Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9399

Accredited to ISO 15189:2012

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Microbiology Contact: Dr Matthew Strutt

William Harvey Hospital

Tel: +44 (0)1233 616760

Kennington Road E-Mail: matthew.strutt@nhs.net
Willesborough Website: www.ekhuft.nhs.uk/pathology

Ashford TN24 0LZ

United Kingdom

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	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.
	General microbiology	
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-024 MIC-LP-034
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

Assessment Manager: HL Page 1 of 10



Schedule of Accreditation issued by

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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.
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 MIC-LP-035
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
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 documented in-house procedure MIC-LP-120

Assessment Manager: HL Page 2 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

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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 relevant to support clinical diagnosis.
Bacterial isolates produced by the laboratory and direct from Blood Cultures	Identification of bacteria	Automated and/or Manual methods using: Mass spectrometry Bruker MALDITOF and using documented inhouse procedure MIC-LP-125 Automated Biochemical identification and photometry using Beckman Coulter Microscan Walkaway Plus and documented inhouse procedure MIC-LP-097 Manual biochemical identification using commercial kits using documented inhouse procedures MIC-LP-035, 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-035 MIC-LP-032 MIC-LP-034 MIC-LP-370 MIC-LP-119
Urine	Detection of white and red blood cells, crystals, epithelial cells, casts, bacteria and yeasts	Manual examination using: Light microscopy using documented inhouse procedures: MIC-LP-034 MIC-LP-126

Assessment Manager: HL Page 3 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

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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 relevantto support clinical diagnosis.
Genital samples; High Vaginal Swab, endocervical, urethral.	Detection of, yeasts, white blood cells, diagnosis of Bacterial vaginosis	Light microscopy using documented in-house procedure: MIC-LP-126 Gram stain using documented in-house procedure: MIC-LP-035
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
Urine	Legionella Antigen Strep pneumonia Antigen	TRU Legionella and TRU Strep Pneumo TRU lateral-flow immunoassay using documented in-house procedure MIC-LP-160
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

Assessment Manager: HL Page 4 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

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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.
Detection of Clostridium difficile GDH (Glutamate dehydrogenase) & toxin	Automated and/or manual method using: EIA plate assay – (Techlab Premie C.difficile GDH antigen test Alere kit) and Stratec Gemini and documented in-house procedures: MIC-LP-173
	MIC-LP-100 Manual EIA pallet test (Techlab C. difficile complete – Alere) and (RIDAQUICK C.diff A/B – Rbiopharm) using documented in-house procedure: MIC- LP-100
Detection of Helicobacter pylori antigen	Automated EIA plate assay (Premier Platinum HpSA Plus (Meridian) using Stratec Gemini and documented in-house procedures: MIC-LP-123 MIC-LP-173
<u>Parasitology</u>	
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
	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) Detection of Clostridium difficile GDH (Glutamate dehydrogenase) & toxin Detection of Helicobacter pylori antigen Parasitology Examination for the presence of

Assessment Manager: HL Page 5 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties	Standard specifications/
	measured/Range of measurement	Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) Parasitology (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.
	,	
Faeces sample	Detection of Cryptosporidium and Giardia antigen	Automated ELISA plate assay (Crypto/Giardia –antigen detection assay) using Stratec Gemini and documented in-house procedures: MIC-LP-040 MIC-LP-173
	Confirmation for Cryptosporidium	Auramine microscopy using documented in-house procedure: MIC-LP-035
Urine	Examination for the presence of Schistosoma haematobium ova	Light microscopy using documented in-house procedure: MIC-LP-040
	Mycology	
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 Mass spectrometry - Bruker MALDI-ToF using documented in-house procedure: MIC-LP-125
Fungal culture isolates produced by the laboratory	Identification of fungi and yeasts of clinical significance	Automated and/or manual method using: Mass spectrometry - Bruker MALDI-ToF using documented inhouse procedure: MIC-LP-125 Manual Light microscopy using documented inhouse procedure: MIC-LP-020

