


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9590</p> <p>Accredited to ISO 15189:2012</p>	<h3>North Tees and Hartlepool NHS Foundation Trust</h3> <p>Issue No: 004    Issue date: 22 October 2021</p>	
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<p><b>Testing performed at the above address only</b></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><u>Microbiological examination activities for the purpose of clinical diagnosis</u></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 of culture media using: NTH_MIC_600 NTH_MIC_601 NTH_MIC_510 NTH_MIC_305 NTH_MIC_034 NTH_MIC_810 NTH_MIC_811 NTH_MIC_812 NTH_MIC_814 NTH_MIC_815 NTH_MIC_816 NTH_MIC_120</p>
<p>Cellular and fluid material contained on swabs</p>	<p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)</p>	<p>Manual inoculation of chromogenic culture media as above and using: NTH_MIC_203</p>
<p>Blood</p>	<p>Isolation of microorganisms of clinical significance</p>	<p>Liquid media culture using: NTH_MIC_503 and BD Bactec FX</p>



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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 PHE SMIs
Sterile site samples: Tissue Swabs Fluid Bone	Isolation of microorganisms of clinical significance	Manual media culture and Liquid media culture using: NTH_MIC_944 NTH_MIC_199 NTH_MIC_937 and BD Bactec FX
Cerebrospinal fluid (CSF)	Detection, identification and quantification (inc. differential) of: White blood cells Red blood cells Bacterial cells	Microscopy & staining (Gram and differential) using: NTH_MIC_049 (Kova slide) NTH_MIC_003 NTH_MIC_504
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: NTH_MIC_504
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: NTH_MIC_300
Ascitic Fluids	Detection, identification and quantification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using: NTH_MIC_510



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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 PHE SMIs
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Automated urinalysis, image capture and recognition using: NTH_MIC_105 and IRIS IQ200 SPRINT  and/or  Manual microscopic examination using: NTH_MIC_102
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.	Manual inoculation and media culture using: NTH_MIC_712 NTH_MIC_709 NTH_MIC_708 NTH_MIC_713 NTH_MIC_716
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual and/or automated biochemical methods using: NTH_MIC_004 NTH_MIC_007 NTH_MIC_008 NTH_MIC_012 NTH_MIC_013 NTH_MIC_015 NTH_MIC_028 NTH_MIC_091 NTH_MIC_100 NTH_MIC_929 NTH_MIC_720 and Brucker MalDI-ToF Matrix-assisted laser desorption/ionisation using: NTH_MIC_111



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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 PHE SMIs
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual antimicrobial susceptibility testing using the latest EUCAST methodology and: NTH_MIC_082 Disc diffusion & gradient minimum inhibitory concentration determination using in-house procedures NTH_MIC_70 NTH_MIC_030 NTH_MIC_036
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis and <i>Trichomonas vaginalis</i>	Microscopic examination using: NTH_MIC_601
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: NTH_MIC_702
Faeces	Detection of <i>Cyclospora</i>	Modified ZN stain using: NTH_MIC_700
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination using in-house procedure: NTH_MIC_702
Sellotape slide Perianal saline swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopic examination using: NTH_MIC_702



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Sputum Bronchial Lavage Pleural Fluid Pus or swabs Tissue, lymph nodes or biopsies CSF Urine	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Auramine phenol staining and microscopy using: NTH_MIC_303
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen and pneumococcal antigen	Membrane immunochromatographic assay using: NTH_MIC_313 And Meridian Tru
Faeces	Rota/adeno virus	NTH_MIC_763 And Apacor Rotavirus/Adenovirus Ag Rapystest
Faeces	C.difficile toxin	NTH_MIC_704 And Techlab Tox A/B Quik Chek
Nasopharyngeal Aspirate	RSV	NTH_MIC_299 And Meridian TRU-RSV
Urine	BHCG Reported as positive/negative	NTH_MIC_917 And Invitech One Step
Faeces	Norovirus	NTH_MIC_752 And Prolab Proflow Tile Test
Skin Hair Nails Tissue	Isolation of clinically significant yeasts and fungi	NTH_MIC_402 And microscopy using Calcofluor white



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	
Faecal extracts	<i>Giardia lamblia</i> & <i>Cryptosporidium</i> antigens	Automated EIA using: NTH_MIC_760 and Launch DS2 Confirmation via lateral flow elisa using: NTH_MIC_762 Techlab Giardia/cryptosporidium Quik Chek Assay
Blood	Quantiferon Test	Automated ELISA using: NTH_MIC_331 And Launch DS2
Faeces	<i>Helicobacter pylori</i> IgG	Automated EIA using: NTH_MIC_761 and Launch DS2



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HUMAN TISSUES AND FLUIDS	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u>	Extraction, PCR amplification and detection using:
Nasopharyngeal aspirate or swab	Molecular diagnostics for:  Detection or exclusion of: Influenza A Influenza B Respiratory Syncytial Virus	Polymerase Chain Reaction (PCR) Using Cepheid Gene Xpert:  NTH_MIC_315 NTH_MIC_PCR_008
Organism from any sample type	Carbapenemase detection	NTH_MIC_037
Faeces	<i>Clostridiodesdifficile</i> toxin	NTH_MIC_704
Faeces	Norovirus	NTH_MIC_756
Urine Genital Swab	Detection of genetic material from: <i>Chlamydia trachomatis</i>	Roche COBAS 4800 series using: NTH_MIC_PCR_5 and confirmation with: Cepheid Gene Xpert NTH_MIC_PCR_6
Nose and Throat swabs in VTM	Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, N2 and E gene targets	Polymerase Chain Reaction (PCR) Using Cepheid Gene Xpert: Sars-CoV-2 RNA Real time-PCR  NTH_MIC_PCR_9 Covid 19 SOP
Nose and Throat swabs in VTM	Detection and differentiation of lineage $\beta$ -betacoronavirus ( $\beta$ - $\beta$ CoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, N and Orf1a/b gene targets	Promega Maxwell RSC 16 (Promega RSC blood DNA kit) and the Qiagen Qiacube Connect QIAamp (Qiagen QIAamp Viral RNA mini kit ) extraction platforms with Roche 11 and Roche 480z light cyclers using the Biotec Certest Viasure Real Time-PCR NTH_MIC_PCR_9 Covid 19 SOP
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