


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8403 Accredited to ISO 15189:2012</p>	University Hospital Southampton NHS Foundation Trust	
	Issue No: 002 Issue date: 30 November 2021	
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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 BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis
Urine	Detection, identification and quantification of : Red cells White cells Bacteria Epithelial cells Urinary casts Yeast cells	Automated urine Microscopy using Menarini Sedimax inverted microscope and centrifugation STH70- Urine Analysis using Menarini Sedimax
Urine	Isolation of bacterial and fungal species of clinical significance	Manual inoculation and culture using SOPs STH61, STH67
Swabs, Tissue, Fluids	Differentiation of organism types: Gram positive/negative/variable Branching organisms Yeasts	Manual Gram Staining and Light microscopy STH332
CSF, CAPD fluids,	Detection and quantification of red cells and white cells	Manual cell counts and light microscopy STH212
Ascitic fluids, joint fluids	Semi-quantitative analysis of white cells and bacteria	Manual cell counts and light microscopy STH197
Genital samples	Detection of bacteria for clinical significance for the purposes of sexual health screen (Trichomonas vaginalis and yeast, bacterial vaginosis)	Manual Acridine Orange Staining and Light microscopy SOP 235



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs, Tissue, Faeces, Fluids, Respiratory samples, CSF</p> <p>MRSA swab</p> <p>Blood, Joint fluids, Pleural fluids, Ascitic fluids, Bone marrow in culture bottles</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Isolation and characterisation of microorganisms of clinical significance.</p> <p>MRSA screening</p> <p>Isolation and characterisation of microorganisms of clinical significance</p>	<p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>Manual inoculation and media culture using in house methods:</p> <p>STH1 STH75 STH176 STH181 STH182 STH183 STH188 STH197 STH212 STH220 STH238 STH240 STH332 STH333 STHW305 STHW55 STH6</p> <p>Manual culture using prepared manufacturer's chromogenic media agar plates Identification using Bio-Rad Staph. Latex.plus kit Positives confirmed by MALDI-TOF STH174</p> <p>Liquid culture/fluorescent growth detection Media culture Liquid cultures including - adult blood cultures, Paediatric blood cultures and Mycobacteria blood cultures Biomerieux BacTAlert 3D Analyser, CO₂, in conjunction with in house documented method: STH62</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis
Sputum, ETA, BAL, BRW, Blood, Joint, Pleural, Ascitic pericardial fluids, CSF, Tissues	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Microscopy and Culture using BD MIGIT in conjunction with in house documented method: STH172 - Reporting of AFB Microscopy (Fluorescence) ZN and Phenol Auramine staining STH169, STH173
Blood	Detection of Mycobacterium tuberculosis	Enzyme Linked Immunoassay STH73- Quantiferon –TB GOLD (In Tube Method)
Clinical isolates cultured in-house (inc. bacteria/yeasts/fungi)	Identification of microorganisms of clinical significance	BRUKER Biotyper MALDI-TOF (Matrix-Assisted Laser Desorption-Ionisation Time-Of-Flight mass spectrometry) in conjunction with in house documented method: STH71
Bacterial isolates cultured in-house	Antimicrobial susceptibility testing (AST)	Media culture Manual antimicrobial susceptibility testing using EUCAST methodology STH275
Bacterial isolates	Antimicrobial susceptibility testing (AST)	Reflex testing Media culture Manual antimicrobial susceptibility testing antibiotic disc diffusion and gradient MIC determination by Etest STH114, STH226
Yeast isolates	Anti-fungal susceptibility testing	Anti-fungal Etests STH241
Bacterial isolate	Screening for Carbapenamase producing Enterobacteriaceae	Antimicrobial susceptibility testing using disc diffusion STH76 Identification using Bruker Maldi-Tof



