


# Schedule of Accreditation

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## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<b>East Kent University Hospitals NHS Foundation Trust</b>	
	<b>Issue No:</b> 002	<b>Issue date:</b> 09 June 2019
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<b>Testing performed at the above address only</b>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<b>HUMAN BODY FLUIDS AND TISSUES</b>  Swabs from eyes, wounds, nose, throat, ears, genital sites, respiratory fluids (sputum, bronchial washings). Invasive medical devices  Urine  Faeces	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>  <u>General microbiology</u>  General isolation and characterisation of organisms for clinical significance  General isolation and characterisation of organisms for clinical significance  General isolation and characterisation of Salmonella, Shigella, Campylobacter, E.coli 0157. Vibrios, Yersinia and Aeromonas	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.  Manual culture using documented in-house procedures: MIC-LP-025 MIC-LP-022 MIC-LP-042 MIC-LP-035 MIC-LP-024 MIC-LP-034 MIC-WI-091 MIC-WI-068 MIC-WI-069  Manual culture using documented in-house procedure: MIC-LP-034  Manual culture and commercial kits (E.coli 0157 – Remel and API20E – Biomerieux) using documented in-house procedure: MIC-LP-039



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Whole blood	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.</p> <p>Automated and manual methods using: Colorimetry using Biomerieux Bact Alert 3D and using documented in-house procedure: MIC-LP-130</p> <p>Manual culture and microscopy using documented in-house procedures: MIC-LP-019 MIC-LP-035</p>
Fluids from CSF, CAPD, ascitic and peritoneal fluids. Other sterile fluids and tissues	General isolation and characterisation of organisms for clinical significance	Manual culture and microscopy using documented in-house procedures: MIC-LP-022 MIC-LP-032 MIC-LP-035 MIC-LP-119 MIC-WI-534 MIC-WI-535
Bacterial culture isolates produced by the laboratory and direct from Blood Cultures	Antimicrobial susceptibility testing	<p>Automated and/or manual methods using: photometry using Beckman Coulter Microscan Walkaway Plus using documented in-house procedure MIC-LP-097</p> <p>Manual disc diffusion using documented in-house procedure MIC-WI-190 MIC LP 144</p>
Yeast culture isolates produced by the laboratory and direct from Blood Cultures	Candida antifungal susceptibility testing	Manual susceptibility testing using documented in-house procedure MIC-LP-120



