


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8639</p> <p>Accredited to ISO 15189:2012</p>	<p>Oxford University Hospitals NHS Foundation Trust</p> <p>Issue No: 005 Issue date: 21 October 2020</p>	
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<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 TISSUES AND FLUIDS</p> <p>Routine samples: Aspirates Cellular and fluid material contained on swabs, catheter tips and intra-uterine contraceptive devices Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine</p> <p>Cellular and fluid material contained on swabs</p> <p>Blood</p>	<p><u>Microbiology</u></p> <p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p> <p>Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)</p> <p>Isolation of microorganisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual or automated inoculation, incubation and image capture of culture media using: M-SOP-75 M-SOP-76</p> <p>M-SOP-212</p> <p>Kiestra InoqULA Kiestra ReadA & ReadA browser</p> <p>Manual or automated inoculation, incubation and image capture of chromogenic culture media as above and using: M-SOP-44</p> <p>Liquid media culture using: M-SOP-17 M-SOP-138</p> <p>BD Bactec FX</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Sterile site samples: Tissue Swabs Fluid Bone	Isolation of microorganisms of clinical significance	Liquid media culture using: M-SOP-72 M-SOP-40 BD Bactec FX
Cerebrospinal fluid (CSF)	Detection, identification and quantification (inc. differential) of: White blood cells Red blood cells Bacterial cells	Microscopy & staining (Gram and differential) using: M-SOP-29
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: M-SOP-29
Bronchoalveolar lavage Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid Sputum	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: M-SOP-137 M-SOP-139 M-SOP-138
Breast milk Corneal grafts Perfusion fluids Islet preparation Bone graft	Sterility check, isolation of microorganisms of clinical significance	Manual inoculation and media culture using: M-SOP-73 M-SOP-74
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues	Detection, identification and quantification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using: M-SOP-46 M-SOP-29 M-SOP-138



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Urine	Detection, identification and quantification of: White blood cells Red blood cells Bacterial cells Casts	Automated urinalysis, image capture and recognition using: M-SOP-209 A.Menarini Diagnostics SediMAX system M-SOP-86 M-SOP-212 Manual microscopic examination using: M-SOP-20985 M-SOP-86
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: <i>Campylobacter</i> spp. <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Pleisiomonas</i> spp.	Manual inoculation and media culture using: M-SOP-111
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Manual and/or automated biochemical methods using: M-SOP-204 BD Phoenix Matrix-assisted laser desorption/ionisation using: M-SOP-202 BD Bruker Maldi-Tof
Cultures isolated in-house from all samples listed above	Antifungal susceptibility testing of clinically significant Fungi	Sensitivity testing using: AIM Nephelometer for sensititre plate MIC Manual Yeastone Sensitire M-SOP-88



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual and/or automated antimicrobial susceptibility testing using EUCAST methodology BD Phoenix using in-house procedure M-SOP-204 Disc diffusion & gradient minimum inhibitory concentration determination using in-house procedure M-SOP-88
Hair Nail Skin	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: M-SOP-128 M-SOP-131 M-SOP-132
Faeces	Detection of ova, cysts and parasites (OCP)	Direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: M-SOP-111
Faeces	Detection of <i>Cryptosporidium</i> (confirmation of EIA positives), <i>Isospora</i> & <i>Cyclospora</i> oocysts	Cold ZN incident-light microscopic examination using: M-SOP-111
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopic examination using in-house procedure: M-SOP-209
Sellotape slide Perianal swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopic examination using: M-SOP-111



