


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2022</p>	<p align="center">Torbay and South Devon NHS Foundation Trust</p> <p align="center">Issue No: 010 Issue date: 21 January 2025</p>	
	<p>Department of Microbiology Level 3 Torbay Hospital Lowe's Bridge Torquay TQ2 7AA United Kingdom</p>	<p>Contact: Nikki Harwood Tel: +44 (0) 1803 655223 E-Mail: nikki.harwood@nhs.net</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
<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>Nasal Swab</p> <p>Blood</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)</p> <p>Screening for Methicillin-Sensitive <i>Staphylococcus aureus</i> (MSSA)</p> <p>Isolation of microorganisms of clinical significance</p>	<p>In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate</p> <p>Manual inoculation, incubation of culture media LP MIC 11 LP MIC 12 LP MIC 13 LP MIC 14 LP MIC 15 LP MIC 17 LP MIC 20 LP MIC 24 LP MIC 88</p> <p>Manual inoculation, incubation of chromogenic culture media LP MIC 16</p> <p>Manual inoculation, incubation of chromogenic culture media LP MIC WOU 003</p> <p>Liquid media culture using BacTec FX and FX40 unit analyser LP MIC 5 LP MIC 6</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Sterile site samples: Tissue Swabs Fluid	Isolation of microorganisms of clinical significance	Manual inoculation, incubation of culture media LP MIC 8 LP MIC 10
Blood units	Isolation of microorganisms of clinical significance	Manual inoculation, incubation of culture media 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) LP MIC 7
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture 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 LP MIC 22 LP MIC 23 LP MIC 25 LP MIC 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 LP MIC 8 LP MIC 12 LP MIC 14 LP MIC 25 LP MIC 58



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Manual microscopic examination LP MIC 20
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual and/or automated biochemical method LP MIC 59 LP MIC 60 LP MIC 61 LP MIC 62 LP MIC 63 LP MIC 64 LP MIC 65 LP MIC 66 LP MIC 67 LP MIC 68 LP MIC 69 LP MIC 70 LP MIC 71 LP MIC 72 LP MIC 73 LP MIC 75 BioMerieux API LP MIC 54
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 LP MIC 1 LP MIC 2 LP MIC 3



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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 as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Hair Nail Skin	Isolation and identification of clinically significant fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) LP MIC 53 LP MIC 55 LP MIC 56 LP MIC 57
Female genital swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopic examination LP MIC 15
Female genital swabs	Microscopic detection of <i>Trichomonas Vaginalis</i>	Wet preparation microscopy LP MIC 15
Faeces	Isolation of microorganisms of clinical significance	Manual inoculation and media culture LP MIC 30
Faeces	Detection of ova, cysts and parasites (OCP)	Using MidiParasep and direct microscopy LP MIC 35
Faeces	Detection of <i>Coccidia oocysts</i>	Modified Ziehl-Neelsen (ZN) stain LP MIC 36
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination LP MIC 21
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen Strep. Pneumoniae antigen	Membrane immunochromatographic assay Launch TRU device LP MIC 47
Faeces	Rotavirus & Adenovirus antigen	R Biopharm RidaQuick device LP MIC 33



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Plasma Serum	Detection of: HIV Ab/Ag combo* HBsAg* Anti-HAV IgM Anti-HBs Anti-HBc Anti-HCV Rubella IgG HIV DUO (Ag/Ab) HBsAg Anti-HCV VZV IgG CMV IgG CMV IgM EBNA IgG EBV VCA IgM LYME IgM LYME IgG Mumps IgG Measles IgG Toxo Competition	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 *). Roche Elecsys platform Immunoassay ELISA assays LP MIC 39 LP MIC 40 LP MIC 42 LP MIC 45 BioMerieux VIDAS, ELISA Immunoassay



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Serum	Syphilis RPR (non-specific antibody for <i>Treponema pallidum</i>)	ASI RPR Card, flocculation test for Reagin Antibodies LP MIC 40
Serum Plasma	Detection of Reagin Abs	Flocculation test LP MIC40
Faeces	<i>Clostridium difficile</i> glutamate dehydrogenase (GDH) <i>C. difficile</i> toxins A & B	Membrane immunochromatographic assay. Alere Quik Chek Complete device LP MIC 32
Faeces	<i>Helicobacter pylori</i> antigen	Membrane immunochromatographic assay. Pro-lab Pro-Flow device 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>	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
Respiratory samples (swabs, secretions and washings)	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 <i>Mycoplasma pneumoniae</i> <i>Chlamydia pneumoniae</i> <i>Bordetella pertussis (ptxP)</i> <i>Bordetella parapertussis (IS1001)</i>	PCR using Biofire FilmArray LP MIC91
Urine Endocervical Swabs Vaginal swabs Oropharyngeal samples	Detection of ribosomal DNA from: <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	Roche Cobas 6800 LP-MIC101
Faeces	Detection of DNA from: C difficile toxin B gene	Serosep Entero-Bio LP MIC30 LP MIC48
Faeces	Detection of DNA for: Salmonella Shigella E.coli O157 Campylobacter Giardia Cryptosporidium	Serosep Entero-Bio system LP MIC30 LP MIC48



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate
CSF	Qualitative Viral Meningitis screen Detection of DNA/RNA of: Enterovirus Parechovirus Herpes simplex 1/2 Virus Varicella zoster virus HHV6 <i>E.coli K1</i> <i>H.influenzae</i> <i>L. monocytogenes</i> <i>N.meningitidis</i> <i>S.agalactise</i> <i>S.pneumoniae</i> <i>C.neoformans/gattii</i>	PCR using Biofire Filmarray LP MIC91
Nasopharyngeal aspirate Nasopharyngeal swab	Detection of RNA: of: Influenza A Influenza B Respiratory syncytial virus SARS CoV-2 RNA sequences E and N2	Polymerase Chain Reaction (PCR) Using Cepheid GeneXpert LP MIC 51
Faeces	Norovirus	
Serum Plasma	Quantitative Hepatitis C viral load	
Plasma	Quantitative HIV-1 viral load	
Sputum	MTB and Rifampin resistance mutations	
Urine Cervical swabs	<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	
Rectal swabs	Vancomycin resistant enterococcus: differentiation vanA and vanB genes	



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HUMAN TISSUES AND FLUIDS (cont'd) Rectal swabs	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u> (cont'd) Detection of DNA: Carba R: differentiation of KPC, NDM, VIM, IMP-1 and OXA-48, OXA-181 & OXA232	In-house documented procedures as referenced and based on UKHSA Standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate Polymerase Chain Reaction (PCR) using Cepheid GeneXpert LP MIC 51
END		