


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9754</p> <p>Accredited to ISO 15189:2012</p>	<h3>Aneurin Bevan University Health Board</h3> <p>Issue No: 004 Issue date: 15 January 2021</p>	
	<p>Headquarters St Cadoc's Hospital Lodge Road Caerleon Newport NP18 3XQ</p>	<p>Contact: Dr Soma Gaur Tel: +44 (0)1633 234463 E-Mail: Soma.Gaur@wales.nhs.uk Website: http://www.wales.nhs.uk/sitesplus/866/page/40569</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Royal Gwent Hospital Newport NP20 2UB</p> <p>Local contact Dr S Gaur (Head of Department)</p> <p>Mr Julian Bendle (Department Manager)</p>	<p>Microbiology Serology Mycology</p>	RGH
<p>Address Nevill Hall Hospital Brecon Road Abergavenny Monmouthshire NP7 7EG</p> <p>Local contact Mrs Karen Llewelyn (Lead Andrologist)</p>	<p>Andrology: Fertility Testing (automated) Fertility Testing (manual) Post-Vasectomy Retrograde ejaculate analysis</p>	NHH
<p>Address Cordell Centre Sexual Health GUM clinic Royal Gwent Hospital Newport NP20 2UB</p> <p>Local contact Dr S Gaur (Head of Department)</p> <p>Mr Julian Bendle (Department Manager)</p>	<p>Microbiology</p>	CC



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)	
Blood	Culture and identification of microorganisms	<ul style="list-style-type: none"> Automated detection of growth using Biomerieux BacTAlert Manual culture using prepared manufacturers agar plates including chromogenic media Manual gram stain <p>Key SOPs: MICR00504 Blood culture SOP MICR00529 (Transfusion reactions)</p>	RGH
CSF and Ascitic fluids	Cell count for red blood cells and/or white blood cells (CSF & Ascitic)	<p>Manual method using haemocytometer and light microscopy Manual Methylene blue differential stain and/or manual Gram stain</p> <p>MICR00507 Investigation of Cerebro-spinal fluid MICX00546 Investigation of fluids from normally sterile sites SOP MICX00512 Miscellaneous laboratory tests and staining methods</p>	RGH



9754

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>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</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>In House documented methods based on related UK Standards for Microbiology Investigations' (SMLs)'</p> <ul style="list-style-type: none"> • Manual culture using prepared manufacturer's agar plates including chromogenic media • Manual gram stain <p>SOPs:</p> <ul style="list-style-type: none"> • 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) 	<p>RGH</p>



9754

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>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</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. (cont'd)</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)'</p> <p>SOPs cont'd</p> <ul style="list-style-type: none"> • MICX021 (Nose) • MICR00507 Investigation of Cerebro-spinal fluid MICX00546 Investigation of fluids from normally sterile sites 	<p>RGH</p>
<p>Clinical isolates cultured in-house</p>	<p>Identification of microorganisms of clinical significance.</p>	<p>Using Bruker Maldi-ToF and manual identification methods</p> <p>SOPs as above</p>	<p>RGH</p>
<p>Clinical isolates cultured in-house</p>	<p>Antibiotic susceptibility testing of micro-organisms of clinical significance.</p>	<ul style="list-style-type: none"> • Antimicrobial susceptibility testing using disc diffusion & EUCAST methodology/criteria. • Gradient MIC determination by E-test & EUCAST criteria (Launch Diagnostic kits) <p>SOPs as above</p>	<p>RGH</p>



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)	
Faeces	Detection of <i>C. difficile</i> glutamate dehydrogenase	Alere TECHLAB C.DIFF CHEK™ - 60 using Dynex DS2 SOP MICR15083 Dynex DS2 SOP MICR15046 Processing of faeces for <i>C. difficile</i>	RGH
	Detection of <i>C. difficile</i> toxin A & B	Alere TECHLAB TOX A/B QUIK CHEK® using Dynex DS2 Alere TECHLAB C.DIFF QUIK CHEK COMPLETE® - Manual rapid membrane immunoassay SOP MICR15083 Dynex DS2 SOP MICR15046 Processing of faeces for <i>C. difficile</i>	RGH
	Detection of <i>Helicobacter pylori</i> antigen	Oxoid Amplified IDEIA™ Hp StAR™ using Dynex DS2 SOP MICR15083 Dynex DS2 SOP MICR15052 Investigation of faeces for <i>H.pylori</i> antigen	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



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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 <i>Cryptosporidium</i> spp. oocysts	Manual Auramine stain Manual modified ZN stain Crypto EIA from Alere Techlab Cryptosporidium II™ using Dynex DS2 SOPs MICR15083 Dynex DS2 MICR15078 Parasitology MICX00512 Miscellaneous laboratory tests and staining methods	RGH



