

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
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|  <p>UKAS MEDICAL 8393</p> <p>Accredited to ISO 15189:2012</p> | <p align="center">Manchester University NHS Foundation Trust (Trading as Manchester Medical Microbiology Partnership)</p> <p align="center">Issue No: 006 Issue date: 25 August 2021</p> | |
| | <p>Clinical Sciences Building Manchester Royal Infirmary Oxford Road Manchester M13 9WL</p> | <p>Contact: Rachel Jones Tel: +44 (0)161 276 5747 E-Mail: Rachel.Jones2@mft.nhs.uk Website: https://www.mft.nhs.uk</p> |
| <p align="center">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 |
|--|---|--|
| HUMAN BODY FLUIDS AND TISSUES | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> | Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis |
| Urine, Suprapubic aspirate | Detection and quantification of white blood cells, red blood cells, epithelial cells and bacteria. General isolation and characterisation of bacterial and fungal isolates of clinical significance from urinary specimens | Differential cell count (flow cytometry) using BioMerieux UF1000i with automated plating on chromogenic agar using Previ-Isola. MMMP-BM-PROC18 Investigation of Urine MMMP-BM-PROC110 Use of Sysmex UF1000i urine analyser Differential cell count (flow cytometry) using BioMerieux UF1000i MMMP-BW-PROC74 Investigation of Urine MMMP-BW-PROC7119 Use of Sysmex UF-1000i urine analyser |
| Blood, Fluids, Aspirates | Culture and detection of microorganisms of clinical significance | BD BacTec FX semi-automated blood culture system: MMMP-BM-PROC3 Investigation of Blood Cultures & Sterile Fluids |
| Wound swab, nose swab, throat swab, ear swab, MRSA swabs | Isolation and characterisation of microorganisms of clinical significance including MRSA | WASPLab total laboratory automation, MMMP-BM-PROC23 Investigation of MRSA Screening Swabs using WASP and Traditional Culture |



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| <p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Superficial and deep-seated wound swabs, tissues, genital specimens, ENT swabs, ocular specimens, biopsies, bone</p> | <p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms of clinical significance.</p> | <p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>Manual inoculation and media culture</p> <p>MMMP-BM-PROC53 Investigation of nose swabs</p> <p>MMMP-BM-PROC54 Investigation of Throat Swabs</p> <p>MMMP-BM-PROC55 Investigation of Specimens for Bordetella Species</p> <p>MMMP-BM-PROC56 Investigations of Ear Swabs and Associated Specimens</p> <p>MMMP-BM-PROC65 Investigation of Skin Superficial & Non-surgical Wound Swabs</p> <p>MMMP-BM-PROC66 Investigation of Abscesses, Pus & Deep-Seated Infections</p> <p>MMMP-BM-PROC85 Investigation of specimens from Burns patients</p> <p>MMMP-BM-PROC64 Investigation of Tissue, Biopsies and Bone</p> <p>MMP-BM-PROC10 Investigation of Genital Tract Specimens</p> <p>MMMP-BM-PROC12 Investigation of GUM Specimens (Genito-urinary med</p> <p>MMMP-BM-PROC51 Investigation of Intraocular Fluids and Corneal Biopsies & Scrapings (routine culture for bacteria)</p> <p>MMMP-BM-PROC99 Investigation of Eye bank specimens</p> <p>MMMP-BM-PROC59 Investigation of Eye Swabs, Canalicular Pus</p> |



