


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>Accredited to ISO 15189:2022</b></p>	<p align="center"><b>Lancashire Teaching Hospitals NHS Foundation Trust</b></p> <p align="center"><b>Issue No: 008    Issue date: 25 February 2025</b></p>	
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<p align="center"><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><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Human samples including swabs, fluids, aspirates, pus, line tips, tissues as specified</p> <p>Specimens from wounds Neonatal swabs and aspirates</p> <p>Swabs from eyes, ears, nose, throat, mouth and genital sites</p> <p>Respiratory specimens (sputum, respiratory secretions &amp; aspirates)</p> <p>CSF and shunt specimens, CAPD's, Ascitic fluids.</p> <p>Swabs including, but not limited to nose, perineum and wound sites</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p><u>General Bacteriology</u></p> <p>Examination activities for the purposes of clinical diagnosis</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>Quantification of white and red blood cells and bacteria</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>Isolation of MRSA</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p>	<p>In-house documented procedures based on PHE SMLs</p> <p>Manual culture using SOPs CL011, CL014, CL015, CL017, CL019, CL020, CL026,</p> <p>Manual culture using SOPs CL001, CL002, CL004, CL005, CL009, CL028</p> <p>Manual culture using SOP CL008</p> <p>Manual microscopy and culture using SOPs CL022, CL025, CL026 &amp; CL027</p> <p>Manual culture on chromogenic agar using SOP CL029</p> <p>SOP CL041 in conjunction with equipment manual using UF5000 by flow cytometry</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on PHE SMIs
Urine	<u>General Bacteriology</u> (cont'd)  General isolation, characterisation and sensitivity testing of micro-organisms of clinical significance	Manual semi-quantitative culture using calibrated loop/surface streak method and susceptibility testing using Disc diffusion method using a documented in-house method (CL041) based on UK Standards for Microbiology Investigations SMI B 41: Investigation of urine
Blood and CAPD	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	SOP CL037 in conjunction with manufacturer's instructions for BacTALERT 3D automated system by colorimetry
Faeces	General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157	Manual culture using selective agar with SOPs EN001, EN010, EN011, EN012 & EN013
Faeces and bowel contents	Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	SOP EN004 in conjunction with manufacturer's (Techlab) instructions using C. difficile Quik Chek Complete by immunochromatography
Faeces	Detection of <i>Clostridium difficile</i> toxin b gene	SOP EN004 in conjunction with manufacturer's instructions using GeneXpert by PCR
Faeces	Detection of <i>Helicobacter pylori</i>	SOP EN022 by manual ELISA using Amplified IDEIA™ Hp StAR
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen and <i>Streptococcus pneumoniae</i>	SOPs CL131 & CL132 in conjunction with manufacturer's instructions using Legionella and Strep pneumonia using Binax Now kit by immunochromatography



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on PHE SMLs
Bacterial cultures (isolated in-house)	<u>General Bacteriology</u> (cont'd)  Identification and characterisation of micro-organisms	SOPs CL101-CL110, CL115-CL116, CL118 - CL120, CL133, CL134, CL135 and CL045 with equipment manuals using Bruker MALDI-TOF and by manual disc diffusion using EUCAST guidelines and MIC determination using E-tests and Vitek 2
Faeces	<u>Parasitology</u>  Detection of <i>Giardia lamblia</i> and <i>Cryptosporidium</i> sp.	SOP EN019 by Manual ELISA using the Tecan F50 Infinite plate reader associated with the detection of <i>Giardia</i> / <i>Cryptosporidium</i> Chek test, and <i>Giardia</i> / <i>Cryptosporidium</i> Quik Chek rapid Immunoassay (Una Health).
Skin scrapings, hair and nail clippings	<u>Mycology</u>  General isolation and characterisation of fungi of clinical significance	Manual method using SOP EN007 by direct microscopy of KOH digested samples and culture on non-chromogenic selective media



