


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p><b>8490</b> Accredited to ISO 15189:2012</p>	<h3>Sheffield Teaching Hospitals NHS Foundation Trust</h3> <p><b>Issue No: 008 Issue date: 10 March 2022</b></p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Serum and Plasma Serum and Plasma Serum and Plasma Serum and Plasma Serum and Plasma Serum and Plasma Serum, Dry Blood Spot and Plasma Serum, Dry Blood Spot and Plasma Serum, Dry Blood Spot and Plasma Serum and Plasma Serum and Plasma</p> <p>Oral fluid samples</p> <p>Serum and plasma</p> <p>Serum and plasma</p>	<p><u>Serology examinations for the purposes of clinical diagnosis</u></p> <p>Detection of the following: Hep A IgM Antibody Hep A Total Antibody Hep B Total Core Antibody Hep B Core IgM Antibody Hep B Surface Antibody Hep B s Antigen Neutralisation Hep B Surface Antigen Hep C Antibody HIV Ag/Antibody combo Rubella IgG Antibody Syphilis Antibody IgG HIV Ab</p> <p>COVID-19 Antibody testing - Anti SARS-CoV-2 total antibody (qualitative)</p> <p>Detection of the following : HBe Ag HBe Ab HBsAg (2nd line) HBsAg Quantitative Hepatitis A Total Antibody Hepatitis C Antibody (2nd line) HIV Ab/Ag (2nd Line) Borrelia IgG CMV IgG CMV IgM CMV Avidity EBV IgM (Clinical) EBV VCA IgG</p>	<p>In-house documented procedures based on related UK SMIs and equipment manuals as relevant</p> <p>Roche Cobas 8000 immunoassay, and SOP VIAS044</p> <p>Roche Cobas 8000 Immunoassay and SOP QUGE014</p> <p>Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Serum and plasma	Detection of the following : EBV NA IgG HSV Immunity HTLV I + II Measles Immunity Measles Clinical Mumps Immunity Mumps Clinical Parvovirus Immunity Parvovirus Clinical Rubella IgM Toxoplasma IgG Toxoplasma IgM VZV Immunity	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045
Oral fluid samples	Detection of HIV Ab	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045, and the HIV Genscreen EIA using SOP VISE035
Serum and plasma	Detection of the following: HIV Ag/Ab, HCV Ag/Ab, Syphilis total antibody Syphilis IgM HEV IgM,HEV IgG, Mycoplasma pneumonia IgG, IgA and IgM, VZV glycoprotein IgG	BioRad Evolis Twin Plus (ETP) Automated EIA platform, using the following kits and SOPs: BioRad Genscreen Ultra BioRad Genscreen Enzygnost Syphilis NMT Syphilis IgM Fortress HEV IgM Fortress HEV IgG Launch Virion/Serion ELISA Classic: Mycoplasma pneumonia IgG, IgA and IgM VaccZyme VZV glycoprotein IgG low level EIA. SOP VISE067
Serum and plasma	Detction of VZV IgG	Manual ELISA using the following kit: VaccZyme VZV glycoprotein IgG low level EIA and SOP VISE058
Serum	Hepatitis E IgG Hepatitis E IgM	Una Fortress HEV IgG VISE038 Una Fortress IgM VISE037



