


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>9693</p> <p>Accredited to ISO 15189:2012</p>	<h3>Northumbria Healthcare NHS Foundation Trust</h3> <p>Issue No: 004 Issue date: 16 June 2021</p>	
	<p>Microbiology Department North Tyneside General Hospital Rake Lane North Shields NE29 8NH</p>	<p>Contact: Mr David Tate Tel: +44 (0)3448118111 E-Mail: david.tate@nhct.nhs.uk Website: www.northumbria.nhs.uk</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS</p> <p>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</p> <p>Cellular and fluid material contained on swabs</p> <p>Blood</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p> <p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) and Methicillin sensitive <i>Staphylococcus aureus</i> (MSSA)</p> <p>Isolation of microorganisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation 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-040 LP-MIC-GEN-N-050 LP-MIC-GEN-N-060 LP-MIC-GEN-N-110 LP-MIC-FLU-N-271 LP-MIC-CAT-N-472 LP-MIC-URI-N-350</p> <p>Manual inoculation and incubation of culture media as above and using: LP-MIC-GEN-N-182</p> <p>Liquid media culture using: LP-MIC-BLD-N-370 and BD BacTec FX</p>



9693

Accredited to
ISO 15189:2012

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

Northumbria Healthcare NHS Foundation Trust

Issue No: 004 Issue date: 16 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: LP-MIC-GEN-N-187
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
Bronchoalveolar lavage Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotracheal 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
Respiratory samples	Isolation of Legionella species	Manual inoculation and media culture using: LP-MIC-CAT-N-470
Respiratory samples Bile	Detection of Acid-alcohol fast bacilli	Auramine Phenol staining and Fluorescent microscopy LP-MIC-STA-N-570
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
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



9693

Accredited to
ISO 15189:2012

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

Northumbria Healthcare NHS Foundation Trust

Issue No: 004 Issue date: 16 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: <i>Campylobacter</i> spp. <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Pleisiomonas</i> spp.	Manual inoculation and media culture using: LP-MIC-FAE-N-200
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Gram stained microscopic examination using: LP-MIC-STA-N-570
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
Faeces	Detection of : Rotavirus/adenovirus	Using: Immunochromatographic assays Biorapid Rota-Adeno LP-MIC-FAE-N-209
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



9693

Accredited to
ISO 15189:2012

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

Northumbria Healthcare NHS Foundation Trust

Issue No: 004 Issue date: 16 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS (cont'd)</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p>	<p>In-house documented procedures following PHE SMIs</p>
<p>Bacterial cultures isolated in-house from all samples listed above</p>	<p>Antimicrobial susceptibility testing of clinically significant bacteria</p>	<p>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</p>
<p>Faeces</p>	<p>Detection of C.diff Toxin- A&B</p>	<p>VIDAS- ELFA</p>
<p>Faeces</p>	<p>H.pylori Antigen</p>	<p>DS2 EIA for qualitative detection LP-MIC-SER-N-871</p>
<p>Faeces</p>	<p>Cryptosporidium/Giardia antigen</p>	<p>DS2 EIA for qualitative detection LP-MIC-SER-N-871</p>
<p>Faeces</p>	<p>Norovirus</p>	<p>LP-MIC-FAE-N-209 Cepheid GeneXpert LP-MIC-SER-N-874 using qualitative determination of genogroups I &II</p>
<p>Rectal swab</p>	<p>Carbapenemase-producing enterobacteriaceae (CPE)</p>	<p>Cepheid Gene Xpert using qualitative differentiation of blaKPC,blaNDM,blaVIM,blaOXA-48,blaIMP-1 using LP-MIC-SER-N-874</p>



9693

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Northumbria Healthcare NHS Foundation Trust

Issue No: 004 Issue date: 16 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	
Plasma Serum	Microbial serology for: HBSAg HBsAb Hepatitis B Core total antigen HAV IgM HAV IgG HCV Ab HIV Ag and Ab Rubella IgG Syphilis IgG Syphilis IgM Gentamicin CMV IgG and IgM EBV IgG and IgM EBNA Toxoplasma total antibody	Chemiluminescent microparticle immunoassay using: LP-MIC-SER-N-873 and Abbott Architect PLUS i200SR 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 (HIV Antibody/Antigen detection, Hepatitis B surface antigen, Syphilis antibody)
Plasma serum	B.pertussis IgG Haemophilus influenza type b Ab S.pneumoniae Ab Parvovirus IgG Parvovirus IgM	Chemiluminescent microparticle immunoassay measured in RLU (relative light units) using : LP-MIC-SER-N-871 And Launch DS2
Plasma serum	Lymes Borrelia IgG and IgM Measles IgG Procalcitonin Varicella IgG	using ELFA: Mini VIDAS and LP-MIC-SER-N-843



9693

Accredited to
ISO 15189:2012

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

Northumbria Healthcare NHS Foundation Trust

Issue No: 004 Issue date: 16 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Respiratory swab</p> <p>Nose/throat swabs in Viral Transport medium or liquid Aimes media</p> <p>Genital swab</p> <p>Genital Swabs for HSV</p> <p>Genital Swabs/urine for CT/GC</p> <p>Urine</p> <p>Urine</p>	<p><u>Serological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Influenza A/B</p> <p>RSV</p> <p>Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences E and N2</p> <p>Chlamydia/GC</p> <p>HSV</p> <p>Chlamydia/GC</p> <p>Streptococcus pneumoniae/Legionella Antigen</p> <p>BhCG</p>	<p>Cepheid Gene Xpert PCR using: LP-MIC-SER-N-874</p> <p>Cepheid Gene Xpert PCR using: LP-MIC-SER-N-874 and the Xpert Xpress SARS-CoV2 assay</p> <p>using Hologic Panther and LP-MIC-SER-N-878:</p> <p>HSV PCR –Target capture, amplification by TMA,detection by fluorescent labelled probes</p> <p>CT/GC Target capture,amplification by Transcription mediated amplification(TMA) and Dual Kinetic Assay(DKA),detection by fluorescent labelled probes</p> <p>Immunochromatographic strips using:</p> <p>Binax NOW Legionella and Strep pneumonia antigen kit and LP-MIC-SER-N-840 also using Alere reader</p> <p>Invitech hCG one step pregnancy test and LP-MIC-SER-N-836</p>

END