


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9510</p> <p>Accredited to ISO 15189:2012</p>	<h3>Public Health Wales NHS Trust</h3> <p>Issue No: 011 Issue date: 27 June 2022</p>	
	<p>Public Health Wales Microbiology and Health Protection 4th Floor No 2 Capital Quarter Tyndall Street Cardiff CF10 4BQ</p>	<p>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>
<p>Testing performed by the Organisation at the locations specified below</p>		

Laboratory locations:

Location details		Activity	Location code
Address	Contact		
Public Health Wales Microbiology, Swansea Singleton Hospital Swansea SA2 8QA	Julian Rogers Prof. Rachel Chalmers Prof. Edward Guy	Bacteriology, Virology, Molecular Testing Cryptosporidium reference Unit Toxoplasma Reference Unit	S CRU TRU
Public Health Wales Microbiology, North Wales (Rhyl Site) Ysbyty Glan Clwyd Rhyl Denbighshire LL18 5UJ	Lisa-Michelle Beumer / Phil Lewis / Clare Allman	Bacteriology, Virology	R
Public Health Wales Microbiology, North Wales (Wrexham Site) Ysbyty Maelor Wrexham Croesnewydd Road Wrexham LL13 7TD	Lisa-Michelle Beumer / Phil Lewis / Clare Allman	Bacteriology	W
Public Health Wales Microbiology, Carmarthenshire West Wales General Hospital Glangwilli Carmarthen SA31 2AF	Sharon Price	Bacteriology	CM



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Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Public Health Wales Microbiology, Aberystwyth Bronglais General Hospital Caradog Road Aberystwyth SY23 1ER	Caroline Longman	Bacteriology	A
Public Health Wales Microbiology, Cardiff University Hospital of Wales Heath Park Cardiff CF14 4XW	Lisa Chichester	Bacteriology	CD
	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	Welsh Specialist Virology Centre	WSVC
	Dr Sally Corden	Pathogen Genomics Unit	PenGU
Public Health Wales Microbiology Cardiff (Wales Centre for Mycobacteria) Llandough Hospital Penlan Road Penarth CF64 2XX	Dr Jason Evans	Wales Centre for Mycobacteria	WCM



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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
<p>HUMAN BODY TISSUES/FLUIDS</p> <p>Faeces (not at CM site), Genital samples, Skin & Superficial wound swabs, Screen swabs: faeces, nose, axilla, groin, perineum, lesions, wounds, indwelling devices, tracheostomy, ear swabs, intravascular cannulae and Associated Specimens, Eye specimens, Mouth swabs, Nose swabs, pernasal swabs and sinus aspirates, Throat/tonsil swabs, Gastric Aspirates and Infection Screen Swabs from Neonates, Investigation of sputum, bronchoalveolar lavage and associated specimens</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of micro-organisms of clinical significance.</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Using microscopy, manual gram stain, and manual culture.</p> <p>Becton Dickinson workcell automation Kiestra at Rhyl (not for faeces and respiratory samples)</p> <p>MDBSOP 030 (not at CM site) MDBSOP 028 MDBSOP 011 MDBSOP 024</p> <p>MDBSOP 001 MDBSOP 020 MDBSOP 002 MDBSOP 004</p> <p>MDBSOP 005 MDBSOP 009 MDBSOP 023 MDBSOP 057</p> <p>MDBSOP 053 MDBSOP 047</p>	<p>A, S, CD, CM, R</p>
<p>Bone joint samples, Sterile fluids, continuous ambulatory peritoneal dialysis (CAPD), Abscesses and Deep Wound infection samples: pus, wound drain fluid, Tissues and Biopsies, CSF</p>	<p>Isolation and characterisation of micro-organisms of clinical significance.</p>	<p>Using microscopy, manual gram stain, and manual culture</p> <p>Becton Dickinson workcell automation Kiestra at Rhyl</p> <p>MDSOP 042 MDBSOP 026 MDBSOP 025 MDBSOP 014 MDBSOP 017</p>	<p>A, S, CD, CM, R, W</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	
Blood	Isolation and characterisation of micro-organisms of clinical significance.	Using microscopy, manual gram stain, manual culture, biochemical test kits, agglutination test kits and sera as appropriate. Automated culture using BD BacTec FX MDBSOP 037	A, S, CD, CM, R, W
Urine, expressed prostatic secretions	Isolation and characterisation of micro-organisms of clinical significance.	Using microscopy, manual gram stain, and manual culture MDBSOP 041 MDBSOP 003	A (urine only), S, CD, CM, R
Urine	Cell count and isolation and characterisation of micro-organisms of clinical significance.	Automated, using Sysmex UF-5000 by fluorescence flow cytometry MDBSOP 041	CD, S, CM, A, R



