Schedule of Accreditation

Organisation Name	National Virus Reference Laboratory
Trading As	
INAB Reg No	326MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	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	NVRL Satellite Laboratory Backweston (NSLB)	Lab 5, Dept. of Agriculture Food and the Marine, Backweston Laboratory Campus, Ballymadeer, Celbridge, Celbridge, Kildare, Ireland, W23X3PH
2	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
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Altona SARS-CoV-2 RT-PCR	Respiratory swabs	MagNa Pure 96	CE Marked	Qualitative	LP-CL3-065
	Aptima Mycoplasma Genitalium Assay	Aptima collection device - Anal swab, endocervical swab, urine	Hologic Panther System	CE Marked	Qualitative	VAL/MVIR/225 and LP/MVIR/186
	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 viruses in CSF samples using the Altona RealStar HSV, VZV & Entero PCR kits	CSF, Serum, Plasma	EasyMAG ® Automated Extractor, Qiagility	CE Marked	Detected, Not Detected	LP/MVIR/220
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
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
Immunodeficiency virus type 1		Abbott real time assay	CE	Quantitative Range 40-10*7 Copies/ml	LP/MVIR/120
NxTAG Respiratory Pathogen Panel Luminex	Respiratory secretion specimens and respiratory swabs	MagNA pure 96 (Roche), MAGPIX (Luminex)	CE Marked	Detected, Negative	LP/MVIR/198
Parvovirus	Human serum and plasma	Taqman 7500 analyser	CE marked with validated modification	200-108 IU/ml - Quantitative value reported	LP/MVIR/101
RealStar Altona HHV-6 Assay	Plasma, saliva, swab, CSF	Taqman 7500 Fast	CE Marked	Qualitative	LP/MVIR/112 and VAL/MVIR/233
Real-Time PCR for BK virus DNA (Quantitative)	Serum, Plasma, and Urine samples	Taqman 7500	CE	Quantitative range 1000- 10*9 Copies/mll	LP/MVIR/177
Real-Time PCR for Hepatitis E Virus	Serum	Taqman 7500	CE marked with validated modification	Positive HEV RNA results > 1x10(4) IU/ml reported quantitatively. b) Samples with a viral load greater than 1x10(10) IU/ml. this reported as > 10.0 log IU/ml. c)Positive HEV RNA	LP/MVIR/160

					results below 1x10(4) IU/ml reported as “DETECTED < 10,000 IU/ml (< 4.0 LogIU/ml)” d) Negative HEV RNA results are reported as “Not detected”	
	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	Blood / CSF - quantitatively as (a) DETECTED < 2.0 Log10 IU/mL (b) If between 90 and 9e10 IU/mL then report number (c) DETECTED > 11.0 Log10 IU/mL	LP/MVIR/152
	Real-Time RT-PCR for Enterovirus and Parechovirus RNA	Stool, Swab	Taqman 7500	in-house developed	Detected cT < 38	0 LP/MVIR/134
	RT PCR for the detection and quantification of HIV type 1 (HIV-1)	Plasma	GeneXpert Instrument	CE Marked Commercial	Quantitative Copies /ml	LP/MVIR/173
	The GeneXpert HCV Viral Load Assay	Plasma	Cepheid GeneXpert IV System	CE Marked	Qualitative range reported as detected <1.08 log IU/ml. Quantitative value reported >1.0 to 8 log IU/ml.	LP-MVIR-173
	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	In-House HIV Genotypic Antiretroviral Resistance Assay	Plasma	Applied Biosystems 3500 Genetic Analyser	In House	N/A	LP/MVIR/176

