


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9510</p> <p>Accredited to ISO 15189:2022</p>	<p align="center">Public Health Wales NHS Trust</p> <p align="center">Issue No: 019 Issue date: 24 March 2025</p> <table border="1"> <tr> <td data-bbox="403 443 882 689"> Public Health Wales Microbiology and Health Protection 4th Floor No 2 Capital Quarter Tyndall Street Cardiff CF10 4BQ </td><td data-bbox="882 443 1477 689"> Contact: Rebecca Rowlands Tel: +44 (0) 29 2074 8560 E-Mail: rebecca.rowlands@wales.nhs.uk Website: www.wales.nhs.uk/sites3/page.cfm?orgId=457&pid=25400 </td></tr> </table>	Public Health Wales Microbiology and Health Protection 4th Floor No 2 Capital Quarter Tyndall Street Cardiff CF10 4BQ	Contact: Rebecca Rowlands Tel: +44 (0) 29 2074 8560 E-Mail: rebecca.rowlands@wales.nhs.uk Website: www.wales.nhs.uk/sites3/page.cfm?orgId=457&pid=25400
Public Health Wales Microbiology and Health Protection 4th Floor No 2 Capital Quarter Tyndall Street Cardiff CF10 4BQ	Contact: Rebecca Rowlands Tel: +44 (0) 29 2074 8560 E-Mail: rebecca.rowlands@wales.nhs.uk Website: www.wales.nhs.uk/sites3/page.cfm?orgId=457&pid=25400		
<p align="center">Testing performed by the Organisation at the locations specified below</p>			

Laboratory locations:

Location details		Activity	Location code
Address Public Health Wales Microbiology Singleton Hospital Swansea SA2 8QA	Contact Julian Rogers Richard Hopkins Jenny Hudson Prof. Rachel Chalmers Prof. Edward Guy	Bacteriology, Virology and Molecular Testing Bacteriology Virology Cryptosporidium Reference Unit Toxoplasma Reference Unit	S CRU TRU
Public Health Wales Microbiology Ysbyty Glan Clwyd Rhyl Denbighshire LL18 5UJ	Phil Lewis Clare Allman	Bacteriology	R
Public Health Wales Microbiology West Wales General Hospital Glangwilli Carmarthen SA31 2AF	Rhian Lodwig	Bacteriology	CM
Public Health Wales Microbiology Bronglais General Hospital Caradog Road Aberystwyth SY23 1ER	Caroline Longman	Bacteriology	A



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Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Public Health Wales Microbiology University Hospital of Wales Heath Park Cardiff CF14 4XW	Lisa Chichester	Bacteriology, Virology & Molecular Testing	CD
	Shanine Mitchell	Bacteriology	
	Trefor Morris	UK Anaerobe Reference Unit	ARU
	Dr Mandy Wootton	Specialist Antimicrobial Chemotherapy Unit	SACU
	Dr Lewis White	Mycology Regional Reference Unit	MRRU
	Jonathan Evans	Wales Specialist Virology Centre	WSVC
Public Health Wales Microbiology (Wales Centre for Mycobacteria) Llandough Hospital Penlan Road Penarth CF64 2XX	Dr Jason Evans	Wales Centre for Mycobacteria	WCM
Public Health Wales Microbiology North Wales (Wrexham Site) Ysbyty Maelor Wrexham Croesnewydd Road Wrexham LL13 7TD	Phil Lewis Clare Allman	Molecular Blood Culture Microscopy Sterile fluids Microscopy	WRE HL
Public Health Wales Microbiology Morriston Hospital Hot Lab Pathology Department Heol Maes Eglwys Morriston Swansea SA6 6NL	Ellen O'Brien Alec Stewart	Molecular	MOR HL
Public Health Wales Microbiology Prince Charles Hospital Hot Lab Pathology Department Merthyr Tydfil CF47 9DT	Ellen O'Brien Alec Stewart	Molecular	PCH HL