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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 (all sites) Identification using Maldi-ToF: Bruker Maldi-ToFs at Swansea, Cardiff, and Rhyl. MDBSOP 100	A, S, CD, CM, R, W
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 MDBSOP 052GS	A, S, CD, CM, R, W
Clinical isolates cultured in-house from blood culture specimens		In-house direct susceptibility testing MDBSOP 037	A, S, CD, CM, R, W
Clinical isolates cultured in-house from urine specimens		In-house direct susceptibility testing MDSOP 041	A
Clinical isolates cultured in-house	Identification and antibiotic susceptibility testing 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	A, S, CD, CM, R, W



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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 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 Followed by confirmation by conventional culture MDBSOP 030	A, CD, R, S
Faeces	Detection of Clostridium difficile toxins A & B	Using Alere Tox A/B Quik Chek Enzyme Immunoassay MDBSOP 010	S, CD R
Gastric washings, BAL, bronchial washings, CSF, sterile body fluids, blood, urine, skin/tissue, laryngeal swab, bone marrow, sputum	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



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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	
Swabs from nose, groin, throat, perineum, lesions, wounds, indwelling devices, tracheostomy, CSU	Isolation and identification of MRSA	Using manual culture, biochemical test kits, agglutination test kits and sera as appropriate. Identification using MALDI-ToF: Bruker MALDI-ToFs at Swansea, Cardiff, and Rhyl. Becton Dickinson workcell automation Kiestra at Rhyl MDBSOP 029	A, S, CD, CM, R
Synovial fluid	Detection of birefringent crystals	Microscopic examination of wet preparations using polarising microscopy SWBSOP 126	S
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 039 MDBSOP 039 Manual Lactofuchsin red SWBBA 039 CMBBA 039	A, S, CM A, S, CM CM, S,
Clinical isolates cultured in-house	Identification of fungi of clinical significance.	Using manual biochemical tests and microscopy MDBSOP 039 MDBSOP 053	A, S, CM,



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Parasitology examination activities for the purpose of clinical diagnosis</u> Detection and identification of the following:	In house documented methods incorporating manufacturer's instructions where relevant In house documented methods incorporating manufacturer's instructions where relevant	
Faeces	Ova, cysts and parasites	Manual Parasep concentration method and microscopy MDBSOP 031 Manual ZN/Auramine stain for cyclospora MDBSOP 031	A, S, CD, CM CM



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	
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	VIDAS-3 using ELFA technique SWVE 009	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	
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
Blood	Confirmatory testing of HIV Ag/Ab	Manual Alere Determine HIV 1/2 Ag/Ab Combo kit Immunochromatography technique (ICT) CDVSOP 116	WSVC
Blood	Confirmation and differentiation of Individual antibodies to HIV-1 and HIV-2	Manual immunochromatographic test using BioRad Geenius HIV1/2 kit CDVSOP 115	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	
Urine	Detection of Legionella Urinary Antigen	Binax Legionella Urinary Antigen EIA on Dynex DS2 SWVSOP 041 CDVSOP 041	S, W SVC
Urine		Binax NOW® Legionella Urinary Antigen rapid immuno-chromatographic assay, read on the Alere (Digival) card reader at Swansea CDVSOP 042 SWVSOP 042 NWVSOP042	S, R, W
Blood	Detection of Helicobacter pylori IgG	Quanta Lite Helicobacter pylori EIA kit on Dynex DS2 WBSOP 006 CDVSOP 051	W SVC
Blood	Detection of Herpes Simplex IgG	NovaLisa EIA Herpes Simplex Virus 1 & 2 (HSV) IgG kit on Dynex DS2 CDVSOP 024	W SVC
Blood	Measles IgG	NovaLisa EIA measles virus IgG kit on Dynex DS2 CDVSOP 024	W SVC



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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	
Blood	Measles IgM	NovaLisa EIA measles virus IgM kit on Dynex DS2 CDVSOP 024	WSVC
Blood	Mumps IgM	NovaLisa EIA mumps virus IgM kit on Dynex DS2 CDVSOP 024	WSVC
Blood	Detection of Varicella zoster IgG	Binding Site VaccZyme VZV glycoprotein IgG low level EIA Kit WVSOP 001 WVSOP 002 WVSOP 003 CDVSOP 021 SWVSOP 020	WSVC S
Serum	Confirmatory test: detection of reagin antibodies	ASI Rapid Plasma Reagin flocculation test SWVSOP 043	S
Serum	Confirmatory test: detection of antibodies to <i>Treponema Pallidum</i>	Fortress diagnostics indirect haemagglutination TPHA kit	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	
Urine	Detection of Strep. Pneumoniae urinary antigen	Binax NOW® Str. pneumoniae Urinary Antigen rapid immuno-chromatographic assay kit NWVSOP402	R, W
Serum	Detection of the following: Parvovirus IgM	Using Dynex DS2 analyser CDVSOP 007 SWVE 007	
Serum	Parvovirus IgG	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 CDVSOP 025	WSCV
Serum	Hepatitis E IgM	Fortress Enzyme Immunoassay CDVSOP 025	WSCV
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 WVSOP 001 WVSOP 002 WVSOP 003 CDVSOP 209 SWVSOP 209	S WSVC