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures
	<u>Viral Serology</u>	
	Detection of:	In-house procedures in conjunction with manufacturer's instructions by chemiluminescence using Diasorin Liaison with reference to:
Serum/plasma (unless stated)	Cytomegalovirus IgM and IgG antibody and avidity	SOP SE062
	Epstein Barr Virus IgM, IgG (Viral capsid) and EBNA IgG antibody	SOP SE061
	Varicella Zoster virus IgG antibody	SOP SE050
	Hepatitis B e Antibody*	SOP SE005
	Hepatitis B e Antigen*	SOP SE005
Blood	Lyme's IgM and IgG Antibody	SOP SE063
	Parvovirus IgM and IgG antibody	SOP SE029
	Measles IgM and IgG antibody	SOP SE047
	Mumps IgM and IgG antibody	SOP SE045
	Rubella IgM antibody	SOP SE022
	Hepatitis B core-IgM antibodies*	SOP SE004
	Toxoplasma IgG antibody and avidity	SE054
Blood	Toxoplasma IgM Antibody	SOP SE054



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)  <u>Viral Serology</u> (cont'd)	In house documented procedures and manufacturers' instructions  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 (*)  In-house procedures in conjunction with manufacturer's instructions by electrochemiluminescence using Roche Cobas e601 with reference to:
Serum/plasma (unless stated) (cont'd)	Detection of: Hepatitis A IgM antibody Hepatitis A (total) Antibody Hepatitis B Surface Antibody* Hepatitis B core-IgG Hepatitis B Surface Antigen Rubella IgG antibody Hepatitis C total antibody HIV 1 & 2 antibody and p24 antigen* Syphilis total antibody* HTLV I/II total IgG and IgM antibodies	SOP SE011 SOP SE011 SOP SE012 SOP SE003 SOP SE001 SOP SE022 SOP SE007 SOP SE008 SOP SE019 SOP SE066



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	<u>Viral Serology</u> (cont'd)	
Serum/plasma (unless stated)	Detection of:	In-house procedures in conjunction with manufacturer's instructions by immunoassay using mini-Vidas with reference to:
	HIV 1 & 2 antibody and p24 antigen*	SOP SE008
	Hepatitis B Surface Antigen*	SOP SE001
	Hepatitis C total antibody	SE007
	Hepatitis E IgG antibodies	SE065
Serum/plasma (unless stated)	Detection of:	In-house procedures in conjunction with manufacturer's instructions with reference to:
	Detection of Syphilis antibody* ( <i>Treponema pallidum</i> )	SOP SE019 in conjunction with manufacturer's instructions using RPR and ASI TPHA (Arlington Scientific)
	Hepatitis E IgM antibodies	SOP SE065 by Euroimmun® manual ELISA
Serum/plasma (unless stated)	Detection of:	In-house procedures in conjunction with manufacturer's instructions with reference to:
	Detection of Antistreptolysin O antibody	SOP SE044 by manual agglutination using Rheumajet ASO
Blood	HIV Confirmation Assay*	SOPSE008 using Immunochematogenic Assay and Geenius Reader



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures and manufacturers' instructions
	<u>Molecular Serology</u>	
Genital, throat and eye swabs, urine	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i> DNA	Polymerase Chain Reaction using SOP MR016 in conjunction with manufacturer's instructions using Roche Cobas 4800 and confirmation if required on the Cepheid GeneXpert
Sputum	Detection of <i>Mycobacterium tuberculosis</i> including rifampicin resistance gene	Polymerase Chain reaction using Cepheid GeneXpert SOPCL040
		Polymerase Chain Reaction using Roche Cobas 4800 with reference to:
Blood	Detection of Hepatitis B Viral Load	SOP MR025
Blood	Detection of HIV Viral Load	SOP MR007
Blood	Detection of Hepatitis C Viral Load	SOP MR008
Blood	Detection of Hepatitis C Genotyping	SOP MR023
Anogenital Swabs	Detection of Herpes Simplex 1 & 2 DNA	SOPs MR024
END		