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| Respiratory specimens, sputum, broncho-alveolar lavage, endotracheal specimens, tissue, pleural fluid, cough swabs | Isolation and characterisation of microorganisms from respiratory specimens of clinical significance | MMMP-BM-PROC17 Investigation of Sputum and associated specimens MMMP-BM-PROC96 Investigation of Sputum and associated specimens from Cystic Fibrosis, PCD and Bronchiectasis patients MMMP-BM-PROC100 Investigation of Post-Mortem samples |
| CSF, PD fluid, Sterile Fluids, Aspirates, Joint Fluids | Detection and quantification of white blood cells, red blood cells, | Manual cell using and SOPs: MMMP-BM-PROC63 Investigation of Sterile Fluids MMMP-BM-PROC15 Investigation of Continuous Ambulatory Peritoneal Dialysis Fluid MMMP-BM-PROC16 Investigation of Cerebrospinal Fluid MMMP-BM-PROC61 Investigations of Sinus Aspirate MMMP-BW-PROC94 Investigation of prosthetic joint infection and prosthetic vascular graft infection samples |
| CSF, PD fluids, sterile fluids, aspirates, joint fluids | Differentiation of different organism types: Gram positive/negative/variable, branching organisms, yeasts | Gram staining and light microscopy MMMP-BM-PROC63 Investigation of Sterile Fluids MMMP-BM-PROC15 Investigation of Continuous Ambulatory Peritoneal Dialysis Fluid MMMP-BM-PROC61 Investigations of Sinus Aspirate MMMP-BM-PROC16 Investigation of Cerebrospinal Fluid MMMP-BW-PROC94 Investigation of prosthetic joint infection and prosthetic vascular graft infection samples |



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| Swabs | Isolation and characterisation of carbapenemase producing Enterobacteriaceae | Manual methods using MMMP-BW-PROC-125 Detection of Carbapenemase Producing Enterobacteriaceae |
| Rectal swabs and bacterial isolates | Molecular detection of carbapenemase producing Enterobacteriaceae | MMMP-BM-PROC130 Cepheid GeneXpert Infinity 48 System for the detection of carbapenemase producing Enterobacteriaceae and MMMP-BM-PROC91 CPE Using a Manual Screening Method |
| Sputum, BAL, pus, urine | Isolation and characterisation of mycobacteria | BD MGIT and manual culture on Lowenstein Jenson media. MMMP-BM-PROC14 Investigation of specimens for Mycobacterium species MMMP-BM-PROC121 Examination of specimens for isolation of mycobacteria using BD BACTEC MGIT 960 |
| Blood and bone marrow | Isolation and characterisation of mycobacteria | MMMP-BM-PROC147 Examination of Blood Cultures, Bone Marrow for the Isolation of Mycobacteria-BD Bactec FX40 |
| Sputum, BAL, pus, urine | Molecular detection of mycobacteria | Cepheid GeneXpert PCR and HAIN Geno Type Mycobacteria DNA strip technology |
| | HAIN for detection of MTB complex, rifampicin and isoniazid resistance | MMMP-BM-PROC69 Molecular Detection of Mycobacterium using HAIN Geno Type Mycobacteria DNA strip technology |
| | Cepheid for detection of MTB complex, and 13 other Mycobacterium species, and rifampicin resistance | MMMP-BM-PROC115 Cepheid GeneXpert ® MTB/RIF User Guide for the Detection of Mycobacterium Tuberculosis complex |



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| Sputum, BAL, pus, urine | Detection of acid-fast bacilli | Manual auramine stained smears and fluorescent microscopy MMMP-BM-PROC14 Investigation of specimens for Mycobacterium species MMMP-BM-PROC21 Microscopical preparations and staining techniques |
| Faeces | Isolation and characterisation of microorganisms of clinical significance | Manual inoculation and media culture MMMP-BM-PROC47 Examination procedure Enterics |
| Faeces | Detection of the following: Giardia lamblia Cryptosporidium Helicobacter pylori antigen C. difficile GDH and toxin AB | Dynex DS2 automated ELISA processor MMMP-BM-PROC47 Examination procedures Enterics Techlab Giardia Cryptosporidium CHEK Oxoid H. pylori IDEIA Hp STAR Techlab C. difficile CHEK 60 Techlab C. difficile Tox A/BII |
| Faeces | Detection of the following: Clostridium difficile GDH Clostridium difficile toxin A & B | MMMP-BM-PROC47 Examination procedures Enterics Lateral flow membrane immunoassay, Quik Check MMMP-BM-PROC129 C.difficile Quik Chek Complete Test Procedure MMMP-BM-PROC101 Examination of immunochromatic assays |
| Faeces, urine, Sellotape slide, pus, fluids, tissue | Identification/confirmation of faecal parasites | Microscopic examination using wet preparation, dry slide and Parasep concentration MMMP-BM-PROC25 Parasitology |



