab		Manual	CE	≤0.899 Negative 0.900-1.000 Equivocal 1.001-2.999 Weak Positive ≥3.00 Positive	LP/VSER/075	
Mumps IgG		Diasorin Liaison XL	CE	Negative ≤9 Equivocal ≥9.0 to ≤10.99 Weak positive ≥11.0 to ≤49.99 Positive ≥50	LP/VSER/077	
Mumps IgM	Human serum and plasma and oral fluid	Manual	CE	Oral Fluid <0.750 Negative ≥ 0.750 - <1.000 Equivocal ≥ 1.000 - <2.000 Weak Positive ≥2.000 Positive Serum <0.856 Negative ≥ 0.856 - <1.000 Equivocal ≥ 1.000 - <2.000 Weak Positive ≥2.000 Positive	LP/VSER/075	
Murex HBsAg	Human serum and plasma	Manual	CE	≤0.899 Negative 0.9 – 1.000 Equivocal 1.001-2.999 Weak Positive ≥3.000 Positive	LP/VSER/075	
Murex HBsAg Confirmatory		Manual	CE	Positive/Negative	LP/VSER/075	
Murex HTLV I/II		Manual	CE	≤0.899 Negative 0.900-1.000 Equivocal 1.001-2.999 Weak Positive ≥3.00 Positive	LP/VSER/075	
Ortho HCV		Manual	CE	≤0.899 Negative 0.900-1.000 Equivocal 1.001-2.999 Weak Positive ≥3.00 Positive	LP/VSER/075	
Syphilis IgM		Manual	CE	≤0.899 Negative 0.9-1.000 Equivocal 1.001-1.999 Weak Positive	LP/VSER/075	

					≥2.000 Positive	
	Toxo IgG II		Vidas	CE	Negative <4 Equivocal ≥4 to <8 Positive ≥8	LP/VSER/001
	Toxo IgM		Vidas	CE	Negative <0.55 Equivocal ≥0.55 to <0.65 Positive ≥6.5	LP/VSER/001
	Vidas HIV 1 P24 11 Confirmatory		Vidas	CE	Neutralisation % ≥60% p24 antigen confirmed ≤60% negative	LP/VSER/001
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	Negative Indeterminate Positive	LP/VSER/016
	INNO-LIA HIV I/II		Immunoblot	CE	Negative Indeterminate Positive	LP/VSER/016
	INNO-LIA HTLV I/II Score		AUTO-LIA	CE	Negative Indeterminate Positive	LP/VSER/016
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	S/CO ≤ 0.999 Negative S/CO 1.000 – 2.999 Weak Positive S/CO ≥ 3.000 Positive	LP/VSER/050
	Anti-HBc II		Architect i4000	CE	S/CO ≤ 0.899 Negative S/CO 0.900 - 1.000 Equivocal S/CO 1.001 - 1.999 Weak Positive S/CO ≥ 2.000 Positive	LP/VSER/050
	Anti-HBe		Architect i4000	CE	S/CO ≥ 1.101 Negative S/CO 1.002 - 1.100 Equivocal S/CO 0.800 - 1.001 Weak Positive S/CO ≤ 0.800 Positive	LP/VSER/050

Anti-HBs	Architect i4000	CE	0.0 - 0.49 mIU/ml No antibodies detected 0.50 – 9.99 mIU/ml Less than 10 mIU/ml ≥ 10 mIU/mL mIU/ml value reported	LP/VSER/050
	Diasorin Liaison XL	CE	≤10 IU/ml 10.1-99.9 mIU/ml ≥100 IU/ml	LP/VSER/077
Anti-HCV	Architect i4000	CE	S/CO ≤ 0.799 Negative S/CO 0.800 - 1.000 Equivocal S/CO 1.001 - 4.999 Weak Positive S/CO ≥ 5.000 Positive	LP/VSER/050
Borrelia IgG	Diasorin Liaison XL	CE	Negative ≤9.99 Equivocal ≥10.0 to ≤14.99 Weak positive ≥15.0 to ≤29.99 Positive ≥30	LP/VSER/077
CMV IgG	Architect i4000	CE	≤ 5.999 AU/mL Negative 6.000 – 14.999 AU/mL Weak Positive ≥ 15.000 AU/mL Positive	LP/VSER/050
CMV IgM	Architect i4000	CE	Index ≤ 0.849 Negative Index 0.850 – 0.999 Equivocal Index 1.000 – 1.999 Weak Positive Index ≥2.000 Positive	LP/VSER/050
EBNA IgG	Diasorin Liaison XL	CE	Negative ≤4.99 Equivocal ≥5.00 to ≤20.00 Weak positive ≥20.01 to ≤30.00 Positive ≥30.01	LP/VSER/077
EBV IgM	Diasorin Liaison XL	CE	Negative ≤19.9 Equivocal ≥20.0 to ≤39.9 Weak Positive ≥40.0 to ≤79.9 Positive ≥80	LP/VSER/077
EBV VCA IgG	Diasorin Liaison XL	CE	Negative ≤19.9 Equivocal ≥20.0	LP/VSER/077

