## **Schedule of Accreditation**

issued by

## **United Kingdom Accreditation Service**

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



Accredited to ISO 15189:2012

## The Shrewsbury & Telford Hospital NHS Trust

Issue No: 012 Issue date: 11 February 2025

Department of Pathology Royal Shrewsbury Hospital Mytton Oak Road

Shrewsbury SY3 8XQ

**United Kingdom** 

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www.sath.nhs.uk/services/pathology/default.aspx

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	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods based on manufacturer's operating instructions
Urine	Isolation of bacterial and fungal species of clinical significance	Manual inoculation and media culture SOP - SHBACT 002
Blood	Isolation and characterisation of microorganisms of clinical significance	BACTEC FX liquid culture/fluorescent growth detection Media culture Liquid cultures including adult blood cultures, paediatric blood cultures SOP - SHBACT007/SHBACT007A Light microscopy – manual gram staining- manual interpretation SOP - SHBACT041
CSF	Detection and quantification of white & red blood cells and isolation and characterisation of microorganisms of clinical significance	Modified Fuchs Rosenthal counting chamber, light microscope SOP - SHBACT004 Previ-color cytospin- manual gram stain- manual interpretation SOP - SHBACT004 / SHBACT041 Non selective, enriched culture plates SOP - SHBACT004
Isolates from urines, swabs, faeces	Screening for Carbapenemase (CRE) resistant organisms (OXA-48, KPC, NDM, VIM) assay	SHBACT 76 SHBACT41-RESIST 4 OKNVI kit based on immunochromatographic test

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on Manufacturer's instructions
Blood cultures, Swabs, Tissues, Faeces, Fluids, Respiratory samples	Isolation and characterisation of microorganisms of clinical significance	Manual inoculation and media culture SOP - SHBACT007 SOP - SHBACT003 SOP- SHBACT006 SOP- SHBACT-009 SOP - SHBACT010 SOP - SHBACT014 SOP - SHBACT027A,B,C SOP - SHBACT041 SOP - SHBACT045 SOP - SHBACT046 SOP - SHBACT047 SOP - SHBACT048 SOP - SHBACT049 SOP - SHBACT076 SOP - SHBACT077 SOP - SHBACT078
Tissue culture, sterile fluid cell line Cartilage graft culture fluid	Identification of microorganisms of clinical significance	BACTEC FX liquid culture/fluorescent growth detection Media culture SOP - SHBACT007/SHBACT007A, SHBACT048 Light microscopy – manual gram staining- manual interpretation SOP - SHBACT041
Skin scapings, Nail clippings, Hair samples	Isolation and identification of fungi of clinical significance  Presence or absence of fungal elements	Media culture, macroscopic examination Light microscope Wet film microscopy SOP – SHBACT008
Clinical isolates cultured inhouse (inc. bacteria/yeasts/fungi)	Identification of microorganisms of clinical significance	Bruker Microflex Biotyper (MALDI-TOF) Mass spectrometry Commercial Reagents SOP – SHBACT075 SOP – SHBACT041 SHBACT010 SHBACT007

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on Manufacturer's instructions
Urine	Detection and quantification of red cells, white cells, bacteria, epithelial cells, urinary casts and small particles	Automated urine microscopy The Iris IQ200 Sprint SOP – SHBACT080
Urine	Identification of Schistosoma haematobium	Light Microscope SOP - SHBACT10B
Urine	Legionella pneumophila serogroup 1 antigen	Lateral flow EIA device Manual immunochromatographic assay – Binax Now Legionella urinary antigen SOP - SHBACT 002
Urine	Pneumococcal soluble antigen	Lateral flow EIA device Manual immunochromatographic assay – Binax Now Streptococcus pneumoniae urinary antigen SOP - SHBACT 002
Swabs, Fluids	Detection and quantification of white blood cells, red blood cells and epithelial cells	Light microscope Centrifuge Wet film microscopy SOP - SHBACT003 SOP - SHBACT014 SOP - SHBACT041 SOP - SHBACT045 SOP - SHBACT046 SOP - SHBACT048 SOP - SHBACT057
Sterile fluids – Ascitic, Peritoneal	Detection and quantification of white blood cells	Modified Fuchs Rosenthal counting chamber, light microscope, manual interpretation SOP - SHBACT048

