

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 10296</p> <p>Accredited to ISO 15189:2012</p>	<p>Norfolk and Norwich University Hospital NHS Foundation Trust trading as Eastern Pathology Alliance</p> <p>Issue No: 004 Issue date: 08 October 2021</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 BODY FLUIDS AND TISSUES</p> <p>Specimens from genital tract CAPD fluid ENT specimens (ear, nose, per nasal, nasopharyngeal, throat & mouth swabs & sinus aspirate) Canalicular Pus, Intraocular Fluids Skin & superficial wounds, post-op wounds, tissues, fluids & bile Sterile tissues and fluids Orthopaedic Samples Intravascular cannulae Neonatal infection screen</p> <p>Specimens from genital tract CAPD fluid ENT specimens (ear, nose, per nasal, nasopharyngeal, throat & mouth swabs & sinus aspirate) Canalicular Pus, Intraocular Fluids Skin & superficial wounds, post-op wounds, tissues, fluids & bile Sterile tissues and fluids Orthopaedic Samples Intravascular cannulae Neonatal infection screen</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis:</u></p> <p>Isolation of bacterial isolates of clinical significance.</p> <p>Isolation of bacterial isolates of clinical significance.</p>	<p>In house documented culture methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.</p> <p>Automated inoculation using the WASP system and SOPs EMC-BSOP-019, EMC-BSOP-025, EMC-BSOP-026</p> <p>Manual inoculation and culture: Using EMC-BSOP-025, EMC-BSOP-026,</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented culture methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Urine	Isolation of clinically significant bacteria and fungi	Manual culture (BD Orientation) EMC-BSOP-002
Urine	Detection, identification & quantification of White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Automated microscopy by UF 5000 (Sysmex) EMC-BSOP-002
Blood	Culture, isolation and identification of bacterial isolates of clinical significance.	Automated growth detection using Biomerieux BacTALERT and EMC-BSOP-001
Swabs	Screening specimens for MRSA	Manual culture using EMC-BSOP-012
Faeces/rectal swabs	Screening specimens for ESBL, CPE and VRE	Culture using chromogenic media for ESBL, CPE and VRE EMC BSOP-012 CPE by Cepheid Expert PCR EMC-BSOP-034
Sputum, Bronchoalveolar lavage, pleural fluid, swabs	Isolation of clinically significant bacteria and fungi	Manual culture EMC-BSOP-003
Cerebrospinal fluid (CSF)	Quantification of white and red blood cells, detection of bacteria, fungi, Cryptococcal antigen	Manual culture, microscopy – Kovo disposable counting chamber/Fuchs Rosenthal counting chamber, identification by Gram stain WBC differential by Toluidine Blue Cryptococcus antigen detection by IMMY CrAg lateral flow procedure EMC-BSOP-014



