


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8707</p> <p>Accredited to ISO 15189:2012</p>	<p>Bolton NHS Foundation Trust</p> <p>Issue No: 011 Issue date: 10 February 2025</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Swabs from ear, pus, wounds, eye, ulcer, uro-genital, penile and line sites. Bodily fluids – joint aspirates, CSF, ascitic fluid, pleural fluid Respiratory samples – sputum, BAL, NBL, NPA, ETube Bone CVP tips</p> <p>Faeces</p> <p>Whole blood</p> <p>Vaginal-rectal swabs</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General microbiology</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance</p> <p>Group B streptococci enrichment</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Manual culture using documented in-house procedures MB-INS-042 Genital samples MB-CSI-SW-002 Reading & Reporting of Consultants Special Interest Patients MB-INS-060 Reading & Reporting (Swabs/Sputa)</p> <p>Manual culture using documented in-house procedures MB-ENT-SW-030 Faeces Put up MB-ENT-SW-001 Enteric Bench Read</p> <p>Automated culture using BD Bactec FX system. Documented in-house procedures MB-BC-SOP-1 Blood Culture SOP</p> <p>Manual culture using documented in-house procedures Inoculation into LIM enrichment broth and subculture to Strep selective media for screening of Group B strep MB-SYS-SOP-7</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant
Yeast culture isolates produced by the laboratory	General microbiology (cont'd) Antifungal susceptibility testing	MB-SENS-SOP-4 Antimicrobial Sensitivity SOP
Faeces, line sites, wound swabs	Multidrug resistant organism screening	MB-SYS-SOP-3 VRE screening MB-SENS-SW-019 Screening for Carbapenemase producers.
Bacterial/fungi/yeasts culture isolates produced by the laboratory	Identification of bacteria/fungi/yeasts	Manual methods Oxidase, chemical reaction: MB-ID-SW-004 Oxidase Staph latex, agglutination: MB-ID-SW-007 Staphylococcal Latex Test Strep latex grouping (Prolab) agglutination: MB-ID-SW-008 Streptococcal Grouping Test Enteric Serology, agglutination: MB-ENT-SW-002 Enteric slide agglutinations β -lactamase, chemical reaction and/or enzyme detection: MB-SENS-SW-009 β -lactamase test MB-SENS-SOP-4 Antimicrobial Sensitivity SOP – ESBL, Optochin, growth inhibitor: MB-MISC-DOCS-4 Optochin Testing



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Blood Culture, Pus samples, eye swabs, genital swabs</p> <p>Sputum, NBL, BAL, Pleural Fluid, PUS, Tissue, Bone, enhanced broth cultures from positive MGIT culture tubes</p> <p>Genital samples; High Vaginal Swab, endocervical, urethral.</p> <p>Swabs from nose/groin or from clinically suspected sites (wound, line sites). Urine CVP tips</p> <p>Bacterial/fungi/yeasts culture isolates produced by the laboratory and direct from Blood Cultures</p> <p>Bacterial culture isolates produced by the laboratory</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>General microbiology (cont'd)</p> <p>Differentiation between different organism types: gram positive/negative/variable, branching organisms, yeast, fungal hyphae, presence of clue cells.</p> <p>Acid Fast Bacilli</p> <p>Trichomonas vaginalis, yeasts, white blood cells, clue cells.</p> <p>Isolation of MRSA</p> <p>Identification of bacteria/fungi</p> <p>Identification of bacteria and Antibiotic susceptibility testing</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Gram stain (light microscopy) MB-SYS-SW-003: Reporting of Gram films MB-INS-042 Genital samples</p> <p>Auramine phenol stain (fluorescent microscopy) and ZN stain (light microscopy) for confirmation of Auramine positive slides MB-MISC-DOCS-27 Staining Procedures in Microbiology</p> <p>Wet films (light microscopy) MB-INS-042 Genital samples</p> <p>Chromogenic media: MB-SYS-SOP-4 MRSA screening</p> <p>Automated - BRUKER/BD Sirius Maldi-TOF by Matrix-assisted laser desorption/ionization. MB-SENS-SOP-1 MALDI-TOF-Operation Manual MALDI-TOF Sepsityper MB-BC-SOP-1 – Blood culture SOP</p> <p>Automated – BD Phoenix M50 ID: Biochemical Reactions to provide a profile which matches to a database. MB-SENS-SOP-4 Antimicrobial Sensitivity SOP</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant
Urine	General microbiology (cont'd) Examination for White Blood Cells and Epithelial Cells	Automated using the Sysmex UF-5000 with flow cytometry MB-URI-SOP-2 Manual microscopy – MB-SOP-13 Investigation of Urines
CSF, pleural fluids, ascitic fluids	Examination for white and red blood cells, bacteria and yeasts	Manual microscopy using FAST READ 102 Counting Slide MB-SOP-5 Investigation of CSF MB-SF-SOP-1 Sterile fluid SOP
Urine	Legionella Antigen	Alere EIA MB-URI-SW-013: Legionella antigen testing
Urine	Strep pneumonia Antigen	Alere EIA MB-URI-SW-014: Pneumococcal antigen testing
Faeces	<i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> Glutamate dehydrogenase & toxin	GDH/CDT (Techlab) Glutamate dehydrogenase & toxin detection EIA combined cartridge test. MB-ENT-SW-033: Rapid detection of <i>Clostridioides</i> GDH/Toxin