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| <p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Faeces</p> <p>Clinical isolates cultured in-house (including, bacteria, yeasts, fungi)</p> | <p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Molecular detection of Clostridium difficile</p> <p>Identification of microorganisms of clinical significance.</p> | <p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>GeneXpert PCR MMMP-BM-PROC112</p> <p>Bruker Microflex Biotyper (MALDI-TOF), mass spectrometry MMMP-BM-PROC119</p> <p>Biomerieux Vitek 2XL MMMP-BM-PROC39</p> <p>Biomerieux Vitek Compact MMMP-BM-PROC39</p> <p>Biomerieux API identification strips MMMP-BM-PROC13 Identification of Organisms</p> <p>Oxoid Latex agglutination MMMP-BM-PROC6 Identification of E. coli 0157</p> <p>Biorad Latex agglutination MMMP-BM-PROC105 Identification of Staphylococcus</p> |



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| Clinical isolates cultured in-house (including, bacteria, yeasts, fungi) | Identification of microorganisms of clinical significance. | Prolab Serology Kits MMMP-BM-PROC50 Identification of Salmonella Streptococcal grouping MMMP-BM-PROC13 Identification of Organisms |
| Skin, hair, nail, swabs, BAL, sputum, CSF, tissues | Isolation and identification of fungi of clinical significance. Presence or absence of fungal elements | Media culture and wet film microscopy using Calcofluor and Indian Ink MMMP-BM-PROC24 Investigation of Mycology specimens |
| Bacterial and yeast isolates | Antimicrobial susceptibility testing (AST) | Fully automated Vitek XL using EUCAST breakpoint data Manual antimicrobial susceptibility testing using disc diffusion and EUCAST and BSAC methodology Antibiotic disc diffusion and gradient MIC determination (Etest and Lilofilchem) MMMP-BM-PROC29 Antimicrobial sensitivity testing: Disk testing MMMP-BM-PROC91 Screening bench: resistant enzymes MMMP-BM-PROC102 Antimicrobial sensitivity testing: E-tests |



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| HUMAN BODY FLUIDS AND TISSUES | <u>Serology examination activities for the purpose of clinical diagnosis</u> | Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis |
| Serum, plasma, dried blood spot | Qualitative detection of the following: Syphilis (total) HIV antigen & antibody Human T-cell Lymphotropic Virus (HTLV) antibody Hepatitis A IgG & IgM Hepatitis B surface antibody Hepatitis B Core ab (total) Hepatitis B core IgM Hepatitis B surface antigen Hepatitis B e antigen Hepatitis B e antibody Hepatitis C antibody Cytomegalovirus IgG & IgM Rubella IgG & IgM Toxoplasma IgG, IgM & avidity Herpes Simplex Virus 1 IgG Herpes Simplex Virus 2 IgG | Roche Cobas 8000 analyser using electrochemiluminescence and MMMP-SEROL-PROC75 MMMP-SERO-PROC 78 MMMP-SEROL-PROC 80 MMMP-SEROL-PROC 95 MMMP-SEROL-PROC28 MMMP-SEROL-PROC85 MMMP-SEROL-PROC86 MMMP-SEROL-PROC84 MMMP-SEROL-PROC89 MMMP-SEROL-PROC90 MMMP-SEROL-PROC 81 MMMP-SEROL-PROC91 MMMP-SEROL-PROC92 MMMP-SEROL-PROC83 MMMP-SEROLPROC 82 MMMP-SEROL-PROC 88 MMMP-SEROLPROC79 MMMP-SEROLPROC87 MMMP-SEROL-PROC96 MMMP-SEROLPROC97 MMMP-SEROL-PROC115 MMMP-SEROLPROC93 MMMP-SEROLPROC94 |
| Serum, plasma | Syphilis confirmation TPPA titre Syphilis confirmation RPR titre | Serodia TPPA using particle agglutination MMMP-SEROL-PROC128 Biokit RPR reditest using microparticle agglutination MMMP-SEROL-PROC128 |



