


# 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>	<b>East Kent Hospitals University NHS Foundation Trust</b> Issue No: 010 Issue date: 04 December 2025	
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### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES  Swabs from eyes, wounds, nose, throat, ears, genital sites, respiratory fluids (sputum, bronchial washings). Invasive medical devices  Urine  Faeces	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p><u>General microbiology</u></p> <p>General isolation and characterisation of organisms for clinical significance</p> <p>General isolation and characterisation of organisms for clinical significance</p> <p>General isolation and characterisation of Salmonella, Shigella, Campylobacter, E. coli 0157, Vibrios, Yersinia and Aeromonas</p>	<p>In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.</p> <p>Manual culture using documented in-house procedures:                      MIC-LP-025                      MIC-LP-022                      MIC-LP-042                      MIC-LP-128                      MIC-LP-024                      MIC-LP-034</p> <p>Automated culture using Beckman Coulter DxM Autoplak System and documented in-house procedure:                      MIC-LP-189</p> <p>Manual culture using documented in-house procedure:                      MIC-LP-034</p> <p>Manual biochemical identification using commercial kits (E. coli 0157 – ProLab and API20E – Biomerieux) using documented in-house procedures                      MIC-LP-039</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Whole blood</p> <p>Fluids from CSF, CAPD, ascitic and peritoneal fluids. Other sterile fluids and tissues</p> <p>Bacterial culture isolates produced by the laboratory and direct from Blood Cultures</p>	<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>General isolation and characterisation of organisms for clinical significance</p> <p>Antimicrobial susceptibility testing</p>	<p>In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.</p> <p>Automated and manual methods using: Colorimetry using Biomerieux Bact Alert VirtuO and using documented in-house procedure: MIC-LP-130</p> <p>Manual culture and microscopy using documented in-house procedures: MIC-LP-019</p> <p>Manual culture and microscopy using documented in-house procedures: MIC-LP-022 MIC-LP-032 MIC-LP-119</p> <p>Automated and/or manual methods using: Microbroth methodology and 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 LP 144</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 relevant, to support clinical diagnosis.
Isolated colonies from plates	Identification and antibiotic sensitivity testing of medically important bacterial species Gram negative combination panel NM62 ( <i>E. coli</i> ATCC 25922, <i>P. aeruginosa</i> ATCC 27853, <i>K. pneumoniae</i> NCTC 13368 ESBL+, <i>K. pneumoniae</i> NCTC 13440 MBL+, <i>K. pneumoniae</i> NCTC 13442 OXA 48+, <i>K. pneumoniae</i> NCTC 13438 KPC+)	MicroScan Walkaway 96 system (Beckman Coulter) using a 2-fold microbroth dilution system for microbial screening, by determination of MIC LabPro expert system software for the interpretation and analysis of results obtained MIC-LP-097
Yeast culture isolates produced by the laboratory or referred from external Laboratories	Candida and Cryptococcal antifungal susceptibility testing	Manual susceptibility testing using Yeastone for systemic for topical using documented in-house procedure MIC-LP-120
Bacterial isolates produced by the laboratory and direct from Blood Cultures	Identification of bacteria	Manual biochemical identification using commercial kits using documented in-house procedures MIC-LP-039
Blood Culture, Pus samples, eye swabs, genital swabs, wound swabs, fluids, urine, invasive medical devices	Differentiation between different organism types: gram positive/negative/variable, branching organisms, yeast, fungal hyphae	Gram stain using Light microscopy and documented in-house procedures:  MIC-LP-032 MIC-LP-034  MIC-LP-119 MIC-LP-126 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 relevant, to support clinical diagnosis.
Urine	Detection of white and red blood cells, crystals, epithelial cells, casts, bacteria and yeasts	Automated urine microscopy using Iris iQ Sprint and documented in-house procedure: MIC-LP-183  Manual examination using: Light microscopy using documented in-house procedures: MIC-LP-034 MIC-LP-126
Genital samples; High Vaginal Swab, endocervical, urethral.	Detection of, yeasts, white blood cells,	Light microscopy and Gram stain using documented in-house procedure: MIC-LP-126
Swabs from nose/axilla, groin/throat or from open lesion and Urine	Isolation of MRSA and Staph aureus	Direct culture using chromogenic agar and documented in-house procedure: MIC-LP-023
CSF, pleural fluids, ascitic fluids	Examination for white and red blood cells, bacteria, yeasts and parasites	Light microscopy using documented in-house procedures: MIC-LP-032 MIC-LP-119 MIC-LP-126
Faeces	Norovirus antigen	Manual EIA using RIDAQUICK Norovirus Kit, R-biopharm and documented in-house procedures: MIC-LP-171
Faeces	Rota/Adenovirus antigen detection	Manual EIA using a commercial kit (RIDA QUICK Rota/Adenovirus – R-biopharm) using documented in-house procedure MIC-LP-171