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Bacterial isolates produced by the laboratory and direct from Blood Cultures</p> <p>Blood Culture, Pus samples, eye swabs, genital swabs, wound swabs, fluids, urine, invasive medical devices</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Identification of bacteria</p> <p>Differentiation between different organism types: gram positive/negative/variable, branching organisms, yeast, fungal hyphae</p> <p>Detection of white and red blood cells, crystals, epithelial cells, casts, bacteria and yeasts</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.</p> <p>Automated and/or Manual methods using: Mass spectrometry Bruker MALDI-ToF and using documented in-house procedure MIC-LP-125</p> <p>Automated photometry using Beckman Coulter Microscan Walkaway Plus and documented in-house procedure MIC-LP-097</p> <p>Manual biochemical identification using commercial kits using documented in-house procedures MIC-LP-035, MIC-LP-039</p> <p>Gram stain using Light microscopy and documented in-house procedures: MIC-LP-035 MIC-LP-032 MIC-LP-034 MIC-LP-370 MIC-LP-119 MIC-WI-674</p> <p>Automated and/or manual examination using: Digital image technology Menarini Sedimax and documented in-house procedures: MIC-LP-034 MIC-WI-674</p> <p>Light microscopy using documented in-house procedures: MIC-LP-034 MIC-LP-126 MIC-WI-674</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Genital samples; High Vaginal Swab, endocervical, urethral.</p> <p>Swabs from nose/axilla, groin/throat or from open lesion and Urine</p> <p>CSF, pleural fluids, ascitic fluids</p> <p>Urine</p> <p>Faeces</p> <p>Faeces</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of Trichomonas vaginalis, yeasts, white blood cells, clue cells.</p> <p>Isolation of MRSA</p> <p>Examination for white and red blood cells, bacteria and yeasts</p> <p>Legionella Antigen Strep pneumonia Antigen</p> <p>Norovirus antigen</p> <p>Rota/Adenovirus antigen detection</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.</p> <p>Light microscopy using documented in-house procedure: MIC-LP-126 Gram stain using documented in-house procedure: MIC-LP-035</p> <p>Direct culture using chromogenic agar and documented in-house procedure: MIC-LP-023</p> <p>Light microscopy using documented in-house procedures: MIC-LP-032 MIC-LP-119</p> <p>TRU Legionella and TRU Strep Pneumo TRU lateral-flow immunoassay using documented in-house procedure MIC-LP-160 Manual EIA using RIDAQUICK Norovirus Kit, Biopharm and documented in-house procedures: MIC-LP-035 MIC-LP-039</p> <p>Manual EIA using a commercial kit (RIDA QUICK Rota/Adenovirus – Biopharm) using documented in-house procedure MIC-LP-035, MIC-LP-039</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.
Faeces	Detection of <i>Clostridium difficile</i> Glutamate dehydrogenase & toxin	Automated and/or manual method using: EIA plate assay – (Techlab C.difficile GDH antigen test Alere kit) and DYNEX DS2 and documented in-house procedures: MIC-LP-129 MIC-WI-163 MIC-WI-164  Manual EIA pallet test (Techlab C. difficile complete – Alere) and (RIDAQUICK C.diff A/B – Biopharm) using documented in-house procedure: MIC-WI-163
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Automated EIA plate assay (IDEIA Hp StAR Oxoid EIA) using DYNEX DS2 and documented in-house procedures: MIC-LP-123 MIC-LP-129
Primary Faeces sample	<u>Parasitology</u> Examination for the presence of parasites of clinical significance	Concentration using commercial faecal parasite concentrators (PARASEP-DYNEX) Light microscopy using documented in-house procedure: MIC-LP- 040 and measurement of parasites using graticule



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.
Primary Faeces sample	<u>Parasitology</u> (cont'd) Detection of Cryptosporidium and Giardia antigen	Automated ELISA plate assay (RIDAQUICK Crypto/Giardia – Biopharm) using DYNEX DS2 and documented in-house procedures: MIC-LP-040 MIC-LP-129 MIC-WI-758
Urine	Confirmation for Cryptosporidium Examination for the presence of Schistosoma haematobium	Auramine microscopy using documented in-house procedure: MIC-LP-035 Light microscopy using documented in-house procedure: MIC-LP-040
Primary samples of Nail, Hair, Skin, Tissue	<u>Mycology</u> General isolation and characterisation of fungi and yeasts of clinical significance	Manual culture Light microscopy and Calcofluor white stain and using documented in-house procedure: MIC-LP-020
Fungal culture isolates produced by the laboratory	General identification and characterisation of fungi and yeasts of clinical significance	Automated and/or manual method using: Mass spectrometry - Bruker MALDI-ToF using documented in-house procedure: MIC-LP-125 Manual Light microscopy using documented in-house procedure: MIC-LP-020



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.
Swabs in manufacturers sample collection tube (high vaginal, endocervical, urethral, rectal and throat) Urine	<u>Molecular Testing</u>  Detection of Chlamydia trachomatis & Neisseria gonorrhoeae (GC) RNA (ribonucleic acid)	Automated Polymerase Chain Reaction (PCR) using Hologic Panther and documented in-house procedure: MIC-LP-122
Swabs in viral transport media (throat, vesicle, eye, rectal and genital)	Confirmation of Chlamydia & Neisseria gonorrhoea (GC) RNA  Detection of HSV 1&2 DNA	Automated PCR using Hain Fluorocycler using documented in-house procedures: MIC-LP-047 MIC-LP-124
Swabs in virus transport medium (nasopharyngeal and throat), BAL, nasopharyngeal aspirates, endotracheal secretions	Detection of: Bocavirus DNA Coronavirus RNA Enterovirus RNA Metapneumovirus RNA Respiratory syncytial virus RNA Influenza A & B RNA Parainfluenza RNA Rhinovirus RNA	Automated PCR using Seegene Allplex and using documented in-house procedures: MIC-LP-105 MIC-LP-047
Serum/Plasma	HIV viral load HCV viral load HBV viral load CMV viral load	Automated PCR using Abbott M2000 using documented in-house procedure MIC-LP-138, MIC-LP-139, MIC-LP-141, MIC-INF-3, MIC-INF-4, MIC-LP-162
Faeces	Qualitative detection of: <i>Salmonella</i> spp. <i>Campylobacter</i> spp. ( <i>jejuni</i> and <i>coli</i> only) Shigellosis disease causing agents [ <i>Shigella</i> spp. and Enteroinvasive <i>E. coli</i> (EIEC)] Shiga-toxin producing organisms	Automated RT-PCR BD MAX System with the BD MAX Enteric Bacterial Panel using the documented in-house procedure MIC-LP- 140



