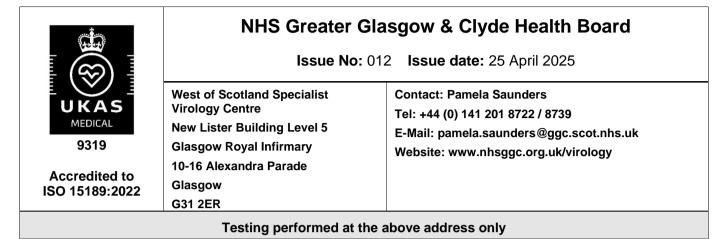
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS AND TISSUES BAL Eye and Conjunctival swab CSF Faeces Gargles Genital swabs NAS & NPA Plasma Serum Throat & Nose swabs Rectal swabs Skin swab/vesicle Sputum Urine Nail Tissue Vomit	Virology examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Extraction Roche MagnaPure 96 SOP;-EQP EOP 105	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for</u> <u>the purpose of clinical diagnosis</u> (cont'd) Molecular Diagnostics (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Extraction (cont'd)
BAL Eye and Conjunctival swab CSF Dried Blood Spots Gargles Genital Swabs NAS & NPA Plasma Rectal swabs Skin swab/vesicle Sputum Throat and Nose swabs Urine Nail Tissue Vomit		Biomerieux Easy Mag
Extracted DNA		Multiplex/Real time PCR, ABI 7500.
	Qualitative detection of:	
	HSV 1 and 2, VZV, Enterovirus and Parechovirus	MID-SOP-114
	H5 Influenza A virus RNA	MID-SOP-101
	Subtyping of Influenza A virus (H1, H3 and H275Y)	MID-SOP-102
	Novel Coronavirus upE	MID-SOP-129
	H7N9 Flu virus RNA	MID-SOP-130 Qiagen Rotorgene Q



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for</u> <u>the purpose of clinical diagnosis</u> (cont'd) Molecular Diagnostics (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Urine, Genital swabs, rectal swabs	CT/NG	MID-SOP-122
		EQP-EOP-061



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purpose of clinical diagnosis (cont'd) Serology (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Biomerieux Vidas Analyser Enzyme Linked Fluorescent Assay (ELFA) EQP-EOP-101 plus individual kit SOPS - see below
Serum, Plasma	Hepatitis B surface antigen	VS-BBV-SOP-014
	Hepatitis B core antibody	VS-BBV-SOP-019
	HIV 1 / 2 antibody/antigen	VS-BBV-SOP-023
	Hepatitis A IgM antibody	VS-BBV-SOP-018
	CMV IgG antibody	VS-BBV-SOP-105
	Varicella zoster IgG antibody	VS-SER-SOP-029
	Rapid Plasma Reagin (RPR) - a non-treponemal serological screening test for syphilis	Biorad kit – macroscopic agglutination test VS-SER-SOP-061
	Syphilis IgM antibody	Mikrogen Kit - Enzyme Linked Immunosorbent Assay. VS-SER-SOP-060
	Syphilis	Fujirebio kit – line blot immunoassay. VS-SER-SOP-062



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and
	Serology (cont'd)	methodology:
	Hepatitis E IgG antibody	Mikrogen kit – Enzyme Linked Immunosorbent Assay. VS-BBV-SOP-103
	Hepatitis E IgM antibody	Mikrogen kit – Enzyme Linked Immunosorbent Assay. VS-BBV-SOP-102
	HIV 1 / 2 confirmatory differentiation	Biorad Geenius HIV 1/2 confirmatory system. Immunochromatographic test. VS-SER-SOP-077
		Diasorn Liaison XL analyser – CLIA – Chemiluminescence Immunoassay
	Measles IgG antibody	VS-SER-SOP-064
	Mumps IgG antibody	VS-SER-SOP-065
	Herpes simplex IgG antibody	VS-SER-SOP-066
	B19 IgG antibody	VS-SER-SOP-067
	B19 IgM antibody	VS-SER-SOP-068
	Varicella zoster IgG antibody	VS-SER-SOP-075
	Helicobacter pylori antibody	DS2 Automated Elisa System Premier H.pylori Elisa kit VS-SER-SOP-076



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for</u> <u>the purpose of clinical diagnosis</u> (cont'd) Serology (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum/plasma	Virology examination activities for the purpose of clinical diagnosis Serology:	Abbott Alinity-i analyser using Abbott Alinity-i kits : Chemiluminescent microparticle immunoassays (CMIA) plus Abbott GLP system E-3, WI-9 and EQP-EOP-111 in combination with specific test procedures below
	Hepatitis B surface Antigen (Qualitative test)	VS-BBV-SOP-163
	Hepatitis B surface Antigen (Quantitative test)	VS-BBV-SOP-168
	Hepatitis B surface Antigen Neutralisation	VS-BBV-SOP-157
	Hepatitis B core antibody	VS-BBV-SOP-150
	Hepatitis B core IgM antibody	VS-BBV-SOP-149
	Hepatitis B e-antigen	VS-BBV-SOP-162
	Hepatitis B e-antibody	VS-BBV-SOP-155
	Anti-Hepatitis B surface antibody	VS-BBV-SOP-152
	Hepatitis C antibody	V-LP20
	HIV 1 / 2 antibody	VS-BBV-SOP-147
	Hepatitis A IgG antibody	VS-BBV-SOP-164
	Hepatitis A IgM antibody	VS-BBV-SOP-151
	Syphilis antibody	VS-BBV-SOP-166
	Rubella IgG antibody	VS-BBV-SOP-165



