Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9693

Accredited to ISO 15189:2022

Northumbria Healthcare NHS Foundation Trust

Issue No: 008 Issue date: 03 February 2025

Microbiology Department

North Tyneside General Hospital

Rake Lane

North Shields

NE29 8NH

Contact: Mr Jonathan Boxshall

E-Mail: Jonathan.boxshall@nhct.nhs.uk

Website: www.northumbria.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 As above	Local contact As above	Microbiology Serology Molecular	A
PCR room Pathology department Northumbria Specialist Emergency care hospital Northumbrian Way Cramlington NE23 6NZ	As above	Molecular	В



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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	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
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 Tissues Urine	Isolation of microorganisms of clinical significance	Manual inoculation and Automated inoculation using the WASP and incubation of culture media using: LP-MIC-GTS-N-280 LP-MIC-GEN-N-187LP-MIC-GEN-N-009 LP-MIC-GEN-N-010 LP-MIC-GEN-N-020 LP-MIC-GEN-N-050 LP-MIC-GEN-N-050 LP-MIC-GEN-N-050 LP-MIC-GEN-N-110 LP-MIC-GEN-N-110 LP-MIC-GEN-N-271 LP-MIC-CAT-N-271 LP-MIC-CAT-N-472 LP-MIC-URI-N-350	A
Cellular and fluid material contained on swabs	Screening for Methicillin- Resistant Staphylococcus aureus (MRSA) and Methicillin sensitive Staphylococcus aureus (MSSA)	Manual inoculation and Automated inoculation using the WASP incubation of culture media as above and using: LP-MIC-GEN-N-182	A
Blood	Isolation of microorganisms of clinical significance	Liquid media culture using: LP-MIC-BLD-N-370 and BD BacTec FX	А
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: LP-MIC-GEN-N-187	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Cerebrospinal fluid (CSF)	Detection and identification of: White blood cells Red blood cells Bacterial cells	Microscopy & staining (Gram and differential) using: LP-MIC-GEN-N-187	А
Bronchoalveolar lavage Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotrachael tube specimens Nasopharyngeal aspirate Pleural fluid Sputum	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: LP-MIC-CAT-N-400 LP-MIC-CAT-N-471	A
Respiratory samples	Isolation of Legionella species	Manual inoculation and media culture using: LP-MIC-CAT-N-470	А
Respiratory samples Bile	Detection of Acid-alcohol fast bacilli	Auramine Phenol staining and Fluorescent microscopy LP-MIC-STA-N-570	A
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues	Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using: LP-MIC-GEN-N-187 LP-MIC-STA-N-570	A
Hair Nail Skin	Isolation and identification of clinically significant dermatophyte fungi and other significant non-dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: LP-MIC-FUN-N-190 LP-MIC-STA-N-570	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: Campylobacter spp. Clostridium difficile Escherichia coli O157 Salmonella sp. Shigella spp. Vibrio spp. Yersinia spp. Pleisiomonas spp.	Manual inoculation and media culture using: LP-MIC-FAE-N-200	A
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopic examination using: LP-MIC-STA-N-570	A
Faeces	Detection of ova, cysts and parasites (OCP)	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: LP-MIC-FAE-N-208	A
Faeces	Detection of : Rotavirus/adenovirus	Using: Immunochromatographic assays Proflow Dual test Rota-Adeno LP- MIC-FAE-N-209	A
Urine	Pneumococcal Antigen Legionella Antigen	Using Apacor Immuview Immunochromatographic assay LP- MIC-SER-N-840	A
Urine	BhCG	Immunochromatographic strips using:Invitech hCG one step pregnancy test and LP-MIC-SER- N-836	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Bacterial cultures isolated inhouse from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual and/or automated antimicrobial susceptibility testing using the latest CLSI methodology and: Vitek 2XL and LP-MIC-SEN-N-410 Disc diffusion & gradient minimum inhibitory concentration determination using in-house procedure LP-MIC-SEN-N-410 and LP-MIC-SEN-N-440	A
Faeces	Detection of C.diff Toxin- A&B	VIDAS- ELFA	А
Faeces	Cryptosporidium/Giardia antigen	DS2 EIA for qualitative detection LP-MIC-SER-N-871	А
Faeces	Norovirus	LP-MIC-FAE-N-209 Cepheid GeneXpert LP-MIC-SER-N-874 using qualitative determination of genogroups I &II	А
Rectal swab	Carbapenemase-producing enterobacteriaceae (CPE)	Cepheid Gene Xpert using qualitative differentiation of blaKPC,blaNDM,blaVIM,blaOXA-48,blaIMP-1 using LP-MIC-SER-N-874	А
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual biochemical methods using: LP-MIC-IDE-N-500 Matrix-assisted laser desorption/ionisation using: LP-MIC-VMS-N-001 and Biomerieux MS and MYLA systems	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Serum	Hepatitis A Total Ab Hepatitis A IgM Hepatitis B Surface antigen* Hepatitis B Surface antibody Hepatitis B core total antibody Hepatitis C Specific Antibody Rubella IgG HIV I/II antibodies* HIV p24 antigen* Syphilis Total antibody* CMV IgG and IgM Toxoplasma IgG and IgM SARS CoV 2 antibody SARS CoV 2 spoke antibody Procalcitonin	Roche Cobas e801 using Chemiluminescence immunoassay method LP-MIC-SER-N-880 Documented In House methods to meet the requirements of the IDPS programme handbook as defined in the current version of 'infectious diseases in pregnancy screening: Laboratory QA evidence requirements' for antenatal screening (*tests only)	A
Plasma/serum	EBV VCA IgG EBV VCA IgM EBNA IgG VZV IgG Parvovirus IgM/IgG	Diasorin Liaison XL Chemiluminescence Immunoassay using LP-MIC-SER-N-883	A
Faeces	H. Pylori	Diasorin Liaison XL Chemiluminescence Immunoassay using LP-MIC-SER-N-883	A
Plasma serum	Haemophilus influenza type b Ab S.pneumoniae Ab B.pertussis IgG	Chemiluminescent microparticle immunoassay measured in RLU (relative light units) using: LP-MIC-SER-N-871 And Launch DS2	А
Plasma serum	Lymes Borrelia IgG and IgM Measles IgG	using ELFA: Mini VIDAS and LP-MIC-SER-N- 843	A
Respiratory swab	Influenza A/B/RSV/Sars-Cov-2	Cepheid Gene Xpert PCR using Multiplex kit and LP-MIC-SER-N- 874	А, В

