

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9810</p> <p>Accredited to ISO 15189:2012</p>	<h3>St George's University Hospitals NHS Foundation Trust</h3> <p>Issue No: 003 Issue date: 01 October 2021</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 BODY FLUIDS AND TISSUES (unless specified)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods and manufacturer's operating instructions
Urine	Detection, identification and quantification of: White blood cells, Red blood cells, Squamous epithelial cells, Bacterial cells, parasites, Casts and Spermatozoa	Manual microscopy using an inverted microscope BSOP020
Urine	Automated cell count	Biomerieux UF1000: Automated urinalysis, BSOP106
Urine VBU	Isolation of bacterial and fungal species of clinical significance	Manual inoculation and media culture inc chromogenic media BSOP020
Urine culture	Isolation of bacterial and fungal species of clinical significance; direct susceptibility testing and identification tests	MAST Urisystem BSOP105
Urine	Detection of <i>Schistosoma haematobium</i> ova	Manual microscopy using an inverted microscope BSOP020



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Routine non sterile and sterile specimens with the inclusion of Pus, Tissues/Biopsies, Fluids (e.g. Joint, drain, pleural, Ascitic, peritoneal, pericardial, Amniotic, Bile, CSF), Bone, Aspirates / Vesical fluid and Bone Marrow, Tips and IUCD</p> <p>Respiratory samples Sputum, Bronchial Alveolar lavage (BAL), Nasopharyngeal Aspirate, Swabs,</p> <p>Swabs (Wound swabs, Skin, Ear, Nose, Cervical, Eye, Mouth, Rectal, Sub-prep, Throat, Urethral and Vaginal)</p> <p>Tips</p> <p>Genito urinary medicine (GUM) direct taken samples</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection, identification and quantification of: White blood cells Bacterial cells Yeast cells and fungal hyphae</p> <p>Isolation and characterisation of bacterial and fungal isolates of clinical significance</p> <p>Isolation and characterisation of bacterial and fungal isolates of clinical significance</p> <p>Isolation and characterisation of bacterial and yeast isolates of clinical significance</p>	<p>Documented in-house methods and manufacturer's operating instructions</p> <p>Manual inoculation and media culture Staining (inc. Gram) and microscopic examination using BSOP089 Ascitic fluids BSOP118 CAPD fluids BSOP039 ENT Bench BSOP013 CSF Bench BSOP003 Tissues, Biopsies And Associated Specimens BSOP066 Bile BSOP068 Bone Marrow BSOP114 Prosthetic Joint and Related Specimens</p> <p>Manual inoculation and media culture BSOP004 Kiestra TLA: incubation and image capture of routine and chromogenic culture media</p> <p>Using Kiestra TLA: Inoculation, incubation and image capture of routine and chromogenic culture media BSOP072 skin and superficial wound swabs BSOP037 - HVS BSOP102 Kiestra TLA BSOP039 ENT</p> <p>Using Kiestra TLA: incubation and image capture of routine and chromogenic culture media BSOP102 Kiestra TLA BSOP011</p> <p>Manual light Microscopy BSOP127 - Genital Specimen Investigation and Handling in the GUM Clinic for Microbiology BSOP040 - Specimens from Genito-Urinary Medicine Clinics</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions
MRSA swabs Urines Sputum VRE swabs	Detection of MRSA Detection of VRE/GRE (Glycopeptide Reistant Enterococci)	KIESTRA TLA: Inoculation, incubation and image capture of culture media BSOP102 Kiestra TLA BSOP007 MRSA screening BSOP007 MRSA screening BSOP088 VRE/GRE screening BSOP090 Gram negative screening
Gram negative screening swabs	Gram negative screening	
Faeces	Isolation, identification and Antimicrobial Susceptibility of bacterial pathogens including: Campylobacter spp. Escherichia coli O157 Salmonella sp. Shigella spp. Vibrio spp. Yersinia spp. Pleisiomonas spp. Aeromonas sp	Manual and automated biochemical and serological methods, Automated - BRUKER/BD MALDI-TOF by Matrix-assisted laser desorption/ionization, in conjunction with manufacturer's instructions. BSOP012
Skin scraping Nail clippings Hair samples	Isolation and identification of fungi of clinical significance Presence or absence of fungal elements	Manual culture, macroscopic examination Light microscope BSOP014
Clinical isolates cultured in-house (inc. bacteria/yeasts/fungi)	Identification of microorganisms of clinical significance.	Bruker/BD MALDI-TOF Mass spectrometry ESOP029
Bacterial and fungal isolates cultured in-house	Antimicrobial susceptibility testing (AST)	Manual antimicrobial susceptibility (disc diffusion) testing (EUCAST) Phoenix Automated AST and ETEST (gradient MIC) BSOP128-Eucast Antimicrobial Sensitivity testing BSOP104 BD Phoenix Automated AST



