


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8157 Accredited to ISO 15189:2012	Leeds Teaching Hospitals NHS Trust Issue No: 010 Issue date: 02 September 2021	
	Department of Microbiology Leeds General Infirmary Old Medical School Great George Street Leeds LS1 3EX	Contact: Nicola Millican Tel: +44 (0)113 392 8831 E-Mail: nicola.millican@nhs.net Website: www.pathology.leeds.nhs.uk
Testing performed by the Organisation at the locations specified		

Laboratory locations:

Location details	Activity	Location code
Address Leeds General Infirmary Old Medical School Great George Street Leeds LS1 3EX	Local contact As above	Bacteriology (including molecular) Mycology Molecular Virology Serology
Address Block 46 St James' University Hospital Beckett Street Leeds LS9 7TF	Local contact As above	Antifungal drug assays
Address Ward L43 Neonatal Special Care Clarendon Wing Leeds General Infirmary Great George Street Leeds LS1 3EX	Local contact As above	Blood culture incubation & detection of microbial growth



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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
HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Routine samples: Swabs, fluids and tissues	Isolation of microorganisms of clinical significance	Manual or automated (WASP) inoculation and manual or automated incubation SOPs: MBBEP 001-002 MBBEP 004-005 MBBEP 09 MBBEP 011 MBBEP 014 MBBEP 017 MBBEP 020 MBBEP 022 MBBEP 025-026 MBBEP 042 MBBEP 044 Gram staining and Microscopic examination of sterile fluids and tissues for bacteria and white cells	A
Cerebrospinal fluid	Quantification and differentiation of white and red cells Isolation of microorganisms of clinical significance	Manual cell count using modified Fuchs-Rosenthal chamber Manual inoculation and incubation MBBEP027 MBBEP022	A
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Automated processing, incubation and digital plate imaging using Brilliance culture media and WASP or manual culture methods using Brilliance culture media SOP: MBBEP029	A
Blood	Detection of microbial growth	Liquid media culture using Using Bactec FX and Bactec FX40	A
	Isolation & characterisation of microorganisms of clinical significance	Subsequent manual culture and Gram staining SOP: MBBEP037	C A



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
Respiratory samples: Sputum, Broncho-alveolar lavage, Bronchial Washings, Naso-pharyngeal Aspirate Naso-pharyngeal swabs, Sinus/Antral Washout	Isolation of microorganisms of clinical significance	Manual inoculation and media culture SOPs: MBBEP003 MBBEP019 MBBEP006	A
Urine	General isolation and characterisation of micro-organisms of clinical significance Antibiotic susceptibility testing	Semi-automated - Mast URI Plus Culture and sensitivity utilising multipoint technology and breakpoint methodology to EUCAST principles SOP: MBBEP041	A
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells	iQSprints: flow cytometry SOP: MBBEP041	A
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: <i>Campylobacter</i> spp. <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Pleisiomonas</i> spp. <i>C.perfringens</i> <i>B.cereus</i> <i>B.subtilis</i> <i>B.lichenformans</i> <i>S.aureus</i>	Manual inoculation and media culture SOP: MBBEP030	A



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Female genital tract liquid swabs	General isolation and characterisation of micro-organisms of clinical significance	Automated processing, incubation and digital plate imaging (WASP) SOP: MBBEP028	A
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Using manual biochemical methods SOPs: MBBT008 MBBT026 MBBIP016 And Automated BD MalDI-ToF Matrix-assisted laser desorption/ionisation SOP: MBBT004	A
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual antimicrobial susceptibility testing using EUCAST methodology and manual Reading SOP: MBBEP045	A
Faeces CSF, Bile, Pus, Duodenal/Jejunal Aspirate, Sputum, Tissue (where appropriate)	Detection of clinically significant ova, cysts and parasites (OCP)	Faecal concentration using Evergreen FPC kit and direct Microscopic examination SOP: MBBEP031	A
Clear adhesive tape' slide/perianal swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Direct Microscopic examination SOP: MBBEP031	A
Urine	Detection of <i>Schistosoma haematobium</i> ova	Sedimentation of Urine and Microscopic Identification SOP: MBBEP031	A