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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 relevant, to support clinical diagnosis.
Faeces	Detection of <i>Clostridium difficile</i> GDH (Glutamate dehydrogenase) & toxin	Manual method using: Manual EIA pallet test (Techlab C. difficile complete – Alere) and (RIDAQUICK C.diff A/B – Rbiopharm) using documented in-house procedure: MIC-LP-100
Isolated colonies from bacteria and Candida	Microorganism identification	Vitek MS Prime system, MALDI-TOF MIC-LP-245
Primary samples of Nail, Hair, Skin, Tissue	<u>Mycology</u> Isolation and characterisation of fungi and yeasts of clinical significance	Manual culture Light microscopy and Calcoflor white stain and using documented in-house procedure: MIC-LP-020
Fungal culture isolates produced by the laboratory	Identification of fungi and yeasts of clinical significance	Manual Light microscopy using documented in-house procedure: MIC-LP-020



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology 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 relevant, to support clinical diagnosis.
Swabs in manufacturers sample collection tube (high vaginal, endocervical, urethral,rectal and throat) Urine	Detection of Chlamydia trachomatis Neisseria gonorrhoeae (GC) (nucleic acid)  Detection of Mycoplasma genitalium (nucleic acid)	Automated Polymerase Chain Reaction (PCR) using Abbott Alinity-M STI assay and documented in-house procedure: MIC-LP-201 MIC-LP-202
Endocervical and vaginal swabs, and urine	<i>Trichomonas vaginalis</i>	Abbott Alinity-M STI assay automated RT-PCR MIC-LP-202
Endocervical and vaginal swabs, and urine	Confirmation of Neisseria gonorrhoea (GC) DNA	Automated Polymerase Chain Reaction (PCR) using ELITE Ingenius and documented in-house procedure: MIC-LP-195
Lesion/mucosal swabs	Detection of HSV 1&2 DNA	Abbott Alinity-M HSV1&2 and VZV (HSV1&2/VZV) AMP assay (RT-PCR) MIC-LP-249
Urogenital samples and urine	<i>Mycoplasma genitalium</i> DNA and macrolide resistance-associated mutations	ELITE Ingenius automated RT-PCR MIC-LP-236
CSF	Meningitis virus panel 1 and 2, including: HSV 1&2 VZV Enterovirus Parechovirus (hPeV) Adenovirus (hAdV)	ELITE Ingenius automated RT-PCR MIC-LP-234



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology 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 relevant, to support clinical diagnosis.
EDTA plasma and serum	Hepatitis E RNA	ELITe Ingenius automated RT-PCR using HEV ELITe MGB kit MIC-LP-241
Sputum, directed and non-directed BAL	Tuberculosis	ELITe Ingenius automated RT-PCR using tuberculosis MTB EXTRA ELITe kit and MDR/MTB ELITe MGB kit MIC-LP-246
Buccal/urine swabs, urine, VTM and EDTA plasma	CMV DNA	ELITe Ingenius automated RT-PCR using CMV ELITe MGB kit MIC-LP-235
Respiratory samples	Identification of respiratory pathogens	AusDiagnostics HighPlex, MT-processor, MT-analyser (MT-PCR) MIC-LP-247
Swabs in virus transport medium (nasopharyngeal and throat), nasopharyngeal aspirates	Detection of: Respiratory syncytial virus RNA Influenza A & B RNA and SARS-CoV-2	Automated PCR using the Abbott Alinity-M Respiratory 4-plex assay and using documented in-house procedures: MIC-LP-201 MIC-LP-203



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology 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 relevant, to support clinical diagnosis.
Cerebrospinal fluid *	Detection of the following microorganisms using the Meningitis/Encephalitis panel:	Biomerieux Biofire film array Multiplexed nucleic acid molecular detection using documented in-house procedure: MIC-LP-148
*Excludes samples from immunocompromised patients	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	
Serum/Plasma	HIV viral load HCV viral load HBV viral load	Automated PCR using Abbott Alinity-M using documented in-house procedure MIC-LP-198 MIC-LP-199 MIC-LP-200 MIC-LP-201
Plasma	BKV	Abbott Alinity-M BKV assay (RT-PCR) MIC-LP-250
Plasma	EBV	Abbott Alinity-M EBV assay (RT-PCR) MIC-LP-252
EDTA plasma and serum	HIV-1 viral load (diagnostic confirmatory testing, no qualitative results)	Abbott Alinity-M HIV-1 viral load assay (RT-PCR) MIC-LP-198