Assessment Manager: HL Page 6 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

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Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

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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 relevat, to support clinical diagnosis.
	Molecular Testing	отр
Swabs in manufacturers sample collection tube (high vaginal, endocervical, urethral, rectal and throat) Urine	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
	Confirmation of Chlamydia & Neisseria gonorrhoea (GC) RNA	Automated Polymerase Chain Reaction (PCR) using Hologic Panther and documented in-house procedure: MIC-LP-122 MIC-WI-875
Swabs in viral transport media (throat, vesicle, eye, rectal and genital)	Detection of HSV 1&2 DNA	WIIC WI 675
Swabs in virus transport medium (nasopharyngeal and throat), nasopharyngeal aspirates	Detection of: Respiratory syncytial virus RNA Influenza A & B RNA Detection of the following microorganisms using the Meningitis/Encephalitis panel:	Automated Rapid PCR using the Liaison MDX and using documented in-house procedures: MIC-LP-165
Cerebrospinal fluid * *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	Biomerieux Biofire film array Multiplexed nucleic acid molecular detection using documented in house procedure: MIC-LP-148

Assessment Manager: HL Page 7 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd) Serum/Plasma	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) Molecular Testing cont'd HIV viral load HCV viral load HBV viral load CMV viral load	In House documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevat, to support clinical diagnosis. Automated PCR using Abbott M2000 using documented in-house procedure MIC-LP-138, MIC-LP-139, MIC-LP-141, MIC-INF-3, MIC-LP-162
Faeces	Qualitative detection of: Salmonella spp. Campylobacter spp. (jejuni and coli only) Shigellosis disease causing agents [Shigella spp. and Enteroinvasive E. coli (EIEC)] Shiga-toxin producing organisms Clostridium. difficle B toxin gene	Automated RT-PCR BD MAX System with the BD MAX Enteric Bacterial Panel using the documented in-house procedure MIC-LP- 140 MIC-LP-163
Serum/Plasma	Virology 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 anitbody 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 Detection of Hepatitis C antibody	MIC-LP-154 Automated immunoassay using Abbott Architect i2000SR and documented in-house procedures: MIC-LP-104

Assessment Manager: HL Page 8 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

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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 relevat, to support clinical diagnosis.
		'Documented -in-house methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'NHS Infectious Diseases in Pregnancy Screening (IDPS): laboratory QA evidence requirements'
Serum/Plasma	Virology cont'd 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
Serum/Plasma	Detection of Syphilis antibody	Automated immunoassay using Abbott Architect i2000SR using documented in-house procedure MIC-LP-104
Serum/Plasma	Detection of: HIV p24 antigen and antibody to HIV 1 and 2 (combined assay) Hepatitis B surface antigen Hep E IgG/IgM	Automated immunoassay using Biomerieux mini-VIDAS and using documented in-house procedure: MIC-LP-115
Serum/Plasma	Detection of Hepatitis C virus Ab	VIDAS using documented procedure MIC-LP-153
Serum/Plasma	Detection of Rubella IgG	Manual latex assay using Biokit Rubagen using documented procedure MIC-LP-147
HUMAN BODY FLUIDS AND	Microbiology examination activities	In House documented methods

Assessment Manager: HL Page 9 of 10



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East Kent University Hospitals NHS Foundation Trust

Issue No: 004 Issue date: 15 April 2021

Testing performed at main address only

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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) Virology (cont'd)	based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant, to support clinical diagnosis.
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
Serum/plasma	Detection of: Parvovirus IgM Parvovirus IgG Measles IgG Mycoplasma IgM Lymes IgG Quantitative detection of: Varicella zoster virus IgG	Automated immunoassay using the Diasorin Liaison XL and using documented in-house procedure: MIC-LP-150
END		

Assessment Manager: HL Page 10 of 10