


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8916</p> <p>Accredited to <b>ISO 15189:2022</b></p>	<h3>Torbay and South Devon NHS Foundation Trust</h3> <p><b>Issue No:</b> 012    <b>Issue date:</b> 16 October 2025</p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	<u>Microbiological 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
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	Isolation of microorganisms of clinical significance	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
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual inoculation, incubation of chromogenic culture media LP MIC 16
Nasal Swab	Screening for Methicillin-Sensitive <i>Staphylococcus aureus</i> (MSSA)	Manual inoculation, incubation of chromogenic culture media LP MIC 16
Blood	Isolation of microorganisms of clinical significance	Liquid media culture using BacTec FX200, FX400 and FX40 unit analyser LP MIC 5 LP MIC 6



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Sterile site samples: Tissue Swabs Fluid</p> <p>Cerebrospinal fluid (CSF)</p> <p>CSF</p> <p>Bronchoalveolar lavage Bronchial aspirate, brushings &amp; washings Cellular and fluid material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid Sputum Cystic fibrosis samples</p> <p>Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Isolation of microorganisms of clinical significance</p> <p>Detection, identification and quantification (inc. differential) of: White blood cells Red blood cells Bacterial cells</p> <p>Isolation of microorganisms of clinical significance</p> <p>Isolation of microorganisms of clinical significance</p> <p>Detection, identification and quantification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae</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 8 LP MIC 10</p> <p>Microscopy &amp; staining (Gram and differential) LP MIC 7</p> <p>Manual inoculation and media culture LP MIC 7</p> <p>Manual inoculation and media culture LP MIC 25 LP MIC 26 LP MIC 97</p> <p>Staining (inc. Gram) and microscopic examination LP MIC 8 LP MIC 12 LP MIC 14 LP MIC 25 LP MIC 58</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Urine</p> <p>Cultures isolated in-house from all samples listed above</p> <p>Bacterial cultures isolated in-house from all samples listed above</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts</p> <p>Identification of microorganisms of clinical significance</p> <p>Antimicrobial susceptibility testing of clinically significant bacteria</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 microscopic examination LP MIC 20</p> <p>Manual 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</p> <p>BioMerieux API LP MIC 54</p> <p>Manual antimicrobial susceptibility testing using EUCAST methodology Antibiotic disc diffusion and gradient MIC determination LP MIC 1 LP MIC 2 LP MIC 3</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 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 oocysts of <i>Cryptosporidium</i> , <i>Cyclospora</i> , and <i>Cystoisospora belli</i> ,	Modified Ziehl-Neelsen (ZN) stain LP MIC 36
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination LP MIC 21



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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* Syphilis total antibody Anti-HAV IgM Anti-HBs Anti-HBc Anti-HCV Rubella IgG	Roche Cobas e801 Immunoassay ELISA assays LP MIC 39 LP MIC 40 LP MIC 42 LP MIC 45
Plasma Serum	Detection of:  HIV DUO (Ag/Ab) HBsAg Anti-HCV	BioMerieux VIDAS 3, ELISA Immunoassay LP MIC41



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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
Plasma Serum (cont'd)	Detection of: (cont'd)  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 3, ELISA Immunoassay LP MIC41
Serum	Syphilis RPR (non-specific antibody for <i>Treponema pallidum</i> )	ASI RPR Card, flocculation test for Reagin Antibodies LP MIC 40
Faeces	<i>Clostridioides difficile</i> glutamate dehydrogenase (GDH) <i>C. difficile</i> toxins A & B	Membrane immunochromatographic assay. Alere C. diff 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 bioMerieux Biofire FilmArray LP MIC91 RP 2.1 Plus
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. agalactiae</i> <i>S. pneumoniae</i> <i>C. neoformans/gattii</i>	PCR using bioMerieux Biofire Filmarray LP MIC91 ME panel
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 Cobas CT/NG



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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
Faeces	Detection of DNA from: C difficile toxin B gene	Serosep Enteric-Bio LP MIC30 LP MIC48 Enteric <i>Clostridioides difficile</i>
Faeces	Detection of DNA for: <i>Salmonella</i> spp. <i>Shigella</i> spp. Shiga toxin 1 and 2 <i>Campylobacter</i> sp Giardia Cryptosporidium	Serosep Enteric-Bio system GP2 Panel LP MIC30 LP MIC48
Nasopharyngeal aspirate Nasopharyngeal swab	Detection of RNA: of:  Influenza A Influenza B Respiratory syncytial virus SARS CoV-2 RNA sequences E and N2	Real Time PCR Using Cepheid GeneXpert LP MIC 51  Xpert Xpress CoV-2/Flu/RSV plus
Faeces	Norovirus	Xpert Norovirus
Serum Plasma	Quantitative Hepatitis C viral load	Xpert HCV Viral Load
Plasma	Quantitative HIV-1 viral load	Xpert HIV-1 Viral Load XC
Urine Cervical swabs	<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	Xpert CT/NG
Rectal swabs	Vancomycin resistant enterococcus: differentiation vanA and vanB genes	Xpert vanA/vanB
Rectal swabs	Carba R: differentiation of KPC, NDM, VIM, IMP-1 and OXA-48	Xpert Carba-R
END		