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Faeces	General microbiology (cont'd) <i>Helicobacter pylori</i> antigen	H.pylori (Prolab), antigen detection Monoclonal Antibody Binding Reaction test strip MB-ENT-SW-032: Helicobacter antigen testing in faeces
Sputa, broncho-alveolar lavage, sterile fluids, tissue, bone	Acid Fast Bacilli of clinical significance. (Positive samples sent to Reference lab for ID+Sens)	Automated using BD MGIT 320 analyser MB-MNL-015 TB manual in conjunction with manufacturers' instructions
Urine, urethral, vulvo-vaginal, rectal, throat	Molecular testing Molecular detection of Chlamydia trachomatis and Neisseria gonorrhoeae	Automated: Cepheid (real time-PCR): MB-MOL-SW-9 using Cepheid GeneXpert
Faeces	Molecular detection of <i>Clostridioides difficile</i> and <i>Clostridioides difficile</i> toxins (tcdB (toxin B gene), cdt (binary toxin gene), and deletion at position 117 of the tcdC gene)	MB-ENT-SOP-5 using Cepheid GeneXpert and Xpert C. difficile BT assay
Sputa	<i>M. tuberculosis</i> complex DNA	LM-MB-46 Mycobacteria TB PCR using Xpert MTB-RIF Ultra
MRSA Cultured Isolates or Direct from swabs of wound sites or screening sites.	MRSA DNA	MB-VPR-SOP-1 MRSA PCR for Cepheid GeneXpert
Rectal swab, bacterial isolate	Carbapenemase resistance gene detection	MB-VPR-SOP-4 Carbapenemase PCR for Cepheid GeneXpert



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CSF	<p>Molecular testing (cont'd)</p> <p>Multiplexed nucleic acid molecular detection of the following microorganisms using the Meningitis/Encephalitis panel:</p> <ul style="list-style-type: none"> Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus Enterovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Human parechovirus Varicella zoster virus Cryptococcus neoformans/gattii 	<p>Automated:</p> <p>Biomerieux Biofire Film Array MB-MOL-SOP-1 in conjunction with manufacturers' instructions</p>
Urine, urethral, vulvo-vaginal, rectal, throat samples	Molecular detection of Chlamydia trachomatis and Neisseria gonorrhoeae	MB-MOL-SOP-7 using the Hologic Panther



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Primary Faeces sample	<u>Parasitology</u> Examination for the presence of parasites of clinical significance	Manual microscopy using documented in-house procedure MB-ENT-SW-017: Faeces Parasite Concentration. MB-ENT-SW-016: Cryptosporidium testing
Urine	Schistosoma haematobium	Manual microscopy using documented in-house procedure MB-URI-SW-031: Examination of Urine for Schistosoma haematobium
Primary samples of Nail, Hair, Skin, Tissue	<u>Mycology</u> General isolation and characterisation of fungi and yeasts of clinical significance	Manual method using documented in-house procedure MB-FUN-1 MYCOLOGY SOP
Fungal culture isolates produced by the laboratory	General identification and characterisation of fungi and yeasts of clinical significance	Stain/light microscopy – Fungal microscopy Lactophenol cotton blue MB-FUN-1 MYCOLOGY SOP
Culture isolates produced by the laboratory	Candida	Chromogenic media: MB-SW-025 Candida Reading & Reporting
Faeces	<u>Virology</u> Norovirus antigen	MB-ENT-SW-019 Rapid detection of Norovirus via EIA Cartridge, RidaQuick Norovirus kit (R-Biopharm-Rhone Ltd) MB-ENT-SW-019)



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Nasopharyngeal swabs	Virology (cont'd) SARS-CoV-2 RNA detection (ORF1ab)	Aptima SARS-CoV-2 assay using the Hologic Panther MB-MOL-SOP-6
Nasopharyngeal swabs, sputum, and nasopharyngeal aspirates	SARS-CoV-2 RNA (N2 and protein envelope E-gene), Influenza A and B, and RSV detection	Cepheid Genexpert, MB-MOL-SOP-4
Nasopharyngeal swabs	SARS-CoV-2 RNA (ORF1ab and N gene) and Influenza A and B detection	Roche Liat MB-MOL-SW-5
END		