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purpose of clinical diagnosis (cont'd) Serology (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum/plasma (cont'd)	Virology examination activities for the purpose of clinical diagnosis Serology	Abbott Alinity-i analyser using Abbott Alinity-i kits : Chemiluminescent microparticle immunoassays (CMIA) plus Abbott GLP system E-3, WI-9 and EQP-EOP-111 in combination with specific test procedures below
	HTLV 1 / 2 antibody	VS-BBV-SOP-148
	CMV IgG antibody	VS-BBV-SOP-154
	CMV IgM antibody	VS-BBV-SOP-160
	CMV avidity	VS-BBV-SOP-167
	Epstein Barr nuclear antigen (EBNA) IgG antibody	VS-BBV-SOP-153
	Epstein Barr Virus Capsid Antigen (VCA) IgG antibody	VS-BBV-SOP-156
	Epstein Barr Virus IgM antibody	VS-BBV-SOP-159
	Toxoplasma gondii IgG antibody	VS-BBV-SOP-161
Dried blood spots	Hepatitis B, Hepatitis C and HIV	BBV-SOP-118
		Abbott Alinity-M System Real time PCR extraction and amplification analyser V-LP21
Plasma	Viral load for HIV, HBV and HCV	
Dried blood spots	Detection of HCV	
Urine, Genital swabs, Rectal swabs, Throat swabs, and Eye swabs	Detection of Chlamydia trachomatis/Neisseria gonorrhoeae CT/NG	
Respiratory samples, Nasopharyngeal and Oropharyngeal swabs, Sputum, and Gargles	Detection of SARS-CoV2, Influenza A, B, Respiratory Syncytial virus (RSV)	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for</u> <u>the purpose of clinical diagnosis</u> (cont'd) Molecular Specialist Testing	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Extraction platforms
Serum, Plasma Whole blood Respiratory sample Clinical isolates		Biomerieux Easymag extractor
Respiratory sample		Roche MagnaPure 96 SOP;-EQP EOP 105
Extracted DNA	Resistance testing of HIV-1 clinical isolates and sequence analysis of the <i>pol</i> gene (encodes protease and reverse transcriptase)	ABI GeneAmp PCR system 9700, RunOne Electrophoresis System 220V, ABI 3500xI sequencer, ReCall software and Stanford HIV drug resistance database. MD- SOP-002
	Resistance testing of HIV-1 clinical isolates and sequence analysis of the <i>pol</i> gene (encodes integrase)	MD-SOP-026
Extracted DNA/RNA	Prediction of co-receptor tropism (i.e. CCR5/CXCR4) in patients infected with HIV-1	PCR of proviral DNA or RT/PCR of viral RNA followed by sequence analysis. MD-SOP-036
Extracted DNA	Genetic characterisation of influenza B viruses by sequencing of the hemagglutinin (HA) gene.	Use of PCR reagents, ABI GeneAmp PCR system 9700, RunOne Electrophoresis System 220V, ABI 3500xI sequencer and sequence analysis software. MD- SOP-007
	Genetic characterisation of influenza A H1N1sw1 viruses by sequencing of the hemagglutinin (HA) gene.	As above MD-SOP-028
	Genetic characterisation of influenza A H3 viruses by sequencing of the hemagglutinin (HA) gene.	As above MD-SOP-035



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	measured/Range of measurement	Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purpose of clinical diagnosis (cont'd) Molecular Specialist Testing (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Extracted DNA (cont'd)		ABI GeneAmp PCR system 9700, ABI 7500.
	Genotyping of HCV	VS-BBV-SOP-109
	Genotyping of HCV by sequence analysis of the <i>core</i> gene	RunOne Electrophoresis System 220V, ABI 3500xI sequencer and ReCall software. MD-SOP-001
	Quantitative analysis of Hepatitis Delta virus (HDV)	ABI GeneAmp PCR system 9700, ABI 7500. VS-BBV-SOP-115
	Genotyping of Hepatitis B virus (HBV) by sequence analysis of the surface gene (partial sequencing of the overlapping polymerase gene allows lamivudine resistance determination)	ABI GeneAmp PCR system 9700, RunOne Electrophoresis System 220V, ABI 3500xI sequencer, sequence analysis software and Stanford HBV drug resistance database. MD-SOP-003
	Resistance testing of HBV clinical isolates and sequence analysis of the surface gene/overlapping polymerasegene (can determine lamivudine, adefovir and/or entecavir resistance).	As above MD-SOP-027
	HIV-1 Pol Resistance	As above and ReCall software and Stanford HIV drug resistance database MD-SOP-037
Respiratory samples	Nucleic acid extraction	Nucleic Acid extraction using the Hamilton STARlet (Sequential Transfer and Aliquoting Robot) and Kingfisher Flex extraction platform with MagMAX Viral/Pathogen II Nucleic Acid Isolaton Kit NGS-LP6



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SARS-CoV2 Positive samples only Extracted nucleic acids	Whole genome sequencing	Whole genome sequencing of SARS-CoV-2 utilising the Illumina COVIDSeq Test and Illumina NextSeq 2000 NGS-LP4 Subsequent data analysis of fastq files performed by public health Scotland as part of the Scottish Illumina Pipeline
	END	