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Location details		Activity	Location code
Public Health Wales Microbiology University Hospital Llandough Hot Lab Penlan Road Llandough Penarth Vale of Glamorgan CF64 2XX	Ellen O'Brien Alec Stewart	Molecular	UHL HL
Public Health Wales Microbiology Prince Philip Hospital Hot Lab Pathology Department Dafen Llanelli SA14 8QF	Ellen O'Brien Alec Stewart	Molecular	PPH HL
Public Health Wales Microbiology North Wales (Bangor Site) Ysbyty Gwynedd Bangor Gwynedd LL57 2PW	Aliyeh Abolghasemi	Molecular	BAN HL
Public Health Wales Microbiology Princess of Wales Hospital – Hot lab Coity Road Bridgend CF31 1RQ	Ellen O'Brien Alec Stewart	Molecular	POW HL
Public Health Wales Microbiology Wales Genomic Health Centre Cardiff Edge Life Sciences Park Longwood Drive Cardiff CF14 7YU	Sally Corden	Genomics	PenGU



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES/FLUIDS	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> Isolation and characterisation of micro-organisms of clinical significance	SOP references are a combination of Welsh Bacteriology/Virology (WB/WV) and Microbiology Devision MDB/MDV followed by Laboratory Location Identification code (CD, S, CM, A, R, W,). In house documented methods incorporating manufacturer's instructions where relevant Using microscopy, manual gram stain, and manual culture. Identification of target organisms: SOP 053 Automated pre analytical instrument for swabs and urines – PreLud (Prolab) Becton Dickinson workcell automation Kiestra at Rhyl (not for faeces and respiratory samples) SOP 030 (not CM) WBSOP 028 WBSOP 011 WBSOP 002 WBSOP 004 WBSOP 005 WBSOP 009 WBSOP 057, WBSOP 047 WBSOP 001 WBSOP 020 WBSOP 042 WBSOP 026 WBSOP 025 WBSOP 014 WBSOP 017 WBSOP 027, WBSOP 022	A S CD CM R CD S R
Faeces Genital tract samples Skin & superficial wound Eye specimens Mouth Nose pernasal swabs & Sinus aspirates Throat swabs Sputum and associated specimens (BAL) Ear swabs Intravascular cannulae Bone & prosthetic samples Sterile fluids CAPD Abscesses & deep wound (pus & wound drain fluid) Tissues & biopsies CSF & CSF shunt			



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<p>HUMAN BODY TISSUES/FLUIDS (cont'd)</p> <p>Screening for target organisms: faeces, nose, axilla, groin, perineum, indwelling devices, respiratory secretions</p> <p>Neonatal screening: gastric aspirates. nose, axilla, groin, perineum, throat swabs, ear</p> <p>Blood</p> <p>Blood</p> <p>Clinical isolates cultured in-house from blood culture specimens</p> <p>Urine Prostatic secretions</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Isolation and characterisation of micro-organisms of clinical significance.</p> <p>Isolation and characterisation of micro-organisms of clinical significance.</p> <p>Antibiotic susceptibility testing of micro-organisms of clinical significance.</p> <p>Isolation and characterisation of micro-organisms of clinical significance.</p> <p>Cell count and isolation and characterisation of micro-organisms of clinical significance.</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>WBSOP 024</p> <p>WBSOP 023</p> <p>Using microscopy, manual gram stain, manual culture, biochemical test kits, agglutination test kits and sera as appropriate.</p> <p>Automated culture using BD BacTec FX</p> <p>Using microscopy, manual gram stain</p> <p>Automated culture using BD BacTec FX</p> <p>In-house direct susceptibility testing MDBSOP 037 MDBSOP 037 DAST</p> <p>Using microscopy, manual gram stain, and manual culture MDBSOP 041 MDBSOP 003 (not site A)</p> <p>Automated, using Sysmex UF-5000 by fluorescence flow cytometry MDBSOP 041</p>	<p>ASCDMR</p> <p>WRE HL</p> <p>ASCDMR</p> <p>ASCDMR</p> <p>CDSCMAR</p>