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Genital swab Throat swab Rectal swab</p> <p>Fluids CSF Ascitic fluid CAPD CSF Prosthetic joint fluid</p> <p>Paediatric Blood</p> <p>Whole Blood and sterile fluid (using both aerobic and anaerobic bottles as per manufacturers instructions and following in house protocol see notes)</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of <i>N.gonorrhoeae</i>/ <i>N.meningitidis</i></p> <p>Detection and quantification of white blood cells, red blood cells, epithelial cells, yeast.</p> <p>Culture and detection of microorganisms of clinical significance</p>	<p>Documented in-house methods and manufacturer's operating instructions</p> <p>Manual antimicrobial susceptibility testing using the latest British Society for Antimicrobial Susceptibility Testing (BSAC) methodology BSOP128-EucastEUCAST EXT 314 Agar Medium for Antimicrobial Susceptibility Testing of <i>Neisseria gonorrhoeae</i> EXT 143 BSAC Guidelines</p> <p>Light microscopy Cell count using FastRead@102 cell count method Differential staining BSOP089 Ascitic fluids BSOP118 CAPD fluids BSOP013 CSF Bench</p> <p>Becton Dickinson BACTEC™ FX400 and FX40– liquid culture/fluorescent growth detection BSOP010, BSOP108, BSOP116 Using both aerobic and anaerobic bottles as per manufacturers instructions and following in house protocol in the following circumstances</p> <p>Likely severe anaerobic infections on ITU</p> <ul style="list-style-type: none"> o Abdominal infections o Deep abdominal abscesses o Skin and soft tissue infections (particularly nec. Fasciitis) o Pelvic gynaecological infections o Severe throat infections - Lemierre's syndrome <p>Immunosuppressed haem/oncology patients Investigation of PUO</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions, where relevant
Tissue, Fluids, Corneal scrapes, CSF	Differentiation of different organism types: gram positive/negative/variable, branching organisms, yeasts.	Light microscopy Gram staining BSOP089 Ascitic fluids BSOP118 CAPD fluids BSOP013 CSF Bench
Swabs	Presence or absence of <i>Trichomonas vaginalis</i>	Manual light microscopy Wet prep microscopy BSOP037 HVS
Faeces Sellotape slides/perianal swabs	Detection of <i>Enterobius vermicularis</i>	Light microscopy BSOP124 Parasites
Faeces, Bile, Pus Duodenal/jejunal aspirates Sputum/ Broncheolar Lavage CSF, Urine	Detection of ova, cysts and parasites (OCP)	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination - Parasep tubes BSOP124
CSF, serum, plasma, whole blood (venous and finger stick)	Qualitative detection of the capsular polysaccharide antigens of <i>Cryptococcus</i> species complex (<i>Cryptococcus neoformans</i> and <i>Cryptococcus gottii</i>)	Lateral Flow Assay immunochromatographic test IMMY Cryptococcal antigen BSOP119
Sputum, BAL, Joint Fluid, Pleural Fluid, CSF Tissues, Lymph Nodes Skin Specimens, FNA, Pus, Faeces, Bone, Biopsy	Presence or absence of Acid Fast Bacilli	UV microscopy Auramine stain microscopy BSOP008 <i>Mycobacterium</i> species
Sputum, BAL, Urines, Joint Fluid, Pleural Fluid, CSF, Tissues, Lymph Nodes, Skin Specimens, FNA, Pus, Gastric Washings, Faeces, Bone, Biopsy	Isolation and presumptive identification of <i>Mycobacterium</i> species	Automated mycobacterial culture (Becton Dickinson MGIT) Fluorometric growth detection Manual culture using LJ slopes BSOP107 & BSOP008
Blood	Isolation of <i>Mycobacterium</i> species	BD FX40 BSOP008 <i>Mycobacterium</i> species BSOP116 BD FX40



