


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8545</p> <p>Accredited to ISO 15189:2012</p>	<p>Lancashire Teaching Hospitals NHS Foundation Trust</p> <p>Issue No: 005 Issue date: 20 August 2021</p>	
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<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 BODY FLUIDS AND TISSUES</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 & 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 SMIs</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 & CL027</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs including, but not limited to nose, perineum and wound sites</p> <p>Urine</p> <p>Urine</p> <p>Blood and CAPD</p> <p>Faeces</p> <p>Faeces and bowel contents</p> <p>Faeces</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>General Bacteriology</u> (cont'd)</p> <p>Isolation of MRSA</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p> <p>General isolation, characterisation and sensitivity testing of micro-organisms of clinical significance</p> <p>Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance</p> <p>General isolation and characterisation of <i>Salmonella</i>, <i>Shigella</i>, <i>Campylobacter</i> & <i>E. coli</i> 0157</p> <p>Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B</p> <p>Detection of <i>Clostridium difficile</i> toxin <i>b</i> gene</p> <p>Detection of <i>Helicobacter pylori</i></p>	<p>In-house documented procedures based on PHE SMIs</p> <p>Manual culture on chromogenic agar using SOP CL029</p> <p>SOP CL041 in conjunction with equipment manual using UF1000i by flow cytometry</p> <p>SOP CL041 in conjunction with manufacturer's instructions using Mast Urisystem by culture</p> <p>SOP CL037 in conjunction with manufacturer's instructions for BacTALERT 3D automated system by colorimetry</p> <p>Manual culture using selective agar with SOPs EN001, EN010, EN011, EN012 & EN013</p> <p>SOP EN004 in conjunction with manufacturer's instructions using C. difficile Quik Chek Complete by immunochromatography</p> <p>SOP EN004 in conjunction with manufacturer's instructions using GeneXpert by PCR</p> <p>SOP EN022 by manual ELISA using Amplified IDEIA™ Hp StAR</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 SMI
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 Coris Legionella K set" and Strep pneumonia using Binax Now kit by immunochromatography
Urine	Detection of HCG	SOP CL007 in conjunction with manufacturer's instructions using Alere hcG cassette 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, fluids, urine & perianal swabs	<u>Parasitology</u> Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	SOPs EN009, EN019 EN021 by manual microscopy and/or concentration using Parasep system
Faeces, fluids, urine & perianal swabs	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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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma (unless stated)</p> <p>Blood</p> <p>Blood</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Viral Serology</u></p> <p>Detection of:</p> <p>Cytomegalovirus IgM and IgG antibody and avidity</p> <p>Epstein Barr Virus IgM, IgG (Viral capsid) and EBNA IgG antibody</p> <p>Varicella Zoster virus IgG antibody</p> <p>Hepatitis B e Antibody</p> <p>Hepatitis B e Antigen</p> <p>Lyme's IgM and IgG Antibody</p> <p>Parvovirus IgM and IgG antibody</p> <p>Measles IgM and IgG antibody</p> <p>Mumps IgM and IgG antibody</p> <p>Rubella IgM antibody</p> <p>Hepatitis B core-IgM antibodies</p> <p>Toxoplasma IgG antibody and avidity</p> <p>Toxoplasma IgM Antibody</p>	<p>In-house documented procedures</p> <p>In-house procedures in conjunction with manufacturer's instructions by chemiluminescence using Diasorin Liaison with reference to:</p> <p>SOP SE062</p> <p>SOP SE061</p> <p>SOP SE050</p> <p>SOP SE005</p> <p>SOP SE005</p> <p>SOP SE063</p> <p>SOP SE029</p> <p>SOP SE047</p> <p>SOP SE045</p> <p>SOP SE022</p> <p>SOP SE004</p> <p>SE054</p> <p>SOP SE063</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> <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 & 2 antibody and p24 antigen</p> <p>Syphilis total antibody</p> <p>Hepatitis A total antibody</p> <p>HTLV I/II total IgG and IgM antibodies</p>	<p>SOP SE011</p> <p>SOP SE064</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 SE064</p> <p>SOP SE066</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma (unless stated)</p> <p>Serum/plasma (unless stated) (cont'd)</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>HIV 1 & 2 antibody and p24 antigen</p> <p><i>Borrelia burgdorferi</i> IgM and IgG antibodies</p> <p>Hepatitis B Surface Antigen</p> <p>Hepatitis C total antibody</p> <p>Hepatitis E IgG antibodies</p> <p>Detection of:</p> <p>Detection of Syphilis antibody</p> <p>Detection of <i>Campylobacter jejuni</i> IgA, IgM and IgG antibodies</p> <p>Hepatitis E IgM antibodies</p> <p>Detection of <i>Mycoplasma pneumoniae</i> total antibody</p>	<p>In house documented procedures and manufacturers' instructions</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 SE063</p> <p>SOP SE001</p> <p>SE007</p> <p>SE065</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 TPPA</p> <p>SOP SE031 using Virion/Serion manual ELISA</p> <p>SOP SE065 by in house manual ELISA</p> <p>SOP SE059 by manual agglutination using Fujirebo Serodia-Myco II</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
Faeces	Norovirus	Polymerase Chain reaction using Cepheid GeneXpert SOPMR020
CSF	Detection of Enterovirus DNA	Polymerase Chain reaction using Cepheid GeneXpert SOP MR021
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