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Clinical isolates cultured in-house	Identification of microorganisms of clinical significance.	Using manual biochemical tests CDBSOP 300 NWBSOP 300 ABERBSOP 300 SWBSOP 300 CMB SOP 300	A S CD CM R
Clinical isolates cultured in-house	Antibiotic susceptibility testing of micro-organisms of clinical significance.	Identification using Bruker Maldi-ToF MDBSOP 100	S CD R
Clinical isolates cultured in-house	Antibiotic susceptibility testing of micro-organisms of clinical significance.	Antibiotic susceptibility testing, based on EUCAST and BSAC guidance, using disc diffusion and gradient strips MDBSOP 052DD (Disc diffusion) MDBSOP 052GS (gradient strip)	A S CD CM R W
Clinical isolates cultured in-house	Identification of microorganisms of clinical significance.	Automated using Vitek 2 ABERSOP 200	A
Sterile fluids including: CSF CSF shunts CAPD	Detection, identification and quantification of red cells and white cells of clinical significance	Cell count, light microscopy, manual gram stain, manual differential stain MDBSOP 027 MDBSOP 022 MDBSOP 025	A S CD CM R WRE HL
Faeces	Detection of enteric pathogens: Campylobacter Salmonella Shigella VTEC Cryptosporidium Giardia C Difficile Norovirus	Nucleic acid extraction and PCT amplification using SeroSep EntericBio heatstation and workstation, Eppendorf mixmate and centrifuge, and Roche Lightcycler 480 II MDBSOP 030M (molecular) Followed by confirmation by conventional culture MDBSOP 030	A CD R S



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Faeces	Detection of Clostridium difficile toxins A & B	Using Tox A/B Quik Chek Enzyme Immunoassay MDBSOP 010	S CD R
Gastric aspirate Sputum and related specimens (BAL) Sterile body fluids Urine Tissue and swabs Faeces	Detection of Mycobacterium species	Using microscopy, manual auramine stain, manual modified ZN stain for acid-fast bacilli (ZN not at site A), MDBSOP 040	A S CM R
Skin, hair, nails and tissue	Isolation and characterisation of fungi of clinical significance	Using microscopy, manual KOH method, and manual culture MDBSOP 039 Manual Calcofluor method ABERBBA SOP 039 MDBSOP 039 Manual Lactofuchsin red SWBBA SOP 039 CMBBA SOP 039	A S CM A S CM CM S
Clinical isolates cultured in-house	Identification of fungi of clinical significance.	Using manual microscopy MDBSOP 039 MDBSOP 053	A S CM



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Parasitology examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Detection and identification of the following:		
Faeces	Ova, cysts and parasites	Manual Parasep concentration method and microscopy MDBSOP 031	A S CD CM
Faeces	Ova, cysts and parasites	Manual ZN stain for cyclospora MDBSOP 031	CM CD A S
Faeces	Detection of Helicobacter pylori antigen	Dynex DS2 using Meridian Bioscience Premier Platinum HpSA PLUS MDSOP 056	S



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Blood	Detection of -Hepatitis B Surface Antigen (HBsAg) -Hepatitis B Surface Antibody (Anti-HBs) -Hepatitis B Total Core Antibody (Anti-HBc) -Hepatitis B Core IgM (Anti-HBc IgM) -Hepatitis B e Antigen (HBe) -Hepatitis B e Antibody (Anti-HBe) -Hepatitis A IgM -Hepatitis A IgG -Cytomegalovirus IgG -Hepatitis C Antibody (HCV Ab) -HIV Ag/Ab -HTLV 1&2 -Rubella IgM -Rubella IgG -Syphilis (Total Ab) -Toxoplasma IgG -Cytomegalovirus IgM -Epstein Barr Virus Nuclear Antigen IgG (EBNA) -Epstein Barr Virus Viral Capsid Antigen (VCA) IgM -Epstein Barr Virus Viral Capsid Antigen (VCA) IgG	Abbott Alinity using Chemiluminescent microparticle (CMIA) technology MDVSOP 001	WSVC S
Serum and plasma	Detection of - HBsAG - Anti-HBc Total	VIDAS-3 using ELFA technique SWVE SOP 009	S
Serum and Plasma	Confirmatory testing of HIV Ag/Ab	Manual Alere Determine HIV 1/2 Ag/Ab Combo kit, Immunochromatography technique (ICT) CDVSOP 116	WSVC