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Sputum, broncho-alveolar lavage/washings. Gastric Aspirates/Washings Sterile body fluids Pus and pus swabs Skin or tissue including lymph nodes Bone Faeces Urine	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Liquid culture, auramine phenol staining and incident-light fluorescence microscopy Using BD BacTec MGIT 960 (fluorescence)	A
Blood		BD BacTec FX40 SOP: MBBEP040	
Faeces	<i>Clostridium difficile</i> glutamate dehydrogenase GDH <i>C. difficile</i> toxins A & B <i>C. difficile</i> toxin B and binary toxin genes	GDH EIA using Dynex DS2 In house tissue culture method SOPs: MBBEP010 MBBTP017 Cepheid Gene Xpert Real-time PCR SOP: MBBOP013 MBBGENT60	A
Faeces	<i>Giardia lamblia</i> & <i>Cryptosporidium</i> antigens Rotavirus / <i>Helicobacter pylori</i> antigens	Dynex DS2 – ELISA SOP: MBBTP018 SOPs: MBBTP006 MBBTP007	A
Faeces Rectal Swabs	Detection of Carbapenemase Genes (KPC,VDM,OXA-48,IMP1 & VIM)	Cepheid Gene Xpert Real-time PCR SOP: MBBOP013 MBBIP010	A



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
Blood/serum, bronchoalveolar lavage (BAL)	Aspergillus antigen	Manual ELISA Platelia Antigen Kit SOP: MBYTP006 MBYEP003	A
Blood/serum	Qualitative detection of Beta D glucan	ACC Fungitell (kinetic) Assay and ELX 808 Ultra Microplate Reader SOP: MBYTP037	A
Blood/serum, CSF	Cryptococcal antigen	Latex agglutination (IMMY lateral flow kit) SOP: MBYTP035	A
Hair Nail Skin	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained (lactophenol cotton blue, KOH/Calcoflour white & unstained) SOP: MBYEP001 MBYTP017	A
Mould isolates Fluid from normally sterile sites, bile, pus and swabs, antral washout Skin, tissue biopsies Corneal Scrapes	Isolation and identification of clinically significant moulds	Culture. Macroscopic and microscopic identification using lactophenol cotton blue for staining SOPs: MBYTP017 MBYEP002 MBYEP004 MBYEP005	A



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Yeast isolates Fluid from normally sterile sites, bile, pus and swabs, antral washout, oral rinse, urine Skin, tissue biopsies Corneal Scrapes Swabs from genito-urinary tract</p> <p>Blood, serum</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation, identification and susceptibility testing of clinically significant yeasts</p> <p>Antifungal drug levels; Itraconazole, Posaconazole, Voriconazole</p>	<p>In-house documented procedures incorporating manufacturers instructions where relevant</p> <p>Culture on chromogenic agar SOPs: MBYEP002, MBYEP005 Identification using the Automated BD Maldi-ToF Matrix-assisted laser desorption/ionisation SOP: MBYTP029 Disc diffusion susceptibility testing (CLSI) SOP: MBYTP027 MIC susceptibility testing (Sensititre). SOP: MBYTP015 Examination of fungal isolates MBYEP004</p> <p>LC-MS/MS SOP: MBYTP036</p>	<p>A</p> <p>B</p>



