

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189:2012

Blackpool Teaching Hospitals NHS Foundation Trust

Issue No: 014 Issue date: 20 February 2025

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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 samples including swabs, fluids, aspirates, pus, line tips, tissues as specified	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> <u>General Bacteriology</u> Examination activities for the purposes of clinical diagnosis	In-house documented procedures based on PHE SMLs
Specimens from wounds, eyes, ears, nose, throat, mouth, ulcers, pus, tissue, genital sites, joint fluids and heart valves	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOPs MB01, MB02, MG004, MG002, MB500 & MG010
Urine	Quantification of white and red blood cells, bacteria and epithelial cells yeasts and casts.	Manual microscopy using SOP MB03 and inverted microscopy
Urine	<u>Microscopy Investigation</u> <u>-White Blood Cells</u> <u>-Red Blood Cells</u> <u>-Epithelial Cells</u> <u>-Yeast Cells</u> <u>-Bacterial Cells</u>	SedimaxConTRUSTPRO Urine analyser using automated light microscopy using SOP MB03
CSF	General isolation, characterisation and sensitivity testing of micro-organisms of clinical significance	Manual culture using SOP MB03
	Quantification of white and red blood cells and bacteria	Manual microscopy and culture using SOP MG004
	General isolation and characterisation of micro-organisms of clinical significance	



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	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on PHE SMIs
	<u>General Bacteriology</u> (cont'd)	
Respiratory specimens (sputum, respiratory secretions, aspirates, pleural fluids, ascitic fluids, lymph nodes, tissues and pus)	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOP MG005
Bacterial and yeast cultures isolated in-house	General identification of micro-organisms of clinical significance	General API standardised or biochemical kit-based identification methods
Bacterial and yeast cultures isolated in-house	General identification of micro-organisms of clinical significance isolated from clinical samples	Identification of microorganisms using mass spectrometry on Bruker MALDI-TOF Using SOP MB06
Faeces	General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157, <i>Vibrio</i> sp. and <i>Aeromonas</i> sp.	Manual culture using selective agar and SOP MB17
	Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	SOP MI030_03 in conjunction with manufacturer's instructions using C. difficile Quik Chek Complete
Swabs, tissues and fluids including, nose, perineum and wound sites	Isolation of MSSA & MRSA	Manual culture on chromogenic agar using SOP MG009
Swabs, fluids, tissue and faeces	Isolation of Carbapenemase producing bacteria	Manual culture on chromogenic agar and ertapenem disc using SOP MG017
Blood	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	Virtuo Blood Culture Analyser using SOP MG007 Blood Cultures
Bacterial Isolates	Antimicrobial susceptibility testing of clinically significant bacteria and determination of minimum inhibitory concentration (MIC)	Manual antimicrobial susceptibility procedures (Disc Diffusion) using EUCAST methodology using SOP: SOPMI100_03 Sensitivity Testing



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Urine and CSF	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u> <u>General Bacteriology (cont'd)</u> Detection of Legionella pneumophila antigen and Streptococcus pneumoniae antigen	Using Strep pneumoniae and Legionella pneumophila Urinary Antigen Test SOP and Immuvue – S. pneumoniae Antigen Test
Urine and CSF	Detection of Streptococcus pneumoniae antigen	Using Strep pneumoniae Antigen Test SOP and Immuvue – S.pneumoniae Antigen Test
Faeces	Confirmatory testing of Cryptosporidium and Giardia positive ELISA <u>Mycology</u> Examination activities for the purposes of clinical diagnosis	Immunocard STAT using SOP MB19
Nail Clippings, Skin Scrapings, Hair	General isolation and characterisation of fungi of clinical significance <u>Parasitology</u>	Manual microscopy and culture using SOP MG006
Faeces, clear adhesive tape slides	Examination activities for the purposes of clinical diagnosis Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	In-house documented procedures based on PHE SMLs SOPs MI045_03 by manual microscopy and/or concentration using ParaSep system
Genital swabs	Examination for presence and detection of <i>Trichomonas vaginalis</i>	MI031_03 using ProLab Trichomonas stains
Serum	Detection of 1-3-Beta-D-glucan	Automated Lab Kinetics PKF08 Using Fungitell STAT kinetic assay



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Serum (unless stated)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
	<u>Viral Serology</u>	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the NHS Infectious diseases in pregnancy screening: laboratory quality assurance evidence requirements (relevant targets marked with *)
	Examination activities for the purposes of clinical diagnosis	In house documented procedures based on and in conjunction with manufacturer's instructions
	Detection of Antistreptolysin O antibody	SOP MV008 by latex agglutination using Biokit Rheumajet
	Detection of EBV IgM	SOP MV065 by LFD using Clearview kit
	*Detection of Treponema pallidum antibodies	SOPs MV017 using RPR
	Detection of Treponema pallidum antibodies	Using ASI TPHA kit
	Detection of Cytomegalovirus IgM	SOP MV023 in conjunction with manufacturer's instructions using Biomerieux Vidas
	Detection of Hepatitis A IgG total	
	*Detection of Hepatitis B core IgM, core total antibody, e antibodies, e antigen, surface antigen	
	Detection of Hepatitis C anti HCV antibody	
	*Detection of HIV 1 & 2 antibody and p24 antigen	
	Detection of Measles IgG	
	Detection of Mumps IgG	
	Detection of Rubella IgM	