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Serum and Plasma	Confirmation and differentiation of Individual antibodies to HIV-1 and HIV-2	Manual immunochromatographic test using BioRad Geenius HIV1/2 kit CDVSOP 115	WSVC
Blood	Detection of: Borrelia burgdorferi (Lymes) IgG Borrelia burgdorferi (Lymes) IgM Mumps IgG VzV IgG Measles IgG HBsAg Anti-HBc Hepatitis A IgM Cytomegalovirus IgG HIV Ag/Ab	VIDAS-3 using ELFA technique CDVSOP 005	WSVC
Urine	Detection of Legionella Urinary Antigen	Binax Legionella Urinary Antigen EIA on Dynex DS2 SWVSOP 041 CDVSOP 042	S WSVC
Urine	Detection of Legionella Urinary Antigen	Binax NOW® Legionella Urinary Antigen rapid immuno-chromatographic assay, read on the Alere (Digival) card reader SWVSOP 042 CMVSOP 042 ABERSOP 042	A CM HL S
Urine	Detection of Legionella Urinary Antigen	Binax NOW® Legionella Urinary Antigen rapid immuno-chromatographic assay NWVSOP042	R WRE



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Urine	Detection of Strep. Pneumoniae Urinary Antigen	Binax NOW® Str. pneumoniae Urinary Antigen rapid immuno-chromatographic assay kit, read on the Alere (Digival) card reader SWVSOP 042A CMVSOP 042A ABERSOP 042	S A CM HL
Serum	Detection of Herpes Simplex IgG	NovaLisa EIA Herpes Simplex Virus 1 & 2 (HSV) IgG kit on Dynex DS2 CDVSOP 024	WSVC
Serum	Measles IgG	NovaLisa EIA measles virus IgG kit on Dynex DS2 CDVSOP 024	WSVC
Serum	Measles IgM	NovaLisa EIA measles virus IgM kit on Dynex DS2 CDVSOP 024	WSVC
Serum	Mumps IgM	NovaLisa EIA mumps virus IgM kit on Dynex DS2 CDVSOP 024	WSVC
Serum	Confirmatory test: detection of reagin antibodies	ASI Rapid Plasma Reagin flocculation test SWVSOP 043	S
Serum	Confirmatory test: detection of antibodies to Treponema Pallidum	Fortress diagnostics indirect haemagglutination TPHA kit SWVSOP 043	S



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
	Detection of the following:	Using Dynex DS2 analyser CDVSOP 007 SWVE 007	
Serum	Parvovirus IgM	Serion Parvovirus B19 IgM Enzyme Immunoassay ELISA CDVSOP 016 SWVSOP 017	WSVC S
Serum	Parvovirus IgG	Serion Parvovirus B19 IgG Enzyme Immunoassay ELISA CDVSOP 016 SWVSOP 017	WSVC S
Serum	Hepatitis E IgG	Fortress Enzyme Immunoassay EIA on Dynex DS2 CDVSOP 025	WSVC S
Serum	Hepatitis E IgM	Fortress Enzyme Immunoassay EIA on Dynex DS2 CDVSOP 025	WSVC S
Faeces	Qualitative detection of group-specific proteins, including the major inner capsid protein (VP6), present in Group A rotaviruses.	ProSpecT Rotavirus enzyme immunoassay. DS2 at Swansea Manual at Cardiff CDVSOP 209 SWVSOP 209	S WSVC
Serum	Confirmatory test: Detection of antibodies to Treponema pallidum	Fortress Diagnostics TPHA Haemagglutination CDVSOP 043	WSVC
Serum	Confirmatory test: Detection of reagin antibodies	ASI RPR Card Test for syphilis using the ASi Manager AT Reader CDVSOP 043b.	WSVC



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Blood	Hepatitis B DNA	Abbott m2000. Reverse transcription-polymerase chain reaction (RT-PCR)	WSVC
Blood	Hepatitis C RNA	Abbott RealTime HBV assay CDVSOP 105	
Blood	Hepatitis C Genotype	Abbott RealTime HCV assay CDVSOP 104	
Blood	Hepatitis C Genotype	Abbott RealTime HCV Genotype II assay. CDVSOP 108	
Blood	HIV Viral Load	Abbott RealTime HIV assay. CDVSOP 104	
Urine Vulvovaginal swabs Endocervical swabs	Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) Nucleic Acid Amplification Test: qualitative detection of CT and/or NG DNA	PCR using Cobas 4800 SWVSOP 300	S
Skin swabs Genital swabs Mouth swabs Eye swabs Blister swab	Detection of Herpes Simplex virus	In-house PCR assay using ABI Fast analyser CDVSOP 220	WSVC
Whole blood	Detection of EBV DNA	QPCR using Vela Sentosa SX EBV quantitative PCR assay plus Rotorgene CDVSOP 061	WSVC
	Detection of the following:	RT PCR using ABI 7500 FAST. Extraction using Easy Mag or EZ-1	WSVC
CSF Respiratory Swabs Urine, Faeces	Enterovirus RNA	CDVSOP 204 CDVSOP 230	
	Measles RNA	CDVSOP 230	



