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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
REFERRED MICROBIOLOGICAL CULTURES	<u>Microbiology Examinations for the purpose of clinical diagnosis</u>	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)'
	Determination of antibiotic MIC	Using culture media and E-Test strips (BioMerieux), (SSRL_SOP_140) (SSSCDRL_SOP_145)
	Enterobacterales & Non-fermentative Gram-negative rods for determination of antibiotic MIC	Broth Microdilution AST using the Bioconnections Micronaut System (RL-LP10)
	H. influenzae isolates for determination of antibiotic MIC	MIC determination using commercially available antibiotic gradient strips (RL-LP25)
	Identification of *Shigella* Enteropathogens	Using commercial biochemical kits (RL-LP23)

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REFERRED MICROBIOLOGICAL CULTURES (cont'd)	Microbiology Examinations for the purpose of clinical diagnosis (cont'd)	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)
	Ribotyping of *C. difficile*	By conventional end-point PCR using GeneAmp 9700 (Applied Biosystems) thermocycler, gel electrophoresis & Digital Camera (Bio-Rad). SSCDRL-SOP-143
	Genotyping of *S.aureus*	By SPA typing (polymorphic locus sequence based method of strain characterisation & analysis using a 3500XL Genetic Analyser (Applied Biosystems & Ridom software). (SMRSA_LP075.)
	Determination of antibiotic MIC (MRSA)	Using culture media, E-Test (BioMerieux) & M.I.C.E. Evaluator strips (Liofichem), (RL-LP22
CSF, Tissue, Fluids, Blood, blood culture fluid, bacterial isolates	16S rRNA PCR	PCR and by sanger sequencing using EasyMag, Rotor-gene, thermocyclers and ABI3500XL RL-LP57

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REFERRED MICROBIOLOGICAL CULTURES (cont'd)	Microbiology Examinations for the purpose of clinical diagnosis (cont'd) Parasitology	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)
Faeces	Identification of Cryptosporidium oocysts	Using Concentration centrifugation, auramine-phenol staining and fluorescent microscopy. (SPDRL-MI01)
Referred EDTA-whole blood	Malaria speciation • P. falciparum, • P. ovale, • P. vivax, P. malariae	Using Manual DNA extraction kit reagents (in-house PCR reagents Real-Time PCR, using LightCycler 480 (Roche) Real-Time PCR system SPDRL- -SOP-P001
Faeces	Detection of *C.hominis* and *C.parvum* DNA	Manual DNA extraction kit reagents centrifuge, real-time PCR. using LightCycler 480 (Roche) Real-Time PCR system (SPDRL-SOP-P001)
Faeces	DNA GP60 Subtyping of C.hominis and/or C.parvum	Manual DNA extraction kit reagents (conventional PCR using GeneAmp 9700 (Applied Biosystems) thermocycler, gel electrophoresis. Then sequenced using a 3500xL Genetic Analyser (Applied Biosystems) (SPDRL-SOP-P002)
Micro-organism DNA Extracts	Identification of Salmonella species	RT-PCR using Roche LightCycler 480 (RL-LP53)

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HUMAN BODY FLUIDS AND TISSUES	Microbiology Examinations for the purpose of clinical diagnosis (cont'd)	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)
Urine	*Detection of Legionella* spp. urinary Ag.	*Legionella* urinary antigen detection using ELISA, spectrophotometer, pipettes, microtitre plate washer. (SHLMPRL_SOP_012 and (SHLMPRL_SOP_014)
Sputum, tracheal aspirate, bronchial lavage, post mortem lung	*Detection of Legionella* spp.	Culture of Legionella spp using culture media, water bath, moist chamber. (RL-LP11)
	Identification of: Legionella. pneumophila Sg1, Sg2-14 Legionella species	Using culture media, latex agglutination (Oxoid). and U/V lamp. (RL-LP6)
	Antimicrobial susceptibility and MIC for *Neisseria.meningitidis & Strep.pneumoniae.*	Using culture media, E-Test (BioMerieux) & M.I.C.E. Evaluator strips (Oxoid) AST (RL-LP25) BRIS (RL-LP15)
	Confirmation of *N.meningitidis (B, ACY, W1350,* *S.pneumoniae* *H.influenzae.*	Using culture media and agglutination: (SHLMPRL_SOP_056) *N.meningitidis* B/ (Wellcogen-Oxoid- Latex), *N. meningitides* ACY W135 (Wellcogen-Oxoid – Latex) (SHLMPRL-SOP- 60 and 61) S. pneuminiae co-agglutinating reagents using certified antisera from Statens Serum Institute (SHLMPRL_SOP_065, *Haemophilus influenzae* agglutinating sera (Remel-Oxoid) (SHLMPRL_MED_033) (SHLMPRL_SOP_055)

