Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8050

Accredited to ISO 15189:2012

University Hospitals Plymouth NHS Trust

Issue No: 009 Issue date: 29 May 2025

University Hospitals Plymouth NHS

Trust

Derriford Hospital
Derriford Road

Plymouth PL6 8DH

Contact: Lee Tuddenham Tel: +44 (0)1752 792369

E-Mail: lee.tuddenham1@nhs.net

Website: www.plymouthhospitals.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	Microbiology examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant
Swabs from wounds, genital sites, eyes, nose, throat, ears; respiratory and gastric fluids, CSF, CAPD fluids, bone marrow, tissue.	General isolation and characterisation of microorganisms of clinical significance and antimicrobial susceptibility testing	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 enterobacteriacae (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

Assessment Manager: SS1 Page 1 of 7



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

Assessment Manager: SS1 Page 2 of 7



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs 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	BD MGIT automated culture system and SOP M-308
	fast bacilli (inc. Mycobacterium species)	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 fungiand yeasts of clinical	Manual microscopy using KOH and sellotape preparations and SOP M-319
	significance	Manual culture using SOP M-319
Bronchial lavage	Detection of Galactomannan LFA	Manual assay using SOP M-317
BAL or Sputum	MTB/Rif detection	GeneXpert using SOP M-308
Stool or Colony	Carbapenemase detection	GeneXpert using SOP M-678

Assessment Manager: SS1 Page 3 of 7



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological examinations for the purpose of clinical diagnosis	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
Serum	Detection of Chlamdia trachomatis IgG	Diasorin Liaison XL using SOP M-214
QFT blood tubes	Detection of Quantiferon TB	Quantiferon TB Gold and Diasorin Liaison XL using SOP M-176
Serum	Detection of: EBVNA/CA IgG; Toxoplasma IgG; CMV IgG	Vidas using SOP M-195, M-196 and M-19

Assessment Manager: SS1 Page 4 of 7



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant
		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 *)
Serum, plasma	Detection of the following:	Architect i2000sr random access analyser
	Rubella IgG Hepatitis B surface antigen* Hepatitis B core antibody Hepatitis B surface antibody 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	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)
Serum	Detection of Syphilis RPR	Manual assay using ASI and SOP M-109

Assessment Manager: SS1 Page 5 of 7



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs as relevant
	Detection of the following:	Using the BD-MAX analyser:
Nasal swabs	Detection of Staph aureus mecA and mecC gene	MRSA detection by PCR (SOP M-152)
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)
Serum, plasma	Detection of DNA/RNA (Viral Loads) for the following:	CMV and EBV DNA by Abbott realtime PCR (SOP M-194)
	CMV EBV	
Serum, plasma	Detection of DNA for the following: Adenovirus BK virus	Argene Adenovirus and BKV PCR kit SOP M-178
Urine, Vaginal, rectal and throat swabs	Detection of: Chlamydia trachomatis; Neisseria gonorrhoeae	Alinity using SOP M-225
UTM swabs	Detection of SARS-CoV-2	Cepheid Xpert Xpress SARS-CoV-2 assay on the GeneXpert using SOP M- 213
UTM swabs	Detection of SARS Cov2- Flu A/B and RSV	SARS CoV2-Flu A/B- RSV plus PCR test on the GeneXpert using SOP M-213
Bronchial lavage	Detection Pneumocystis pneumonia (PCP)	Progenie Pneumocystis Jirovecii PCR assay using ABI Prism using SOP M- 187

Assessment Manager: SS1 Page 6 of 7



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals and follow current UKHSA SMIs 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 Repiratory 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
END		

Assessment Manager: SS1 Page 7 of 7