Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Issue No: 009



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University Hospital of North Durham

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County Durham

Accredited to ISO 15189:2022

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Issue date: 30 May 2025

Website: www.cddft.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Microbiology Department University hospital of North Durham North Road Durham County Durham DH1 5TW	Local contact As above	Microbiology	UHND
Address Blood Sciences Department Darlington Memorial Hospital Hollyhurst Road Darlington DL3 6HX	Local contact As above	Microbiology	DMH

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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Routine samples: Aspirates Cellular and fluid material contained on swabs, catheter tips and intra- uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Semen Tissue Urine Bone Surgical Implants Sputum Bronchoalveolar lavage/aspirate Respiratory samples Nasopharyngeal secretions Nasal secretions	Isolation of microorganisms of clinical significance	Manual culture methods using various solid agar media: LP/PA/MB/EXAM5 LP/PA/MB/EXAM4 LP/PA/MB/EXAM21 LP/PA/MB/EXAM7 LP/PA/MP/EXAM19 LP/PA/MB/EXAM18 LP/PA/MB/EXAM15	
Cultures isolated in-house from all samples listed above.	Identification of microorganism of clinical significance.	Maldi Biotyper MBT Compass IVD Matrix Assisted Laser Desorption/Ionisation Time of Flight Mass Spectrometry LP/PA/MB/EQUIP37 and LP/PA/MB/EXAM30 Conventional identification methods including biochemical, latex agglutinations: LP/PA/MB/KIT4 LP/PA/MB/KIT2	
Cellular and fluid material contained on swabs	Screening for Methicillin- Resistant <i>Staphylococcus</i> <i>aureus</i> (MRSA)	Manual culture using chromogenic selective solid agar media using: LP/PA/MB/EXAM3	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Blood and fluids from sterile sites	Isolation of microorganisms of clinical significance	Liquid media culture using automated continuous monitoring system: BD BACTEC Fx Blood Culture analyser using manufacturer's instruction and: LP/PA/MB/EQUIP26	
Fluids: Ascitic fluid Joint fluids Cerebrospinal fluid (CSF) Pus Drain fluids Peritoneal fluid Continual Peritoneal Ambulatory Dialysis Wound Bile	Isolation of microorganisms of clinical significance	Manual culture methods using various solid agar media: LP/PA/MB/EXAM18 LP/PA/MB/EXAM3	
Intra-ocular fluid Corneal scrapes	Isolation of microorganisms of clinical significance	Manual culture methods using various solid agar media: LP/PA/MB/EXAM26	
Cellular and fluid material contained on swabs	Screening for Carbapenemase-producing Enterobacteriaceae (CPE)	Manual culture using chromogenic selective solid agar media using: LP/PA/MB/EXAM22	
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: Campylobacter spp. Clostridium difficile Escherichia coli O157 Salmonella sp. Shigella spp. Vibrio spp. Yersinia spp.	Manual culture methods using various solid agar media: LP/PA/MB/EXAM21	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Cultures isolated in-house from all samples listed above	Identification of Staphylococcal isolates	Bio-rad Pastorex Staph Plus LP/PA/MB/KIT6	
Cultures isolated in-house from all samples listed above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Streptococcal Grouping kit. LP/PA/MB/KIT7	
Cultures isolated in house from the above	Detection of Salmonella polyvalent 'O' (PSO) and Salmonella polyvalent 'H' (PSH); Shigella species	Oxoid agglutination sera	
Cultures isolated in house from the above	Identification of E. coli O157	Oxoid E.coli O157 Latex Test LP/PA/MB/KIT9	
Bacterial cultures isolated in- house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual (EUCAST) by disc diffusion and gradient MIC using SOPs: LP/PA/MB/EXAM23 LP/PA/MB/KIT14	
Fluids Tissues Pus Cerebrospinal fluid Ascitic fluid Genital swabs	Detection, identification and semi-quantification of: White blood cells Bacterial cells Yeast cells and fungal hyphae Clue cells	Direct examination using staining techniques and light microscopy and Gram staining. LP/PA/MB/KIT33	
Cerebrospinal fluid Ascitic fluids	White blood cell type differential	Direct examination using staining techniques and light microscopy and Gram and Methylene blue staining. LP/PA/MB/KIT33	
Cerebrospinal fluid Ascitic fluids	Quantification of white and red blood cells.	Direct manual microscopy using light microscopy: LP/PA/MB/EXAM18 LP/PA/MB/EXAM3 LP/PA/MB/EXAM25	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Urine	Quantification of white blood cells and epithelial cells.	Automated microscopy: 1Q200 Sprint urine analyser using manufacturer's instructions and LP/PA/MB/EQUIP25 Direct examination using light microscopy and SOP: LP/PA/MB/EQUIP25 (contingency)	
Urine	Detection and characterisation of urinary casts	Automated microscopy: 1Q200 Sprint urine analyser using manufacturer's instructions and LP/PA/MB/EQUIP25 Direct examination using light microscopy and SOP: LP/PA/MB/EQUIP25(contingency)	
Faeces	Detection of ova, cysts and parasites	Concentration using midi-parasep concentrator and examination of deposit by light microscopy following manufacturer's instructions and SOP: LP/PA/MB/EXAM11	
Pus/fluids	Detection of ova, cysts and parasites	Direct preparations observed using light microscopy following SOP: LP/PA/MB/EXAM11	
Perianal Swab	Detection of <i>E.vermicularis</i> ova and larvae	Concentration using centrifugation and examination of deposit using light microscopy following SOP: LP/PA/MB/EXAM11	
Urine	Detection of Schistosoma spp	Concentration using centrifugation and examination of deposit using light microscopy following SOP: LP/PA/MB/EXAM11	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Faeces	Detection of Cryptosporidia spp and Cyclospora spp	Fluorescent microscopy using an auramine phenol stain and confirmation using a Ziehl Neelsen staining and light microscopy following SOP: LP/PA/MB/EXAM11	
Cellular and fluid material contained on swabs (genital)	Detection of <i>Trichomonas</i> vaginalis	Culture using liquid broth media and examination with light microscopy following SOP: LP/PA/MB/EXAM7	
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopy examination using: LP/PA/MB/EXAM5	
Skin Nail hair	Isolation and identification of clinically significant dermatophyte fungi	Direct microscopy of KOH digested samples and culture on selective solid agar media using SOP: LP/PA/MB/EXAM9	
Faeces	Detection of toxigenic Clostridium difficile GDH antigen	Lateral flow chromatograph for detection of GDH antigen (Pro-lab) using manufacturer's instructions and SOP: LP/PA/MB/KIT11	
Faeces	Detection of toxigenic Clostridium difficile Toxin A&B	Enzyme linked fluorescent immunoassay (ELFA) for detection of toxin A&B using a mini-Vidas (Biomerieux) following manufacturer's instructions and SOP: LP/PA/MB/KIT8	
		Cepheid GeneXpert real time PCR with manufacturer's instructions and LP/PA/MB/EQUIP30	
Faeces	Gene detection for Toxin A&B of toxigenic <i>Clostridium difficile</i>	SOP: LP/PA/MB/KIT22	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	UHND
Throat swab Nasal swab Throat/nasal swab Nasopharyngeal secretions	Detection of RSV and Influenza A & B	SOP: LP/PA/MB/KIT24	
Nasal swab Groin swab	Detection of Methicillin- Resistant <i>Staphylococcus</i> <i>aureus</i> (MRSA)	LP/PA/MB/KIT23	
Nasal and throat swab	Detection of RSV and Influenza A & B	CEPHEID Xpert Xpress real time PCR with manufacturer's instructions and LP/PA/MB/EQUIP30	DMH
Faeces	Detection of Rota Virus and Adenovirus	Lateral flow immunochromatograph Certest for Rotavirus and Adenovirus antigens using manufacturer's instructions and SOP LP/PA/MB/KIT12	
Faeces	Detection of Norovirus	Lateral flow immunochromatograph (r- Biopharm) for Norovirus antigen using manufacturer's instructions and SOP LP/PA/MB/KIT10	