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular detection for the purpose of clinical diagnosis	In-house documented procedures following PHE SMIs	
Nose/throat swabs in Viral Transport medium or liquid Aimes media	Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences E and N2	Cepheid Gene Xpert PCR using: LP-MIC-SER-N-874 and the Xpert Xpress SARS-CoV2 assay	A
		using Hologic Panther and LP-MIC- SER-N-878:	А
Genital Swabs	HSV	HSV PCR –Target capture, amplification by TMA,detection by fluorescent labelled probes	А
Genital Swabs Urine	Chlamydia/GC	CT/GC Target capture,amplification by Transcription mediated amplification(TMA) and Dual Kinetic Assay(DKA),detection by fluorescent labelled probes	А
Nose/throat swabs	ORF1ab region 1 and ORF1ab region 2	Hologic Panther Sars-Cov-2 multiplex RT-PCR kit using LP- MIC-SER-N-078	А
Urine/Genital swabs	Trichomonas RNA ribosomal subunit	Hologic Aptima Trichomonas vaginalis assay using LP-MIC- SER-N-883	А
Nose/throat swabs	ORF1ab, N and S gene	Thermo fisher Quantstudio 5 with TaqPath Covid 19 Assay, Kingfisher extraction using MagMix kits and EP- motion handling system using LP-MIC-SER-N-885	А
Rectal Swabs	Detection of Carbapenemase- producing Enterobacteriaceae (CPE) genes detected blaKPC, blaNDM, blaVIM, blaOXA48, blaIMP-1	Cepheid GeneXpert MIC-MOL-SOP-3	В
Faeces	Detection of Norovirus Genotypes I&II	Cepheid GeneXpert MIC-MOL-SOP-3	В

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular detection for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Nose/ throat swabs, BAL, Sputum, NPS	Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human metapneumovirus Rhinovirus/enterovirus Influenza A Influenza B MERS-CoV Parainfluenza virus 1-4 RSV SARS-CoV-2 Chlamydia pneumoniae Mycoplasma pneumoniae Bordatella parapertussis Bordatella pertussis	Biomerieux Biofire Filmarray Torch nested multiplex PCR and high resolution melting point using LP- MIC-SER-N-879	A, B
CSF	Meningitis/encephalitis panel including: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus Enterovirus HSV1/2 Human herpes virus 6 Human Parechovirus VZV Cryptococcus neoformans/gattii		A
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