Schedule of Accreditation

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Aneurin Bevan University Health Board

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Headquarters
St Cadoc's Hospital
Lodge Road
Caerleon
Newport
NP18 3XQ

Contact: Dr Nidhika Berry
Tel: +44 (0)1633 234463
E-Mail: Nidhika.Berry@wales.nhs.uk
Website: http://www.wales.nhs.uk/sitesplus/866/page/40569

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Royal Gwent Hospital Newport NP20 2UB	**Local contacts** Dr N Berry (Head of Department) Mr Julian Bendle (Department Manager)	Microbiology Serology Mycology	RGH
Address Nevill Hall Hospital Brecon Road Abergavenny Monmouthshire NP7 7EG	**Local contact** Mrs Catherine Milton (Lead Andrologist)	Andrology: Fertility Testing (automated) Fertility Testing (manual) Post-Vasectomy Retrograde ejaculate analysis	NHH

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES	Microbiology examination activities for the purpose of clinical diagnosis	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)'	
Blood	Culture and identification of microorganisms	• Automated detection of growth using Biomerieux BacTAlert • Manual culture using prepared manufacturers agar plates including chromogenic media • Manual gram stain Key SOPs: MICR00504 Blood culture SOP MICR00529 (Transfusion reactions)	RGH
CSF and Ascitic fluids	Quantitation of RBC WBC	Manual method using haemocytometer and light microscopy Manual Methylene blue differential stain and/or manual Gram stain MICR00507 Investigation of Cerebro-spinal fluid MICX00546 Investigation of fluids from normally sterile sites SOP MICX00512 Miscellaneous laboratory tests and staining methods	RGH
MSU, CSU, clean-catheter urine, suprapubic aspirate, bag urine, pad urine, ileal conduit/urostomy urine, cystoscopy urine, ureteric urine	Quantitation of RBC WBC Epithelial cells Bacteria Yeast	Sysmex UF-5000 for automated urine microscopy using flow cytometry SOP MICX0051	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd) Faeces, swabs (rectal, vaginal, endocervical, cervical, genital, penile, urethral, wound), ear, nose, sinus, throat, pernasal, mouth, eye, contact lens and case, antral washouts, ascitic fluid, CAPD fluid, CSF, respiratory samples (sputum, bronchial lavage, pleural fluid), pus, tissue, intravascular cannulae and associated devices, urine, semen, intra-uterine contraceptive device, products of conception, placental swab, foreign body, bone marrow, prostate secretions	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) Isolation and characterisation of micro-organisms of clinical significance.	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' • Manual culture using prepared manufacturer's agar plates including chromogenic media • Manual gram stain SOPs: • MICX00523 (Genital) • MICR00548 (GUM) • MICR00508 (Faeces) • MICR00505 (Containment level 3 SOP - respiratory) • MICR00511 (Legionella culture) • MICX00546 (sterile fluids) • MICR00519 Bone Bank specimens • MICR15094 Investigation of specimens associated with bones and prosthetic joints • MICR15093 Investigation of tissues and biopsies • MICR00509 (H Pylori) • MICX023 (IV cannulae) • MICX00515 (Urine) • MICR15034 (Prostatitis) • MICX00528 (Skin and superficial wound swabs) • MICX010 (Eye) • MICX011 (Mouth) • MICX013 (Throat) • MICX009 (ear) • MICX00518 (Deep seated wound)	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)'	
Faeces, swabs (rectal, vaginal, endocervical, cervical, genital, penile, urethral, wound), ear, nose, sinus, throat, pernasal, mouth, eye, contact lens and case, antral washouts, ascitic fluid, CAPD fluid, CSF, respiratory samples (sputum, bronchial lavage, pleural fluid), pus, tissue, intravascular cannulae and associated devices, urine, semen, intra-uterine contraceptive device, products of conception, placental swab, foreign body, bone marrow, prostate secretions (cont'd)	Isolation and characterisation of micro-organisms of clinical significance. (cont'd)	SOPs (cont'd) • MICX021 (Nose) • MICR00507 Investigation of Cerebro-spinal fluid • MICX00546 Investigation of fluids from normally sterile sites	RGH
Clinical isolates cultured in-house	Identification of microorganisms of clinical significance.	Using Bruker Maldi-ToF and manual identification methods SOPs as above	RGH
Clinical isolates cultured in-house	Antibiotic susceptibility testing of micro-organisms of clinical significance.	• Antimicrobial susceptibility testing using disc diffusion & EUCAST methodology/criteria. • Gradient MIC determination by E-test & EUCAST criteria (Launch Diagnostic kits) SOPs as above	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)'	
Swabs (nose, perineum, throat, wound) and urine, sputum, wound sites	Isolation and identification of MRSA	• Manual culture using prepared manufacturers agar plates with chromogenic media • Antimicrobial susceptibility testing using disc diffusion & EUCAST methodology/criteria. • Gradient MIC determination by E-test & EUCAST criteria • Identification using Bruker Maldi-ToF and manual identification methods SOP MICX00526 MRSA	RGH
Swabs (rectal, wound) faeces, urine, respiratory specimens	Screening for Carbapenemase-producing Enterobacteriaceae	• Manual culture using prepared manufacturers agar plates with chromogenic media • Antimicrobial susceptibility testing using disc diffusion & EUCAST methodology/criteria. • Gradient MIC determination by E-test & EUCAST criteria • Identification using Bruker Maldi-ToF and manual identification methods SOP MICR15090 CPE	RGH