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis
Hair, Nail, Skin, Swabs	Isolation and identification of dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (light and fluorescence) Calcofluor white LactoFuschin using: STH239, STH72, STH241
Faeces	Detection and Identification of enteric parasites	Light Microscopy Midi Parasep concentration method STH177
Faeces	Detection of H.pylori faecal antigen	Commercial kit IDEIA Hp Star ELISA STH185- Detection of H Pylori Antigens in Faecal Samples by ELISA
Faeces	Detection of Clostridium difficile DNA	Enteric Bio Platform - PCR STH337 STH192- Isolation and identification of Clostridium difficile from stool specimens
Faeces	Detection of Clostridium difficile toxin A and B	Commercial kit Launch C diff Toxin A and B ELISA STH184
Faeces	Detection of E coli 0157 Shigelle sp Salmonella sp Campylobacter sp Giardia Cryptosporidium	Enteric Bio Platform - PCR STH338 Gastro Panel



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Faeces	Isolation and characterisation of microorganisms of clinical significance	Microscopy and Culture for isolation of pathogens STH176-Investigation of faecal samples for routine enteric pathogens STH177- Examination of specimens for Ova, Cysts and Parasites STH179-Isolation of Vibrio cholera/parahaemolyticus STH181- Identification of food poisoning outbreaks STH182- Isolation of Yersinia enterocolitica STH183- Plesiomonas shigelloides and aeromonas STH178-Preparation of positive control slides for Cryptosporidium
Blood culture	Detection of Cryptococcal antigen	Commercial test IMMY Immunochromatographic Lateral flow assay STH330



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Blood</p>	<p><u>Serological examination activities for the purpose of clinical diagnosis</u></p> <p>Qualitative detection of</p> <p>Microparticle immunoassay (CMIA) HIV 1&2 antibody + p24 antigen Hepatitis B core antibody (HBcAb) Hepatitis B e antigen (HBe) Hepatitis B e antibody (anti HBe) Hepatitis A antibody Hepatitis A IgM Hepatitis C IgG Syphilis total antibody HTLV 1&2 antibody Parvovirus B19 IgG Parvovirus B19 IgM Epstein Barr Virus(EBV) EBNA IgG EBV VCA IgG EBV VCA IgM Cytomegalovirus IgG Cytomegalovirus IgM CMV IgG avidity Toxoplasma IgG Toxoplasma IgM Rubella IgM Borrelia IgG Borrelia IgM Measles IgG Mumps IgG</p>	<p>Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis</p> <p>Manufacturer's instructions for Diasorin Liaison XL in conjunction with in house documented method: STH159 - Operation of the Diasorin Liaison XL Chemiluminescence</p>



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Blood	Quantitation of Anti HBs Rubella IgG VZV IgG Hepatitis B surface antigen(HBsAg)	Manufacturer's instructions for Diasorin Liaison XL in conjunction with in house documented method: STH159 - Operation of the Diasorin Liaison XL Chemiluminescence
Blood	Qualitative detection of HIV antigen and antibody Hepatitis B core IgM	Biomerieux VIDAS Elfa Automated Analyser in conjunction with in house documented method: STH139
Blood	Quantitation of Mycoplasma IgM	Manual commercial kit EuroImmune STH151 - Enzyme immunoassay for the detection of IgM to Mycoplasma pneumoniae in serum



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Blood	Semi-quantitative detection of Mycoplasma antibody	Commercial kit by MAST STH143 - Agglutination test for the detection of antibodies to Mycoplasma pneumoniae
Blood	Semi-quantitative detection of Antistreptolysin O	Commercial kit by Biokit STH152- Latex agglutination test for the detection of Antibodies to Streptolysin O (ASO)
Blood	Quantitation of Anti DNase B	Commercial kit by Biomerieux STH154 - Quantitative assay to determine the presence of antibodies to DNase-B in the serum Enzyme inhibition assay
Blood	Detection of Hepatitis E IgG and IgM	Commercial kit by Fortress Diagnostic STH155 - Enzyme-linked immunosorbent assay for the qualitative detection of IgM and IgG class antibodies to Hepatitis E virus
Blood	Detection of Syphilis IgM	Commercial kit by Lab21 STH150 - Enzyme immunoassay (EIA) for the qualitative detection of Syphilis IgM
Blood	Confirmation of HIV type 1 and 2	Immunochromatography using BioRad Geenius analyser STH300
Blood	Detection of Treponema pallidum (TPPA)	Commercial kit by MAST STH141- Particle agglutination test for the detection of antibodies to Treponema pallidum
Blood	Quantitation of Rapid Plasma Reagin (RPR/VDRL)	Commercial kit by Biokit Particle agglutination STH142