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods using analysers specified	
	Detection of the following:	RT PCR using ABI 7500 FAST. Extraction using Easy Mag or EZ-1	WSVC
Culture isolates	N. gonorrhoeae	CDVSOP 230	
Swabs			
Urine			
EDTA Whole blood, CSF	Meningococcal spp	CDVSOP 230	
EDTA Whole blood, CSF	Pneumococcal spp	CDVSOP 230	
	Detection of the following:	Extraction using EZ-1. PCR using Qiagen Rotorgene 6000 CDVSOP 230	WSVC
CSF	Herpes Simplex DNA	Qiagen Artus HSV-1/2 RGPCR kit	
Swabs	Varicella zoster DNA	Qiagen Artus VZV RGPCR kit	
Urine			
Nose or throat swabs, nasopharyngeal aspirates	Detection and identification of nucleic acids from the following respiratory viruses and bacteria	DNA/RNA extraction using BioMerieux EasyMag. Amplification using ABI Veriti thermocycler. RT-PCR method using the Luminex MAGPIX with NxTAG RPP + SARS-CoV- 2 kit CDVSOP 203	WSVC
BAL			
	Influenza A (H1, 2009 H1N1, H3) and B RNA		
	Rhinovirus/Enterovirus RNA		
	Parainfluenza 1, 2, 3 & 4 RNA		
	Respiratory Syncytial Virus (RSV) subtype A and B RNA		
	Human Metapneumovirus (HMPV) RNA		
	Adenovirus DNA		
	SARS-CoV-2		



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Nose or throat swabs, nasopharyngeal aspirates BAL.	Detection and identification of nucleic acids from the following respiratory viruses and bacteria	DNA/RNA extraction using BioMerieux EasyMag. Amplification using ABI Veriti thermocycler. RT-PCR method using the Luminex MAGPIX with NxTAG RPP + SARS-CoV- 2 kit CDVSOP 203	WSVC
	Human Bocavirus Chlamydia pneumoniae Legionella pneumophila Coronavirus 229E, OC43, NL63, HKU1 Mycoplasma pneumoniae		
Nose or throat swabs, nasopharyngeal aspirates BAL.	Confirmation Mycoplasma pneumoniae	Secondary testing of potential Mycoplasma pneumoniae positive samples using in -house RT- PCR assay on ABI 7500 FAST	WSVC



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Throat swabs	Viral Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Sever acute Respiratory Syndrome Coronavirus 2 (SARS- CoV-2) Human Metapneumovirus Human Rhinovirus/Enterovirus Influenzae A Influenzae B Parainfluenzae Virus 1 Parainfluenzae Virus 2 Parainfluenzae Virus 3 Parainfluenzae Virus 4 Respiratory Syncytial Virus Bacteria Bordetella parapertussis (IS 1001) Bordetella pertussis (ptxP) Chlamydia pneumonia Mycoplasma pneumoniae	Biofire Filmarray – Nested multiplex PCR Respiratory 2.1 plus panel MDMSOP 600 MDME 600	CD CM A S R WRE HL PCH HL PPH HL UHL HL POW HL BAN HL MOR HL