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AFB smear positive BD MGIT tubes	Identification of Mycobacterium tuberculosis complex	Chromatographic immunoassay for the qualitative detection of Mycobacterium tuberculosis complex (MTBC) antigen form. BSOP122 BD MGIT TBc Identification
Whole blood	Detection of IFN- γ to identify cell-mediated immune (CMI) responses associated with Mycobacterium tuberculosis	QuantiFERON®-TB Gold (QFT®) ELISA on the DS2 BSOP112
Faeces	Detection of Clostridium difficile GDH antigen	Dynex DS2 Analyser ESOP028 Premier <i>C. difficile</i> GDH BSOP109
Faeces	Detection of Clostridium difficile Toxin A + B	Dynex DS2 Analyser ESOP028 Enzyme Immunoassay Techlab TOX A/B II EIA BSOP109
Faeces	Detection of Clostridium difficile GDH and toxin	Manual TECHLAB® C.DIFF QUIK CHEK COMPLETE® test (lateral flow) BSOP110
Urine	Detection of <i>Legionella pneumophila</i> serogroup 1 antigen	Lateral Flow EIA Device Manual immunochromatographic assay – Alere Binax Now Legionella urinary antigen BSOP085 Legionella Urine Antigen
Urine CSF	Detection of Pneumococcal soluble antigen	Lateral Flow EIA Device Manual immunochromatographic assay – Alere Binax Now Streptococcus pneumoniae antigen BSOP086 Pneumococcal Antigen
Faeces	Detection of <i>Helicobacter pylori</i> stool antigen	Enzyme Immunoassay (EIA) – Premier Platinum HpSA PLUS kit on Dynex DS2 ESOP028 BSOP101 Detection of <i>Helicobacter pylori</i> Antigens in Stool



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Faeces	Qualitative detection of Adenovirus and Rotavirus antigen	Lateral Flow EIA Device Manual immunochromatographic assay ROTA_ADENO Kit BSOP125 Proflow™ Rotavirus-Adenovirus Combi
	<u>Serological examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods and manufacturer's operating instructions, where relevant
Serum	Determination of HIV antibody only (third generation)	Alere - Manual quick test membrane-based EIA VSOP009 HIV confirmation using the Determine
Serum	Detection of RPR (Syphilis) non-treponemal antibody	Alere Syphilis screen RPR - card-based manual agglutination assay VSOP010 Syphilis Serology - RPR
Serum	Detection of TPPA (treponemal antibody confirmation test)	Serodia TPPA, manual agglutination assay VSOP077 Syphilis Serology - TPPA
Serum Clotted blood	Detection of: CMV IgG CMV IgM Hepatitis A IgM Hepatitis A total Hepatitis B surface antibody Hepatitis B core total Hepatitis B core IgM Hepatitis B e antigen Hepatitis B e antibody Hep B surface antigen	Roche COBAS® e602 random access immunoassay analyser on C8000 system VSOP072 Use and Maintenance of COBAS 8000 Roche Analyser Series



