

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<b>University Hospitals Plymouth NHS Trust</b>	
	<b>Issue No: 003    Issue date: 26 November 2018</b>	
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<b>Testing performed at the above address only</b>		

### 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></p> <p>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</p> <p>Manual culture and cell count as relevant using SOPs</p> <p>M-301 Investigation of Gastric and Respiratory Aspirates  M302 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 SOP315.  Anti-microbial MIC determination using E Test and SOP315</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) Detection of H pylori antigen 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 SOP361 Bacterial and yeast identification usingaldi-tof Mass Spectrometry and SOP M393</p> <p>Manual culture using SOP M-305 Anti-microbial susceptibility testing by EUCAST disc diffusion and SOP315</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 150</p> <p>Oxoid IDEIA HpStAR kit and SOP 107 Oxoid ProSpecT ELISA and SOP 127</p> <p>Techlab Giardia/Crypto CHEK kit EIA SOP M-183 Techlab rapid card confirmation kit SOP M-183</p> <p>Membrane immunoassay using TechLab C diff Quik Chek kit and SOP 150</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Urine</p> <p>Respiratory samples, body fluids and tissue samples</p> <p>Whole blood</p> <p>Joint fluid</p> <p>Skin, nail, hair</p>	<p><u>Microbiology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of white blood cells, red blood cells, casts, epithelial cells, bacteria</p> <p>Isolation of clinically significant organisms</p> <p>Detection and presumptive identification of acid-alcohol fast bacilli (inc. Mycobacterium species)</p> <p>Detection of microbial growth and general isolation of micro-organisms of clinical significance</p> <p>Detection of crystals</p> <p>Detection and general isolation and characterisation of fungi and yeasts of clinical significance</p>	<p>In-house documented procedures based on equipment manuals and follow current PHE SMLs as relevant</p> <p>Iris IQ Sprint urine analyser using digital imaging and particle counting, SOP M-307</p> <p>Manual Culture, SOP M-307</p> <p>BD MGIT automated culture system and SOP M308</p> <p>Manual culture on Löwenstein-Jensen medium and SOP M-308. Confirmation microscopy using Ziehl Neelsen and SOP 381</p> <p>Fluorescent microscopy using phenol auramine stained smears and SOP M-308</p> <p>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</p> <p>Manual microscopy using birefringent microscopy and SOP M383</p> <p>Manual microscopy using KOH and sellotape preparations and SOP M319</p> <p>Manual culture using SOP M-319</p>



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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 114
Naso pharyngeal aspirate	Detection of RSV	Membrane assay using Binax NOW RSV kit and SOP 128
Urine	Detection of Legionella pneumophila serogroup 1 and Strep pneumoniae antigen	Membrane assay using Binax NOW Legionella and Strep pneumoniae kit and SOP 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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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum, plasma</p> <p>Blood</p> <p>Serum, plasma</p>	<p><u>Serological examinations for the purpose of clinical diagnosis</u></p> <p>Detection of the following:</p> <p>Varicella Zoster IgG</p> <p>Measles IgG</p> <p>Parvovirus B19 IgM Parvovirus B19 IgG</p> <p>Hepatitis E IgG &amp; IgM</p> <p>Quantiferon TB (Interferon <math>\gamma</math> Release Assay (IGRA)</p> <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 antigen and antibody</p> <p>Syphilis antibody IgG CMV IgG &amp; IgM HTLV I&amp;II antibody Hepatitis A IgG &amp; IgM</p> <p>Toxoplasma IgG &amp; IgM Epstein Barr virus: VCA IgM, VCA IgG, EBNA IgG</p>	<p>In-house documented procedures based on equipment manuals and follow current PHE SMLs as relevant</p> <p>Dynex DS2 ELISA analyser</p> <p>Binding site VaccZyme VZV Low level IgG EIA and SOP M151</p> <p>Novalisa Measles IgG EIA kit and SOP M-169</p> <p>BIOTRIN ELISA and SOP M-133 BIOTRIN ELISA and SOP M-137</p> <p>HEV IgG / IgM EIA (Fortress diagnostics) SOP M-179</p> <p>Quantiferon Plus TB Gold ELISA kit and DS2 SOP M176</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 &amp; IgM (SOP M-196) Architect HTLV-I/II (SOP M-201) Architect HAV Ab IgG and IgM (SOP M-193) Architect Toxo IgG &amp; 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 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	Diagenode Influenza A/B using the BD Max (SOP M-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 HBV	HIV & HCV PCR using M2000 (SOP M-191) 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 178
Sputum, bronchoalveolar lavage	Detection of DNA for Pneumocystis jirovecii	PCR using Progenie kit and Smartcycler SOP M-174



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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 Bocavirus	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 M172
Vesicle fluid, penile, cervical, vaginal swabs	Detection of HSV type 1 and 2 DNA	Real time PCR using Cepheid Smart HSV ½ kit and Smartcycler, SOP
Faeces	Detection of DNA of Norovirus	FTD Norovirus PCR kit and SOP M153
CSF	Detection of DNA for the following: HSV, Enterovirus, VZV, Mumps, and Parechovirus	FTD Viral meningitis PCR kit and SOP M154
END		