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Anaerobe reference unit examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Bacterial colonies	Isolation and identification of anaerobic bacteria of clinical significance	Identification using Bruker Maldi-ToF and/or manual culture, and biochemical test kits, as appropriate.	ARU
Bacterial colonies (further identification)	Identification of anaerobic bacteria of clinical significance	DNA extraction and primary target gene PCR using PCR thermocycler: ProFlex Thermocycler and HotStar Taq ARU SOP 021	ARU
Externally generated DNA sequence data (further identification)	Identification of anaerobic bacteria of clinical significance	Analysis of DNA sequence data generated externally by 16s rRNA/rpoB sequencing using Bionumerics Software Applied Maths and NCBI BLASTn ARUSOP 046 ARUSOP 021	ARU
Bacterial colonies (Antimicrobial susceptibility testing)	Antibiotic Susceptibility testing of anaerobic bacteria of clinical significance using: 1) Agar dilution 2) Gradient strips	Using manual culture, MIC strips, Antibiotic infused agar plates (including fastidious anaerobe agar), the MAST uriDOT multipoint inoculator ARUSOP 115 ARUSOP 114	ARU
Bacterial colonies, Faeces	Sequencing and typing of C. difficile	Automated DNA extraction method using e-MAG/easyMAG platform ARUSOP 118	ARU
Nucleic Acid extracts from ARU		Next Generation Sequencing using Illumina MiSeq or Illumina NextSeq 550 PGUSOP 010	PenGU
DNA sequence data from PenGU		Analysis of DNA sequence data generated by PenGU dept using in-house validated bioinformatics pipeline	ARU



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Clinical isolates	Detection of presumptive carbapenamase positive and negative B fragilis isolates	Bruker MaldiToF Biotyper subtyping module ARUSOP 117	ARU
	<u>Toxoplasma reference unit examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Serum, Plasma, CSF	Sabin-Feldman Toxoplasma Dye Test: Quantitation of total anti-Toxoplasma antibody	Dye test by visualisation of dye take up by standard tachyzoite preparation in presence of compliment. TRUSOP 006	TRU
Serum, Plasma, CSF	Toxoplasma IgM	In-house manual Enzyme Immunoassay using Anthos Fluido 2 washer and Thermo Scientific Multiskan FC spectrophotometer TRUSOP 008	TRU
Serum, Plasma, CSF	Detection of Toxoplasma IgM and IgA	Using Biomerieux TOXO-ISAGA IgA and IgM immunosorbant agglutination assay kits TRUSOP 012 TRUSOP 011	TRU
Serum, Plasma	Toxoplasma IgG avidity	In-house manual Enzyme Immunoassay using Jencons Millenium hw2 washer and Thermo Scientific Multiskan FC spectrophotometer. TRUSOP 009	TRU
Blood (whole EDTA), CSF, Amniotic fluid, Tissues, Bronchoalveolar lavage, Ocular fluid	Confirmatory testing for Toxoplasma	Rotorgene Q and 6000 In-house real-time PCR TRUSOP 058 TRUSOP 050	TRU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Cryptosporidium Reference Unit examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Faeces	Cryptosporidium genotyping: species identification (all species) and subtyping of C.parvum and C.hominis	DNA extraction using spin columns conventional PCR, and real time PCR technology using Rotor-gene Q 6plex/RG6000. Amplicon referred to an external provider for Sanger sequencing. Analysis of DNA sequence data from Sanger sequencing. CRUSOP 005 CRUSOP 030 CRUSOP 041 CRUSOP 061 CRUSOP070	CRU
Faeces Fluids Respiratory	Cryptosporidium specialist detection	Using microscopic examination of Immunofluorescence antibody stained slides DNA extraction using spin columns, conventional PCR, and real-time technology using Rotor-gene Q 6plex/RG6000. Amplicon referred to an external provider for Sanger sequencing. Analysis of DNA sequence data from Sanger sequencing. CRUSOP 017 CRUSOP 005 CRUSOP 030 CRUSOP 070	CRU
Faeces	Giardia genotyping	DNA extraction using spin columns, Rotor-gene Q 6plex/RG6000 using real-time PCR technology. CRUSOP 005 CRUSOP 063	CRU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Cryptosporidium Reference Unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Faeces	Detection of Cryptosporidium oocysts, and Cyclospora oocysts	Microscopy of wet preparation, or of immunofluorescence antibody or modified Ziehl-Neelson stained slides. CRUSOP017	CRU
DNA samples	MLVA subtyping, analysis of multiple gene loci	Multiplex PCR and fragment sizing using Conventional PCR and analysis of fragment size data CRUSOP 069.	CRU
	<u>Specialist antimicrobial chemotherapy unit examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Bacterial isolates	Identification of bacterial pathogens up to 96 hours old	Bruker Maldi-ToF MDBSOP 100 SACUBA 065 SACUSOP 065 SACUBA 065F1 SACUBA 065F2	SACU
Bacterial isolates	Identification of Streptococcus pneumoniae	Manual bile solubility test SACUSOP 008	SACU
Bacterial isolates	Detection of the following in gram negative bacteria:	Using manual culture, MIC gradient strips, double ended gradient strips, ROSCO discs	SACU
	Carbapenemase	SACUSOP 001 SACUSOP 003 SACUSOP 004	SACU
	Cephalosporinase	SACUSOP 001 SACUSOP 004	SACU
Bacterial isolates	Colistin susceptibility	Antibiotic susceptibility testing, based on EUCAST guidance. Using manual culture and microbroth dilution SACUSOP 022	SACU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Specialist antimicrobial chemotherapy unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Bacterial isolates	Qualitative detection of vanA, vanB and PVL genes	RotorGene Q (Qiagen): real time-PCR utilising fluorescent probes SACUSOP 040	SACU
Bacterial isolates	Qualitative detection of VIM, IMP, NDM, KPC and OXA-48-like genes	Quant Studio 6-Flex platform (Life Technologies); real time-PCR using SYBR green fluorescence and melt curve analysis SACUSOP 041	SACU
Bacterial isolates	Qualitative detection of CTX-M, TEM, SHV and GES genes	Quant Studio 6-Flex platform (Life Technologies); real time-PCR using SYBR green fluorescence and melt curve analysis SACUSOP 042	SACU
Bacterial isolates	Qualitative detection of Mobile Colistin Resistance (MCR) markers	Quant Studio 6-Flex platform (Life Technologies); real time-PCR using melt curve analysis SACUSOP044	SACU
Bacterial isolates	Qualitative detection of OXA-23-like, OXA-24-like and OXA-58-like genes	RotorGene Q (Qiagen): real time-PCR utilising fluorescent probes SACUSOP 043	SACU
Bacterial isolates	Methicillin resistance detection & identification in <i>S. aureus</i> .	Using disc diffusion, Proflex PCR thermocycler, gel electrophoresis using E-gel SYBR safe and Power Snap system SACUSOP 012 SACUSOP 052 SACUSOP 053 SACUSOP 055	SACU
Bacterial isolates	Qualitative detection of methicillin resistance markers (mecA and mecC) for <i>Staphylococcus spp</i> isolates	Rotor-Gene Q (Qiagen) real time PCR SACUSOP 046 SACUSOP 046RT	SACU



