


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9576</p> <p>Accredited to ISO 15189:2012</p>	<h3>Gloucestershire Hospitals NHS Foundation Trust</h3> <p>Issue No: 003    Issue date: 25 August 2020</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
HUMAN TISSUES and FLUIDS	<u>Microbiological examinations for the purposes of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Swabs, Fluids and Tissue	Isolation, characterisation and identification of organisms of clinical significance from the specified samples:	Manual inoculation, culture and identification using in-house methods:
Wounds/ENT/Ocular samples		MISOPB006
Genital		MISOPB060
Sputum, bronchial washings, pleural fluids, coughs swabs, nasopharyngeal aspirates		MISOPB040
Tissue resection		MISOPB132
Prosthetic joints and bone		MISOPB148
CSF		MISOPB039
Ascitic fluids, pericardial fluids		MISOPB042
Peritoneal fluids		MISOPB052
Joint fluids		MISOPB042
Urine		MISOPB055



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Microbiological examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Skin scrapings, hair, nail clippings	Isolation, characterisation and identification of organisms of clinical significance	Direct microscopy of KOH digested samples and manual inoculation and culture: MISOPB054
Faeces	Isolation, characterisation and identification of organisms of clinical significance	Manual inoculation and culture MISOPB053
Cellular and fluid material contained on swabs, urine, sputum	MRSA	Manual inoculation and culture MISOPB041
Cellular and fluid material contained on swabs, urine, sputum, faeces	Carbapenemase producing organisms Vancomycin resistant enterococci (VRE), Methicillin sensitive Staphylococcus aureus (MSSA) Acinetobacter spp Pseudomonas aeruginosa	Manual inoculation and culture using chromogenic agar MISOPB117 MISOPB155
Cellular and fluid material contained on swabs, fluids, tissues	Detection, identification and quantification of: White blood cells Bacterial cells Epithelial cells	Manual Gram stain followed by microscopy MISOPB 010
CSF	Detection, identification and quantification of: White blood cells and differential count Red blood cells Bacterial cells	Manual light microscopy MISOPB039
Fluids from sterile sites	Quantitation of white blood cells, red blood cells	Manual light microscopy MISOPB042
Synovial Fluids	Identification of monosodium urate and calcium pyrophosphate crystals	Polarised light microscopy MISOPB042



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Microbiological examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Whole blood	Isolation, characterisation and identification of microorganisms of clinical significance	BactAlert 3D Automated liquid culture colorimetric microbial Co2 detection followed by manual subculture MISOPB050
Bacterial and yeast isolates cultured in house from the above	Identification of clinically significant organisms	Biomerieux Vitek 2 semi-automated identification system using colourimetric and enzymatic tests MISOPB159
Bacterial and yeast isolates cultured in house from the above	Antimicrobial susceptibility testing (AST)	Biomerieux Vitek 2 semi-automated MIC determination system MISOPB159
Bacterial isolates cultured in-house from the above sample types	Antimicrobial susceptibility testing (AST)	Manual antibiotic susceptibility testing using disc diffusion (EUCAST) and in-house methods: MISOPB 170
Urine	Quantification of white and red blood cells, bacteria, yeasts epithelial cells	Automated SediMax sediment analyser and manual inverted microscopy MISOPB112
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 antigen	Binax NOW Legionella urinary antigen manual immunochromatographic assay MISOPB077
Urine	Detection of <i>Streptococcus pneumoniae</i> antigen	Binax NOW Strep pneumo manual immunochromatographic assay MISOPS 100
Urine	Detection of bHCG	Invitech one-step manual immunochromatographic assay MISOPB101



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Microbiological examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Urine	Examination for the presence of Schistosoma spp.	Centrifugation and manual light microscopy MISOPB097
Faeces	Detection of Giardia and Cryptosporidium antigens	DS2 automated ELISA MISOPB166
Faeces	Confirmation of Cryptosporidium or Giardia antigens	Techlab Crypto/Giardia QuikChek manual immunochromatographic assay MISOPB166
Faeces	Detection of C. difficile Glutamate Dehydrogenase (GDH) antigen	Techlab C. difficile Chek 60 GDH MISOPB108
Faeces	Detection of C. difficile toxin A and B	Techlab C. difficile Toxin A/B II MISOPB108
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Manufacturer's instructions for Parasep concentration system and manual light microscopy MISOPB068 MISOPB070
Faeces	Examination for oocysts of Cryptosporidium sp.	In house method for manual Auramine staining MISOPB06649
Faeces	Detection of Rotavirus antigen	Immunocard Stat Rotavirus manual Immunochromatographic assay MISOPB049



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Microbiological examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Respiratory samples sputum, bronchoalveolar lavage, pleural fluids, urine, CSF, sterile fluids, tissue	Detection of microbial growth and isolation of Mycobacteria spp of clinical significance	Automated liquid culture BactAlert 3D colourimetric detection followed by manual microscopy using auramine and Ziehl Neelsen stain MISOPB024 (Auramine) MISOPB025 (Ziehl Neelsen) MISOPB057 (Automated culture)
Serum	<u>Serological examinations for the purposes of clinical diagnosis</u>  CMV IgM EBV IgM Hepatitis A IgG Hepatitis A IgM Hepatitis B surface antigen Hepatitis B core IgM Hepatitis B core total Ab Hepatitis B e antigen Hepatitis B e Ab Hepatitis C Ab HIV Ab/Ag Borrelia IgG Borrelia IgM Measles IgG Mumps IgG Rubella IgG Rubella IgM VZ IgG	Manufacturer's instructions for Biomerieux Vidas3 Enzyme Linked Fluorometric Assay (ELFA) and in-house document method MISOPS232



