



UCD National Virus
Reference Laboratory

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The NVRL declares that the devices described in the accompanying table are only manufactured and used in the NVRL. As described, these devices meet* the applicable general safety and performance requirements (GSPR) either of the medical device Regulation (EU 2017/745), or of the in vitro diagnostic medical devices Regulation (EU 2017/746).

*A reasoned justification is provided for cases in which the applicable general safety and performance requirements are not fully met.

Name, function and signature(s) of responsible person(s):

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UCD National Virus Reference Laboratory

Article 5.5(f) Public Declaration

Device Identification (e.g. name, description, reference number)

Molecular:	Sequencing:	Serology:	WHO:	CL3:
Artus CMV Kit	HIV Genotypic Resistance (LDT)	RPR CARBON ANTIGEN	Microimmune Measles IgM Capture EIA	Chikungunya Rt - Pcr Kit 2.0
Artus EBV Kit	HIV 1 Integrase (LDT)	Newbio TPHA	Microimmune Rubella IgM capture EIA	Realstar Cchfv Rt-Pcr Kit
Artus Parvo Kit	HBV Genotyping / Resistance	SERION ELISA classic Cytomegalovirus IgM	Immundiagnostik AG Immunglobulin G ELISA	Altona Realstar Dengue Rt- Pcr Kit 3.0
Altona HEV Kit	HCV Genotype Sequence (LDT)			Altona Realstar Wnv Rt-Pcr Kit 2.0
Altona HAV Kit	Hepatitis A Genotype (LDT)			Realstar Ortho Pox Rt-Pcr Kit
Altona PJP Kit	Hepatitis E Genotype (LDT)			Realstar Filovirus Screen Rt-Pcr Kit 1.0
Altona HSV Kit	Enterovirus Genotype (LDT)			Realstar Zika Pcr Kit 1.0 Internal Control 2
Altona VZV Kit	WGS for SARS-CoV-2			Altona Realstar Zika Rt-Pcr Kit 1.0
Altona EV Kit	RSV Whole Genome Sequencing (LDT)			Altona Realstar Lassa Virus Rt-Pcr Kit 2.0
Altona AdV kit	Influenza Whole Genome Sequencing			Realstar Yellow Fever Rt-Pcr Kit
Altona HHV-6 kit	Adenovirus Genotype (LDT)			Orthopox LDT
Altona JC kit	Measles Genotyping			Euroimmun Flavivirus Profile 2 IgG
Altona BK kit	Rubella Genotyping			Euroimmun Flavivirus Profile 2 IgM

LDT: PV	Abbott HCV Genotyping			Euroimmun Chikungunya IgG IFA
LDT: EV68				Euroimmun Chikungunya IgM IFA
LDT: HSV				Euroimmun Sandfly Fever Virus IgG IFA
LDT: VZV				Euroimmun Sandfly Fever Virus IgM IFA
LDT: Gastro				Panbio Dengue IgM Capture
Abbott HIV VL				Panbio Dengue IgG Direct
Abbott HCV VL				Dengue Ns1 Ag Rapid Device
Abbott HBV VL				Euroimmun Anti-Zika Virus Elisa IgG
				Euroimmun Anti-Zika Virus Elisa IgM
				Euroimmun Anti-Hanta Virus Pool 1 Eurasia IgG
				Euroimmun Anti-Hanta Virus Pool 1 Eurasia IgM
				Euroimmun West Nile Virus Elisa IgG
				Euroimmun West Nile Virus Elisa IgM
				Euroimmun TBE Virus Elisa IgG
				Euroimmun TBE Virus Elisa IgM