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.
Serum/Plasma	<u>Virology</u>  Detection of: Hepatitis A IgG & IgM Hepatitis B surface antigen Hepatitis B e-antigen anti HBe anti HBs Hepatitis B core IgM Hepatitis B total core antibody Rubella antibody IgG Rubella antibody IgM Cytomegalovirus IgG Toxoplasma IgG Cytomegalovirus avidity testing Cytomegalovirus IgM Toxoplasma IgMHTLV I/II	Automated immunoassay using Abbott Architect i2000SR and using documented in-house procedure: MIC-LP-104
Serum/Plasma	EBV IgG/IgM EBNA	MIC-LP-154
Serum/Plasma	Detection of Hepatitis C antibody	Automated immunoassay using Abbott Architect i2000SR and documented in-house procedures: MIC-LP-104 MIC-WI-555
Serum/Plasma	Detection of HIV p24 antigen and antibody to HIV 1 and 2 (combined assay)	Automated immunoassay using Abbott Architect i2000SR using documented in-house procedures: MIC-LP-104 MIC-WI-545
Serum/Plasma	Detection of Syphilis antibody	Automated immunoassay using Abbott Architect i2000SR using documented in-house procedure MIC-LP-104, MIC-WI-653





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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Virology (cont'd)</u></p> <p>Detection of: Varicella-Zoster antibody Measles IgG Mumps IgG HIV p24 antigen and antibody to HIV 1 and 2 (combined assay) Hepatitis B surface antigen Lymes IgG</p> <p>Hep E IgG/IgM</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.</p> <p>Automated immunoassay using Biomerieux mini-VIDAS and using documented in-house procedure: MIC-LP-115</p>
CSF/Serum Serum/Plasma		
Serum	Detection of Varicella-zoster virus IgG	Automated ELISA plate assay (Binding site) using DYNEX DS2 and documented in-house procedure: MIC-LP-114
Serum/Plasma	Detection of Parvovirus IgG and IgM	Automated Biotrin ELISA plate assay using DYNEX DS2 using documented in-house procedure MIC-LP-114
Serum/Plasma	Detection of Hepatitis C virus Ab	VIDAS using documented procedure MIC-LP-153
Serum/Plasma	Detection of Mycoplasma pneumonia IgM	Automated ELISA plate assay Novalisa using DYNEX DS2 using documented in-house procedure: MIC-LP-114
Serum/Plasma	Detection of Rubella IgG	Manual latex assay using Biokit Rubagen using documented procedure MIC-LP-147



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where, to support clinical diagnosis.
Nasopharyngeal aspirates	<u>Virology (cont'd)</u> RSV fusion protein antigen detection	Lateral flow using nitrocellulose strip (Bioconnections RSV Respi-strip) and documented in-house procedure: MIC-LP-047
CSF or Serum	Detection of Cryptococcal antigen	Lateral flow assay using a commercial kit (CrAg –IMMY) using documented in-house procedure: MIC-LP-047
Serum/Plasma	Differential detection of antibodies to HIV 1 and 2	Automated immunoassay using Biorad Geenius and using documented in-house procedures: MIC-LP-055 MIC-WI-745
Cerebrospinal fluid * *Excludes samples from immunocompromised patients	Detection of the following microorganisms using the Meningitis/Encephalitis panel:  Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cryptococcus gattii/neoformans Cytomegalovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Enterovirus Human parechovirus Varicella zoster virus Cryptococcus neoformans/gattiiA	Biomerieux Biofire film array Multiplexed nucleic acid molecular detection using Procedure MIC-LP-148



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