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Bacterial and fungal isolates cultured in house from above.</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p>Identification of bacterial isolates of clinical significance.</p>	<p>In house documented culture methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.</p> <p>Manual: Direct latex agglutination: Strep PathoDxtra (Oxoid) PROLEX STAPH XTRA LATEX KIT (Prolab) Immunocromatic assay (strip): PENICILLIN-BINDING PROTEIN (PBP2) LA (ALERE) EMC-BSOP-013 EMC-BSOP-015 EMC-BSOP-017 EMC-BSOP-018 EMC-BSOP-019 EMC-BSOP-035 EMC-BSOP-020 EMC-BSOP-021 EMC-BSOP-022 EMC-BSOP-024 Microscopy (Gram stain) on pus and fluids for presence of WBCs and organisms by manual staining or by bioMérieux: PREVI-Color Gram EMC-BSOP-010</p>
<p>Bacterial and fungal isolates cultured in house from above.</p>	<p>Identification of bacterial isolates of clinical significance.</p>	<p>Automated: EMC-BSOP-010 PREVI-Color Gram EMC-BSOP-027 VITEK 2 Systems EMC-BSOP-008 VITEK MS (MALDI-TOF): EMC-BSOP-028 EntericBio EMC-BSOP-040</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented culture methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Sputum, Bronchoalveolar lavage, pleural fluid, swabs	Isolation and investigation of Mycobacteria sp of clinical significance.	Microscopy by Fluorescent auramine stain for presence of Mycobacterium spp EMC-BSOP-006 Culture by BD MGIT 960 MP and LJ slopes EMC-BSOP-006 Dagatron staining EMC-BSOP-039
Faeces	Microbiological examination for <i>Salmonella and Shigella spp</i> <i>Campylobacter spp</i> <i>Escherichia coli 0157:H7</i> <i>Yersinia enterocolitica</i> <i>Vibrio spp</i> <i>Plesiomonas</i>	EntericBio PCR - EMC-BSOP-040 Confirmations by manual culture using EMC-BSOP-029
Sellotape anal impression slide	Microscopy for Enterobius ova	Direct light microscopy EMC-BSOP-030
Faeces	Detection of OCP including Cryptosporidium oocysts and <i>Giardia lamblia</i> trophozoites	EMC-BSOP-030 Cryptosporidium/Giardia by EntericBio PCR EMC-BSOP-040
Nail clippings, skin scrapings, hair	Isolation and identification of clinically significant fungi	Manual culture and fluorescent microscopy using calco-fluor white (Oxoid) and light microscopy using lactofuchsin stain (Prolab) for identification: EMC-BSOP-011
Laboratory isolates	Susceptibility testing	Automated antimicrobial susceptibilities: using EUCAST guidelines VITEK 2 Systems, EMC-BSOP-008 Cepheid EMC-BSOP-034



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented culture methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Laboratory isolates	Susceptibility testing	Manual susceptibilities by disc (Oxoid) diffusion following EUCAST and by (BSAC) EMC-BSOP-036 Confirmation using EMC-BSOP-024: Mastdiscs combi – ESBL & AmpC Detection Following EUCAST - Disc Sets (MAST) EMC-BSOP-024 Mastdiscs combi – Carbapenemase Detection Antibiotic gradient strips for MICs (Oxoid) EMC-BSOP-036
HUMAN BODY FLUIDS AND TISSUES	<u>Serological examination activities for the purposes of clinical diagnosis:</u>	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Serum	Detection of Bartonella	EMC-VSP-010 – IFA IgG (Focus Diagnostics)
Serum	Detection of Streptococci	ASO: EMC-VSP-016 - Latex agglutination (Biokit) ADB: EMC-VSP-017 - Neutralisation immunoassay (bioMérieux)
Serum	Detection of:	bioMérieux VIDAS using ELFA measurement:
	EBV	IgG: EMC-VSP-002 App 5 IgM: EMC-VSP-002 App 5
	CMV	IgG: EMC-VSP-002 App 3 IgM: EMC-VSP-002 App 3 Avidity: EMC-VSP-002 App 4



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Serum	Detection of: <i>Borrelia burgdorferi</i> (lyme Disease) IgG Hepatitis B anti-HBc IgM Human immunodeficiency virus (HIV) confirmation Toxoplasma IgG Hepatitis C confirmation Rubella Serology	bioMérieux VIDAS using ELFA measurement: EMC-VSP-002 App 9 EMC-VSP-002 App 6 EMC-VSP-002 App 8 EMC-VSP-002 App 11 EMC-VSP-002 App 7 IgM: EMC-VSP-002 App 10
Serum	Detection of: Hepatitis A Serology Hepatitis B anti-HBc (Total) Hepatitis B anti-HBe Hepatitis B anti-HBs Hepatitis B e antigen Hepatitis B surface antigen (HBsAg) <u>Hepatitis B surface antigen (HBsAg) confirmation</u> Hepatitis C Serology Human immunodeficiency virus (HIV) serology Rubella	Abbott Architect using CMIA: IgG: EMC-VSP-001 App 6 IgM: EMC-VSP-001 App 7 EMC-VSP-001 App 4 EMC-VSP-001 App 11 EMC-VSP-001 App 5 EMC-VSP-001 App 11 Screen: EMC-VSP-001 App 3 EMC-VSP-001 App 10 - Murex HBsAg confirmatory kit (neutralisation) Screen: EMC-VSP-001 App 2 Screen: EMC-VSP-001 App 1 IgG: EMC-VSP-001 App 8