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Serological examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions
Serum	Detection of:	Manufacturer's instructions for DS2 automated ELISA and in-house method MISOPS178 MISOPS224
	HIV Ab/Ag	Documented in-house methods to meet the requirements of the NHS Infectious Diseases in Pregnancy screening programme as defined in the July 2018 "NHS Infectious Diseases in Pregnancy screening: laboratory QA evidence requirements"  Genscreen Ultra HIV
	Syphilis Ab	Bioelisa Syphilis
	Hepatitis B surface Ag	Bioelisa HbsAg
	H. pylori antibody	Premier H, Pylori MISOPS090
	Parvovirus B19 (Erythrovirus) IgG	Biotrin Parvovirus B19 IgG MISOPS065
	Parvovirus B19 (Erythrovirus) IgM	Biotrin Parvovirus B19 IgM MISOPS064
	Bordetella pertussis anti PT IgG	SeroPertussis Toxin IgG MISOPS227
	EBNA IgG	Novalisa EBNA IgG Kit MISOPS 235
Serum	Hepatitis C antigen and antibody	Manual EIA methods:  Monolisa HCV Ag/Ab Ultra MISOPS 204



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<p>HUMAN TISSUES and FLUIDS (cont'd)</p> <p>Serum</p> <p>Serum</p> <p>Nasopharyngeal aspirates and Bronchiolar lavage specimens</p>	<p><u>Serological examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>CMV Influenza A Influenza B HSV Measles Mumps Mycoplasma pneumoniae Chlamydomphila group Coxiella burnetii phase 1 and 2 Varicella zoster</p> <p>Detection of:</p> <p>Hepatitis A IgM Hepatitis B surface antibody Hepatitis B core anti body total Hepatitis B surface antigen Hepatitis C antibody HIV Ag/Ab Rubella IgG Rubella IgM Toxoplasma antibody</p> <p>Detection of:</p> <p>Influenza A Influenza B Respiratory syncytial virus Parainfluenza Adenovirus P. jirovecii</p>	<p>In-house documented procedures and relevant manufacturer's instructions</p> <p>MISOPS011 MISOPS010</p> <p>Manufacturer's instructions for Roche Cobas e411 immunoassay analyser and in-house methods:</p> <p>MISOPS200</p> <p>Manufacturer's instructions for Light Diagnostics immunofluorescence kit and manual processing and in-house method</p> <p>MISOPS094 MISOPS095</p>





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HUMAN TISSUES and FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	
Respiratory samples (nose, throat) Nasopharyngeal swabs	Detection of:  Influenza A RNA Influenza B RNA Respiratory Syncytial Virus RNA	Manufacturer's instructions for Cepheid GeneXpert PCR analyser and in-house methods: MISOPB152
Faeces	C. difficile toxin gene DNA	MISOPB119  Manufacturer's instructions for AUS Diagnostics MT-Prep extractor/Easy Plex multiplex tandem (High-Plex) PCR analyser analyser and in-house methods:
Respiratory samples (nose, throat) Nasopharyngeal swabs Bronchoalveolar lavage	Influenza A RNA Influenza B RNA Respiratory Syncytial Virus RNA	MSOPB 186 MISOPB 171
Nose and throat swabs in viral transport medium	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene targets ORF1a and ORF8	MISOPB 186 MISOPB 187
Nose and throat swabs in viral transport medium	Detection of SARS-CoV-2 virus RNA specific gene sequences ORF1ab and Nucleoprotein	Manufacturer's instructions for Real-World Diagnostics SAMBA II PCR analyser and in-house method  MISOPB 191
Nose and throat swabs in viral transport medium	Detection of SARS-CoV-2 virus RNA specific gene sequences ORF1ab and E	Manufacturer's instructions for Launch Prepito/Bosphore/ QuantStudio-5 PCR analyser and in-house method  MISOPB 190



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Urine, Endocervical, self-taken vaginal swabs	Detection of:  Detection of:  C trachomatis DNA N. gonorrhoeae DNA	Manufacturer's instructions for Roche 4800 PCR analyser analyser and in-house method:  MISOPB123
Urine, Endocervical, swabs, self-taken vaginal swabs	C trachomatis DNA N. gonorrhoeae DNA	Manufacturer's instructions for Cepheid GeneXpert PCR and in-house method:  MISOPB154
Plasma and serum	Quantitation of:  HIV DNA HCV RNA HBV DNA	Manufacturer's instructions for Hologic Panther RT PCR and in-house method:  MISOPS237 MISOPS238 MISOPS239
Ejaculate	<u>Andrology examinations for the purposes of clinical diagnosis</u>  Semen pH Semen volume sperm concentration sperm motility sperm morphology	In house documented method based on WHO Laboratory manual 5th ed (2010)  MISOPB094  In house manual method using fixed depth large volume slides and the ABA guidelines (2016)
Ejaculate	Sperm presence/absence Sperm Concentration	Post vasectomy testing MISOPB095

END