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant
Serum and plasma	Detection of the following: Mycoplasma IgA, IgM, IgG	Manual ELISA using Launch Virion/Sirion VISE060
Serum	Qualitative detection of the following: ASO Anti-DNase B	Latex agglutination using Rheumajet ASO and VISE046 bioMerieux Anti DNase B and VISE001
Serum and CSF	Treponema pallidum IgG	Particle agglutination using Serodia TPPA and VISE019
Serum	Toxoplasma total antibody	Latex agglutination assay using the following kit: Biokit Toxocell Latex (VISE065)
Serum and CSF	Antibodies to VDRL antigen	Slide flocculation using Axis Shield Syphilis Screen RPR and VISE017
Serum and Plasma	Detection of HIV antibody	Bio-Rad Geenius immunochromatographic and SOP VISE057
Faeces	Qualitative detection of the following: H pylori antigen C difficile GDH C difficile toxin A & B Rotavirus	ELISA using Dynex DS2 analyser and the following kits and SOPs: Oxoid IDEA Hp StAR, BAEN015 Tech Lab C.diff CHEK 60, BAEN002 RIDAQUICK lateral flow (GDH and Toxin A/B), BAEN002 Tech Lab TOX A/B II, BAEN002 Oxoid ProSpecT Rotavirus, BAEN023
Urine	Detection of Legionella urinary antigen	Sofia EIA and SOP BAUR011
Serum, CSF	Cryptococcal antigen	IMMY CrAg lateral flow assay (BASFO14)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant
Serum and plasma	Quantitative detection of HBV and HCV viral load	Quantitative PCR using the Hologic Panther Aptima and SOP VIMO0051
Dry blood spots	Qualitative detection of HCV	Qualitative PCR using Hologic Panther Aptima and SOP VIMO0051
Genital swabs and urine	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	Hologic Panther quantitative TMA and SOP VICH023
Genital swabs	Detection of DNA from Trichomonas vaginalis	Hologic Panther using quantitative TMA SOP VICH023
Serum and plasma	Quantitative detection of: HIV type 1 RNA	Quantitative assay using the Hologic Panther Aptima assay (VIMO051)
Serum, plasma, Roche PCR product	Hep C genotyping	Autoblot 3000 Immunoblot assay and SOP VIMO003
Blood, plasma, dry blood spot, urine, CSF	Quantitative detection of: CMV viral load EBV viral load	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification using SOP VIMO035
Blood, plasma, swabs, CSF, NPA, sputum, BAL, urine	Quantitative detection of: BK virus HHV6	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification
Blood, swabs, tissue	Quantitative detection of: Parvovirus	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Blood, plasma, swabs, CSF, NPA, Sputum, BAL, faeces, vomit	Qualitative detection of the following:  Respiratory virus (Influenza A, B, H1N1, RSV, Rhinovirus, Parainfluenza 1, 2, 3, 4, HMPV, Coronavirus, Adenovirus) Herpes simplex VZV Adenovirus Enterovirus Norovirus Measles	Qualitative PCE using Roche Magnapure 96 extraction and ABI 7500 amplification and SOPs: VIMO020  VIMO027 VIMO027 VIMO020 VIMO006 VIMO019 VIMO045
Swabs, CSF, sputum, urine	Qualitative detection of Mumps	Qualitative PCR, using Roche Magnapure 96 extraction and ABI 7500 amplification SOP VIMO048
Blood, plasma Swabs, Induced sputum, BAL	Quantitative detection of:  Hepatitis E Pneumocystis jiroveci (PCP)	Quantitative PCR, using Roche Magnapure 96 extraction and ABI 7500 amplification SOP VIMO049 SOP VIMO039
Swabs, sputum, NPA, BAL	Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	PCR and Extraction using the Qiagen Qiacube platform and Amplification and detection using the ABI7500 SOP VIMO056
Swabs, sputum, BAL	Detection of Atypical respiratory organisms (Mycoplasma pneumoniae, Chlamydia pneumoniae & Chlamydia psittaci)	PCR and Extraction using the Roche MP96 and Amplification and Detection using the ABI7500 SOP VIMO046 and VIMO047
All respiratory samples (swabs, BAL, NPA, ETS)	Detection of respiratory viruses: Parainfluenza 1-4, Rhinovirus, Coronavirus, RSV A/B, Human Metapneumovirus and Adenovirus	PCR using the Roche FLOW system and MagnaPure 96 extraction system SOP VIMO052 and VIMO053



