


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9576</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Gloucestershire Hospitals NHS Foundation Trust</b></p> <p>Issue No: 008 Issue date: 29 September 2023</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
HUMAN TISSUES and FLUIDS	<u>Microbiological examinations for the purposes of clinical diagnosis</u>	In-house documented procedures following current UKHSA 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 UKHSA 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 UKHSA 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 UKHSA 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	Detection of Rotavirus antigen	Immunocard Stat Rotavirus manual Immunochromatographic assay MISOPB049



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<p>HUMAN TISSUES and FLUIDS (cont'd)</p> <p>Respiratory samples sputum, bronchoalveolar lavage, pleural fluids, urine, CSF, sterile fluids, tissue</p> <p>Serum</p>	<p><u>Microbiological examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of microbial growth and isolation of Mycobacteria spp of clinical significance</p> <p><u>Serological examinations for the purposes of clinical diagnosis</u></p> <p>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</p>	<p>In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturer's instructions</p> <p>Automated liquid culture BactAlert 3D colourimetric detection followed by manual microscopy using auramine and Ziehl Neelsen stain MISOPB024 (Auramine) MISOPB023 (ZN Stain for Mycobacteria) MISOPB057 (Automated culture)</p> <p>Manufacturer's instructions for Biomerieux Vidas3 Enzyme Linked Fluorometric Assay (ELFA) and in-house document method MISOPS232</p>



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Serological examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures following current UKHSA 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
	H. pylori antibody	Premier H, Pylori MISOPS090
	EBNA IgG	Novalisa EBNA IgG Kit MISOPS 235
	Parvovirus B19 IgG/IgM	Parvovirus B19 IgG/IgM Serion MISOPS 250
Serum	Hepatitis C antigen and antibody	Manual EIA methods: Monolisa HCV Ag/Ab Ultra MISOPS 204



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Serum	Detection of:	Manual agglutination methods and in-house methods:
	Rapid plasma reagin (non-specific syphilis antibodies)	Rapid Plasma Reagin test Biokit RPR Reditest MISOPS225
	T. pallidum total antibody	Capitia Syphilis Total Ab MISOPS202
	Anti-DNAse B	BioMérieux ASD kit MISOPS081
	HIV 1 /2 Ag/Ab	Alere HIV 1/ 2 Ag/Ab combo MISOPS193
	HIV I/II (confirmation)	Biorad HIV I/II Geenius Immuno chromatographic assay MISOPS233
	HIV Genscreen	HIV Genscreen MISOPS 264



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HUMAN TISSUES and FLUIDS (cont'd)  Serum	<u>Serological examinations for the purposes of clinical diagnosis (cont'd)</u>  Detection of:  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 Syphilis total antibodies*	In-house documented procedures and relevant manufacturer's instructions  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". Targets indicated*  Manufacturer's instructions for Roche Cobas e411 immunoassay analyser and in-house methods:  MISOPS200





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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: MISOPB 201
VSwabs, Nasopharyngeal aspirate Faeces	Asymptomatic and Symptomatic screening for SARS-CoV-2 C. difficile toxin gene DNA	MISOPB 119
Cultures of Staphylococcus aureus	Detection of PVL and MecA genes in cultures of Staphylococcus aureus	AUS Diagnostics, multiplex two part PCR to amplify DNA and identification of targets by melt curve analysis. MISOPB 151
Viral Swabs, Nasopharyngeal aspirates.	Detection of respiratory viruses and bacteria: Bordetella/Bordetella pertussis Rhinovirus/Enterovirus Human Parainfluenza 1-4 Human Adenovirus Human Metapneumovirus Mycoplasma pneumoniae	Manufacturer's instructions for AUS Diagnostics MT-Prep extractor/Easy Plex multiplex tandem (High-Plex) PCR analyser and in-house methods: MISOPB 171
Respiratory samples (nose, throat) Nasopharyngeal swabs Bronchoalveolar lavage	Influenza A RNA Influenza B RNA Respiratory Syncytial Virus RNA	MISOPB 186 MISOPB 187 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



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HUMAN TISSUES and FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	
Viral swabs	Asymptomatic and symptomatic screening for SARS-CoV-2	Hologic Panther, TMA amplification assay end to end sample to qualitative result. MISOPB 194
Urine, Endocervical, self-taken vaginal swabs	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
Viral Swabs Plasma and serum	Quantitation of:  Detection of HSV 1 and 2 HIV DNA HCV RNA HBV DNA	Manufacturer's instructions for Hologic Panther RT PCR and in-house method:  MISOPS 243 MISOPS237 MISOPS238 MISOPS239



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u> Detection of sperm Sperm concentration	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons)  Manual method using fixed depth large volume slides/ manual microscopy and documented in-house procedure MISOPB095
Semen	<u>Fertility testing:</u>  Volume pH Sperm morphology including TZI scoring Sperm concentration Sperm motility	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure MISOPB094  Volume/weight  Colorimetric strips  Stained slides (Papanicolau) microscopy (Bright field)  Microscopy (Phase contrast)  Microscopy (Phase contrast)

END