


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8545</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Lancashire Teaching Hospitals NHS Foundation Trust</b></p> <p>Issue No: 006    Issue date: 07 September 2023</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><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><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>In-house documented procedures based on PHE SMI's</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>



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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 based on PHE SMIs
Swabs including, but not limited to nose, perineum and wound sites	<u>General Bacteriology (cont'd)</u> Isolation of MRSA	Manual culture on chromogenic agar using SOP CL029
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	SOP CL041 in conjunction with equipment manual using UF5000 by flow cytometry
Urine	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 instructions using <i>C. difficile</i> Quik Chek Complete by immunochromatography
	Detection of <i>Clostridium difficile</i> toxin <i>b</i> 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



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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
Urine	<u>General Bacteriology</u> (cont'd) 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
Bacterial cultures (isolated in-house)	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 sp.</i>	SOP EN019 by ELISA using Giardia/Cryptosporidium Chek test, and Giardia/Cryptosporidium Quik Chek rapid Immunoassay.
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)	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Viral Serology</u> (cont'd)</p>	<p>In house documented procedures and manufacturers' instructions</p> <p>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 (*)</p> <p>In-house procedures in conjunction with manufacturer's instructions by electrochemiluminescence using Roche Cobas e601 with reference to:</p>
Serum/plasma (unless stated) (cont'd)	<p>Detection of:</p> <p>Hepatitis A IgM antibody</p> <p>Hepatitis A (total) Antibody</p> <p>Hepatitis B Surface Antibody*</p> <p>Hepatitis B core-IgG</p> <p>Hepatitis B Surface Antigen</p> <p>Rubella IgG antibody</p> <p>Hepatitis C total antibody</p> <p>HIV 1 &amp; 2 antibody and p24 antigen*</p> <p>Syphilis total antibody*</p> <p>HTLV I/II total IgG and IgM antibodies</p>	<p>SOP SE011</p> <p>SOP SE011</p> <p>SOP SE012</p> <p>SOP SE003</p> <p>SOP SE001</p> <p>SOP SE022</p> <p>SOP SE007</p> <p>SOP SE008</p> <p>SOP SE019</p> <p>SOP SE066</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Viral Serology</u> (cont'd)</p>	<p>In house documented procedures and manufacturers' instructions</p>
Serum/plasma (unless stated)	<p>Detection of:</p> <p>HIV 1 &amp; 2 antibody and p24 antigen*</p> <p>Hepatitis B Surface Antigen*</p> <p>Hepatitis C total antibody</p> <p>Hepatitis E IgG antibodies</p>	<p>In-house procedures in conjunction with manufacturer's instructions by immunoassay using mini-Vidas with reference to:</p> <p>SOP SE008</p> <p>SOP SE001</p> <p>SE007</p> <p>SE065</p>
Serum/plasma (unless stated) (cont'd)	<p>Detection of:</p> <p>Detection of Syphilis antibody* (<i>Treponema pallidum</i>)</p> <p>Hepatitis E IgM antibodies</p>	<p>In-house procedures in conjunction with manufacturer's instructions with reference to:</p> <p>SOP SE019 in conjunction with manufacturer's instructions using RPR and ASI TPHA (Arlington Scientific)</p> <p>SOP SE065 by Euroimmun® manual ELISA</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma (unless stated) (cont'd)</p> <p>Blood</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Viral Serology</u> (cont'd)</p> <p>Detection of:</p> <p>Detection of Antistreptolysin O antibody</p> <p>HIV Confirmation Assay*</p>	<p>In house documented procedures and manufacturers' instructions</p> <p>In-house procedures in conjunction with manufacturer's instructions with reference to:</p> <p>SOP SE044 by manual agglutination using Rheumajet ASO</p> <p>SOPSE008 using Immuno-chromatogenic Assay and Geenius Reader</p>



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Genital, throat and eye swabs, urine	<u>Molecular Serology</u> 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
Nose & throat swabs, Nasopharyngeal aspirates and respiratory secretion	Detection of Influenza A & B Detection of Respiratory Syncytial Virus RNA	Polymerase Chain reaction using Cepheid GeneXpert SOPMR022
Sputum	Detection of <i>Mycobacterium tuberculosis</i> including rifampicin resistance gene	Polymerase Chain reaction using Cepheid GeneXpert SOPCL040
Blood	Detection of Hepatitis B Viral Load	Polymerase Chain Reaction using Roche Cobas 4800 with reference to: 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		