


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8050</p> <p>Accredited to ISO 15189:2012</p>	<h3>University Hospitals Plymouth NHS Trust</h3> <p>Issue No: 006 Issue date: 03 August 2021</p>	
	<p>University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Road Plymouth PL6 8DH</p>	<p>Contact: Felicity Newman-Webb Tel: +44 (0)1752 792369 E-Mail: felicity.newman-webb@nhs.net Website: www.plymouthhospitals.nhs.uk</p>
<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
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Swabs from wounds, genital sites, eyes, nose, throat, ears; respiratory and gastric fluids, CSF, CAPD fluids, bone marrow, tissue.</p>	<p><u>Microbiology examinations for the purpose of clinical diagnosis</u> General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing</p>	<p>In-house documented procedures based on equipment manuals and follow current PHE SMLs as relevant Manual culture and cell count as relevant using SOPs</p> <p>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 -387 Sonication of prosthetic joints M-313 MRSA screening M-392 MSSA screening M-678 Carbapenem resistant enterobacteriaceae (CRE) screening Carbapenemase testing using CORIS and SOP M-678 Sample preparation using WASP sample processor 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</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs from wounds, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, CAPD fluids, bone marrow, tissue.</p> <p>Faeces</p>	<p><u>Microbiology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance and antimicrobial susceptibility testing</p> <p>General isolation and characterisation and sensitivity testing of microorganisms of clinical significance</p> <p>Detection of faecal ova, cysts and parasites</p> <p>Detection of C difficile glutamate dehydrogenase (GDH)</p> <p>Detection of H pylori antigen</p> <p>Detection of Rotavirus antigen</p> <p>Detection of Cryptosporidium and Giardia</p> <p>Detection of C difficile GDH and toxin A and B</p>	<p>In-house documented procedures based on equipment manuals and follow current PHE SMLs as relevant</p> <p>Manual culture and cell count as relevant using SOPs</p> <p>Antifungal susceptibility testing using Sensititre YeastOne and SOP M-361</p> <p>Bacterial and yeast identification using Maldi-tof Mass Spectrometry and SOP M-393</p> <p>Manual culture using SOP M-305</p> <p>Anti-microbial susceptibility testing by EUCAST disc diffusion and SOP M-315</p> <p>Manual microscopy following faecal concentration using Midi-parasep kit and SOP M-305</p> <p>DS2 analyser using:</p> <p>TechLab C diff Chek-60 DGH kit and SOP M-150</p> <p>Oxoid IDEIA HpStAR kit and SOP M-107</p> <p>Oxoid ProSpecT ELISA and SOP M-127</p> <p>Techlab Giardia/Crypto CHEK kit EIA SOP M-183</p> <p>Techlab rapid card confirmation kit SOP M-183</p> <p>Membrane immunoassay using TechLab C diff Quik Chek kit and SOP M-150</p>



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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 PHE SMI's 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 PHE SMLs 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
Serum	Detection of anti-streptodornase B (anti-DNA'se B)	Manual test using Biomerieux ASD kit and SOP M-114
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	Detection of Mycoplasma antibody	Manual agglutination tests using Serodia Myco II and SOP M-120
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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Serum, plasma	Detection of the following: Varicella Zoster IgG Measles IgG Parvovirus B19 IgM Parvovirus B19 IgG Hepatitis E IgG & IgM	Dynex DS2 ELISA analyser Binding site VaccZyme VZV Low level IgG EIA and SOP M-151 Novalisa Measles IgG EIA kit and SOP M-169 BIOTRIN ELISA and SOP M-133 BIOTRIN ELISA and SOP M-137 HEV IgG / IgM EIA (Fortress diagnostics) SOP M-179
Blood	Quantiferon TB (Interferon γ Release Assay (IGRA)	Quantiferon Plus TB Gold ELISA kit and DS2 SOP M-176
Serum, plasma	Detection of the following: Rubella IgG Hepatitis B surface antigen Hepatitis B core antibody Hepatitis B surface antibody Hepatitis B e antigen and antibody Hepatitis C antibody HIV antigen and antibody Syphilis antibody IgG CMV IgG & IgM HTLV I&II antibody Hepatitis A IgM Toxoplasma IgG & IgM Epstein Barr virus: VCA IgM, VCA IgG, EBNA IgG	Architect i2000sr random access analyser 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)



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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 PHE SMLs 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)
Nose & Throat swabs and Nasopharyngeal aspirates	Detection of Influenza A/B and Respiratory Syncytial Virus (RSV)	Viasure Flu A/B and RSV PCR test (SOP 173)
Faeces	Detection of DNA for Clostridium difficile	Procedure for Detection of C.difficile (SOP M-150)
	Detection of DNA for Enteric bacterial pathogens	BD Max Enteric PCR (SOP M-186)
	Detection of the following:	Using the M2000 analyser:
Urine, genital swabs	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	Chlamydia and GC PCR using M2000 (SOP M-198)
Serum, plasma	Detection of DNA/RNA (Viral Loads) for the following: HIV-1 HCV	HIV & HCV PCR using M2000 (SOP M-191)
	HBV	Hepatitis B PCR using M2000 (SOP M-192)
	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
Sputum, broncoalveolar lavage	Detection of DNA for Pneumocystis jirovecii	PCR using Progenie kit and Smartcycler SOP M-174



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HUMAN BODY TISSUES (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and follow current PHE SMI's as relevant
Nose, throat swabs, Bronchial lavage and nasopharyngeal aspirates	Detection RNA for respiratory viruses: Influenza A Influenza B Adenovirus RSV (A & B) Human Metapneumovirus Parainfluenza (1-4) Coronavirus Enterovirus Rhinovirus	PCR using EasyMag extraction, Argene Respiratory PCR kits and ABI prism 7500 (SOP M-173)
Isolates of Staph aureus	Detection of Staph aureus Panton Valentine leucocidin (PVL) gene	Progenie realcycler Staph aureus and PVL detection PCR kit and SOP M-172
Nose & Throat swabs and Nasopharyngeal aspirates	Detection of Influenza and RSV	PCR using Cepheid GeneXpert and GeneXpert Xpress Flu A/B and RSV PCR kit (M-210)
END		