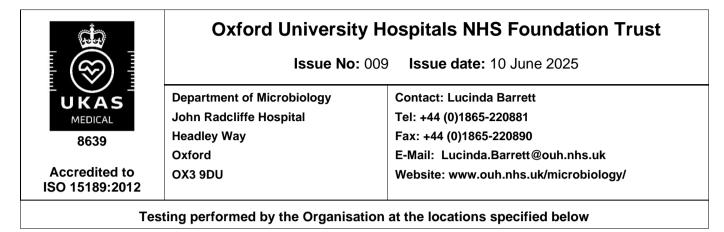
# **Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service** 

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



Locations covered by the organisation and their relevant activities

#### Testing Locations:

Location details		Activity	Location code
Pathology Laboratory Department of Microbiology John Radcliffe Hospital Headley Way Oxford OX3 9DU	Local Contact Lucinda Barrett	Microbiology	A
Hospital Wards Paediatrics Emergency Department John Radcliffe Hospital Headley Way Oxford OX3 9DU	Local Contact Lucinda Barrett	Point of Care Testing	В
Hospital Wards Bellhouse & Drayson CDU West Wing John Radcliffe Hospital Headley Way Oxford OX3 9DU	Local Contact Lucinda Barrett	Point of Care Testing	С
Hospital Wards Accident and Emergency Horton General Hospital Oxford Road Banbury OX16 9AL	Local Contact Lucinda Barrett	Point of Care Testing	D



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Testing performed by the Organisation at the locations specified