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology 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 relevant, to support clinical diagnosis.
EDTA plasma	CMV DNA	Abbott Alinity-M CMV DNA assay (RT-PCR) MIC-LP-232
Faeces	Identification of stool pathogens	Serosep EntericBio RT-PCR, Roche LightCycler, qPCR MIC-LP-196 MIC-LP-171 MIC-LP-228
Faeces	Identification of gastro panel (virus, bacteria and parasites) and panel 1&2 for viral GI disease, including: <i>Salmonella enterica</i> spp. <i>Shigella</i> spp./Enteroinvasive <i>E. coli</i> <i>Campylobacter jejuni/coli/lari</i> VTEC Cryptosporidium Giardia <i>Entamoeba histolytica</i> <i>Clostridium difficile</i> toxin B Enteric viruses Noroviruses Rotavirus A Adenoviruses F40/41 Astroviruses Sapoviruses	Serosep EntericBio RT-PCR and Fastfinder AI result analysis MIC-LP-196 MIC-LP-228



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/Plasma</p>	<p><u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of: HIV Ab/Ag* Hepatitis A IgG Hepatitis A IgM Hepatitis B surface antigen* Hepatitis B e antigen* Anti HBe* Anti HBs* Hepatitis B core IgM* Hepatitis total core antibody Rubella antibody IgG Rubella antibody IgM Cytomegalovirus IgM Cytomegalovirus IgG Mumps IgG Toxoplasma IgG Toxoplasma IgM Hepatitis C antibody Hepatitis E IgG Hepatitis E IgM Parvovirus IgM Parvovirus IgG Measles IgG Mycoplasma IgM Lymes IgG HTLV type I and/or type II Varicella zoster virus COVID-19 antibody EBV IgM EBNA IgG EBV IGG IgG CMV avidity HTLV type I and/or type II Parvovirus B19 IgG Parvovirus B19 IgM</p>	<p>In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.</p> <p>Automated CLIA analyser Diasorin Liaison XL using in-house documented procedure: MIC-LP-150 Parvovirus IgG and IgM Plus</p> <p>MIC-LP-175 Liaison XL Operation MIC-LP-176 Measles IgG MIC-LP-177 Mumps IgG MIC-LP-178 Mycoplasma IgM MIC-LP-179 VZV assay panel MIC-LP-180 Toxoplasma IgG &amp; IgM MIC-LP-181 Lymes IgG MIC-LP-182 Rubella IgG MIC-LP-216 CMV IgM MIC-LP-217 Rubella IgM MIC-LP-219 HIV Ab/Ag MIC-LP-221 SARS-CoV-2 IgG MIC-LP-222 Anti-HCV MIC-LP-223 Anti-HBs MIC-LP-224 Hep B e antigen MIC-LP-225 Anti-HBc MIC-LP-233 MUREX re-HTLV-I/II MIC-LP-239 CMV IgG &amp; avidity MIC-LP-242 Hep A assays MIC-LP-243 Hep E IgG &amp; IgM MIC-LP-244 HBsAg MIC-LP-238 EBV assay</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/Plasma</p> <p>Serum/Plasma</p> <p>Serum/Plasma</p> <p>Serum/Plasma</p>	<p><u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of: Hepatitis B surface antigen* HIV Ag/Ab* Syphilis TP antibody*</p> <p>Differential detection of antibodies to HIV 1 and 2*</p> <p>Detection of Syphilis total antibody *</p> <p>Detection of antibody to Treponema pallidum (TPHA)*</p> <p>Detection of cardiolipin and lecithin (reagin) – non-treponemal antibody test *</p>	<p>In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.</p> <p>Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy (IDPS) screening programme(s) as defined in the Laboratory QC evidence requirements (relevant tests marked with *)</p> <p>Abbott Alinity I, CLIA MIC-LP-253</p> <p>Automated immunoassay using Biorad Geenius and using documented in-house procedures: MIC-LP-206</p> <p>Automated immunoassay using Diasorin Liaison XL using documented in-house procedure MIC-LP-220 Haemagglutination assay using ASI Syphilis TPHA kit and documented in-house procedure: MIC-LP-187</p> <p>Macroscopic flocculation test using ASI Syphilis RPR kit and integrated digital particle analyser ASi-Manager AT with documented in-house procedure: MIC-LP-186</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>CSF or Serum</p> <p>Lithium heparin plasma</p>	<p><u>Serology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of Cryptococcal antigen</p> <p>Detection of Interferon-<math>\gamma</math> response to stimulation by Mycobacterium tuberculosis antigens</p>	<p>In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.</p> <p>Lateral flow assay using a commercial kit (CrAg –IMMY) using documented in-house procedure: MIC-LP-047</p> <p>Automated immunoassay using the QuantiFERON_TB Gold Plus assay on the DiaSorin Liaison XL and documented in-house procedure: MIC-LP-184</p>
END		