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Serum	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u> <u>Viral Serology (cont'd)</u> Detection of Hepatitis E IgG & IgM antibodies Detection of Toxoplasma IgM & IgG Detection of Varicella IgG	Documented in-house methods to meet the requirements of the IDPS screening programme as defined in the NHS Infectious diseases in pregnancy screening: laboratory quality assurance evidence requirements (relevant targets marked with *) SOP MV023 in conjunction with manufacturer's instructions using Biomerieux Vidas Viral serology using the Abbott Architect CMIA SOP MV100
	*Syphilis antibody IgG/M Cytomegalovirus IgM Cytomegalovirus IgG Hepatitis A IgG Hepatitis A IgM *Hepatitis B core total antibody *Hepatitis B surface antigen Hepatitis C antibody *HIV 1 & 2 antibody and p24 antigen *Hepatitis B surface antibody Rubella IgG	SOP MV106 SOP MV112 SOP MV113 SOP MV115 SOP MV114 SOP MV105 SOP MV101 SOP MV103 SOP MV102 SOP MV104 SOP MV107
Nose and throat swabs in VTM	nucleic acid from Flu A/B; RSV; SARS-CoV-2 multiplex	RT-PCR test using Neumodx MV143 and MV144



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	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
	<u>Molecular Biology</u>	
	Examination activities for the purposes of clinical diagnosis	In house documented procedures based on and in conjunction with manufacturer's instructions
Endocervical and vaginal swabs, urines	Detection of Chlamydia trachomatis and Neisseria gonorrhoea DNA	SOP MV086 by Polymerase Chain Reaction using Roche Cobas 4800
Serum /Plasma	*HIV and HCV viral loads	PCR and Cobas 4800 using Cobas HIV-1 kit SOP MV117 and SOP MV118
	Qualitative detection of:	
Urine, genital & rectal swabs	Mycoplasma genitalium resistance	RT-PCR using Cepheid GeneXpert and SpeedX Resistance Plus assay
Urine, genital swabs (including self-collected), rectal, throat & eye swabs	Chlamydia trachomatis and Neisseria gonorrhoeae DNA	RT-PCR using Cepheid GeneXpert and Xpert CT/GC assay
Tonsillar swabs, nasopharyngeal swabs, lesion exudate, scabs & rash swabs	Mpox DNA	RT-PCR using ELiTe Ingenius and Mpox PCR assay
Genital swabs in viral transport media	Herpes Simplex Virus 1 & 2 DNA	RT-PCR using ELiTe Ingenius and HSV1&2 ELiTe MGB assay
Lesion, eye, blister, ulcer & rash swabs in viral transport media	Herpes Simplex Virus 1 & 2 DNA Varicella Zoster RNA Adenovirus RNA Enterovirus RNA	RT-PCR using ELiTe Ingenius and Meningitis Viral ELiTe MGB Panel 1 & panel 2 assays
Urine, cervical, vaginal, rectal & throat swabs in COBAS PCR media collection tubes	Chlamydia trachomatis DNA Neisseria gonorrhoeae DNA Mycoplasma genitalium DNA Trichomonas vaginalis DNA	RT-PCR using ELiTe Ingenius and STI PLUS ELiTe MGB assay



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Nasopharyngeal swabs in viral transport media	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u> <u>Molecular Biology (cont'd)</u> Influenza A (subtypes H1N1/2009, H1, H3) Influenza B Coronavirus 229E, HKU1, NL63, OC43. Parainfluenza virus 1, 2, 3, 4. Respiratory Syncytial Virus (RSV) A/B Human Metapneumovirus A/B Adenovirus Human Bocavirus Rhinovirus/Enterovirus <i>Mycoplasma pneumoniae</i> <i>Legionella pneumophila</i> <i>Bordetella pertussis</i>	RT-PCR using QIAstat-DX PCR analyser and QIAstat-DX Respiratory SARS-CoV-2 Panel assay
CSF	<i>Escherichia coli</i> K1 <i>Haemophilus influenzae</i> <i>Listeria monocytogenes</i> <i>Neisseria meningitidis</i> (encapsulated) <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Mycoplasma pneumoniae</i> <i>Streptococcus pyogenes</i> Herpes simplex virus 1 Herpes simplex virus 2 Human herpes virus 6 Enterovirus Human parechovirus Varicella-zoster virus <i>Cryptococcus neoformans/gattii</i> .	RT-PCR using QIAstat-DX PCR analyser and QIAstat-DX Respiratory ME Panel assay
END		