#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS	Microbiology Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)	
Routine samples: Cellular and fluid material contained on swabs Genital samples Semen	Isolation of microorganisms of clinical significance	Manual or automated inoculation, incubation and image capture of culture media using: M-SOP-75 M-SOP-76 M-SOP-212 Kiestra InoquIA Kiestra ReadA & ReadA browser	A
Cellular and fluid material contained on swabs	Screening for Methicillin- Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual or automated inoculation, incubation and image capture of chromogenic culture media as above and using: M-SOP-44	A
Blood	Isolation of microorganisms of clinical significance	Liquid media culture using: M-SOP-17 M-SOP-138 BD Bactec FX	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Sterile site samples: Tissue Swabs Fluid Bone Heart valve (homograft)	Isolation of microorganisms of clinical significance	Liquid media culture using: M-SOP-72 M-SOP-40 BD Bactec FX	A
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	A
CSF	Isolation of microorganisms of clinical significance	Manual inoculation and media culture using: M-SOP-29	A
Bronchoalveolar lavage Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotrachael 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	A
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	A
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	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (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	A
	Legionella antigen	M-SOP-86 STANDARD F Legionella Ag FIA M-SOP-221 SD Biosensor STANDARD F 200	A
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	A
Faeces	C.diff GDH, Toxin A & Toxin B	QuikChek Lateral flow device M-SOP-221	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	In-house documented procedures following PHE SMIs	
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	A
		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	A
Plasma Serum	Beta D-Glucan antigen detection	Fujifilm Wako MT-6500 Turbidity M-SOP-230	А
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 NG-Test Carba 5 M-SOP-221	A
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	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Faeces	Detection of ova, cysts and parasites (OCP)	Direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: M-SOP-111	А
Faeces	Detection of <i>Cryptosporidium</i> (confirmation of EIA positives), <i>Isospora &amp; Cyclospora</i> oocysts	Cold ZN incident-light microscopic examination using: M-SOP-111	A
Urine	Detection of <i>Schistosoma</i> haematobium ova	Microscopic examination using in- house procedure: M-SOP-209	A
Sellotape slide Perianal swab	Detection of <i>Enterobious</i> vermicularis larvae and ova	Microscopic examination using: M-SOP-111	A
Bile Duodenal aspirates Jejunal aspirates	Detection of OCP including: Strongyloides stercoralis larvae, Giardia lamblia trophozoites Cryptosporidium oocysts Cyclospora cayetanesis oocysts Cystoisospora belli oocysts	Microscopic examination (stained & unstained) using: M-SOP-111	A
Aspirates Cellular and fluid material contained on swabs Fluids Sputum Tissue	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Liquid culture, auramine phenol staining and incident-light fluorescence microscopy using: M-SOP-139	A
Urine		TBc ID kit M-SOP-221	
		BD Bactec MGIT 960	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Bronchoalveolar lavage	Detection Aspergillus antigen	OLM AspLFD M-SOP-221	А
Nasopharyngeal aspirate Nasopharyngeal swab	Detection or exclusion of: Influenza A Influenza B Respiratory syncytial virus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Molecular diagnosis using: M-SOP-184 Cepheid GeneXpert	A
Faeces	Norovirus GI & GII	Molecular diagnosis using: M-SOP-184 Cepheid GeneXpert	A
Faeces	C.diff Toxin B, Ribotype 027, Binary Toxin, tcdC	Molecular diagnosis using: M-SOP-184 Cepheid GeneXpert	A
BAL Sputum	MTB & Rif	Molecular diagnosis using: M-SOP-184 Cepheid GeneXpert	A
Genital swabs	Mycoplasma genitalium	Molecular diagnosis using: M-SOP-184 Cepheid GeneXpert	A
Genital swabs, Rectal swabs, Throat swabs, Urine	STI Screening Panel – Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis	BD COR 3-plex RT-PCR M-SOP-231	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following PHE SMIs	
Nose / Throat swabs	Influenza A antigen Influenza B antigen	STANDARD F Influenza A/B FIA M-SOP-221	A
		SD Biosensor STANDARD F 200	
Sera Culture isolates BALs Nose & Throat swabs Urine Respiratory samples	Detection of: Mycobacterium tuberculosis Galactomannan Aspergillus Carbapenamase Legionella Influenza A&B antigens	lateral flow rapid chromatographic immunoassay M- SOP-221	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Serology Serological examination activities for the purpose of clinical diagnosis	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme (IDPS) screening programme as defined in the 'NHS Infectious Diseases in Pregnancy Screening Programme: laboratory quality assurance evidence requirements'.	