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Serum Clotted blood	Detection of: Hepatitis C antibody HSV type 1 antibody HSV type 2 antibody HIV 1/2 Ag / Ab antigen/antibody 4 th	Roche COBAS® e 602 on C8000 system (cont'd)
Plasma EDTA ultra low volume	Rubella IgG Syphilis total antibody EIA Toxoplasma IgG Toxoplasma IgM Hep B surface antigen	
Paediatric tube, finger prick / heel prick, capillary blood Paediatric tube, finger prick / heel prick, capillary blood	Hepatitis C antibody	
Clotted blood	Detection of Anti-streptolysin O titre	Roche c702 on COBAS® 8000 track VSOP008
Serum	Detection of: Bordetella pertussis IgG and IgA Borrelia IgG antibody Borrelia IgM antibody CMV IgG CMV IgM EBV IgG(VCA IgG) EBV IgG(EBNA IgG) EBV IgM(VCA) HIV Antigen and Antibody 4th gen (reported separately) HSV IgG total HTLV 1 + 2 Hep A total antibodies(Diasorin) Hepatitis A IgM (Diasorin) Hep B surface Ag quantitative Hep B core total (Diasorin) Hep B core IgM (Diasorin) Hep B surface Ag (Diasorin) Hepatitis C antibody(Diasorin) qualitative	Diasorin Liaison XL automated chemiluminescence (CLIA) VSOP073



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Serum	Detection of: Measles IgG antibody Mumps IgG antibody Parvovirus B19 IgM ELISA Parvovirus B19 IgG ELISA Rubella IgG Syphilis (treponemal) screen total antibody VZV IgG quantitative	Diasorin Liaison XL automated chemiluminescence (CLIA) cont'd VSOP073
Serum	Qualitative detection of HDV total antibody	Anti HD EIA (plate based EIA processed on DS2 liquid handler) VSOP078 Qualitative Determination of Total Antibodies to Hepatitis Delta Antigen (ANTI-HD) by EIA
Serum	Detection of: CMV IgG (VIDAS) HIV DUO Antigen & Antib (VIDAS 4th gen) VZV IgG Hepatitis B core total (VIDAS) Hep B surface antigen Anti-HCV (Vidas) Rubella IgG	Enzyme linked fluorescent assay (ELFA) using BioMerieux VIDAS 3 VSOP075
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis</u>	Documented in-house and manufacturer's operating instructions
Throat swab, nose swab, NPA, BAL, ETT	Detection of Influenza (A & B)	PCR using GeneXpert PSOP070
Sputum, BAL, Joint Fluid, Pleural Fluid, CSF, Tissues, Lymph Nodes, Skin Specimens, FNA, Pus, Gastric Washings, Faeces	Qualitative detection of M. tuberculosis complex and the presence/absence of mutations conferring resistance to rifampicin	PCR using GeneXpert PSOP071 Xpert MTB/RIF PCR
Faeces	Clostridium difficile test	PCR using GeneXpert PSOP072



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Genital swab Urine Throat swab Rectal swab	Detection of <i>N.gonorrhoeae</i>	PCR confirmation using the GeneXpert PSOP074
Stool / rectal swab	Detection of Norovirus	PCR using GeneXpert PSOP083
Nose and groin swabs	Detection of MRSA (mecA)	Utilising real time PCR Cepheid MRSA BSOP115 NxG on the GeneXpert
Bacterial isolates - colonies identified as being resistant to ertapenem (Enterobacteriaceae) and meropenem (non-Enterobacteriaceae)	Detection of carbapenemase encoding genes (blaVIM, blaNDM, blaOXA, blaKPC and blaIMP)	Using the Xpert Carba-R assay on the Cepheid GeneXpert. BSOP111
Vaginal/Throat/Rectal swabs Urine	Nucleic acid detection of: Chlamydia trachomatis (dual target MOMP/plamid genes) Neisseria gonorrhoeae (dual target-conserved DR9 and sequence variant of N. gonorrhoeae DNA)	Roche COBAS® 6800 PCR PSOP003 PSOP002
Plasma EDTA (standard volumes) and Plasma EDTA -ultra-low volume (200 microL paediatric tube) finger prick/heel prick - capillary blood	Quantitation of : Roche Taqman® HBV DNA (iu/ml) Roche Taqman® HCV RNA (iu/ml) Roche Taqman® HIV-1RNA (iu/ml)	Roche COBAS® 6800 analyser system using real-time PCR PSOP003



