Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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TN24 0LZ

United Kingdom

East Kent Hospitals University NHS Foundation Trust

Issue No: 008 Issue date: 21 May 2025

Microbiology Contact: Naomi Rogers
William Harvey Hospital Tel: +44 (0)1233616213

Kennington Road E-Mail: naomi.rogers@nhs.net
Willesborough Website: www.ekhuft.nhs.uk/health-

Ashford professionals/services/pathology-

external-services

Testing performed at the above address only

DETAIL OF ACCREDITATION

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

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) General microbiology (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.
Whole blood	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	Automated and manual methods using: Colorimetry using Biomerieux Bact Alert VirtuO and using documented in-house procedure: MIC-LP-130
		Manual culture and microscopy using documented in-house procedures: MIC-LP-019
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-119
Bacterial culture isolates produced by the laboratory and direct from Blood Cultures	Antimicrobial susceptibility testing	Automated and/or manual methods using: Microbroth methodology and photometry using Beckman Coulter Microscan Walkaway Plus using documented in-house procedure MIC-LP-097 Manual disc diffusion using
		documented in-house procedure MIC LP 144
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

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) General microbiology (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.	
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	Gram stain using Light microscopy and documented in-house procedures:	
medical devices	organisms, yeast, fungal hyphae	MIC-LP-032 MIC-LP-034	
		MIC-LP-119 MIC-LP-126 MIC-LP-020	
Urine	Detection of white and red blood cells, crystals, epithelial cells, casts, bacteria and yeasts	Automated urine microscopy using Iris iQ Sprint and documented inhouse procedure: MIC-LP-183	
		Manual examination using: Light microscopy using documented inhouse procedures: MIC-LP-034 MIC-LP-126	
Genital samples; High Vaginal Swab, endocervical, urethral.	Detection of, yeasts, white blood cells, diagnosis of Bacterial vaginosis	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	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevantto support clinical diagnosis.
	General microbiology (cont'd)	
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
Faeces	Detection of Clostridium difficile 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
	<u>Parasitology</u>	
Faeces sample	Examination for the presence of parasites of clinical significance	Concentration using commercial faecal parasite concentrators (PARASEP-Apacor) Light microscopy using documented in-house procedure: MIC-LP- 040 and measurement of parasites using graticule
Urine	Examination for the presence of Schistosoma haematobium ova	Light microscopy using documented in-house procedure: MIC-LP-040

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (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.
	<u>Mycology</u>	
Primary samples of Nail, Hair, Skin, Tissue	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
	Molecular Testing	
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
	genitalium (nucleic acid)	WIG-LP-202
	Confirmation of Neisseria gonorrhoea (GC) DNA	Automated Polymerase Chain Reaction (PCR) using ELITe Ingenius and documented in-house procedure: MIC-LP-195
Swabs in viral transport media (throat, vesicle, eye, rectal and genital)	Detection of HSV 1&2 DNA	Automated Polymerase Chain Reaction (PCR) using ELITe Ingenius and documented in-house procedure: MIC-LP-195 MIC-LP-197
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 Rapid PCR using the bbott Alinity-M Respiratory 4-plex assay and using documented inhouse procedures: MIC-LP-201 MIC-LP-203
HUMAN BODY FLUIDS AND	Microbiology examination activities	In-house documented methods

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
TISSUES (cont'd)	for the purpose of clinical diagnosis (cont'd) Molecular Testing (cont'd)	based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.
Nasopharyngeal and oropharyngeal swabs	Detection of COVID-19 RNA	VIASURE SARS-CoV-2 Real Time PCR Detection Kit using documented in-house procedure MIC-LP-190 using: Extraction platform Promega Maxwell and detection platform Bio-rad CFX96 using documented in-house procedure: MIC-LP-227 and MIC-LP-192 Extraction system Biomek i5 using documented in-house procedure: MIC-LP-215
*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 documented in house procedure: MIC-LP-148
HUMAN BODY FLUIDS AND	Microbiology examination activities	In-house documented methods

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TISSUES (cont'd)	for the purpose of clinical diagnosis (cont'd) Molecular Testing (cont'd)	based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.
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
HUMAN BODY FLUIDS AND	Microbiology examination activities	Documented in-house methods to

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TISSUES (cont'd)	for the purpose of clinical diagnosis (cont'd) Virology	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 *)
Serum/Plasma	Detection of: HIV Ab/Ag* Hepatitis A IgG Hepatitis B surface antigen* Hepatitis B e antigen* Anti HBe* Anti HBs* Hepatitis B core IgM* Hepatitis B 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 IgG Measles IgG Mycoplasma IgM Lymes IgG Varicella zoster virus IgG COVID-19 antibody	Automated CLIA analyser Diasorin Liaison XL using in-house documented procedure: MIC-LP-150 Parvo IgG MIC-LP-151 Parvo IgM 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 IgG MIC-LP-180 Toxoplasma IgG & 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-239 CMV IgG & avidity MIC-LP-242 Hep A assays MIC-LP-243 Hep E IgG & IgM MIC-LP-244 HBsAg
HUMAN BODY FLUIDS AND	Microbiology examination activities	In House documented methods

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TISSUES (cont'd)	for the purpose of clinical diagnosis (cont'd)	based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevat, to support clinical diagnosis.
	<u>Virology</u> (cont'd)	
Lithium heparin plasma	Detection of Interferon-y response to stimulation by Mycobacterium tuberculosis antigens	Automated immunoassay using the QuantiFERON_TB Gold Plus (QFT-Plus) assay on the DiaSorin Liaison XL and documented inhouse procedure: MIC-LP-184
		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 *)
Serum/Plasma	Detection of Syphilis total antibody *	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
Serum/Plasma	Detection of antibody to Treponema pallidum (TPHA)* Detection of cardiolipin and lecithin (regain) – non-treponemal antibody test *	Macroscopic flocculation test using ASI Syphilis RPR kit and integrated digital particle analyser ASi-Manager AT with documented inhouse procedure: MIC-LP-186
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-206
END		

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