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HUMAN TISSUES AND FLUIDS	<u>Serology examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
Blood; serum/plasma	Hepatitis (Anti-HAV IgM, Anti HAV Total, HBsAg*, Anti HBs, Anti HBc IgM*, HBeAg*, Anti HBe*, Anti HCV, HBcT*) Antigen/Antibody detection, HIV-1 & HIV-2 Antibodies and HIV-1 p24 Antigen* detection, Syphilis* Antibody detection, Rubella Antibody detection and Toxoplasma antibody detection	Siemens Centaur; enzyme immunoassay SOP: MBSEREP003 MBSEROP14	A
Blood; serum/plasma	CMV (IgG & IgM), EBV (IgG & IgM), HSV (IgG), VZV (IgG), HTLV (IgG), Measles (IgG & IgM), Mumps (IgG & IgM), Parvovirus (IgG & IgM), Mycoplasma pneumonia (IgM) antibody detection. Hepatitis B core antibody Hepatitis D total antibodies CMV Avidity	DiaSorin XL Liaison; enzyme immunoassay SOPs: MBSEROP011 MBSEREP068 MBSEREP003	A
Blood; serum/plasma	Confirmatory second line testing for: HIV-1 & HIV-2 Antibodies and HIV-1 p24 Antigen Hepatitis C antibody Hepatitis B surface antigen		
Blood; serum/plasma	CMV antibody detection (confirmatory second line testing)	Siemens Immulite Xpi MBSEREP068 MBBGSER133	A



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HUMAN TISSUES AND FLUIDS	<u>Serology examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
Urine	<i>Legionella pneumophila</i> serotype 1 antigen	Trinity Biotech Bartels ELISA Legionella Urinary Antigen detection kit on Dynex Ds2 SOPs: MBSEROP012 MBSEREP037	A
Urine Swabs – urethral, cervical	Detection of ribosomal RNA from: <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i>	Nucleic acid amplification technique (NAAT) Hologic Gen-Probe Panther system SOP: MBOPPAN01	A
Blood; serum/plasma	VZV Confirmation antibody detection	Binding Site VaccZyme VZV glycoprotein IgG Low Level EIA kit Dynex DS2 EIA SOPs: MBSEROP005 MBSEREP067	A
Blood; serum/plasma, CSF	Confirmatory testing for syphilis by detection of <i>Treponema pallidum</i> antibodies /antigen	RPR Commercial assay, Reagin Antigen (VDRL) Semi-quantitative TPPA Commercial Assay Antibody detection Antibody detection on Dynex DS2 EIA IgM test Captia Syphilis EIA SOP: MBSEROP005 All assays SOP: MBSEREP051	A
Blood; serum/plasma	Hepatitis E IgG & Hepatitis E IgM	Abia manual EIA SOPs: MBSEROP005 MBBGSER110 MBSEREP003	A
Blood; serum/plasma	HIV confirmation and differentiation of HIV-1 and HIV-2 antibodies	Biorad Geenius Confirmation Assay. Manual single use Immunochromatographic assay SOP: MBBGSER109	A



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HUMAN TISSUES AND FLUIDS	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
Yeast/mould isolates	Identification of clinically significant yeast & mould	Manual Nucleic Acid extraction; in-house manual chloroform extraction SOP ref: MBYTP028 Polymerase chain reaction (PCR) and sequence analysis. ABI 7500 fast ABI 3130xl SOPs: MBYTP028, MBNTP64	A
EDTA blood, urine, CSF, tissue, BAL, Amniotic Fluid and placenta	CMV, EBV, adenovirus Quantitative	Nucleic Acid extraction; Qiagen MDX Biorobot, QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; Stratagene MX3000 Qiagen QiAgility robot SOP: MBNTP55	A
EDTA blood, CSF, swabs (skin, mouth, eye)	HSV, adenovirus, VZV Qualitative	Nucleic Acid extraction; Qiagen MDX BioRobot, QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; ABI 7500 fast Qiagen QiAgility robot SOP: MBNTP88	A
CSF, EDTA blood, swabs (skin, eye) faeces	Enterovirus and parechovirus Qualitative	Nucleic Acid extraction; Qiagen MDX BioRobot, QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; ABI 7500 fast Qiagen QiAgility robot SOP: MBNTP25	A
Genital swabs	HSV 1 and 2, <i>Treponema pallidum</i> Qualitative	Nucleic Acid extraction; Qiagen MDX BioRobot, QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; ABI 7500 fast Qiagen QiAgility robot SOPs: MBNTP29	A