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology Examinations for the purpose of clinical diagnosis (cont'd)	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)
	Subtyping of • *N. meningitidis* • *H. influenzae,* • *Legionella. speciesInvasive Group A Streptococci* • *S. pneumoniae.*	DNA, extraction and PCR performed using ABi 2720 (Applied Biosystems) thermocylcer MLST performed using a 3500xL Genetic Analyser (Applied Biosystems), RL-LP28 (isolates) and SHLMPRL_SOP_083 (clinical samples), (SHLMPRL_SOP_100)
	Detection of *N. meningitidis*, *S. pneumoniae* *H.influenzae*.	By Multiplex PCR, using LightCycler 480 (Roche) Real-Time PCR system to detect bacterial DNA in clinical samples of whole blood, serum and CSF. (RL-LP2)
Referred microbiological cultures	Genotyping of Neisseria spp *Haemophilus spp* Strep. pneumococci	DNA sequencing using 3500xL sequencer (Applied Biosystems) & CLC software. (SHLMPRL_SOP_158 and 109)
	Serology examinations for the purpose of clinical diagnosis	
Serum	Serology: Detection of *Bordetella pertussis* IgG	using Virion Serion ELISA and DS2 automated system SHLMPRL_ SOP_ 015
	Molecular examinations for the purpose of clinical diagnosis	Automated DNA extraction
Whole blood Serum CSF Stools Respiratory samples Ocular specimens		NucliSENS easyMAG (biomerieux) extraction platform SPDRL-SOP-2
Bacterial cultures (overnight culture plates or broths)		Qiagen Symphony extraction platform coupled with Qiagen Symphony with DSP DNA minikit SSSCDRL_SOP_002

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology Examinations for the purpose of clinical diagnosis (cont'd) Molecular examinations for the purpose of clinical diagnosis (cont'd)	In House documented methods based on UK Standards for Microbiology Investigations' (SMIs)
Referred Isolates of carbapenemase-producing organisms (CPO)	Identification of carbapenemase resistance genes (IMP, KPC, OXA-48, NDM & VIM)	RT-PCR using the Qiagen Rotor-Gene –Q SSSCDRL_SOP__005
Sputum Tracheal aspirates, bronchial lavage PM lung tissue DNA extracts	Detection of *Legionella* species and *Legionella pneumophila*	RT-PCR using the ABI7500 SHLMPRL-SOP-165
Micro-organism DNA Extracts	Identification of: Staph aureus & Veterinary Staphylococcal species Acinetobacter species	RT-PCR using the ABI7500 (Applied Biosystems) (RL-LP45 & RL-LP46)

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 the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Molecular Diagnostics	Extraction Roche MagnaPure 96 SOP;-EQP EOP 105
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		
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

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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 methodology:
Extracted DNA	Qualitative detection of:	Multiplex/Real time PCR, ABI 7500.
	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
		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
Serum, Plasma	Hepatitis B core antibody	VS-BBV-SOP-019
Serum, Plasma	HIV 1 / 2 antibody/antigen	VS-BBV-SOP-023
Serum, Plasma	Hepatitis A IgM antibody	VS-BBV-SOP-018
Serum, Plasma	CMV IgG antibody	VS-BBV-SOP-105
Serum, Plasma	*Varicella zoster* IgG antibody	VS-SER-SOP-029
Serum, Plasma	Rapid Plasma Reagin (RPR) - a non-treponemal serological screening test for syphilis	Biorad kit – macroscopic agglutination test VS-SER-SOP-061
Serum, Plasma	Syphilis IgM antibody	Mikrogen Kit - Enzyme Linked Immunosorbent Assay. VS-SER-SOP-060
	Syphilis	Fujirebio kit – line blot immunoassay. VS-SER-SOP-062

