


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Lancashire Teaching Hospitals NHS Foundation Trust	
	Issue No: 004 Issue date: 26 September 2019	
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Testing performed at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES Human samples including swabs, fluids, aspirates, pus, line tips, tissues as specified Specimens from wounds Neonatal swabs and aspirates Swabs from eyes, ears, nose, throat, mouth and genital sites Respiratory specimens (sputum, respiratory secretions & aspirates) CSF and shunt specimens, CAPD's, Ascitic fluids.	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> <u>General Bacteriology</u> Examination activities for the purposes of clinical diagnosis General isolation and characterisation of micro-organisms of clinical significance General isolation and characterisation of micro-organisms of clinical significance General isolation and characterisation of micro-organisms of clinical significance Quantification of white and red blood cells and bacteria General isolation and characterisation of micro-organisms of clinical significance	In-house documented procedures based on PHE SMIs Manual culture using SOPs CL011, CL014, CL015, CL017, CL019, CL020, CL026, Manual culture using SOPs CL001, CL002, CL004, CL005, CL009, CL028 Manual culture using SOP CL008 Manual microscopy and culture using SOPs CL022, CL025, CL026 & CL027



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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
Swabs including, but not limited to nose, perineum and wound sites	<u>General Bacteriology</u> (cont'd) 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 UF1000i by flow cytometry
Urine	General isolation, characterisation and sensitivity testing of micro-organisms of clinical significance	SOP CL041 in conjunction with manufacturer's instructions using Mast Urisystem by culture
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 C. difficile Quik Chek Complete by immunochromatography
	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



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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 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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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
	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
	Detection of:	In-house procedures in conjunction with manufacturer's instructions by electrochemiluminescence using Roche Cobas e601 with reference to:
Serum/plasma (unless stated)	Hepatitis A IgM antibody	SOP SE011



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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>Viral Serology (cont'd)</u>	
	Detection of:	In-house procedures in conjunction with manufacturer's instructions by electrochemiluminescence using Roche Cobas e601 with reference to:
Serum/plasma (unless stated) (cont'd)	Hepatitis B Surface Antibody	SOP SE012
	Hepatitis B core-IgG	SOP SE003
	Hepatitis B Surface Antigen	SOP SE001
	Rubella IgG antibody	SOP SE022
	Hepatitis C total antibody	SOP SE007
	HIV 1 & 2 antibody and p24 antigen	SOP SE008
	Syphilis total antibody	SOP SE019
	Hepatitis A total antibody	SOP SE064
	HTLV I/II total IgG and IgM antibodies	SOP SE066
	Detection of:	In-house procedures in conjunction with manufacturer's instructions by immunoassay using mini-Vidas with reference to:
Serum/plasma (unless stated)	HIV 1 & 2 antibody and p24 antigen	SOP SE008
	<i>Borrelia burgdorferi</i> IgM and IgG antibodies	SOP SE063
	Hepatitis B Surface Antigen	SOP SE001
	Hepatitis C total antibody	SE007
	Hepatitis E IgG antibodies	SE065



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<p><u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Viral Serology (cont'd)</u></p>	In house documented procedures and manufacturers' instructions
Serum/plasma (unless stated) (cont'd)	Detection of:	In-house procedures in conjunction with manufacturer's instructions with reference to:
	Detection of Syphilis antibody	SOP SE019 in conjunction with manufacturer's instructions using RPR and TPPA
	Detection of <i>Campylobacter jejuni</i> IgA, IgM and IgG antibodies	SOP SE031 using Virion/Serion manual ELISA
	Hepatitis E IgM antibodies	SOP SE065 by in house manual ELISA
	Detection of <i>Mycoplasma pneumoniae</i> total antibody	SOP SE059 by manual agglutination using Fujirebo Serodia-Myco II
	Detection of Antistreptolysin O antibody	SOP SE044 by manual agglutination using Rheumajet ASO
Blood	HIV Confirmation Assay	SOPSE008 using Immuno-chromatogenic 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
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
		Polymerase Chain Reaction using Roche Cobas 4800 with reference to:
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		