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| Serum, plasma | Detection of HIV 1 and 2 antibodies | Biorad Geenius immunoblot lateral flow device MMMP-SEROL-PROC71 |
| Urine | Detection of Legionella and Streptococcus pneumoniae antigen | Binax NOW kit and immunochromatography, MMMP-SEROL-PROC123 |
| CSF | Detection of Cryptococcal antigen | Latex antigen kit MMMP-SEROL-PROC125 |
| | Detection of ASD antibodies | BioMerieux ASD by enzyme inhibition MMMP-SEROL-PROC127 |
| Serum, plasma | Qualitative detection of the following: Epstein Barr Virus (EBV)CA IgG, IgM & EBNA IgG Measles IgG & IgM HSV IgG & IgM Parvovirus IgG & IgM Varicella Zoster IgG & IgM Mumps IgG & IgM Chlamydia IgG CMV IgG and avidity Syphilis IgG HIV antigen & antibody Hepatitis B surface antigen Hepatitis delta antibody | Diasorin Liaison XL analyser using chemiluminescence, MMMP-SEROL-PROC57, MMMP-SEROL-PROC28 and MMMP-SEROL-PROC124 |



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| Serum, plasma | Qualitative detection of: HIV P24 antigen Lyme IgG & IgM Hepatitis B Core antibody (total) | BioMerieux automated analyser VIDAS 3 User Guide MMMP-SEROL-PROC74 MMMP-SEROL-PROC98 MMMP-SEROL-PROC99 MMMP-SEROL-PROC100 MMMP-SEROL-PROC10 |
| Serum, plasma | Qualitative detection of: Syphilis IgM Hepatitis C Virus antibody confirmation Hepatitis E Virus (HEV) IgM | Werfen DS2 automated ELISA analyser Trinity Biotech Syph IgM MMMP-SEROL-PROC68 Ortho HCV MMMP-SEROL-PROC65 HEV IgM Fortress Diagnostics MMMP-SEROL-PROC64 |



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| HUMAN BODY FLUIDS AND TISSUES | <u>Molecular examination activities for the purposes of clinical diagnosis</u> | Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis |
| Blood | Quantitative viral load for: HIV RNA Hepatitis B DNA Hepatitis C RNA | Roche Cobas 6800 MMMP-MOL-PROC-95 MMMP-MOL-PROC-94 MMMP-MOL-PROC-93 |
| Blood, urine | Quantitative detection of CMV DNA | MMMP-MOL-PROC44 |
| Blood | Quantitative detection of EBV DNA | MMMP-MOL-PROC66 |
| Blood, swabs | Quantitative detection of Adenovirus DNA | MMMP-MOL-PROC2 |
| Respiratory sample, nose and throat swabs and CSF | Qualitative detection of Mycoplasma pneumoniae DNA | MMMP-MOL-PROC91MMMP-MOL-PROC29 |
| Genital and skin swabs, vitreous fluids, CSF, blood | Varicella zoster DNA | |
| Swabs, CSF, fluids | Treponema pallidum DNA | MMMP-MOL-PROC56 |
| Blood, plasma, serum, CSF | Meningococcal (incorporating ctrA gene and serogroup B) and pneumococcal DNA Meningococcal serogroups A, C, Y, W confirmatory assays | MMMP-MOL-PROC40 |



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| CSF, blood, amniotic fluid | Qualitative detection of Toxoplasma gondii DNA | MMMP-MOL-PROC46 |
| BAL, sputum, CSF, blood, swabs | Qualitative Detection of Candida DNA | MMMP-MOL-PROC8 |
| BAL, sputum, CSF | Qualitative Detection of Aspergillus DNA | MMMP-MOL-PROC8 |
| Genital and skin swabs, CSF, vitreous fluids, blood | Qualitative detection of Herpes simplex 1 & 2 DNA | MMMP-MOL-PROC18 |
| CSF, faeces, blood, swabs, respiratory samples | Qualitative detection of Enterovirus and Parechovirus RNA | MMMP-MOL-PROC59 |
| CSF, blood | Qualitative detection of Human Herpes virus 6 & 7 DNA | MMMP-MOL-PROC14 |
| Throat swabs, urines | Qualitative detection of Measles RNA | MMMP-MOL-PROC35 |
| CSF, urine, serum, blood | Qualitative detection of Polyoma (BK and JC) DNA | MMMP-MOL-PROC3 |
| Blood, tissues, amniotic fluid | Qualitative detection of Parvovirus B19 DNA | MMMP-MOL-PROC23 |
| BAL, sputum, blood | Qualitative detection of Pneumocystis jiroveci DNA | MMMP-MOL-PROC24 |