9754

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Mycology examination activities for the purpose of clinical diagnosis</u>	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	<ul style="list-style-type: none"> • 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 diplo-cocci and yeasts.	Manual Gram stain Light microscopy SOP : MICR00548 Genitourinary medicine SOP MICX00512 Miscellaneous laboratory tests and staining methods	CC
Vaginal samples	Identification Bacterial vaginosis and <i>Trichomonas vaginalis</i> .	Light microscopy Manual Gram stain Examined and graded using Modified Ison-Hays criteria SOP : MICR00548 Genitourinary medicine SOP	CC
		Wet film preparations Light microscopy SOP MICX00512 Miscellaneous laboratory tests and staining methods	RGH



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Serology examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods and manufacturer's instructions for use for Abbott Architect analyser	
Serum	Antenatal screens (Rubella Ab, Syphilis Ab, Hep B sAg, HIV Ag/Ab)	Immunoassay SOP MICR15045 Serology Architect MICR15082 Abbott Architect Serology BMS User Guide	RGH
Serum	Occupational Health screens (Hep B sAb, VZV Ab, Rubella Ab)		
Serum	GUM screens (Hep B sAg, Hep C Ab, HIV)		
Serum	Renal dialysis screens (Hep B sAg, Hep C Ab, HIV Ag/Ab)		
Serum	Clinical hepatitis serology (Hep A IgM, Hep BsAg, Hep B cAb, Hep C Ab)		
Serum	HIV Ag/Ab requests.		
Blood	Gentamicin	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA) BI1066 YYF/RGH Abbott Architect Automated Equipment c16000, c8000 and i2000	RGH
Blood	Tobramycin	PETINIA BI1066 YYF/RGH Abbott Architect Automated Equipment c16000, c8000 and i2000	RGH



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Blood	Vancomycin	PETINIA on Abbott Architect	RGH
		BI1066 YYF/RGH Abbott Architect Automated Equipment c16000, c8000 and i2000	
Serum	ASO	Quantia ASO kit on Abbott Architect	RGH
		Turbidimetric assay BI1069 Group A Streptococcal serology	
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.	RGH
		MICR05003 Biomerieux VIDAS SOP	
Urine	Detection of: <i>Streptococcus pneumoniae</i> antigen and <i>Legionella pneumophila</i> serogroup 1 antigen	Meridian TRU kit Immuno-chromatographic method SOP MICR05007 Legionella and Streptococcus pneumoniae urinary antigen test	RGH
Urine	Detection of Pneumococcal soluble antigen	Alere Binax NOW kit Immuno-chromatographic method SOP MICR05007 urinary antigen test	RGH



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
Swabs from nose, throat, groin	Detection of MRSA DNA	PCR using Cepheid GeneXpert MICX00526 Investigation of specimens for screening for MRSA MICR15107 MRSA PCR Bench Guide	RGH
	Detection of Influenza A/B and RSV RNA	MIC15140 Flu/RSV testing using the Cepheid GeneXpert MICR15107 MRSA PCR Bench Guide	RGH
Ejaculate	<u>Andrology examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures based on WHO Laboratory Manual 5 th Edition (2010):	
	Fertility testing including:	Manual method using documented in-house procedure SOP MICN005 (infertility)	NHH
	pH	Colorimetric strips	NHH



9754
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Aneurin Bevan University Health Board

Issue No: 004 Issue date: 15 January 2021

Testing performed by the Organisation at the locations specified

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>Andrology examination activities for the purpose of clinical diagnosis cont.</u>	Documented in-house methods using manual methods specified	
	Sperm morphology	Stained slides (Hema "Gurr" Diff Quik stain) - Bright field microscopy	NHH
	Sperm concentration	Phase contrast Microscopy	NHH
	Sperm motility	Microscopy	NHH
	Sperm vitality	Stained slide (Microm VitalScreen™ eosin-nigrosin kit) - Bright field microscopy	NHH
Urine, Semen	Sperm motility Sperm concentration	Documented in-house procedure in conjunction with manufacturer's instructions for analysis using CASA SAMi (Automated) SOP MICN005 Semen Analysis (Fertility)	NHH
	<u>Assessment of retrograde ejaculation</u>	Documented in-house methods using methods specified In line with 2010 WHO laboratory manual for the examination and processing of human semen	NHH
	Detection of sperm Sperm concentration Sperm Motility	Using manual methods and phase-contrast microscope (incl. centrifugation) SOP MICR15081	
Semen	<u>Post Vasectomy semen analysis</u>	in line with 2016 Laboratory Guidelines for Post vasectomy Semen Analysis: Association of Biomedical Andrologists	NHH
	Detection of sperm Sperm concentration Sperm Motility	Using fixed depth counting chambers and phase contrast microscopy SOP MICX024	
END			