


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8916 Accredited to ISO 15189:2012</p>	<h3>Torbay and South Devon NHS Foundation Trust</h3>	
	<p>Issue No: 004 Issue date: 23 September 2021</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 TISSUES AND FLUIDS</p> <p>Routine samples: Aspirates Cellular and fluid material contained on swabs, catheter tips and intra-uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine Intravascular cannulae</p> <p>Cellular and fluid material contained on swabs</p> <p>Blood</p> <p>Sterile site samples: Tissue Swabs Fluid</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p> <p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Vancomycin resistant enterococcus (VRE), carbapenemase producing enterobacteriaceae (VRE)</p> <p>Isolation of microorganisms of clinical significance</p> <p>Isolation of microorganisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation, incubation of culture media using: LP MIC 11/12/13/14/15/17/20/24/88</p> <p>Manual inoculation, incubation of chromogenic culture media using: LP MIC 16</p> <p>Liquid media culture using: LP MIC 5/6 BacTec FX and FX40 unit analyser</p> <p>Manual inoculation, incubation of culture media using: LP MIC 8/10</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Blood units	Isolation of microorganisms of clinical significance	Manual inoculation, incubation of culture media using LP MIC 19
Cerebrospinal fluid (CSF)	Detection, identification and quantification (inc. differential) of: White blood cells Red blood cells Bacterial cells	Microscopy & staining (Gram and differential) using: LP MIC 7
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: LP MIC 7
Bronchoalveolar lavage Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid Sputum Cystic fibrosis samples	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: LP MIC 22/23/25/26
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues	Detection, identification and quantification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using: LP MIC 8/12/14/25/58
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Manual microscopic examination using: LP MIC 20



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual and/or automated biochemical methods using: LP MIC 59-75 and BioMerieux API LP MIC 54 and BioRad Auxacolor
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual and/or automated antimicrobial susceptibility testing using EUCAST methodology Antibiotic disc diffusion and gradient MIC determination and procedures: LP MIC 1/2/3
Hair Nail Skin	Isolation and identification of clinically significant fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: LP MIC 53/55/56/57
Female genital swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopic examination using: LP MIC 15
Faeces	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using : LP MIC 30



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Faeces	Detection of ova, cysts and parasites (OCP)	Using MidiParasep and direct microscopy and SOP: LP MIC 35
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Modified Ziehl-Neelsen (ZN) stain using LP MIC 36
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination using in-house procedure: LP MIC 21
Aspirates Cellular and fluid material contained on swabs Fluids Sputum Tissue Urine	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Solid culture, auramine phenol staining and incident-light fluorescence microscopy using: LP MIC 27/28
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen Strep. Pneumoniae antigen	Membrane immunochromatographic assay using: Launch: TRU device and LP MIC 47
Faeces	Rotavirus & Adenovirus antigen	R Biopharm RidaQuick device and LP MIC 33



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	
Plasma/serum	Microbial serology for: HIV Ab/Ag combo HBsAg Anti-HBs	Documented in-house methods to meet the requirements of the PHE IDPS screening programme as defined in the current version of " <i>Infectious diseases in pregnancy screening: laboratory QA evidence requirements</i> "
Plasma Serum	Microbial serology for: HIV Ab/Ag combo HBsAg Anti-HAV IgM Anti-HBs Anti-HBc Anti-HCV Syphilis antibody (<i>T.pallidum</i>) SARS CoV2 antibody N	Roche Elecsys platform Immunoassay ELISA assays and procedures: LP MIC 39/40/42/45
Plasma/Serum	HIV DUO (Ag/Ab) HBsAg Anti-HCV VZV IgG CMV IgG CMV IgM EBNA IgG EBV VCA IgG EBV VCA IgM LYME IgM LYME IgG Mumps IgG Measles IgG Toxo Competition	BioMerieux VIDAS, ELISA Immunoassay and Procedure: LP MIC 39/41/42/43/44/45/46



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Plasma Serum	Syphilis RPR (non-specific antibody for <i>Treponema pallidum</i>)	Manual agglutination method using: Axis Shield RPR kit and procedure: LP MIC 40
Faeces	<i>Clostridium difficile</i> glutamate dehydrogenase (GDH) <i>C. difficile</i> toxins A & B	Membrane immunochromatographic assay. Alere Quik Chek Complete device and procedure : LP MIC 32
Faeces	<i>Helicobacter pylori</i> antigen	Membrane immunochromatographic assay. Pro-lab Pro-Flow device and LP MIC 34



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u>	
Respiratory samples (swabs, secretions and washings)	Molecular diagnostics for: Detection of DNA/RNA for: Influenza A Virus (inc H1, H1-2009, H3) Influenza B Virus Respiratory Syncytial Virus (A/B) Metapneumovirus (A/B) Parainfluenza Virus (1-4) Adenovirus Enterovirus Parechovirus Rhinovirus Bocavirus Coronaviruses NL63, 229E, OC43, HKU1 MERS-CoV SARS-CoV2 Mycoplasma pneumoniae Chlamydia pneumoniae Bordetella pertussis (ptxP) Bordetella parapertussis (IS1001)	PCR using Biofire FilmArray and LP MIC91
Urine and genital swabs	Detection of ribosomal RNA from: <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	PCR using Cobas 4800 system and procedure: LP MIC 52
Feaces	Detection of DNA from: C difficile toxin B gene	Serosep Entero-Bio system and procedure: LP MIC 30/48
Feaces	Detection of DNA for: Salmonella Shigella E.coli O157 Campylobacter Giardia Cryptosporidium	Serosep Entero-Bio system and procedures: LP MIC 30/48



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CSF	Molecular diagnostics for: Qualitative Viral Meningitis screen Detection of DNA/RNA of: Enterovirus Parechovirus Herpes simplex 1/2 Virus Varicella zoster virus HHV6 E.coli K1 H.influenzae L. monocytogenes N.meningitidis S.agalactise S.pneumoniae C.neoformans/gattii	PCR using Biofire Filmarray and LP MIC91
Nasopharyngeal aspirate Nasopharyngeal swab	Detection of RNA of: Influenza A Influenza B Respiratory syncytial virus SARS CoV-2	Polymerase Chain Reaction (PCR) using: LP MIC 51 and Cephied GeneXpert
Faeces Serum/plasma Plasma	Norovirus Quantative Hepatitis C viral load Quatitative HIV-1 viral load	
Sputum	Detection of DNA of: MTB and Rifampin resistance mutations	



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Urine, cervical swabs	Chlamydia trachomatis and Neisseria gonorrhoeae	
Rectal swabs	Vancomycin resistant enterococcus: differentiation vanA and vanB genes	
Rectal swabs	Carba R: differentiation of KPC, NDM, VIM, IMP-1 and OXA-48, OXA-181 & OXA232	
Nose and throat swabs	Detection of RNA SARS CoV-2	Realtime PCR using Roche Lightcycler Viasure CerTest SARS CoV2 LP MIC 93. Nucleic Acid Extraction Thermofisher LP MIC 49
Nose and throat swabs	Detection of RNA SARS Cov-2	Nucleic acid extraction using QIAmp Viral RNA mini LP MIC 94 and Kingfisher Flex MagMix Viral pathogen kit and MVPII kit LP MIC95
END		