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| Respiratory samples | Qualitative detection of the following: Respiratory viruses, Influenza A RNA (Pandemic, H1, H3, H5, H7) & B, RSV RNA, Parainfluenza 1 RNA, Parainfluenza 2 RNA, Parainfluenza 3 RNA, Adenovirus DNA, Rhinovirus RNA, Metapneumovirus RNA, | PCR using Qiagen Symphony extraction and Applied Biosystems Taqman amplification |
| Respiratory specimens, swabs, BAL, sputum | Oseltamivir resistance | MMMP-MOL-PROC34 MMMP-MOL-PROC39 MMMP-MOL-PROC72 |
| Pernasal swab, nose and throat swab, BAL, sputum, nasopharyngeal aspirate | Bordetella pertussis DNA | MMMP-MOL-PROC42 MMMP-MOL-PROC83 |
| Genital swabs, urine, eye swabs, rectal swabs and throat swabs | Detection of Chlamydia trachomatis RNA, Neisseria gonorrhoeae and Trichomonas vaginalis DNA | PCR using Roche Cobas 8800 MMMP-MOL-PROC67 MMMP-MOL-PROC111 |



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| Cervical swabs, biopsies, paraffin wax tissue sections | Qualitative detection of Human Papilloma virus, types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 HPV genotyping (DNA) Papillocheck assay | Roche Cobas 8800 PCR MMMP-MOL-PROC106 Detection of high risk Human Papillomavirus using the Cobas 68/8800 System MMMP-MOL-PROC69 |
| Nasal and throat swabs in VTM Sputum Bronchoalveolar lavage (BAL) | Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences: E, ORF1ab | Roche Cobas 6800/8800 PCR MMMP-MOL-PROC112 Detection of SARS-CoV-2 using the Roche Cobas 68/8800 System |
| Nasopharyngeal/oropharyngeal, nasal and midturbinate swabs in Viral Transport Medium Sputum Bronchoalveolar lavage (BAL) Tracheal aspirates from organ transplant patients | Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene targets: E, N2 and ORF1a | MMMP-MOL-PROC114 the Cepheid Xpert Xpress SARS-CoV-2 assay for the rapid detection of COVID 19 using Cepheid Xpert Infinity-48 automated PCR System |
| Plasma | Detection of the following Hepatitis B resistance Detection of CMV resistance HIV resistance, integrase, tropism | Sequencing using Qiagen Symphony extraction and Applied Biosystems ABI 3130 sequencer MMMP-MOL-PROC58 MMMP-MOL-PROC41 MMMP-MOL-PROC48, 49, 53 |
| Serum, dried blood spot | Hepatitis C genotyping | BioMerieux EasyMAG extraction and Roche Cobas 4800 qualitative PCR MMMP-MOL-PROC13 MMMP-MOL-PROC100 |
| Nasopharyngeal swabs and aspirates | Detection of Influenza A, B and RSV | GeneXpert Infinity automated PCR system and MMMP-MOL-PROC103 |



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| Faeces | Detection of Norovirus GI and GII, Adenovirus 40/41, Astrovirus, Rotavirus, Sapovirus | Roche FLOW RT-PCR system and MMMP-MOL-PROC108 |
| Nose and throat swab, sputum, bronchoalveolar lavage, lung biopsy | Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) | Altona Real Star qualitative RT-PCR and MMMP-MOL-PROC97 |
| Faeces and C difficile isolates | Identification of ribotypes of C difficile | PCR and gel electrophoresis and MMMP-BM-PROC126 |
| END | | |