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Plasma, serum, capillary blood	Detection of: HepatitisC genotyping (primary specific real-time PCR 1-6 genotypes and subtypes 1a and 1b)	The Roche Cobas® 4800 Systems and Associated Assays PSOP002
Genital swabs (Virocult)	HSV 1/2 DNA detection	
Throat swab	Detection of Measles	PCR using Qiagen EZ1/RGQ PSOP 080
Throat swab	Detection of Mumps	PCR using Qiagen EZ1/RGQ PSOP081
BAL Induced sputum	Detection of Pneumocystis jirovecii	PCR using Qiagen EZ1/RGQ PSOP082
Eye swab	Detection of: HSV I and II VZV Chlamydia trachomatis Adenovirus	PCR using Qiagen EZ1/RGQ PSOP079
CSF	Detection of: HSV I and II VZV Enterovirus Parechovirus Mumps	PCR using Qiagen EZ1/RGQ PSOP077
Vesicle swab	Detection of: HSV I and II VZV	PCR using Qiagen EZ1/RGQ PSOP078
Whole blood (EDTA)	Detection of: Adenovirus CMV EBV	PCR using Qiagen EZ1/RGQ PSOP076
Faeces	Detection of Norovirus	PCR using Roche FLOW using TIB reagents PSOP084



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions
Throat swab, nose swab, NPA, BAL, ETT	Detection of: Influenza A capable of detecting H1N1, H2N2, H3N2, H5N1, H7N9 viruses, Influenza A pH1N109, influenza B, coronavirus type 1 pathogens NL63 and 229E, and coronavirus type 2 pathogens OC43 and HKU1, parainfluenza viruses types 1,2,3, 4a,4b, human metapneumovirus, A and B, rhinovirus, respiratory syncytial viruses A&B, adenovirus, enterovirus and parechovirus, human bocavirus, and Mycoplasma pneumoniae.	PCR using QiaSymphony/RGQ and ROCHE FLOW PSOP075
Faeces	Detection of: Salmonella species, Shigella species/Enteroinvasive E. coli (VTEC), Campylobacter jejuni/coli/lari, Cryptosporidium parvum/ hominis, Giardia lamblia, Yersinia enterocolitica, Vibrio cholera/parahaemolyticus and Entamoeba histolytica	EntericBio PCR using EntericBio Workstation and Roche Light-Cycler 480 II with Gastro Panel 2 assay and EntericBio DX assay
Nose and throat swabs	Detection of SARS CoV-2 antigen E and S gene	Altona Realstar SARS-CoV-2 RT-PCR after extraction on Roche Magpure PSOP094
Nose and throat swabs	Detection of SARS CoV-2 antigen N2 and E gene	Cepheid GeneXpert PSOP098 using Xpert-Xpress SARS-CoV-2 assay
Nose and throat swabs	Detection of SARS CoV-2 antigen ORF1a/b and E gene	Cobas SARS CoV2 RT PCR assay (ORF1a/b and E gene) on Roche Cobas 6800 PSOP095
Serum/plasma	Qualitative detection of antibodies (including IgG) to SARS-CoV-2	Elecsys anti -SARS-CoV2 by ECLIA on Roche Cobas e801 platforms VSOP082
Serum and plasma (EDTA and lithium heparin)	Qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2	Atellica IM SARS-CoV2 Total (COV2T) (chemiluminescence immunoassay) on Siemens Atellica IM analyzer VSOP082
END		