

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8655</b> Accredited to ISO 15189:2012	<b>The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services</b>  Issue No: 006 Issue date: 15 June 2022	
	Department of Microbiology Pathology Centre C37 New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom	Contact: Katy New Tel: +44 (0)1902 07999 ext. 8247 E-Mail: <a href="mailto:katy.new@nhs.net">katy.new@nhs.net</a> Website: <a href="http://www.royalwolverhampton.nhs.uk">www.royalwolverhampton.nhs.uk</a>

Testing performed by the Organisation at the locations specified below

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
Department of Microbiology Pathology Centre C37, New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom  <b>Local contact</b> Susan Lovegrove	General isolation and characterisation of isolates of clinical significance:	A



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Microbiology examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
All liquid swabs, urines, wound drains and emulsified faeces samples	General Isolation and characterisation of microorganisms of clinical significance	COPAN / BioMerieux WASP (Walk Away Specimen Processor) system.for inoculation, incubation and digital imaging of culture plates and documented procedures:  F2.002P.MIC F2.008P.MIC F2.009P.MIC F2.010P.MIC F2.011P.MIC F2.007P.MIC F2.012P.MIC F2.023P.MIC F2.032P.MIC	A
Respiratory, tip and charcoal ear and urethral samples	General Isolation and characterisation of microorganisms of clinical significance	Manual inoculation followed by COPAN / BioMerieux WASP (Walk Away Specimen Processor) system.for incubation and digital imaging of culture plates and documented procedures:	A
Swabs from eyes, wounds, nose, throat, ears, genital sites.	General isolation and characterisation of microorganisms of clinical significance	Manual inoculation F2.009P.MIC/F2.032P.MIC (Wound)  F2.010P.MIC/F2.023P.MIC (Genital) F2.011P.MIC (eye) F2.008P.MIC (ENT) F2.007P.MIC/F2.022P.MIC (Body Fluids) F2.045P.MIC (Tissue/Biopsy Material) F2.009P.MIC (pus/drainage fluid)	A
Swabs from human tissue and body fluids	Presence of white blood cells, organisms and epithelial cells	SOP F2.013P.MIC Gram stain and manual microscopy	A



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs	
Swabs from genital samples	Detection of white blood cells, yeast cells and Trichomonas vaginalis	SOP F2.010P.MIC Wet prep Manual microscopy	A
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	F2.002P.MIC in conjunction with equipment manual using Sysmex UF1000 and by manual microscopy	A
Urine	General isolation of micro-organisms of clinical significance	Documented in house method F2.020P.MIC in conjunction with manufacturer's instructions for Biomerieux Previ Isola F2.043P.MIC	A
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen	SOP F2.004P.MIC in conjunction with manufacturer's instructions using Meridian Tru kit	A
Urine	Detection of <i>Streptococcus pneumoniae</i> antigen	SOP F2.004P.MIC in conjunction with manufacturer's instructions using Meridian Tru kit	A
Urine	Examination for the presence of parasites of clinical significance	SOP F2.012P.MIC by centrifugation and manual microscopy	A
Faeces	General isolation and characterisation of Salmonella, Shigella, Campylobacter & E. coli O157	Semi-automated culture method in conjunction with manufacturer's instructions for Biomerieux Previ Isola F2.043P.MIC and SOP F2.012P.MIC	A
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen and toxin A/B detection	SOP F2.048P.MIC and F2.152P.MIC in conjunction with manufacturer's instructions using Techlab (ELISA) on DS2 analyser	A
Faeces	Detection of <i>Clostridium difficile</i> toxin	SOP F2.048P.MIC and F2.044P.MIC in conjunction with manufacturer's instructions for Cepheid Genexpert	A



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs	
Serum	Detection of <i>Helicobacter pylori</i> antibody	SOP F2.004P.MIC and F2.035P.MIC in conjunction with manufacturer's instructions for Biomerieux Vidas	A
Faeces	Detection of <i>Helicobacter pylori</i> antigen	SOP F2.004P.MIC and F2.152P.MIC in conjunction with manufacturer's instructions for DS2	A
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	SOP F2.012P.MIC by concentration using Parasep system and manual microscopy	A
Faeces	Detection of rotavirus	Manual method SOP F2.012P.MIC	A
CSF, ascitic and peritoneal fluids	Quantification of white and red blood cells and bacteria	SOP F2.007P.MIC and F2.022P.MIC by manual microscopy	A
CSF	Examination for the presence of cryptococcus neoformans	Direct light microscopy using India Ink and SOP F2.013P.MIC	A
Fluids, isolated colonies	Presence of significant organisms	SOP F2.013P.MIC Manual light microscopy	A
Pure culture of isolates	Identification of clinically relevant isolates	SOP F2.049P.MIC in conjunction with manufacturer's instructions for Biomerieux Vitek Maldi ToF	A
Pure culture of isolates	Characterisation of clinically relevant isolates	F2.031P.MIC and manual methods SOP F2.014P.MIC and F2.015P.MIC	A
Swabs from nose, perineum and wound sites? Liquid swabs only	Isolation of MRSA	Semi-automated culture in conjunction with manufacturer's instructions for Biomerieux Previ Isola and SOP F2.043P.MIC	A
Whole blood	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	F2.006P.MIC in conjunction with manufacturer's instructions for BacTAlert 3D automated system	A