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Bile Duodenal aspirates Jejunal aspirates</p> <p>Aspirates Cellular and fluid material contained on swabs Fluids Sputum Tissue Urine</p> <p>Nasopharyngeal aspirate Nasopharyngeal swab</p> <p>Plasma Serum</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of OCP including: <i>Strongyloides stercoralis</i> larvae, <i>Giardia lamblia</i> trophozoites <i>Cryptosporidium</i> oocysts <i>Cyclospora cayetanesis</i> oocysts <i>Cystoisospora belli</i> oocysts</p> <p>Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)</p> <p>Detection or exclusion of: Influenza A Influenza B Respiratory syncytial virus</p> <p><u>Serology</u></p> <p><u>Serological examination activities for the purpose of clinical diagnosis</u></p> <p>Microbial serology for: HIV Ab/Ag combo HBsAg HBsAg (confirmation) Anti-HBs HB Core IgM Anti-HBc</p>	<p>In-house documented procedures following PHE SMIs</p> <p>Microscopic examination (stained & unstained) using: M-SOP-111</p> <p>Liquid culture, auramine phenol staining and incident-light fluorescence microscopy using: M-SOP-139</p> <p>BD Bactec MGIT 960</p> <p>Molecular diagnosis using: M-SOP-184 M-SOP-220</p> <p>Cepheid GeneXpert</p> <p>Chemiluminescence using: M-SOP-54</p> <p>Abbott Architect i2000SR</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u> (cont'd)	
Plasma Serum	Microbial serology for: HBeAg Anti-HBe HAV IgM HAV IgG HCV Ab HCV Ag Rubella IgM Toxoplasma IgM CMV IgG Syphilis total Ab EBV EBNA IgG EBV VCA IgG EBV VCA IgM HTLV I & II Ab CMV IgM Toxoplasma IgG Rubella IgG	Chemiluminescence using: M-SOP-54 Abbott Architect i2000SR (cont'd)
Plasma Serum	Microbial serology for: HSV 1&2 IgG VZV IgG Parvovirus IgM Parvovirus IgG Measles IgG Mumps IgG Borrelia IgG HIV Ab / Ag HCV Ab	Chemiluminescence using: M-SOP-51 DiaSorin Liaison XL
Plasma Serum	Detection of antibodies to HIV1 & HIV2	Bio-Rad Geenius Immuno chromatographic assay M-SOP -221



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	
Plasma Serum	Rapid plasma regain (RPR)	Manual flocculation method using: M-SOP-159 BioKit RPR Reditest
Plasma Serum	Syphilis TP	Fujirebio ESPLINE TP Immunochromaggraphic assay M-SOP-221
Faecal extracts	<i>Clostridium difficile</i> glutamate dehydrogenase (GDH) <i>C. difficile</i> toxins A & B <i>Giardia lamblia</i> & <i>Cryptosporidium</i> antigens	Automated EIA using: M-SOP-160 Dynex DS2
Plasma Serum	<i>Helicobacter pylori</i> IgG Hepatitis E IgM Hepatitis E IgG	Automated EIA using: M-SOP-160 Dynex DS2
	<u>Molecular diagnostics</u>	
	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u>	Extraction, nucleic acid amplification and detection using:
Plasma Serum	Molecular diagnostics for: Quantitative HIV Quantitative HCV Quantitative HBV	Abbott m2000 System: m2000sp (extraction) m2000rt (amplification & detection) M-SOP-53
Faeces	Detection of genomic DNA from bacteria causing infectious gastroenteritis: Salmonella spp., Shigella spp. Enteroinvasive E.coli (EIEC), <i>Campylobacter</i> spp. (jejuni and coli) Shiga toxin-producing organisms (STEC, Shigella dysenteriae)	Automated DNA extraction, amplification & detection on the BD MAX platform. M-SOP- 214



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Whole Blood Plasma</p> <p>CSF (Excludes samples from EVD/shunt/neurosurgical patients)</p>	<p><u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Molecular diagnostics for: (cont'd)</p> <p>Quantitative CMV Quantitative EBV Quantitative BKV HSV1/2 VZV Adenovirus <i>Chlamydia trachomatis</i></p> <p>Detection of the following microorganisms using the Meningitis/Encephalitis panel:</p> <p>Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cryptococcus gattii/neoformans Cytomegalovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Enterovirus Human parechovirus Varicella zoster virus</p>	<p>Extraction, amplification and detection using: M-SOP-189 M-SOP-190 and</p> <p>QIASymphony (extraction) Rotor-GeneQ (amplification & detection)</p> <p>Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Procedure: M-SOP-220</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>NPA BAL Throat Swab (Excludes samples from immunocompromised patients)</p>	<p><u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of the following Viruses / Bacteria using the Respiratory panel</p> <p>Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Middle east Respiratory Syndrome Coronavirus (MERS-CoV) Enterovirus/Rhinovirus Human metapneumovirus Influenza A Influenza A subtype H1 Influenza A subtype H3 Influenza A subtype 2009 H1 Influenza B Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Rhinovirus Respiratory syncytial virus Bordetella parapertussis Bordetella pertussis Chlamydomphila pneumoniae Mycoplasma pneumoniae</p>	<p>Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Procedure: M-SOP-220</p>