				to ≤29.9 Weak positive ≥30.0 to ≤39.9 Positive ≥40	
HAVAb-IgG		Architect i4000	CE	S/CO ≤ 0.899 Negative S/CO 0.900 - 1.000 Equivocal S/CO 1.001 - 1.999 Weak Positive S/CO ≥ 2.000 Positive	LP/VSER/050
HAVAb-IgM		Architect i4000	CE	S/CO ≤ 0.799 Negative S/CO 0.800 - 1.199 Equivocal S/CO 1.200 – 2.999 Weak Positive S/CO ≥ 3.000 Positive	LP/VSER/050
HBeAg		Architect i4000	CE	S/CO ≤ 0.899 Negative S/CO 0.900 - 1.000 Equivocal S/CO 1.001 - 1.100 Weak Positive S/CO ≥1.101 Positive	LP/VSER/050
HBsAg		Architect i4000	CE	S/CO ≤ 0.799 Negative S/CO 0.800 - 1.000 Equivocal S/CO 1.001 - 14.999 Weak Positive S/CO ≥ 15.000 Positive	LP/VSER/050
HCV Ag		Architect i4000	CE	0.000 – 2.999 fmol/L Negative 3.000 – 9.999 fmol/L Weak Positive ≥ 10.000 fmol/L Positive	LP/VSER/050
HIV Ag/Ab Combo		Architect i4000	CE	S/CO ≤ 0.799 Negative S/CO 0.800 - 1.000 Equivocal S/CO 1.001 – 14.999 Weak Positive S/CO ≥15.000 Positive	LP/VSER/050
HSV 1 / 2 IgG	Human serum	Diasorin Liaison XL	CE	Negative ≤0.89 Equivocal ≥0.9 to	LP/VSER/077

					≤ 1.09 Weak positive ≥ 1.10 to ≤ 1.49 Positive ≥ 1.5	
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 plasma samples	CE	Specimens with signal-to-cut-off (S/CO) ratios < 1.00 are considered non-reactive for HTLV I/II antibodies. Specimens with signal-to-cut-off (S/CO) ratios of ≥ 1.00 - 2.99 are wk positive and ≥ 3.00 are considered positive for HTLV I/II antibodies	The manufacturer's direction circular and the NVRL procedure LP/VSER/077 Operation and Maintenance of the Diasorin Liaison XL	
Measles IgG	Human serum and plasma	Diasorin Liaison XL	CE	Negative < 13.5 Equivocal ≥ 13.5 to ≤ 16.49 Weak Positive ≥ 16.5 to ≤ 49.99 Positive ≥ 50	LP/VSER/077	
Parvovirus B19 IgG		Diasorin Liaison XL	CE	Negative < 0.9 Equivocal ≥ 0.9 to < 1.1 Weak positive ≥ 1.1 to < 1.5 Positive ≥ 1.5	LP/VSER/077	
Parvovirus B19 IgM		Diasorin Liaison XL	CE	Negative < 0.9 Equivocal ≥ 0.9 to < 1.1 Weak positive ≥ 1.1 to < 1.5 Positive ≥ 1.5	LP/VSER/077	
Platelia Mycoplasma pneumonia IgM ELISA	Serum	Detection of anti-mycoplasma pneumonia IgM in human serum by enzyme immunoassay.	CE	OD/CO ≤ 0.899 Negative OD/CO ≥ 0.900 to ≤ 1.000 equivocal, OD/CO ≥ 1.001 to ≤ 1.999 Wk Positive OD/CO ≥ 2.000 positive	The manufacturer's direction circular and the NVRL procedure LP/VSER/075 Enzyme linked immunoassay (ELISA) procedure	
rHTLV-I/II	Human serum and plasma	Architect i4000	CE	S/CO ≤ 0.799 Negative S/CO 0.800 - 1.000 Equivocal S/CO 1.001 - 1.999 Weak Positive S/CO ≥ 2.000 Positive	LP/VSER/050	

	Rubella IgG	Architect i4000	CE	≤ 4.999 IU/ml No antibodies detected 5.000 – 14.999 IU/ml As per algorithm ≥ 15.000 IU/mL Greater than 15 IU/ml	LP/VSER/050
		Diasorin Liaison XL	CE	Less than 5 IU/ml <5 IU/ml Detected at low level ≥5.1 to ≤9.999 IU/ml Greater than 10IU/ml ≥10 IU/ml	LP/VSER/077
	Rubella IgM	Architect i4000	CE	S/CO ≤ 0.749 Negative S/CO 0.750 – 1.000 Equivocal S/CO 1.001 – 1.999 Weak Positive S/CO ≥ 2.000 Positive	LP/VSER/050
	Syphilis TP	Architect i4000	CE	S/CO ≤ 0.499 Negative S/CO 0.500 - 1.000 Equivocal S/CO 1.001 - 3.999 Weak Positive S/CO ≥ 4.000 Positive	LP/VSER/050
	Toxo IgM	Architect i4000	CE	S/CO ≤ 0.829 Negative S/CO 0.830 – 0.999 Equivocal S/CO 1.000 – 1.499 Weak Positive S/CO ≥ 1.500 Positive	LP/VSER/050
	ToxoIgG	Architect i4000	CE	≤ 1.599 IU/ml Negative 1.600 – 2.999 IU/mL Equivocal ≥ 3.000 IU/mL Positive	LP/VSER/050
	VZV IgG	Diasorin Liaison XL	CE	Negative ≥100 mIU/ml ≤100 mIU/ml	LP/VSER/077
1029 Miscellaneous - .99 Miscellaneous tests	RPR Reditest Syphilis	Manual	CE	Negative Positive 1:1 Positive 1:2 Positive 1:4 Positive 1:8	LP/VSER/006

					Positive 1:16	
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