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs	
Respiratory samples sputum, bronchoalveolar lavage, tissue	Detection of microbial growth and isolation of Mycobacteria sp.	F2.003P.MIC in conjunction with manufacturer's instructions for MGIT automated system	A
Homogenised respiratory samples and centrifuged urines	Detection of acid fast bacilli	Manual fluorescent microscopy (Auramine) or light microscopy (Ziehl Neelson) stain in conjunction with documented method F2.013P.MIC	A
Screening swabs Axilla, groin, nose and wounds	Isolation of S. aureus	F2.020P.MIC with manual culture	A
Skin scrapings and nail clippings	General isolation and characterisation of fungi of clinical significance	Manual method using SOP F2.018P.MIC by direct microscopy of KOH digested samples and culture on non-chromogenic selective media	A
Screening swabs –rectal swabs and faeces	Detection of carbapenemase producing organisms	F2.020P.MIC with manual culture	A
Clinical isolates from human tissue and body fluids	antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	In house documented methods F2.013P.MIC/F2.016P.MIC/F2.024P.MIC/F2.26P.MIC in conjunction with manufacturer's instructions for Biomerieux Vitek2 and manual methods (EUCAST)	A
Genital samples	Examination for the presence of clinically significant bacteria and Trichomonas vaginalis	In house documented method F2.010P.MIC, F2.023P.MIC manual microscopy	A



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis</u>		
Serum unless otherwise specified:	Qualitative detection of:	In house documented methods in conjunction with manufacturer's instructions for Biomerieux Vidas:	A
	Measles IgG antibody	F2.004P.MIC/F2.035P.MIC	
	EBV IgG/IgM antibodies	F2.004P.MIC/F2.035P.MIC	
	Varicella Zoster IgG antibody	F2.004P.MIC/F2.035P.MIC	
	HIV Antigen/antibody	F2.004P.MIC/F2.035P.MIC	
	Hepatitis B surface antigen	F2.004P.MIC/F2.035P.MIC	
	Hepatitis C antibody	F2.004P.MIC/F2.035P.MIC	
	CMV IgG	Documented procedures & manufacturer's instructions for ABBOTT Architect i2000 analyser with specific reference to:	A
	CMV IgM	F1.142P.CHE	
	HbsAg	F1.142P.CHE	
	HbsAb	F1.142P.CHE	
	HIV 1/2	F1.142P.CHE	
	Hep A IgG	F1.142P.CHE	
	Hep A IgM	F1.142P.CHE	
	Hep B core Ab	F1.142P.CHE	
	Hep C Ab	F1.142P.CHE	
	Rubella IgM	F1.142P.CHE Immunoassay	
	Rubella IgG	F1.142P.CHE	
	Syphilis TP	F1.142P.CHE	
	Toxoplasma IgG	F1.142P.CHE	
	Toxoplasma IgM	F1.142P.CHE	
	Quantitative detection of:	Latex agglutination	A
	Anti Streptolysin O titre	In house documented methods F2.004P.MIC	



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HUMAN BODY FLUIDS (cont'd)	<p><u>Serological examination activities for the purposes of clinical diagnosis</u></p> <p>HbsAg HIV 1/2 Syphilis TP</p> <p>HIV Antigen/antibody Hepatitis B surface antigen</p> <p>Antibodies to Treponema pallidum</p>	<p>Documented -in-house methods to meet the requirements of the IDPS screening programme as defined in the 2018 'Infectious Diseases in Pregnancy screening: laboratory QA evidence requirements' :</p> <p>Documented procedures &amp; manufacturer's instructions for ABBOTT Architect i2000 analyser</p> <p>F1.142P.CHE F1.142P.CHE F1.142P.CHE</p> <p>In house documented methods in conjunction with manufacturer's instructions for Biomerieux Vidas:</p> <p>F2.004P.MIC/F2.035P.MIC F2.004P.MIC/F2.035P.MIC</p> <p>Manufacturer's instructions for the Serodia TPPA assay for semi quantitative agglutination of sensitised particles in conjunction with documented method:</p>	A



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis</u>		
Serum/CSF	Cryptococcal antigen	IMMY Latex Cryptococcal Antigen Detection System F2.004P.MIC	A
	Detection of antibodies to lipoidal material for screening for syphilis	RPR Reditest Biokit F2.004P.MIC	A
	Antibodies to Treponema pallidum	Manufacturer's instructions for the Serodia TPPA assay for semi quantitative agglutination of sensitised particles in conjunction with documented method:	A
	Detection of Parvovirus IgG and IgM	In house documented method SOP F2.004P.MIC/F2.152P.MIC in conjunction with manufacturer's instructions for DS2	A
	<u>Molecular examination activities for the purposes of clinical diagnosis</u>		
	Detection of:	In house documented method in conjunction with manufacturer's instructions for Roche Cobas 4800	A
Urine / Endocervical swabs	Chlamydia trachomatis /Neisseria gonorrhoeae	SOP F2.037P.MIC	
Anogenital Swabs	Herpes Simplex Virus	SOP F2.037P.MIC	
Plasma	Quantitation of HIV Viral load	SOP F2.055P.MIC	
Serum /Plasma	Quantitation of Hepatitis C Viral load	SOP F2.055P.MIC	
Faeces	Detection of Norovirus Type I/II	In house documented method SOP SOP F2.044P.MIC in conjunction with manufacturer's instructions for Cepheid Genexpert	A
END			





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