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis
Blood	Quantification of HCV RNA HIV RNA	Abbott M2000 system in conjunction with in house documented method: STH123 Performance of HIV and HCV viral loads
Blood	Quantification of HBV DNA	STH134- Quantitative detection of Hepatitis B (HBV) DNA using Abbott M2000
Various – including urine, genital swabs, rectal swabs, pharyngeal and eye swabs:	Detection of Chlamydia trachomatis (CT) Neisseria gonorrhoeae (NG)	Hologic GenProbe Panther system in conjunction with in house documented method: STH136- Performance of molecular assays for Chlamydia trachomatis and Neisseria gonorrhoeae on GenProbe panther system
Throat/Nasal Swabs in Virus Transport medium	Detection of SARS-CoV-2 ORF1ab Region 1 and ORF1ab Region 2	Hologic Aptima SARS-CoV-2 Assay Kit and Hologic Panther using Transcription Mediated Amplification (TMA) and Dual Kinetic Assay (DKA) for presumptive results only. In house procedure STH136
Respiratory secretions, broncho-alveolar lavage and upper respiratory tract swabs	Detection of respiratory viruses: Pneumocystis jirovecii Flu a b RSV Metapneumo Rhinovirus Para flu 1,2 and 3	QiaSymphony Extraction Platform Abi 7500 PCR in conjunction with in house documented method: STH121
Respiratory secretions, broncho-alveolar lavage and upper respiratory tract swabs	Detection of Bordetella pertussis	QiaSymphony Extraction Platform Abi 7500 PCR in conjunction with in house documented method: STH163
Respiratory secretions, broncho-alveolar lavage and upper respiratory tract swabs	Detection of Measles RNA	QiaSymphony Extraction Platform Abi 7500 PCR in conjunction with in house documented method: STH115



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Stool samples	Detection of Norovirus genotype 1 and 2	QiaSymphony Extraction Platform Abi 7500 PCR in conjunction with in house documented method: STH115
Blood	Quantitation of Cytomegalovirus(CMV) Epstein Barr virus(EBV)	QiaSymphony Extraction Platform Abi 7500 PCR in conjunction with in house documented method: STH118-Quantification of CMV and/or EBV copy number in clinical samples using real-time duplex PCR
Swabs from any site, blood, stool, respiratory, CSF	Detection of HSV 1 and 2, varicella zoster virus, enterovirus, adenovirus <i>Neisseria meningitidis</i>	QiaSymphony Extraction Platform Abi 7500 PCR STH128 Standard Operating procedure for the applied biosystems™ 7500 fast real-time PCR system STH115- Detection of HSV, VZV, Adenovirus, T. pallidum (syphilis) and Meningococcal nucleic acid in clinical samples using real time PCR STH124; STH125; STH128
Throat/Nasal Swabs in Virus Transport medium	Detection of SARS-CoV-2 ORF1ab and ORF8 genes and other Coronaviruses including Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63 and MERS-CoV.	BioFire Respiratory 2.1 (RP2.1) Panel with BioFire FilmArray Torch System using Real time RT-PCR for presumptive results only. In house procedure STH800
Throat/Nasal Swabs in Virus Transport medium	Multiplexed Real-time RT-PCR for SARS-CoV-2 Envelope E gene and Nucleocapsid N2 gene Detection of Flu A, Flu B and RSV	Cepheid GeneXpert Xpert Xpress SARS-CoV-2, Flu A & B and RSV kit and GeneXpert GX-XVI Processing Unit. In house procedure STH807
END		