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on Manufacturer's instructions
Faeces	Detection of Clostridioides difficile GDH antigen	a single use rapid membrane immunoassay EIA device using Pro- lab Lateral flow SOP - SHBACT042
Faeces	Detection of <i>Clostridioides difficile</i> Toxin A + B	Qualitative detection of <i>C.Difficile</i> Toxin A+B using Meridian Immunocard A+BSOP – SHBACT042
Faeces	Detection of toxogenic C difficile	Molecular biological rapid test for the direct detection of toxigenic <i>C. difficile</i> Amplex eazyplex® <i>C. difficile</i> Basic assay loop mediated isothermal amplification (LAMP) SOP – SHBACT042
Bacterial colonies of Staphylococcus aureus	Detection of MRSA and PVL	Molecular rapid test used for the detection of Methicillin-resistant Staphylococcus aureus (MRSA) and Panton-Valentine leukocidin (PVL) Amplex eazyplex® MRSAplus which uses loop mediated isothermal amplification (LAMP) SOP - SHBACT041
Faeces	Detection of Rotavirus antigen	Lateral flow EIA Device Manual immunochromatographic assay. ImmunoCard STAT! Rotavirus immunoassay SOP – SHBACT010A
Swabs, Tissue, Fluids	Differentiation of different organism types: gram positive/negative/variable, branching organisms, yeasts.	Light microscope, Centrifuge, Gram staining microscopy SOP - SHBACT003 SOP - SHBACT010 SOP - SHBACT014 SOP - SHBACT023 SOP - SHBACT041 SOP - SHBACT045 SOP - SHBACT046 SOP - SHBACT048 SOP - SHBACT057

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on Manufacturer's instructions
Faeces	Detection and quantification of white blood cells, red blood cells; identification/confirmation of faecal parasites	Light microscopy using direct manual microscopy or lodine staining or ova concentration test SOP – SHBACT010B
Faeces	Cyclospora oocysts	Autofluorescence using UV microscopy SOP – SHBACT010B
Faeces	Cryptosporidium oocysts	UV microscope, modified Auramine phenol staining Microscopy SHBACT010B
CSF Fungal isolates	Presence or absence of Cryptococcus species	Light microscope Centrifuge India ink stain SOP – SHBACT004 SOP- SHBACT057

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on Manufacturer's instructions
Clinical isolates cultured in- house (inc. bacteria/yeasts/fungi)	Identification of N. gonorrhoeae	Gonogen II SHBACT03 Immunoassay kit
Clinical isolates (aerobic bacteria and <i>Streptococcus pneumonia</i> cultured in-house from various sample types	Antimicrobial susceptibility testing of clinically significant bacteria	Beckman Coulter MicroScan based on colorimetric optical system- Semi Automated Antibiotic Sensitivity Platform (MIC)

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods based on Manufacturer's instructions
Serum	Antibody / antigen tests  Hepatitis B surface antigen Varicella zoster IgG Rubella IgM HIV Hepatitis C Epstein Barr EBNA IgG Measles IgG Borrelia burgdorfori IgM/ Borrelia burgdorfori IgG	Automated immunoassay system based on VIDAS ELFA principles measurement on VIDAS 3 VIDAS® HBsAg Ultra VIDAS® HBsAg Ultra VIDAS® Rubella IgM VIDAS® Rubella IgM VIDAS® ANTI –HCV VIDAS® EBV EBNA IgG VIDAS® Measles IgG VIDAS HIV DUO Quick VIDAS® Lyme IgM/ VIDAS® Lyme IgG SOP - SHSER017A  Documented-in-house methods to meet the requirements IDPS screening programme as defined in the laboratory QA evidence requirements'
Serum	Detection of antibodies/antigens:  HIV 1&2 antibodies and HIV 1 p24 antigen* Hepatitis B surface antigen* Syphilis Total Antibody* Hepatitis B antibody Hepatitis B total core antibody Hepatitis C antibody HTLV I/II antibody Rubella IgG antibody CMV IgM CMV IgM Toxoplasma IgG Toxoplasma IgM Hepatitis A Total Hepatitis A IgM	Competitive and non-competitive Immunoassays, Roche e801 module Elecsys HIV Duo  Elecsys HBsAg – II Elecsys Syphilis Elecsys Anti HBs – II Elecsys Anti HBc –II Elecsys Anti-HCV – II Elecsys HTLV Elecsys Rubella IgG Elecsys CMVM Elecsys CMV G Elecsys Toxo G Elecsys Toxo M Elecsys Anti HAV Elecsys Anti HAV

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods based on Manufacturer's instructions
Serum	Detection of Antistreptolysin O antibody	Manual Latex agglutination test with visual interpretation in conjunction with manufacturer's instructions using Rheumajet ASO SOP - SHSER001
Serum	HIV Confirmatory Assay - detection of antibodies to HIV-1 and HIV-2	A rapid immunochromatogenic test Bio-Rad Geenius HIV 1/2 Manual process& interpretation SOP-SHSER0037
Blood	Therapeutic drug monitoring:  Gentamicin Vancomycin Tobramycin	ROCHECOBAS c702 based on measurement by turbidometry, colourimetry Cobas GENT2 Cobas VANC3 Cobas TOBR2 SOP - SHBACT022A
Faeces	Faecal calprotectin	Analysed on the Phadia Immunocap 250 using EliA fluorescence enzyme immuno assay SOP – SHBACT082
	Miscellaneous activities for the purpose of clinical diagnosis	Documented in-house methods based on Manufacturer's instructions
Joint fluids	Presence or absence of Calcium pyrophosphate or Uric acid crystals to aid the diagnosis of gout/pseudogout	Polarised microscope Wet film microscopy SOP – SHBACT048
	END	

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