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<p>HUMAN BODY TISSUES/FLUIDS (cont'd)</p> <p>Sputum, Bronchial lavage, Gastric Aspirates, Faeces, CSF, Endometrial curettings, Sterile fluids, Pus, Swabs from superficial sites, Tissue, Skin, Urine</p>	<p><u>Wales Centre for Mycobacteria unit examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of mycobacterium spp of clinical significance.</p>	<p>Documented in-house methods using analysers specified</p> <p>Manual microscopy Auramine and ZN manual stain Culture using automated liquid media on the Becton-Dickinson MGIT 960 incubator and manual culture using LJ slopes. WCMSOP 001 WCMSOP 002 WCMSOP 003 WCMSOP 004 WCMSOP 005 WCMSOP 006 WCMSOP 007 WCMSOP 008 WCMSOP 009 WCMSOP 011 WCMSOP 012 WCMSOP 015 WCMSOP 016 WCMSOP 017 WCMSOP 018 WCMSOP 020 WCMSOP 021 WCMSOP 028 WCMSOP 029 WCMSOP 032 WCMSOP 033 WCMSOP 045</p>	WCM
Blood	Isolation of mycobacterium spp of clinical significance.	<p>Automated culture using BD BacTec FX200 WCMSOP 013 WCMSOP 014</p>	WCM