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	Serological examination activities for the purposes of clinical diagnosis	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the current version of "Infectious diseases in pregnancy screening: laboratory QA evidence requirements"	
Serum	Detection of:	Manufacturer's instructions for Biomerieux Mini Vidas analyser, Enzyme linked fluorescent immunoassay (ELFA) and SOP's	
	Hep B surface Ag Hep C Ab HIVp24 Ag HIV 1 &HIV 2 Ab	LP/PA/MB/EQUIP31	
Serum	Determination of Anti- Streptolysin O titre	Manual test (Biokit) following manufacturer's instructions and LP/PA/MB/KIT15	
Serum	Detection of:	Manufacturer's instructions for Biomerieux Mini Vidas analyser, Enzyme linked fluorescent immunoassay (ELFA) and SOP's	UHND
	Hep B surface Antigen Hep C Antibody HIVp24 Antigen HIV 1 &HIV 2 Antibody	LP/PA/MB/EQUIP31	

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd) Serological examination activities for the purposes of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	
		Manufacturer's instructions for Biomerieux Vidas 30 analyser, Enzyme linked fluorescent immunoassay (ELFA) and SOP's LP/PA/MB/EQUIP34	UHND
	Varicella Zoster IgG Rubella IgG Measles IgG Hep B core antibody Hep A IgM Hep A total antibody	LP/PA/MB/KIT 34 LP/PA/MB/KIT 36 LP/PA/MB/KIT 35 LP/PA/MB/KIT 37 LP/PA/MB/KIT 38 LP/PA/MB/KIT 39	
Serum	HIVp24 Antigen HIV 1 &HIV 2 Antibody Treponema Pallidum (syphilis) antibody Hep B surface Antigen Hep B surface Antibody Hep C Antibody	Manufacturer's instructions for Siemens Advia Centaur XPT analyser and SOP's LP/PA/MB/KIT 40 LP/PA/MB/KIT 41 LP/PA/MB/KIT 42 LP/PA/MB/KIT 43 LP/PA/MB/KIT 44	UHND

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented inhouse procedures by the following methods:	
	Serological examination activities for the purposes of clinical diagnosis (cont'd)		
Swab & Urine	Chlamydia, Gonorrhoea and HSV	Transcription mediated amplification and RTPCR using Hologic Panther LP/PA/MB/EXAM37 LP/PA/MB/KIT68 LP/PA/MB/KIT69 LP/PA/MB/KIT70 LP/PA/MB/KIT71	UHND
Swabs & NPA	SARS-CoV-2, Flu and RSV	PCR using Cepheid GX-16 LP/PA/MB/EQUIP30 LP/PA/MB/KIT72	UHND
Swab & Culture	CPE	Cepheid GX-16 LP/PA/MB/KIT57 LP/PA/MB/EQUIP	UHND
END			

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