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	WSVC
Blood	Hepatitis B DNA	Abbott m2000. Reverse transcription-polymerase chain reaction (RT-PCR) WVSOP 001 WVSOP 002 WVSOP 003 Abbott RealTime HBV assay CDVSOP 105	
	Hepatitis C RNA	Abbott RealTime HCV assay CDVSOP 104	
	Hepatitis C Genotype	Abbott RealTime HCV Genotype II assay. CDVSOP 108	
	HIV Viral Load	Abbott RealTime HIV assay. CDVSOP 104	WSVC, S
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 WVSOP 001 WVSOP 002 WVSOP 003 CDVSOP 255 SWVSOP 300 NWVSOP300	



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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	
Skin swabs. genital swabs. mouth swabs. eye swabs. swab not specified, blister swab	Detection of Herpes Simplex virus	In-house PCR assay using ABI Fast analyser CDVSOP 220	WSVC
Whole blood	Detection of Cytomegalovirus DNA and/or EBV DNA	QPCR using Vela Sentosa SX CMV and 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 CDMSOP 016 CDVSOP 230	WSVC
CSF, Swabs, Respiratory Swabs, Urine, Faeces	Enterovirus RNA	CDVSOP 204	
CSF, Swabs, Respiratory Swabs, urine	Measles RNA		
Culture isolates, swabs and urine	N. gonorrhoeae		
EDTA Whole blood, CSF	Meningococcal spp		
EDTA Whole blood, CSF	Pneumococcal spp		



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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	WSVC
CSF, swabs, urine	Herpes Simplex DNA	Extraction using EZ-1. PCR using Qiagen Rotorgene 6000 CDVSOP 230	
CSF, swabs, urine	Varicella zoster DNA		WSVC
Dry nose or throat swabs, nasopharyngeal aspirates and bronchoalveolar lavage.	Detection and identification of nucleic acids from the following respiratory viruses and bacteria	DNA/RNA extraction using EasyMag. Amplification using ABI Veriti thermocycler. RT-PCR method using the Luminex MAGPIX with NxTAG respiratory pathogen panel CDVSOP 203	
	Influenza A (H1, H1N1, H3) and B RNA		
	Rhinovirus/Enterovirus RNA		
	Parainfluenza 1 to 4 RNA		
	Respiratory Syncytial Virus (RSV) subtype A and B RNA		
	Human Metapneumovirus (HMPV) RNA		
	Adenovirus DNA		



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Anaerobe reference unit examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	ARU
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	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		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	Antibiotic Susceptibility testing of anaerobic bacteria of clinical significance	Using manual culture, MIC strips, Antibiotic infused agar plates (including fastidious anaerobe agar), the MAST uriDOT multipoint inoculator ARUSOP 029 ARUSOP 114	ARU