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HUMAN TISSUES AND FLUIDS	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
EDTA blood, urine	BK polyoma virus Quantitative	Nucleic Acid extraction; Qiagen MDX BioRobot, QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; Stratagene MX3000 Qiagen QiAgility robot SOP: MBNEP083	A
EDTA blood, CSF, tissue	Qualitative detection of JC virus	Nucleic Acid extraction; Qiagen MDX BioRobot, QIA amp all kit SOP: MBNOP056 RealStar Real Time PCR commercial assay; Stratagene MX3000 SOP: MBNTP094	A
Faeces, vomit	Gastroenteritis Virology: Norovirus G1 and G2, rotavirus, astrovirus, sapovirus, adenovirus genus and adenovirus group F Qualitative	Nucleic Acid extraction; Qiagen QIASymphony, DSP Virus/Pathogen MiniKit SOP:MBNOP084 Real Time Multiplex PCR ABI 7500 fast Roche LC480 384 well head Qiagen QiAgility robot SOP: MBNTP021	A
Whole blood, EDTA, serum/plasma and foetal samples (swabs, fluids or tissue). Also, for Measles: oral fluids/swab, urine, throat swabs, and nasopharyngeal aspirates. Also, for HHV6 - CSF, bone marrow aspirates and BAL	Parvovirus B19, HHV6 and Measles Qualitative	Nucleic Acid extraction; Qiagen MDX BioRobot QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; ABI 7500 fast Qiagen QiAgility robot SOP: MBNTP092	A



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HUMAN TISSUES AND FLUIDS	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures incorporating manufacturers instructions where relevant	
EDTA blood	HCV genotyping: Genotypic identification	Nucleic Acid extraction; Qiagen QIASymphony DSP Virus/Pathogen MiniKit SOP:MBNOP084 Qiagen MDX Biorobot QIA amp all kit SOP: MBNOP056 PCR Sequence analysis; Veriti ABI 9700 LiPA Scan HCV assay using Siemens Autoblot 3000H Confirmation via ABI 3130xl sequencing for NS5b region SOP: MBNTP017	A
EDTA blood, CSF	Bacterial Meningitis; detection of <i>Neisseria meningitidis</i> and <i>Streptococcus pneumoniae</i> Qualitative	Nucleic Acid extraction; Qiagen MDX Biorobot QIA amp all kit SOP: MBNOP056 Real time PCR Sequence analysis; ABI 7500 fast SOP: MBNEP062	A
BAL, sputum	<i>Pneumocystis jirovecii</i> (PcP) Qualitative	Nucleic Acid extraction; Qiagen MDX Biorobot QIA amp all kit SOP: MBNOP056 Real Time Multiplex PCR; ABI 7500 fast Qiagen QIASymphony Qiagen QiAgility robot SOP: MBNTP090	A
NPA, perinasal swab, throat swab	Qualitative detection of <i>Bordetella</i> species	Nucleic Acid Extraction; Qiagen QIASymphony DSP Virus/Pathogen MiniKit SOP ref:MBNOP084 Multiplex PCR; ABI 7500 fast In house method SOP: MBNTP093	A



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HUMAN TISSUES AND FLUIDS (cont'd) Mycobacterium sp isolates	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u> detection of drug resistance marker genes TB	In-house documented procedures incorporating manufacturers instructions where relevant Manual Nucleic Acid Extraction; QIAamp DNA mini kit SOP:MBNTP61 Real Time PCR; TB drug resistance genotyping; GenoType MTBDRplus/ GenoType MTBDRsl commercial kits Automated on Verity thermocycler SOP: MBNTP069	A
END			