Plasma Serum	Microbial serology for: HIV Ab/Ag combo HBsAg HBsAg (confirmation) Anti-HBs HB Core IgM Anti-HBc 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 SARS-CoV-2 Anti-N IgG SARS-CoV_2 Anti-S IgG	Chemiluminescence using: M-SOP-54 Abbott Architect /2000SR	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis (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 C. diff GDH C. diff Toxin A C. diff Toxin B Hepatitis E IgG Hepatitis E IgM H. pylori IgG	Chemiluminescence using: M-SOP-51 DiaSorin Liaison XL	A
Plasma Serum	Detection of antibodies to HIV1 & HIV2	Bio-Rad Geenius Immuno chromatographic assay M-SOP -221	A
Plasma Serum	Rapid plasma regain (RPR)	Manual flocculation method using: M-SOP-159 ASI RPR Card Test for Syphilis	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular diagnostics		
	Molecular diagnostic examination activities for the purpose of clinical diagnosis Molecular diagnostics for:	Extraction, nucleic acid amplification and detection using:	
Plasma Serum	Quantitative HIV Quantitative HCV Quantitative HBV Qualitative and quantitative CMV	Abbott Alinity m M-SOP-226	A
	Qualitative and quantitative EBV		
Nasopharyngeal swabs	Winter Respiratory Screen – Influenza A Influenza B RSV SARS-CoV-2	Abbott Alinity m 4-plex RT-PCR	A
Faeces	Detection of genomic DNA from bacteria causing infectious gastroenteritis: Salmonella spp., Shigella spp. Enteroinvasive E.coli (EIEC), <i>Campylobacter spp.</i> (jejuni and coli) Shiga toxin-producing organisms (STEC, Shigella dysenteriae)	Automated DNA extraction, amplification & detection on the BD MAX platform. M-SOP- 214	A
Faeces	Enteric Parasite Panel – Giardia Lamblia, Cryptosporidium pavum and Entamoeba histolytica	Automated DNA extraction, amplification & detection on the BD MAX platform. RT-PCR M-SOP- 214	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd)		
		Extraction, amplification and detection using: M-SOP-189 M-SOP-190 and	A
Whole Blood Plasma CSF Eye swabs Vesicle swabs Vesicle fluid Buccal swabs Urine Amniotic fluid Saliva swab Bronchoalveolar lavage Sputum	Detection of: Quantitative BKV Quantitative CMV Quantitative Adenovirus Quantitative Pneumocysts jirovecii Quantitative Parvovirus B19 Quantitative HEV HSV1 & HSV2 VZVChlamydia trachomatis	ELITe ELITech InGenius, RT PCR, using ELITe MGB assays M-SOP-222	A
Genital swabs	HSV1 and HSV2	ELITe ELITech InGenius, RT PCR, using ELITe MGB assays M-SOP-222	A
Nose/Throat swabs	Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	ThermoFisher MagMax MVP II kit running on the KingFisher Flex (extraction) QuantStudio 5 (Amplification & Detection) using ThermoFisher TaqPath COVID-19 assay	A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd)		
CSF (Excludes samples fromEVD/shunt/neurosurgi cal patients)	Detection of the following microorganisms using the Meningitis/Encephalitis panel: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus gattii/neoformans Cytomegalovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Enterovirus Human parechovirus Varicella zoster virus	Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Procedure: M-SOP-220	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd)		
Joint Fluids	Joint infection panel: Anaerococcus prevotii/vaginalis Clostridium perfringens Cutibacterium avidum/granulosum Enterococcus faecalis Enterococcus faecalis Enterococcus faecium Finegoldia magna Parvimonas micra Peptoniphilus Peptostreptococcus anaerobius Staphylococcus aureus Staphylococcus lugdunensis Streptococcus peumoniae Streptococcus pyogenes Bacteroides fragilis Citrobacter Enterobacter cloacae complex Escherichia coli Haemophilus influenzae Kingella kingae Klebsiella aerogenes Klebsiella pneumoniae group Morganella morganii Neisseria gonorrhoeae Proteus spp. Pseudomonas aeruginosa Salmonella spp. Serratia marcescens Candida albicans Carbapenamases: IMP, KPC, NDM, OXA-48-like, VIM ESBL: CTX-M Methicillin Resistance: mecA/C and MREJ (MRSA) Vancomycin Resistance: vanA/B	Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Biofire Joint Infection (JI) Panel: M-SOP-220	A



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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd)			
NPA BAL Throat Swab (Excludes samples from immunocompromised patients)	Detection of the following Viruses / Bacteria using the Respiratory 2.1 plus panel Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Middle east Respiratory Syndrome Coronavirus (MERS- CoV) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Enterovirus/Rhinovirus Human metapneumovirus Influenza A Influenza A subtype H1 Influenza A subtype H3 Influenza A subtype H3 Influenza B Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus Bordetella parapertussis Bordetella pertussis Chlamydophila pneumoniae Mycoplasma pneumoniae	Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Procedure: M-SOP-220	A	
Nasopharyngeal swabs: COPAN UTM, Sigma Virocult, Remel M4R	SARS-CoV-2 RNA Orf genes	Biomerieux Biofire film array, multiplexed nucleic acid molecular detection using Procedure: M-SOP-220	A	
Nose / Throat Swabs or RNA eluate	SARS-CoV-2 Sequencing	Nanopore GridION M-SOP-228	A	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Provision of Point of Care testing in accordance with ISO 15189: 2022 Appendix A related to the following:	In house documented methods incorporating manufacturers' instructions where relevant		
Nose swabs, Throat swabs	RSV Antigen Detection	F200 FIA Lateral Flow Device M-SOP-221	B, C, D	
END				