


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	University Hospitals of North Midlands NHS Trust	
	Issue No: 012 Issue date: 12 November 2024	
	Department of Infection Sciences North Midlands and Cheshire Pathology Service Royal Stoke University Hospital Main Building – Floor 2 Newcastle Road Stoke-on-Trent Staffordshire ST4 6QG	Contact: Laura Kinghorn-Perry, Pathology Quality Manager Tel: +44 (0)1782 679664 E-Mail: laura.kinghorn-perry@uhnm.nhs.uk Website: www.uhnm.nhs.uk
Testing performed at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES Urine Screening swabs Routine samples: Aspirates Cellular and fluid material contained on swabs, catheter tips Fluids Tissues Cellular and fluid material contained on swabs from genital samples, IUCD	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> General Bacteriology Isolation and characterisation of micro-organisms of clinical significance Isolation and characterisation of micro-organisms of clinical significance Isolation and characterisation of micro-organisms of clinical significance	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant: Automated culture using WASP and WASPlab MLPB236 MLPB229 Manual inoculation of non-selective selective, differential and chromogenic agar plates and liquid enrichment broth using in-house procedures MLPB01 General bacteriology media selection swabs booking MSP47 General Bacteriology Reporting guidelines MLPB31 Eye MLPB32,MSP41 sterile fluids microscopy and cell counts gram plus differential MLPB33 intravascular cannulas MLPB34 Tissues deep wounds MLPB162 Screening for GBS MLPB39 Bone, soft tissue and orthopaedic implants Manual inoculation of non-selective selective, differential agar plates and liquid media using in-house procedure microscopy MLPB02



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
	General Bacteriology (cont'd)	
	Detection and identification of organisms associated with bacterial vaginosis	Light Microscopy and Gram stain MLPB02 and MSP19
Urine	Quantitation of white and red blood cells, bacteria, yeasts, casts and epithelial cells	Sysmex UF5000 flow cytometry MLPB06
Urine	Isolation and characterisation of micro-organisms of clinical significance	Manual culture technique chromogenic agar MLPB06
Urine	Determination of antimicrobial susceptibility of clinically significant microorganisms	Automated antimicrobial susceptibility testing using Vitek 2 XL MLPB43
Faeces	Isolation and characterisation of micro-organisms of clinical significance	Manual confirmation culture of molecular results and culture of microorganisms not included in the molecular panel below MLPB13
	Molecular detection of <i>Salmonella</i> spp. <i>Campylobacter</i> spp. (<i>jejuni</i> & <i>coli</i>) <i>Shigella</i> spp. / <i>Enteroinvasive E. coli</i> (EIEC) Shiga-toxin 1 (<i>stx1</i>) / Shiga toxin 2 (<i>stx-2</i>), <i>Giardia lamblia</i> <i>Cryptosporidium</i> spp. (<i>C. parvum</i> & <i>hominis</i>) & <i>Entamoeba histolytica</i>	BD Max analyser for molecular detection of enteric pathogens. MLPB218.
	Identification of <i>Cryptosporidium</i> spp.	Modified Ziehl Neelsen MLPB13
Whole blood, ascitic fluid, CSF, peritoneal fluid, joint fluid in blood culture bottles pre-inoculated	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	Biomerieux BactAlert VIRTUO colourimetric growth detection and manual culture techniques MLPB09



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
CSF	General Bacteriology (cont'd) Quantitation and differentiation of white blood cells, quantitation of red blood cells	Cell count, Gram film and manual culture techniques MLPB30 MSP41
Swabs from nose, throat, perineum, rectal and wound sites, catheters, urine, faeces,	Isolation of MRSA, MSSA, ESBL, MRGNB	Manual culture techniques chromogenic agar MLPB10 MLPB40
Respiratory samples sputum, bronchoalveolar lavage, tissue	Detection of microbial growth and isolation of Mycobacteria sp.	Becton Dickinson Bactec MGIT Fluorometric growth detection and manual culture and microscopy using Ziehl Neelsen and auramine stains MLPB05
Respiratory samples sputum, bronchoalveolar lavage, tissue	Detection of microbial growth and isolation of Mycobacteria sp.	Becton Dickinson Bactec MGIT Fluorometric growth detection and manual culture and microscopy using Ziehl Neelsen and auramine stains MLPB05
Respiratory samples sputum, bronchoalveolar lavage, tissue	Isolation and characterisation of micro-organisms of clinical relevance	Manual inoculation of non-selective selective, differential and chromogenic agar plates using in-house procedures MLPB08
Cultures isolated in house from routine and blood samples listed above	Identification of micro-organisms of clinical significance	BioMérieux MalDI-ToF Matrix Assisted Laser Desorption Ionization Time-of-Flight MLPB77 Vitek MX Prime MalDI-TOF MLPB77 BioMérieux Vitek 2 MLPB23 MLPB43 Manual biochemical and serological techniques MLPB23 MLPB23 biochemical identification procedures