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Wales Centre for Mycobacteria unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Positive Mycobacterial cultures	Characterisation and speciation of positive mycobacterial cultures: Identification of MTBC isolates Identification of NTM isolates HAIN Common Mycobacterial species test	using manual LJ culture WCMSOP 020 using manual LJ culture WCMSOP 021 using the ABI Veriti Thermal Cycler and Bee Blot automated hybridisation machine. WCMSOP 045	WCM
Positive MTBC cultures	Antibiotic susceptibility testing of Mycobacterium tuberculosis isolates against Isoniazid, Rifampicin, Ethambutol, Ciprofloxacin, Clarithromycin, and Streptomycin	Solid media using manual LJ culture WCMSOP 020 WCMSOP 030	WCM
Positive mycobacterial isolates	Speciation of mycobacteria	Sample preparation WCMSOP 049	WCM
Heat-inactivated mycobacteria	Speciation of mycobacteria	Next Generation Sequencing using Illumina MiSeq and Illumina NextSeq 550 PGUSOP 010 PGUSOP 045	PenGU
Positive mycobacterial isolates	Identification of mutations conferring resistance to Isoniazid and Rifampicin in MTB complex isolates	Sample preparation WCMSOP 049	WCM
Heat-inactivated mycobacteria	Identification of mutations conferring resistance to Isoniazid and Rifampicin in MTB complex isolates	Next Generation Sequencing using Illumina MiSeq and Illumina NextSeq 550 PGUSOP 010 PGUSOP 045	PenGU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Wales Centre for Mycobacteria unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
DNA sequence data from WCM	Mycobacteria species identification and frontline resistotyping	Reporting/interpretation using the Welsh Bioinformatics pipeline PGUSOP 066	PenGU
Serum, plasma, sputum, BAL, NBL	<u>Mycology reference unit examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
	Detection of Aspergillus antigen	ELISA method using BioRad Aspergillus Antigen detection kit, EVOLIS platform, and plate reader WMYCSOP 03 MRRUSOP 029	MRRU
Serum, plasma	Detection of Aspergillus Antibody IgG	ELISA method using BioRad Aspergillus Ab detection kit, EVOLIS platform, and plate reader WMYCSOP 01 MRRUSOP 030	MRRU
Serum, plasma, BAL	Detection of Aspergillus DNA	Biomerieux e-Mag platform Rotogene Q Real-time PCR system WMYCSOP 02 CDMSOP045 WMYCSOP 11 WMYCSOP 12	MRRU
Hair, skin, nail, tissue, BAL/sputum, body fluids (not pleural), body swabs, culture isolates	Isolation and characterisation of fungi, yeast and yeast-like organisms of clinical significance	Using microscopy and manual culture MRRUSOP 024 MDBSOP 039 WMYCSOP 09 WMYCSOP 08 WMYCSOP 10	MRRU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Mycology reference unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Clinical isolates	Identification of fungi and yeast of clinical significance	Using manual biochemical test kits (including Auxacolor) Identification of yeasts using Bruker Maldi-ToF MRRUSOP 025 MRRUSOP 020 MRRUSOP 008	MRRU
Serum, CSF	Detection of cryptococcal antigen.	Using manual IMMY LF Antigen detection kit WMYCSOP 06	MRRU
Bronchoalveolar Lavage, Respiratory swabs	PCP (Pneumocystis jirovecii) detection	PCR using e-Mag extractor, and ABI 7500 Fast amplification unit MRRUSOP 012	MRRU
Serum	Detection of B-D-Glucan	Colorimetric detection and quantification of (1-3)-B-D-Glucan using the Associates of Cape Cod Fungitell Assay on the ELX808 kinetic plate reader MRRUSOP 031	MRRU
Serum Plasma	Detection of Candida species	Rotogene 6000 amplification platform MagNA Pure 96 Extraction platform MRRUSOP 037 Qualitative Detection of Fungal DNA using the OLM Candid Multi-plex Real Time PCR assay MRRUSOP 037	MRRU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Pathogen Genomic Unit</u>	Documented in-house methods using analysers specified	
Plasma	HIV antiretroviral resistance	In-house assay using Illumina MiSeq and NextSeq 550 Next Generation Sequencing, and the Welsh Bioinformatics pipeline PGUSOP 011 PGUSOP 010 PGUSOP 045	PenGU
SARS-CoV-2-positive samples only: Nasal/throat swabs in lysis buffer. Extracted nucleic acids	Genome sequencing, characterisation and variant calling of SARS-CoV-2 virus	Whole Genome Next Generation Sequencing using: Biomerieux e-Mag extractor, Oxford Nanopore Technology GridION and MinION instruments Illumina NextSeq 550 reporting/interpretation using SARS-CoV-2 ARTIC protocol on the PenGU SARS-CoV-2 pipeline PGUSOP 014 PGUSOP 045 PGUSOP 077 PGUSOP 074 PGUSOP 075 PGUSOP 076	PenGU
END			