


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 15189:2022</p> | <h3>University Hospitals Plymouth NHS Trust</h3> <p>Issue No: 011 Issue date: 01 October 2025</p> | |
| | <p>University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Road Plymouth PL6 8DH</p> | <p>Contact: Lee Tuddenham Tel: +44 (0)1752 792369 E-Mail: lee.tuddenham1@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></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 UKHSA SMIs as relevant</p> <p>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-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</p> |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust
Issue No: 010 Issue date: 02 July 2025

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| <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 UKHSA SMIs 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 Bacterial and yeast identification using Maldi-tof Mass Spectrometry and SOP M-393</p> <p>Manual culture using SOP M-305 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>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 M-150</p> |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust

Issue No: 010 **Issue date:** 02 July 2025

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|--|
| 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 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 fast bacilli (inc. Mycobacterium species) | BD MGIT automated culture system and SOP M-308 Manual culture on Löwenstein-Jensen medium and SOP M-308. 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 |
| 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 |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust

Issue No: 010 **Issue date:** 02 July 2025

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| 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 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 Chlamidia 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 |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust
Issue No: 010 **Issue date:** 02 July 2025

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| 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 SMIs as relevant |
| 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-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 | 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 *) 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) |
| Serum | Detection of Syphilis RPR | Manual assay using ASI and SOP M-109 |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust

Issue No: 010 Issue date: 02 July 2025

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|---|
| 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 |
| Serum, plasma | Detection of the following: Detection of DNA for the following: Adenovirus BK virus | Using the BD-MAX analyser: 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 |



8050
Accredited to
ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

University Hospitals Plymouth NHS Trust
Issue No: 010 Issue date: 02 July 2025

Testing performed at main address only

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