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Relevant sample and in house isolated culture	General Bacteriology (cont'd) Identification of Gram negative and Gram-positive organisms	Gram film MSP19
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen	Binax NOW Immunochromatographic assay MLPV04 MLPV45
Urine	Detection of <i>S. pneumoniae</i> antigen	Binax NOW Immunochromatographic assay MLPV04 MLPV46
Cultures isolated in house from all specimen types listed above	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	Automated Vitek 2 and manual disc diffusion methods using EUCAST guidelines MLPB43, MLPB45, MLPB04a &b MLPB11 EUCAST Sensitivity reading
Urine	Detection of bHCG	InstalertImmunochromatographic assay MLPB07,
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen and toxin A/B	QuickChek solid phase immunoassay MLPV22 MLPV83 MLPB161 C.difficile procedures
Faeces/Urine	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Midi ParaSep filtration, concentration and manual microscopy using Lugols iodine MLPB49
Faeces	Detection of rotavirus and adenovirus	Ridaquick immunoassay MLPB219 MLPB221



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Serum unless otherwise specified	<u>Serological examination activities for the purposes of clinical diagnosis</u> CMV IgG CMV IgM EBNA IgG EBV VCA IgG EBV VCA IgM Hepatitis A IgM *Hepatitis B surface antigen Hepatitis B core antibody Hepatitis B core IgM Hepatitis B e antibody and antigen Hepatitis C antibody *HIV I/II Mumps IgG Rubella IgG Rubella IgM Varicella zoster IgG Toxoplasma Total (IgG/IgM), Hepatitis E IgG Hepatitis E IgM	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant and documented in-house methods to meet the requirements of the Infectious diseases in pregnancy screening (IDPS) programme as defined in the laboratory QA evidence requirements (targets marked *) BioMérieux Vidas Enzyme Linked Fluorometric Assay (ELFA) MLPV11 MLPV12 MLPV51 MLPV52 MLPV53, MLPV54 MLPV55 MLPV56 MLPV29, MLPV58 MLPV29, MLPV50 MLPV29, MLPV90 MLPV29, MLPV57 MLPV91 MLPV53 MLPV61 MLPV63, MLPV29 MLPV64 MLPV41 MLPV147 MLPV160 MLPV161



