


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>9319</p> <p>Accredited to ISO 15189:2012</p>	<p>NHS Greater Glasgow & Clyde Health Board</p> <p>Issue No: 007 Issue date: 26 September 2022</p>	
	<p>West of Scotland Specialist Virology Centre New Lister Building Level 5 Glasgow Royal Infirmary 10-16 Alexandra Parade Glasgow G31 2ER</p>	<p>Contact: Pamela Saunders Tel: +44 (0) 141 201 8722 / 8739 E-Mail: pamela.saunders@ggc.scot.nhs.uk Website: www.nhsggc.org.uk/virology</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>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</p>	<p><u>Virology examination activities for the purpose of clinical diagnosis</u></p> <p>Molecular Diagnostics</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Extraction Roche MagnaPure 96 SOP;-EQP EOP 105</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>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</p> <p>Extracted DNA</p>	<p><u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Molecular Diagnostics (cont'd)</p> <p>Qualitative detection of:</p> <p>HSV 1 and 2, VZV, Enterovirus and Parechovirus</p> <p>H5 Influenza A virus RNA</p> <p>Subtyping of Influenza A virus (H1, H3 and H275Y)</p> <p>Novel Coronavirus upE</p> <p>H7N9 Flu virus RNA</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Extraction (cont'd)</p> <p>Biomerieux Easy Mag</p> <p>Multiplex/Real time PCR, ABI 7500.</p> <p>MID-SOP-114</p> <p>MID-SOP-101</p> <p>MID-SOP-102</p> <p>MID-SOP-129</p> <p>MID-SOP-130 Qiagen Rotorgene Q</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Urine, Genital swabs, rectal swabs</p>	<p><u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Molecular Diagnostics (cont'd)</p> <p>CT/NG</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>MID-SOP-122</p> <p>EQP-EOP-061</p>
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p>	<p><u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>(Serology cont'd)</p> <p>Hepatitis C antigen</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>Abbott Architect i2000sr using Abbott Architect reagent kits /Chemiluminescent microparticle immunoassays (CMIA), and EQP-EOP-099 in combination with specific test procedures below:</p> <p>VS-BBV-SOP-119</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Serology (cont'd)	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
	<i>Varicella zoster</i> IgG antibody	VS-SER-SOP-029
	<i>Treponema pallidum</i>	Serodia kit – passive particle agglutination- VS-SER-SOP-059
	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)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Serology (cont'd)	
	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
	<i>Herpes simplex</i> IgG antibody	VS-SER-SOP-066
	B19 IgG antibody	VS-SER-SOP-067
	B19 IgM antibody	VS-SER-SOP-068
<i>Varicella zoster</i> IgG antibody	VS-SER-SOP-075	
<i>Helicobacter pylori</i> antibody	DS2 Automated Elisa System Premier H.pylori Elisa kit VS-SER-SOP-076	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Extraction platforms Biomerieux Easymag extractor
Serum, Plasma Whole blood Respiratory sample Clinical isolates Respiratory sample	Molecular Specialist Testing	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 3130xl 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 3130xl 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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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Extracted DNA (cont'd)</p>	<p><u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Molecular Specialist Testing (cont'd)</p> <p>Genotyping of HCV</p> <p>HCV 1a + 1b</p> <p>Genotyping of HCV by sequence analysis of the <i>core</i> gene</p> <p>Quantitative analysis of Hepatitis Delta virus (HDV)</p> <p>Genotyping of Hepatitis B virus (HBV) by sequence analysis of the surface gene (partial sequencing of the overlapping polymerase gene allows lamivudine resistance determination)</p> <p>Resistance testing of HBV clinical isolates and sequence analysis of the surface gene/overlapping polymerase gene (can determine lamivudine, adefovir and/or entecavir resistance).</p>	<p>In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:</p> <p>ABI GeneAmp PCR system 9700, ABI 7500.</p> <p>VS-BBV-SOP-109</p> <p>MD-SOP-034</p> <p>RunOne Electrophoresis System 220V, ABI 3130xl sequencer and ReCall software. MD-SOP-001</p> <p>ABI GeneAmp PCR system 9700, ABI 7500. VS-BBV-SOP-115</p> <p>ABI GeneAmp PCR system 9700, RunOne Electrophoresis System 220V, ABI 3130xl sequencer, sequence analysis software and Stanford HBV drug resistance database. MD-SOP-003</p> <p>As above MD-SOP-027</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u> Molecular Specialist Testing (cont'd) HIV-1 Pol Resistance	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: As above and ReCall software and Stanford HIV drug resistance database MD-SOP-037
END		