


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	University Hospitals Plymouth NHS Trust	
	Issue No: 008 Issue date: 25 March 2025	
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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 Swabs from wounds, genital sites, eyes, nose, throat, ears; respiratory and gastric fluids, CSF, CAPD fluids, bone marrow, tissue.	<u>Microbiology examinations for the purpose of clinical diagnosis</u> General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant Manual culture and cell count as relevant using SOPs M-301 Investigation of Gastric and Respiratory Aspirates M-302 Investigation of Sputum M-303 Investigation of Wounds and Associated Specimens M-304 Investigation of Genital Swabs M-306 Swabs from Upper Respiratory Tract and Eyes M-310 Procedure for the Examination of CSF M-312 Procedure for the Examination of CAPD Effluent M-330 Procedure for the Examination of Bone Marrow Harvest Cell Samples for Sterility M-313 MRSA screening M-392 MSSA screening M-678 Carbapenem resistant enterobacteriaceae (CRE) screening Anti-microbial susceptibility testing by EUCAST disc diffusion and SOP M-315 Anti-microbial susceptibility testing using Phoenix analyser and SOP M-315. Anti-microbial MIC determination using E Test and SOP M-315



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Swabs from wounds, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, CAPD fluids, bone marrow, tissue. Faeces	<u>Microbiology examinations for the purpose of clinical diagnosis (cont'd)</u> General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing General isolation and characterisation and sensitivity testing of microorganisms of clinical significance Detection of faecal ova, cysts and parasites Detection of C difficile glutamate dehydrogenase (GDH) Detection of H pylori antigen Detection of Rotavirus antigen Detection of Cryptosporidium and Giardia Detection of C difficile GDH and toxin A and B	In-house documented procedures based on equipment manuals and follow current UKHSA SMLs as relevant Manual culture and cell count as relevant using SOPs Antifungal susceptibility testing using Sensititre YeastOne and SOP M-361 Bacterial and yeast identification using Maldi-tof Mass Spectrometry and SOP M-393 Manual culture using SOP M-305 Anti-microbial susceptibility testing by EUCAST disc diffusion and SOP M-315 Manual microscopy following faecal concentration using Midi-parasep kit and SOP M-305 DS2 analyser using: TechLab C diff Chek-60 DGH kit and SOP M-150 Oxoid IDEIA HpStAR kit and SOP M-107 Techlab Giardia/Crypto CHEK kit EIA SOP M-183 Techlab rapid card confirmation kit SOP M-183 Membrane immunoassay using TechLab C diff Quik Chek kit and SOP M-150



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and follow current UKHSA SMLs as relevant
Urine	Detection of white blood cells, red blood cells, casts, epithelial cells, bacteria	Iris IQ Sprint urine analyser using digital imaging and particle counting, SOP M-307
	Isolation of clinically significant organisms	Manual Culture, SOP M-307
Respiratory samples, body fluids and tissue samples	Detection and presumptive identification of acid-alcohol fast bacilli (inc. Mycobacterium species)	BD MGIT automated culture system and SOP M-308 Manual culture on Löwenstein-Jensen medium and SOP M-308. Confirmation microscopy using Ziehl Neelsen and SOP M-381 Fluorescent microscopy using phenol auramine stained smears and SOP M-308
Whole blood	Detection of microbial growth and general isolation of micro-organisms of clinical significance	Bactec FX and Bactec FX40 automated systems using SOP M-309 Saponin extraction of blood culture for Maldi-TOF mass spectrometry using SOP M-393
Joint fluid	Detection of crystals	Manual microscopy using birefringent microscopy and SOP M-383
Skin, nail, hair	Detection and general isolation and characterisation of fungi and yeasts of clinical significance	Manual microscopy using KOH and sellotape preparations and SOP M-319 Manual culture using SOP M-319



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examinations for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant
Serum	HIV confirmation test	Bio-Rad Geenius HIV 1&2 confirmatory assay (SOP M-108)
Serum	Detection of anti-streptolysin O antibody	Manual latex agglutination test using Biokit Rheumajet ASO kit and SOP M-113
Urine	Detection of Legionella pneumophila serogroup 1 and Strep pneumoniae antigen	Membrane assay using Binax NOW Legionella and Strep pneumoniae kit and SOP M-128
Serum	Detection of non-specific antibody for Treponema pallidum	Manual flocculation test using SOP M-109 RPR CARBON by BIOELISA
Serum, plasma	Detection of the following: Hepatitis B surface antigen Hepatitis core IgM Hepatitis B core total Hepatitis C antibody Rubella IgM HIV antigen and antibody Varicella Zoster IgG Lyme Disease IgM and IgG Mumps IgG	Biomerieux VIDAS 3 ELISA analyser and SOP-M175



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and follow current UKHSA SMLs as relevant
Serum, plasma	<p>Detection of the following:</p> <p>Rubella IgG Hepatitis B surface antigen* Hepatitis B core antibody Hepatitis B surface antibody</p> <p>Hepatitis B e antigen and antibody Hepatitis C antibody * HIV-1 & HIV-2 Antibodies and HIV1 p24 Antigen*Syphilis total antibody * CMV IgG & IgM HTLV I&II antibody Hepatitis A IgM Toxoplasma IgG & IgM Epstein Barr virus: VCA IgM, VCA IgG, EBNA IgG</p>	<p>Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme as defined in the laboratory QA evidence requirements' (targets marked *)</p> <p>Architect i2000sr random access analyser</p> <p>Architect Rubella IgG (SOP M-199) Architect HBsAg Qual II (SOP M-104) Architect Anti HBc II (SOP M-104) Architect Hepatitis B surface antibody (SOP M-200) Architect HBeAg and Anti HBe (SOP M-104) Architect Anti HCV (SOP M-106) Architect HIV Ag/Ab Combo (SOP M-108) Architect Syphilis (SOP M-109) Architect CMV IgG & IgM (SOP M-196) Architect HTLV-I/II (SOP M-201) Architect IgM (SOP M-193) Architect Toxo IgG & IgM (SOP M-197) Architect : EBV VCA Igm , EBV VCA IgG, EBV EBNA-1 IgG (SOP M- 195)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant
Nasal swabs	Detection of the following: Detection of Staph aureus mecA and mecC gene	Using the BD-MAX analyser: MRSA detection by PCR (SOP M-152)
Faeces	Detection of DNA for Clostridium difficile Detection of DNA for Enteric bacterial pathogens	Procedure for Detection of C.difficile (SOP M-150) BD Max Enteric PCR (SOP M-186)
Serum, plasma	Detection of DNA/RNA (Viral Loads) for the following: CMV EBV	CMV and EBV DNA by Abbott realtime PCR (SOP M-194)
Serum, plasma	Detection of DNA for the following: Adenovirus BK virus	Argene Adenovirus and BKV PCR kit SOP M-178



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Nose, throat swabs, Bronchial lavage and nasopharyngeal aspirates Isolates of Staph aureus	<u>Molecular examinations for the purpose of clinical diagnosis (cont'd)</u> Detection RNA for respiratory viruses: Influenza A Influenza B Adenovirus RSV (A & B) Human Metapneumovirus Parainfluenza (1-4) Coronavirus Enterovirus Rhinovirus Detection of Staph aureus Panton Valentine leucocidin (PVL) gene	In-house documented procedures based on equipment manuals and follow current UKHSA SMLs as relevant PCR using EasyMag extraction, Argene Respiratory PCR kits and ABI prism 7500 (SOP M-173) Progenie realcycler Staph aureus and PVL detection PCR kit and SOP M-172
END		