	Molecular Respiratory Surveillance Real-time PCR Screen	Respiratory secretion specimens and respiratory swabs	ViiA7, Taqman 7500, MagNApure 96	In house	Qualitative	LP-MVIR-215
	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
	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 the detection of Norovirus, Astrovirus, Sapovirus, Adenovirus type F, Rotavirus and Rotarix (Gastro screen)	Faecal	Roche MagNA Pure 96, ABI 7500/ViiA7	In House	Detected cT ≤35	LP/MVIR/153
	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
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis	HBV Genotyping/Resistance	Serum/Plasma	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	Anti-HBc		Vidas	CE	Negative ≥1.4 Equivocal ≥1 to <1.4 Positive <1	LP/VSER/001

marked commercial systems						
	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 ≥Upper CO Positive	LP/VSER/075
	Fortress HEV IgG		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	LP/VSER/075

				N/A Weak Positive ≥1.1 Positive	
HIV 1 P24 Antigen component of VIDAS assay	Serum and Plasma	Biomerieux VIDAS	CE Marked	<3.0 pg/ml of p24 Ag – Negative ≥ 3.0 and < 5.0 pg/ml of p24 Ag - Equivocal ≥ 5.0 pg/ml of p24 Ag- Positive	LP-VSER-053
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
Innotest HCV	Serum/Plasma	ELISA	CE Marked Commercial	Neg (-/=0.800, -/=3.000)	LP/VSER/075
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 Treponema Screen Assay	Serum and plasma	Diasorin Liaison XL	CE Marked	Qualitative	VAL/VSER/166 and LP/VSER/077
Liaison XL Anti-HBc assay	Serum/Plasma	Chemiluminescence immunoasssay (CLIA) technology for the qualitative determination of total antibodies to hepatitis B core antigen (anti-HBc) inhuman 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
Liaison XL Murex Anti-HDV Assay	Serum and plasma	Diasorin Liaison XL	CE Marked	Qualitative	VAL/VSER/162 and LP/VSER/077
Measles IgM	Human serum and plasma	Manual	CE	Serum ≤0.899 Negative 0.900-1.099 Equivocal 1.100-1.999 Weak Positive ≥2.000 Positive	LP/VSER/075

Monolisa HCV Ab	Human serum and plasma	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	Manual	CE	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
Syphillis IgM		Manual	CE	≤0.899 Negative 0.9-1.000 Equivocal	LP/VSER/075

					1.001-1.999 Weak Positive ≥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 CMV IgG Assay	Serum	BioMerieux VIDAS	CE Marked	Quantitative	LP/VSER/001
	Vidas HIV 1 P24 11 Confirmatory	Human serum and plasma	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/11		Immunoblot	CE	Negative Indeterminate Positive	LP/VSER/016
	INNO-LIA HTLV I/II Score		AUTO-LIA	CE	Negative Indeterminate Positive	LP/VSER/016
	The INNO-LIA Syphilis Score	Serum	Auto Lia 48 Instrument	CE Marked	Positive, Negative, Indeterminate	LP-VSER-016
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE	Anti-HBc IgM	Human serum and plasma	Architect i4000	CE	S/CO ≤ 0.999 Negative S/CO 1.000 – 2.999 Weak Positive S/CO ≥ 3.000 Positive	LP/VSER/050

marked commercial systems						
	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 to ≤29.9 Weak positive ≥30.0 to ≤39.9 Positive ≥40	LP/VSER/077
	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 ≤1.09 Weak positive ≥1.10 to ≤1.49	LP/VSER/077

				Positive ≥1.5	
Liaison XL Murex recHTLV-I/II assay	Serum/Plasma	Chemiluminescence immunoasssay (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	LP/VSER/050

				S/CO 0.800 - 1.000 Equivocal S/CO 1.001 - 1.999 Weak Positive S/CO ≥ 2.000 Positive	
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

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
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	cobas® SARS-CoV-2 & Influenza A/B	Respiratory Swab	cobas® 6800	CE Marked		LP/NSLB/014
	Real-time PCR for SARS-CoV-2		Roche Cobas 6800 system	CE marked Commercial	Detected, Not Detected, Inhibitory	LP/MVIR/226
	Real-Time RT PCR for SARS-CoV-2		Thermofisher Amplitude System	CE Marked Commercial	Detected, Not Detected, Inhibitory	LP/NSLB/004 & LP/NSLB/009