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Faeces</p> <p>Respiratory tract secretions</p> <p>Nose swab, throat swab and combined Nose/Throat Swabs</p> <p>AAFB positive cultures</p>	<p><u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Detection of C difficile toxin gene tcdA</p> <p>Detection of Mycobacterium tuberculosis (MTB) complex DNA and rifampicin-resistance associated mutations of the rpoB gene.</p> <p>Detection of SARS-CoV-2 PCR (qualitative), target genes N2 and E</p> <p>Identification of Mycobacterium tuberculosis complex</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Isothermal helicase method using QUIADEL Amplivue instrument and SOP BAEN004</p> <p>PCR and Cepheid GeneExpert System SOP BARE039</p> <p>Cepheid GeneXpert real-time PCR and SOP VIMO065</p> <p>HAIN TB Check MPT64</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus,</p> <p>Skin, hair, nails Urine</p>	<p><u>Microbiology examinations for the purposes of clinical diagnosis</u></p> <p>Isolation and identification of microorganisms of clinical significance</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs:</p> <p>Wound swabs (inc. T/S, N/S, etc), fluids and tissues from sites not expected to be sterile and Neonate screens [BAWS001, BAWS002 &amp;BAWS003]</p> <p>Genital tract swabs [BAGE001] N.gonorrhoeae [BAGE001]</p> <p>CSF culture and shunts [BASF003]</p> <p>Fluid from sites expected to be sterile</p> <p>CAPD fluid [BASF011]</p> <p>Corneal scrape and anterior chamber and vitreous taps [BAMI002]</p> <p>Contact lenses and fluid and corneal grafts [BAMI001]</p> <p>Heart valve culture [BAMI010]</p> <p>intra-venous lines and pacing wire tips [BAMI003]</p> <p>Bordetella culture [BARE011]</p> <p>Faecal culture [BABC016]</p> <p>H pylori culture [BAEN012]</p> <p>Orthopaedic tissue culture [BATI002]</p> <p>MSSA by culture [BAIC004]</p> <p>Multi-resistant Gram Negatives by culture [BAIC001]</p> <p>MRSA by culture [BAIC006]</p> <p>Vancomycin resistant enterococci (VRE) [BAIC002]</p> <p>Respiratory bacterial pathogens by culture [BARE003, BARE006]</p> <p>Cystic fibrosis respiratory culture [BARE001]</p> <p>Mycology by culture [BAMY001]</p> <p>Urine culture (BAUR001)</p>



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Respiratory fluids, CSF, sterile fluids, pus, tissue, urine	Isolation and identification of microorganisms of clinical significance	Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs:
Urine	Detection of WBC, RBC, epithelial cells, casts	IQ Sprint urine analyser using flow cytometry and BAUR003
Urine	Microscopic examination of for qualitative detection of the following: White and red blood cells, casts, epithelial cells	Light microscopy using inverted microscope and SOP BAUR001
CSF	Cell count and differential cell count	Manual cell count using SOP BASF003
Faeces	Cryptosporidium oocysts	Stained auramine slides by epi-fluorescent microscopy, SOP BAEN022
	Ova, cysts and parasites	Wet preparation using light microscopy and concentration using Parasep(BARE022)
Skin, hair, nails	Fungal elements	Wet preparations on microscope slides using epi-fluorescent microscopy and SOP BAMY001
Vaginal swabs	Clue cells	Stained slides by epi-fluorescent microscopy and SOP BAGE004
Respiratory samples, fluids, tissues	Acid fast bacilli	Stained auramine slides and epi-fluorescent microscopy, BACP002
Blood	Detection of microbial growth	BD FX analyser using SOP BABC016
Blood	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	Bactec BDFX40 using SOP BARE037





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Sputum, tissues, urine, fluids	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	BD MGIT analyser using SOP BARE05  Mycobacterium culture using LJ media and SOP BARE005
Isolates of bacteria and yeasts	Identification of bacteria and yeast	Bruker Maldi-tof Biotyper using mass spectrometry, and Bruker MALDI-SMART SOP BAAS024
Isolates of bacteria	Determination of antimicrobial susceptibility	Disc diffusion using EUCAST method and SOP BAAS001  MIC by strip diffusion using E test and MICE, SOP BAAS003  Breakpoint method using EUCAST breakpoints and multipoint inoculation SOP BAAS001
Isolates of yeast		MIC using Oxoid Yeastone Sensititre and SOP BAAS029
Isolates of bacteria	Detection of carbapenemases OXA-48, KPC, VIM, IMP and NDM	NG-Test CARBA 5 kit, EUCAST method and SOP BAAS055
END		