


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: 006 Issue date: 24 August 2023	
	Department of Microbiology Level B Pathology Block Southampton General Hospital Tremona Road Southampton SO16 6YD	Contact: Diane Matley Tel: +44 (0)23 8120 6408 E-Mail: Diane.Matley@uhs.nhs.uk
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 Semi Automated Antimicrobial susceptibility testing by MAST Uri System in conjunction with documented in house method STH814
Swabs, Tissue, Fluids	Differentiation of organism types: Gram positive/negative/variable Branching organisms Yeasts	Manual Gram Staining and Light microscopy STH332



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>CSF, CAPD fluids,</p> <p>Ascitic fluids, joint fluids</p> <p>Genital samples</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection and quantification of red cells and white cells</p> <p>Semi-quantitative analysis of white cells and bacteria</p> <p>Detection of bacteria for clinical significance for the purposes of sexual health screen (Trichomonas vaginalis and yeast, bacterial vaginosis)</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 cell counts and light microscopy STH212</p> <p>Manual cell counts and light microscopy STH197</p> <p>Manual Acridine Orange Staining and Light microscopy STH 5</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Swabs, Tissue, Faeces, Fluids, Respiratory samples, CSF	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u> Isolation and characterisation of microorganisms of clinical significance.	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis Manual inoculation and media culture using in house methods: STH5 STH6 STH176 STH179 STH197 STH212 STH220 STH238 STH240 STH269 STH331 STH792 STH793 STH794 STH795 STH796 STH808 STHW55 STHW305
MRSA swab	MRSA screening	Manual culture using prepared manufacturer's chromogenic media agar plates Identification using Bio-Rad Staph. Latex.plus kit Positives confirmed by MALDI-TOF STH174
VRE Swab	Screening for Vancomycin Resistant Enterococci	Manual culture using prepared manufacturer's chromogenic media agar plates STH1 Positives confirmed by 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 based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis
CRE Swab	Detection of Carbapenamase producing Enterobacteriaceae	Manual culture using prepared manufacturer's chromogenic media agar plates STH75 Positives confirmed by Cepheid GeneXpert RT-PCR in conjunction with documented in house method STH789
ESBL Swab	Screening for Extended Beta-Lactamase producing Bacteria (Outbreaks)	Manual culture using prepared manufacturer's chromogenic media agar plates STH811 Positives confirmed by MALDI-TOF
Blood, Joint fluids, Pleural fluids Ascitic fluids, Bone marrow in culture bottles, tissues	Isolation and characterisation of microorganisms of clinical significance	Liquid culture growth detection Media culture and light microscopy Liquid cultures including - adult blood cultures, Paediatric blood cultures BD BacTec FX Analyser, in conjunction with in-house documented method STH62, STH197, SMI B37



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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
Bone Marrow and Blood in Blood Culture Bottles	Isolation and presumptive identification of Acid-Alcohol Fast Bacillis (including Mycobacterium spp.)	Liquid culture growth detection using BD BacTec FX40 analyser, in conjunction with in-house documented method STH169, SMI B40
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: STH169 Culture and Isolation of TB
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 STH275 STH226
Yeast isolates	Anti-fungal susceptibility testing	Anti-fungal Etests STH241



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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
Bacterial isolate	Screening for Carbapenamase producing Enterobacteriaceae	Antimicrobial susceptibility testing using disc diffusion STH76 Identification using Bruker Maldi-Tof and confirmed by Cepheid GeneXpert RT-PCR in conjunction with documented in house method STH789
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



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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
Faeces	Detection of Clostridium difficile DNA	Enteric Bio Platform - PCR STH337
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
Faeces	Detection of Adenovirus Rotavirus Sapovirus Astrovirus Norovirus G1 and G11	Enteric Bio Platform - PCR STH804 Viral 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- Culturing for additional Faecal pathogens
Blood culture	Detection of Cryptococcal antigen	Commercial test IMMY Immunochromatographic Lateral flow assay STH330
Bacterial Isolates	Detection of Carbapenamase producing Enterobacteriaceae	Cepheid GeneXpert RT-PCR in conjunction with documented in house method STH789
Sputum, BAL, Bronchial Washings, CSF, Lymph nodes, Sterile tissues, bone and joint aspirates	Detection of Mycobacterium tuberculosis complex DNA	Cepheid GeneXpert RT-PCR in conjunction with in-house documented method STH264



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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)</p> <p>Hepatitis B e antigen (HBe) Hepatitis B e antibody (anti HBe) 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 CMV IgG avidity Borrelia IgG Borrelia IgM Measles IgG Mumps IgG HSV 1 & 2 Hepatitis E IgG Hepatitis E IgM Sars CoV-2 IgG (Trimeric Assay)</p>	<p>Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis</p> <p>Documented in-house methods to meet the requirements of the IDPS screening programme(s) as defined in the July 2018 'Infectious diseases in pregnancy screening: Laboratory QC evidence requirements (relevant tests marked with *)</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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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis
Blood	Quantitation of 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	Semi-Qualitative detection of: Mycobacterium tuberculosis	Manufacturer's instructions for Diasorin Liaison XL in conjunction with in house documented method: STH159 - Operation of the Diasorin Liaison XL Chemiluminescence Using LIAISON QuantiFERON TB Gold Plus
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	Qualitative detection of: HIV 1&2 antibody + p24 & p26 antigen* Hepatitis B core antibody (HBcAb) Hepatitis A antibody Hepatitis A IgM Hepatitis C IgG Cytomegalovirus IgG Cytomegalovirus IgM Toxoplasma IgG Toxoplasma IgM Rubella IgM	Manufacturer's instructions for Beckman Coulter Dxl with in house documented method: STH345 Operation of Dxl Using Microparticle Immunoassay (CMIA)
Blood	Quantitative detection of: Anti HBs Rubella IgG	Manufacturer's instructions for Beckman Coulter Dxl with in house documented method: STH345 Operation of Dxl Using Microparticle Immunoassay (CMIA)



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Blood	Semi-quantitative detection of Antistreptolysin O	Commercial kit Rheumajet ASO STH152- Latex agglutination test for the detection of Antibodies to Streptolysin O (ASO)
Blood	Detection of Syphilis IgM	Commercial kit by Trinity Biotech 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 (TPHA)	Commercial kit by Fortress STH141- Particle agglutination test for the detection of antibodies to Treponema pallidum



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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	Quantitation of Rapid Plasma Reagin (RPR/VDRL)	Commercial kit ASI RPR Particle agglutination STH142
Nasal swabs, throat swabnose-/throat combined, mid-turbinate and nasopharyngeal swabs	Real-Time PCR for Sars CoV-2 Envelope E gene and Nucleocapsid N2 gene Sars CoV-2	Kingfisher (Nimbus Presto) Extraction Platform, Qiagility sample handler with STH128 Standard Operating procedure for the applied biosystems™ 7500 fast real-time PCR in conjunction with in house documented method: STH802 In house CDC-WHCV assay
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: STH115
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: STH115
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
Serum and Plasma Samples	Quantitation of HIV Viral RNA, Hepatitis B DNA Hepatitis C DNA	Manufacturer's instructions for Abbott Alinity M System with in house documented method for STH791 Use of the Abbott Alinity m System
Endocervical swabs, vaginal swabs, urine samples, rectal swabs	Detection of Chlamydia trachomatis Neisseria gonorrhoea	Manufacturer's instructions for Abbott Alinity M System with in house documented method for STH791 Use of the Abbott Alinity m System



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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 SARS-CoV-2 , 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		