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)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum, Plasma	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
Serum, Plasma	Measles IgG antibody	VS-SER-SOP-064
Serum, Plasma	Mumps IgG antibody	VS-SER-SOP-065
Serum, Plasma	*Herpes simplex* IgG antibody	VS-SER-SOP-066
Serum, Plasma	B19 IgG antibody	VS-SER-SOP-067
Serum, Plasma	B19 IgM antibody	VS-SER-SOP-068
Serum, Plasma	*Varicella zoster* IgG antibody	VS-SER-SOP-075
Serum, Plasma	*Helicobacter pylori antibody*	DS2 Automated Elisa System Premier H.pylori Elisa kit VS-SER-SOP-076
	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
Serum, Plasma	Hepatitis B surface Antigen (Qualitative test)	VS-BBV-SOP-163
Serum, Plasma	Hepatitis B surface Antigen (Quantitative test)	VS-BBV-SOP-168
Serum, Plasma	Hepatitis B surface Antigen Neutralisation	VS-BBV-SOP-157

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 the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	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
Serum, Plasma	Hepatitis B core antibody	VS-BBV-SOP-150
Serum, Plasma	Hepatitis B core IgM antibody	VS-BBV-SOP-149
Serum, Plasma	Hepatitis B e-antigen	VS-BBV-SOP-162
Serum, Plasma	Hepatitis B e-antibody	VS-BBV-SOP-155
Serum, Plasma	Anti-Hepatitis B surface antibody	VS-BBV-SOP-152
Serum, Plasma	Hepatitis C antibody	V-LP20
Serum, Plasma	HIV 1 / 2 antibody	VS-BBV-SOP-147
Serum, Plasma	Hepatitis A IgG antibody	VS-BBV-SOP-164
Serum, Plasma	Hepatitis A IgM antibody	VS-BBV-SOP-151
Serum, Plasma	Syphilis antibody	VS-BBV-SOP-166
Serum, Plasma	Rubella IgG antibody	VS-BBV-SOP-165
Serum, Plasma	HTLV 1 / 2 antibody	VS-BBV-SOP-148
Serum, Plasma	CMV IgG antibody	VS-BBV-SOP-154
Serum, Plasma	CMV IgM antibody	VS-BBV-SOP-160
Serum, Plasma	CMV avidity	VS-BBV-SOP-167
Serum, Plasma	Epstein Barr nuclear antigen (EBNA) IgG antibody	VS-BBV-SOP-153

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)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	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
Serum, Plasma	Epstein Barr Virus Capsid Antigen (VCA) IgG antibody	VS-BBV-SOP-156
Serum, Plasma	Epstein Barr Virus IgM antibody	VS-BBV-SOP-159
Serum, Plasma	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)	

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 the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Molecular Specialist Testing:	
Serum, Plasma Whole blood Respiratory sample Clinical isolates Respiratory sample		Extraction platforms: Biomerieux Easymag extractor Roche MagnaPure 96 SOP;-EQP EOP 105
Extracted DNA	Resistance testing of HIV-1 clinical isolates and sequence analysis of the *pol* gene (encodes protease and reverse transcriptase)	ABI GeneAmp PCR system 9700, RunOne Electrophoresis System 220V, ABI 3500xl sequencer, ReCall software and Stanford HIV drug resistance database. MD-SOP-002
	Resistance testing of HIV-1 clinical isolates and sequence analysis of the *pol* 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 3500xl 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 ABI GeneAmp PCR system 9700, ABI 7500.

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Molecular Specialist Testing (cont'd)	
Extracted DNA (cont'd)	Genotyping of HCV	VS-BBV-SOP-109
	Genotyping of HCV by sequence analysis of the *core* gene	RunOne Electrophoresis System 220V, ABI 3500xl 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 3500xl 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

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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:
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 ll Nucleic Acid Isolaton Kit NGS-LP6
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		