

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8357</p> <p>Accredited to ISO 15189:2012</p>	<h3>East Lancashire Hospitals NHS Trust</h3> <p>Issue No: 004 Issue date: 17 October 2024</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
HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on UK SMIs in conjunction with equipment manuals for instruction as stated:
Swabs, tissue, human bodily fluids, pus, IV devices & catheter tips from eyes, wounds, nose, throat, ears, genital sites & IUCD	General Bacteriology General isolation and characterisation of micro-organisms of clinical significance	Manual culture using solid agar media using SOPs ELMIC/E/128 & ELMIC/E/130
Faeces	General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157	Manual culture methods using selective agar and using SOP ELMIC/E/123
Respiratory fluids (sputum, bronchial washings)	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOP ELMIC/E/6168
Intraocular fluids, corneal scrapings	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOP ELMIC/E/6137
Swabs from nose, perineum and wound sites	Isolation of MRSA	Automated method using COPAN WASP and SOP ELMIC/E/6195 Manual culture using chromogenic agar and SOP ELMIC/E/127
Urine	Examination and quantitation for white and red blood cells, bacteria, casts and epithelial cells	SOP ELMIC/E/6173 using Menarini SediMAX conTRUST



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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 based on UK SMLs in conjunction with equipment manuals for instruction as stated:
Urine	General isolation and characterisation of micro-organisms of clinical significance	SOP ELMIC/E/6176 using the MAST Urisystem Manual culture using SOP ELMIC/E/124
Blood cultures and fluids from sterile sites	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	SOP ELMIC/E/044 using Biomerieux BacT/Alert Virtuo automated system and manual culture methods
Human bodily fluids (other than urine) including CSF	Examination and quantitation of white and red blood cells, bacteria	SOP ELMIC/E/131 by manual microscopy
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopy examination and Hay's criteria SOP ELMIC/E/6187 SOP ELMIC/E/130
Human bodily fluids (other than urine) including CSF and tissue	Detection, identification and semi-quantification of: White blood cells, Bacterial cells, Yeast cells and fungal hyphae, and clue cells	Direct examination using staining techniques and light microscopy and Gram staining SOP ELMIC/E/6187
Bacterial cultures (isolated in-house)	Identification and characterisation of micro-organisms	Manual methods using commercial kits (Biomerieux API 20E, 10S and API NH) SOP ELMIC/E/6186 Automated methods using the Bruker MALDI-TOF SOP ELMIC/E/6175



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Bacterial cultures (isolated in-house)</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Antimicrobial susceptibility testing of clinically significant bacteria.</p>	<p>In-house documented procedures based on UK SMLs in conjunction with equipment manuals for instruction as stated:</p> <p>MIC determination using Vitek 2 XL and Densicheck SOP ELMIC/E/6154</p> <p>EUCAST guidelines SOP ELMIC/E/6166</p> <p>Gradient MIC determination by Liofilchem MIC strips SOP ELMIC/E/6166</p> <p>Carbapenamase Producing Organisms using Neo-Rapid Carb test SOP ELMIC/E/6181</p> <p>ESBL detection using EUCAST guidelines with MAST discs SOP ELMIC/E/6166</p> <p>Detection of MecA using immunochromatography, Clearview PBP2a SA culture colony test SOP ELMIC/E/6166</p> <p>Manual disc diffusion using EUCAST guidelines SOP ELMIC/E/6166</p>
<p>Respiratory samples, human body fluids, urine, faeces, pus, swabs, tissue</p>	<p>Detection of <i>Mycobacterium</i> species</p>	<p>Automated platform for culture using the BD MGIT for TB investigation: SOP ELMIC/E/135</p> <p>Manual culture methods using Löwenstein–Jensen media: SOP ELMIC/E/135</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 based on UK SMLs in conjunction with equipment manuals for instruction as stated:
Respiratory samples, human body fluids, urine, faeces, pus, swabs, tissue and positive mycobacterial broth cultures from positive MGIT tubes and organisms from positive LJ slopes	Acid Fast Bacilli	Phenol Auramine stain with fluorescent microscopy: SOP ELMIC/E/6187 SOP ELMIC/E/135
Urine	Detection of Legionella pneumophila antigen	SOP ELMIC/E/6130 using Binax NOW immunochromatography kit
Urine & CSF	Detection of <i>Streptococcus pneumoniae</i> antigen	SOP ELMIC/E/6131 using Binax NOW immunochromatography kit
Nasopharyngeal & tracheal aspirates	Detection of respiratory syncytial virus (RSV) antigen	SOP ELMIC/E/049 using Binax NOW immunochromatography kit
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen	SOP ELMIC/E/6124 using DS2 analyser (ELISA)
Faeces	Detection of <i>Helicobacter pylori</i> antigen	SOP ELMIC/E/6123 using DS2 analyser (ELISA)
	<u>Parasitology</u>	
Faeces, urine & a perianal samples	Examination for the presence of parasites of clinical significance	SOP ELMIC/E/030 Manual microscopy using document in house procedure and/or concentration using Parasep system and manual microscopy
Faeces	Detection of <i>Cryptosporidium</i> and <i>Giardia lamblia</i> antigens	SOP ELMIC/E/6124 using DS2 analyser (ELISA)
Faeces	Detection of <i>Cryptosporidium spp.</i> and <i>Cyclospora spp.</i>	Fluorescent microscopy using an auramine phenol stain and confirmation using a Ziehl Neelsen staining and light microscopy following SOP ELMIC/E/6187



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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 based on UK SMI in conjunction with equipment manuals for instruction as stated:
Hair, skin scrapings & nail clippings	<u>Mycology</u> General isolation and characterisation of fungi of clinical significance	Documented in-house manual procedure ELMIC/E/042 Direct microscopy of KOH digested samples and culture on selective solid agar media using SOP ELMIC/E/042
Fungal culture	Identification of yeasts	Chromogenic agar SOP ELMIC/E/042
Blood	<u>Viral Serology</u> Detection of Gamma Interferon (in response to TB antigen)	SOP ELMIC/E/6162 using QuantiFERON-TB Gold ELISA and DS2 analyser
Serum / plasma	Detection of <i>Varicella-Zoster</i> IgG	SOP ELMIC/E/6148 by immunoassay using Biomerieux mini-Vidas
Nose swab	Detection of influenza A and B	SOP ELMIC/E/6177 Polymerase chain reaction using Abbott ID NOW
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