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p>	<p><u>Serological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Qualitative detection of:</p> <p>Hepatitis A IgM *Hepatitis B surface antigen Hepatitis B core total antibody Hepatitis B surface antibody (quantitative) Hepatitis C antibody *HIV I/II Rubella IgG</p> <p>Quantitative latex agglutination detection of:</p> <p>Anti Streptolysin O titre</p> <p>RPR</p> <p>TPHA</p> <p>Varicella Zoster IgG Parvovirus IgG Parvovirus IgM Measles IgG *Syphilis Total (IgG & IgM) antibody.</p> <p>Helicobacter pylori antigen EBNA IgG EIA</p>	<p>In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant and documented in-house methods to meet the requirements of the Infectious diseases in pregnancy screening (IDPS) programme as defined in the laboratory QA evidence requirements</p> <p>Roche Cobas Pro 801 Immunoassay analyser MLPV12, MLPV201 MLPV12, MLPV201 MLPV12, MLPV201, MLPV29 MLPV12, MLPV201, MLPV29 MLPV12, MLPV201, MLPV29</p> <p>MLPV12, MLPV201 MLPV29 MLPV 12, MLPV201</p> <p>Rheumajet ASO latex agglutination kit MLPV208 manual passive particle agglutination ASO MLPV209</p> <p>Charcoal microparticle assay ASI ready test MLPV210, MLPV216,</p> <p>Manual latex agglutination using Arlington Scientific TPHA kit MLPV268 TPHA procedures</p> <p>Diasorin Liaison XL random access analyser MLPV146 Liaison XL MLPV12 Serology (Reporting) – Review, interpretation and release of results.</p> <p>MLPV146 and MLPB219 Liaison XL MLPV146 Liaison XL</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Faeces	Carbapenamase Detection of Clostridium difficile toxin gene Norovirus	Cepheid GeneXpert multiplex, real-time PCR GeneXpert infinity MLPV133 MLPV117,MLPV 133, MLPV 116, MLPV 100, MLPV187 Norovirus kit insert MLPV100
Nasopharyngeal swabs	Detection of Influenza A/B, RSV, SarS-CoV-2	MLPV117, MLPV187 and MLPV218
Genital swabs/urine	Confirmation of Neisseria gonorrhoeae	Cepheid GeneXpert MLPV156
Genital /Oral swabs	Detection of Herpes simplex	Extraction using Biomerieux eMag analyser MLPV183 ABI7500 real time PCR MLPV86
CSF	Detection of community acquired meningitis/encephalitis pathogens Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cryptococcus neoformans/gattii Cytomegalovirus (CMV) Enterovirus Herpes simplex virus 1 (HSV-1) Herpes simplex virus 2 (HSV-2) Human herpes virus 6 (HHV-6) Human parechovirus Varicella zoster virus (VZV)	BioMérieux Film Array Multiplex PCR MLPV120 MLPV134



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Nose/throat swabs	Detection of Sars-CoV-2	Cobas 8800 molecular analyser and Prolab Viasure kit MLPV157 & MLPV180
	Detection of SarS-CoV-2, Influenza A and Influenza B.	Cobas Liat analyser MLPV211, MLPV219 & MLPV218.
Respiratory samples	Detection of respiratory pathogens: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 MERS-CoV SARS-CoV-2 Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A Influenza B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus Bordatella parapertussis (IS001) Bordatella pertussis (ptxP) Chlamydia pneumonia Mycoplasma pneumoniae	BioMérieux Film Array Multiplex PCR MLPV120 MLPV136



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Blood culture	Detection of pathogenic microorganisms and antimicrobial resistance genes. Gram Negative Bacteria: Acinetobacter calcoaceticus-baumannii complex Bacteroides fragilis Enterobacterales Enterobacter cloacae complex Escherichia coli Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumonia group Proteus spp Salmonella spp Serratia marcescens Haemophilus influenzae Neisseria meningitidis Pseudomonas aeruginosa Stenotrophomonas maltophilia Yeasts: Candida albicans Candida auris Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis Cryptococcus neoformans/gattii Gram Positive Bacteria: Enterococcus faecalis Enterococcus faecium Listeria monocytogenes Staphylococcus spp Staphylococcus aureus Staphylococcus epidermidis Staphylococcus lugdunensis Streptococcus spp Streptococcus agalactiae (Group B) Streptococcus pneumoniae Streptococcus pyogenes (Group A) Antimicrobial Resistance Genes:	BioMérieux Film Array Multiplex PCR MLPV120 MLPV134



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Blood culture	Detection of pathogenic microorganisms and antimicrobial resistance genes (cont'd) CTX-M IMP KPC Mcr-1 mecA/C mec A/C and MREJ (MRSA) NDM OXA-48-like vanA/B VIM	BioMérieux Film Array Multiplex PCR MLPV120 MLPV134 (cont'd)
Genital swabs, eye swabs and urine	Detection of Chlamydia trachomatis and Neisseria gonorrhoeae	Cobas 8800 molecular system MLPV157, MLPV159
Genital swabs and urine	Detection of Trichomonas vaginalis and Mycoplasma genitalium	Cobas 8800 molecular system MLPV157
Plasma and serum	Viral load determination for HIV and hepatitis C	Cobas 8800 molecular analyser MLPV157, MLPV162 & MLPV163
END		