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Bacterial colonies, Faeces	C.difficile ribotyping	Automated DNA extraction method using e-MAG/easyMAG platform PCR thermocycler: ProFlex Thermocycler, and HotStar Taq ABI Capillary Electrophoresis system Bionumerics Software ARUSOP 003, 046, 049, 113	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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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Anaerobe reference unit examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	ARU
Clinical isolates	Detection of presumptive carbapenamase positive and negative B fragilis isolates	Bruker MalDItoF Biotyper subtyping module ARUSOP 117	ARU TRU
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. TRUASOP 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>	<u>Documented in-house methods using analysers specified</u>	CRU
Stool		Oocyst separation by centrifugation and flotation. DNA extraction using spin columns, Rotor-gene Q 6plex/RG6000 using real-time PCR technology, conventional PCR, and gel electrophoresis CRUSOP 004 CRUSOP 005 CRUSOP 028 CRUSOP 030 CRUSOP 034 CRUSOP 041 CRUSOP 061	CRU
DNA sequence data	Cryptosporidium genotyping, species identification (all species) and subtyping limited to <i>C. parvum</i> and <i>C. hominis</i> only	Analysis of DNA sequence data generated externally by sanger sequencing CRUSOP 041 CRUSOP 061	CRU
Stool	Cryptosporidium confirmation	Using microscopic examination of wet preparation, Immunofluorescence CryptoCel FAST, modified Ziehl-Neelson (mZN) and auramine phenol staining CRUSOP 017	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	CRU
Stool Tissue Fluids Respiratory	Cryptosporidium specialist detection	Manual immunofluorescent antibody test by microscopy DNA extraction using spin columns, conventional PCR, gel electrophoresis, and Sanger sequencing. CRUSOP 017 CRUSOP 005 CRUSOP 028 CRUSOP 030 CRUSOP 034	CRU
Stool	Giardia genotyping	DNA extraction using spin columns, Rotor-gene Q 6plex/RG6000 using real-time PCR technology. CRUSOP 005 CRUSOP 063	CRU
Stool	Giardia confirmation	Using microscopic examination of wet preparation, and Immunofluorescence GiardiaCEL CRUSOP 017	CRU
Stool	Cyclospora confirmation	Using microscopic examination of wet preparation, and modified Ziehl-Neelson (mZN) staining CRUSOP 017	CRU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Specialist antimicrobial chemotherapy unit examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	SACU
Bacterial isolates	Identification of bacterial pathogens up to 96 hours old	Bruker MalDI-ToF MDBSOP 100SACUBA 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 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 0224	SACU
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



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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	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 OXA-23-like, OXA-24-like and OXA-58-like genes	RotorGene Q (Qiagen): real time-PCR utilising fluorescent probes SACUSOP 043	SACU
Bacterial colonies	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



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Wales Centre for Mycobacteria unit examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	WCM
Sputum, Bronchial lavage, Gastric Aspirates, Faeces, CSF, Endometrial curettings, Sterile fluids, Pus, Swabs from superficial sites, Tissue, Skin, Urine	Isolation of mycobacterium spp of clinical significance.	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	WCM
Blood	Isolation of mycobacterium spp of clinical significance.	Automated culture using BD BacTec FX200 WCMSOP 013 WCMSOP 014	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	WCM
Positive Mycobacterial cultures	Characterisation and speciation of positive mycobacterial cultures: Identification of MTBC isolates	using manual LJ culture WCMSOP 020	WCM
	Identification of NTM isolates	using manual LJ culture WCMSOP 021	
	HAIN Common Mycobacterial species test	using the ABI Veriti Thermal Cycler and Bee Blot automated hybridisation machine. WCMSOP 045	
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 MOTT cultures	Antibiotic susceptibility testing of Mycobacterium species other than M. tuberculosis against Isoniazid, Rifampicin, Ethambutol, Ciprofloxacin, Clarithromycin, and Streptomycin	Solid media using manual LJ culture WCMSOP 021	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	WCM
Positive mycobacterial isolates	Speciation of mycobacteria	Sample preparation WCMSOP 049	WCM
Heat-inactivated mycobacteria		Next Generation Sequencing using Illumina MiSeq and Illumina NextSeq 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		Next Generation Sequencing using Illumina MiSeq and Illumina NextSeq PGUSOP 010 PGUSOP 045	PenGU
DNA sequence data from WCM	Mycobacteria species identification and frontline resistotyping	Reporting/interpretation using the Welsh Bioinformatics pipeline PGUSOP 066	PenGU



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Mycology reference unit examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	MRRU
Serum, plasma, sputum, BAL, NBL	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 EasyMag extractor 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 and yeast of clinical significance	Using microscopy and manual culture MRRUSOP 024 MDBSOP 039 WMYCSOP 09 WMYCSOP 08 WMYCSOP 10	MRRU
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



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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	MRRU
Clinical isolates cultured in-house	Antifungal susceptibility testing of fungi of clinical significance.	Antifungal susceptibility testing, based on CLSI guidance using Yeast Sensititre One Plates MRRUSOP 007	MRRU
Serum, CSF	Detection of cryptococcal antigen.	Using manual IMMY LF Antigen detection kit Immunochromatography technique (ICT) WMYCSOP 06	MRRU
Bronchoalveolar Lavage, Respiratory swabs	PCP (Pneumocystis jirovecii) detection	PCR using EasyMag extractor, EZ1 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



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HUMAN BODY TISSUES/FLUIDS (cont'd)	<u>Miscellaneous examination activities for the purpose of clinical diagnosis</u>	<u>Documented in-house methods using analysers specified</u>	
Urine	Detection of urinary hCG	Invitech one-step pregnancy test CDVSOP 074	CD
Plasma	<u>Pathogen Genomic Unit</u> HIV antiretroviral resistance	<u>Documented in-house methods using analysers specified</u> In-house assay using Illumina MiSeq and NextSeq 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			