Faeces	Detection and identification of rotavirus	Rotavirus strips from Bioconnections SOP MICR00508	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)'	
Faeces	Detection of *C. difficile* toxin A & B	Alere TECHLAB C.DIFF QUIK CHEK COMPLETE® - Manual rapid membrane immunoassay SOP MICR15046 Processing of faeces for C. difficile	RGH
Lower Respiratory samples (sputum, pleural fluids, BALs), tissue, bone marrow, sterile fluids, Respiratory samples, urine, CSF, swabs (skin/wound/abscess), tissue	Presence or absence of Acid-alcohol Fast Bacilli	Manual ZN stain and light microscopy SOP MICX00512 Miscellaneous laboratory tests and staining methods	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Parasitology examination activities for the purpose of clinical diagnosis</u>	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs)	RGH
Faeces, perianal swabs, urine,	Detection and identification of: ova, cysts and parasites	Apacor Midi Parasep Concentration method and Light/phase microscopy SOP MICR15078 Parasitology	RGH
Faeces	Detection of *Cryptosporidium* spp. oocysts	Manual Auramine stain Manual modified ZN stain MICR15078 Parasitology MICX00512 Miscellaneous laboratory tests and staining methods	RGH
	Molecular examination activities for the purpose of clinical diagnosis		
Faeces	Gastrointestinal panel: Detection of: Campylobacter spp. VTEC Salmonella spp Shigella spp Cryptosporidium spp Giardia lamblia. C.difficile	Serosep EntericBio for molecular detection of enteric pathogens using RT PCT Roche Light Cycler 480 II or ABI 7500 FAST Cycler SOP MICR15155	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Mycology examination activities for the purpose of clinical diagnosis	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs)	
Nail, Hair, skin scrapings	Isolation and identification of dermatophytes, non-dermatophyte moulds and other fungi from skin, nail, tissue and hair specimens	• Manual culture using prepared manufacturers agar plates • Identification using Bruker Maldi-ToF and manual identification methods • Lactophenol cotton blue stain SOP MICX00527 Mycology SOP	RGH
Endocervical samples, urethral samples	Examination for presence or absence of pus cells, Gram negative diplococci and yeasts.	Manual Gram stain Light microscopy SOPs: MICR00548 Genitourinary medicine SOP MICX00512 Miscellaneous laboratory tests and staining methods	RGH
Vaginal samples	Identification Bacterial vaginosis and *Trichomonas vaginalis*.	Light microscopy Manual Gram stain Examined and graded using Modified Ison-Hays criteria SOP MICR00548 Genitourinary medicine SOP	RGH
		Wet film preparations Light microscopy SOP MICX00512 Miscellaneous laboratory tests and staining methods	RGH
Bact/ Alert SA aerobic bottle/ Bact/ Alert SN anaerobic bottle/ Bact/ Alert FA aerobic bottle with antibiotic neutralising supplement/ Bact/ Alert PF paediatric bottle	Culture of microorganisms	Bact/Alert Virtuo continuous monitoring blood culture system using colourimetry (Blood cultures) SOP MICR00504 Investigation of Blood Cultures	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES	Serology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods using analysers specified	
Serum	Detection of the following: Toxoplasma total antibody VZV antibody Hepatitis B surface antibody Rubella IgG Hepatitis E IgG and IgM	Using Biomerieux kits on Biomerieux Vidas. Enzyme-linked fluorescent assay. MICR05003 Biomerieux VIDAS SOP	RGH
Urine	Detection of Pneumococcal soluble antigen	Alere Binax NOW kit Immunochromatographic method SOP MICR05007 urinary antigen test	RGH
Urine	Detection of Legionella pneumophilia serogroup 1 antigen	Alere Binax NOW kit Immunochromatographic method SOP MICR05007 urinary antigen test	RGH
Genital swabs/ Urine	Detection of: *Chlamydia trachomatis* *Neisseria gonorrhoea*	Roche Cobas 6800 by PCR SOP MICR15149 PCR using Cepheid GeneXpert	RGH
Swabs from nose, throat, groin	Detection of MRSA DNA	MICX00526 Investigation of specimens for screening for MRSA MICR15107 MRSA PCR Bench Guide	RGH
Oropharyngeal swabs in VTM	Detection of SARS-Cov-2 N2 and E gene	Cepheid GeneXpert- Xpert Xpress SARS-CoV-2 assay using, RT-PCR	RGH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP MICX024	NHH
Semen	<u>Fertility testing:</u>	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOP MICN005	NHH
	pH	Colorimetric strips	
	Sperm morphology excluding TZI scoring	Stained slides (Diff Quik) microscopy (Bright field)	
	Sperm concentration	Disposable Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	
	Sperm vitality	Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)	
	Sperm motility Sperm concentration	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and documented in-house procedure Semen Analysis in conjunction with manufacturer's instructions for analysis using SAMi CASA	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Andrological examination activities for the purposes of clinical diagnosis (cont'd)		
Urine	Assessment of retrograde ejaculation	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOP MICN005	NHH
	Detection of sperm Sperm concentration Sperm Motility	Using manual methods and phase-contrast microscope (incl. centrifugation) SOP MICR15081	
END			