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Serum	Detection and confirmation of Syphilis (including TPPA and RPR)	Screen: EMC-VSP-001 App 9 - Immunoassay (CMIA) on Abbott Architect; Confirmation: EMC-VSP-008 - Serodia TPPA Confirmation: EMC-VSP-015 - Axis-Shield RPR
Serum	Hepatitis E Serology	IgG: EMC-VSP-013 – EIA (Fortress Diagnostics) IgM: EMC-VSP-013 – EIA (Fortress Diagnostics)
Serum	Human immunodeficiency virus (HIV) typing	Typing: EMC-VSP-005 Geenius HIV 1/2 Confirmatory Assay (ICT)
Serum	Detection of Measles IgG	EMC-VSP-019 - NovaLisa Measles virus IgG (ELISA)
Serum	Detection of total antibody to: Influenza A Influenza B C. burnetti p.2 Chlamydia Mycoplasma Parainfluenza RSV Adenovirus C.burnetti p1 Leptospira sp Enterovirus Brucella	Complement Fixation Testing using Virion Serion reagents: EMC-VSP-009



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Serum/plasma	Parvovirus IgG and IgM	Orgentec Alegria ELISA analyser using Alegria Parvovirus IgG and IgM kit following : EMC-VSP-003 EMC-VSP-003 Appendix 7
Blood	Varicella zoster virus IgG	EMC-VSP-003 App 4 – ORGENTEC Alegria ELISA
Faeces	Adenovirus Antigen	EMC-VSP-020 - EIA (Oxoid ProSpecT)
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Faeces	<i>Clostridium difficile</i> antigen and toxin detection	Screening for toxin gene by EntericBio PCR EMC-BSOP-040 Toxin detection by Rapid EIA with TechLab Cl.difficile Tox A/B QuickChek EMC-BSOP-041 TechLab C. DIFF QUIK CHEK COMPLETE for urgent requests (GDH/Toxin)
Faeces	Detection of <i>Helicobacter pylori</i> Antigen	EMC-VSP-012 App 1 – EIA (Premier Platinum HpSA PLUS)
Faeces	Detection of Rotavirus Antigen	EMC-VSP-021 - EIA (Oxoid ProSpecT)
Urine	Detection of Legionella urinary antigen	EMC-VSP-006 - Bartels EIA
Urine	Detection of <i>Streptococcus pneumoniae</i> urinary antigen test	EMC-VSP-024 - Immunoassay, Meridian TRU



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis:</u>	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Urine, swabs (endocervical, urethral, vaginal)	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i>	Hologic Panther DTS System EMC-VMP-007 using Transcription Mediated Amplification (NAATs)
Urine, swabs (endocervical, urethral, vaginal)	Detection of <i>Trichomonas vaginalis</i> (TV) DNA	Hologic Panther DTS System using Transcription Mediated Amplification (NAATs) following: EMC-VMP-007
Bacterial isolates	Molecular detection of MRSA	PCR using Cepheid GeneXpert following: EMC-BSOP-034 EMC-BSOP-034 Appendix 11
Faeces, rectal swabs	Norovirus 1&2 RNA	EMC-VMP-006 – Nucleic Acid Extraction. EMC-VMP-005 - Real-Time PCR on RIDAGene
Serum	Detection of:	QIASymphony SP/AS/RQ real-time qPCR:
	Hepatitis B DNA	EMC-VMP-009
	Hepatitis C RNA	EMC-VMP-009
	HIV-1 RNA	EMC-VMP-009
	CMV DNA	EMC-VMP-009
	EMV DNA	EMC-VMP-009



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Bronchoalveolar lavage, nasopharyngeal aspirate, sputum, Nasal or throat swab	Detection of respiratory viruses: Influenza A (including H1N1 typing), Influenza B, Parainfluenza, RSV, hMPV, Adenovirus, Enterovirus, Rhinovirus, Coronavirus (HKU1, NL40)	EMC-VMP-006 – Nucleic Acid Extraction. EMC-VMP-004 - Amplification and Detection by real-time PCR using AusDiagnostics HighPlex
CSF, swabs, fluids (vesicle, vitreous)	Systemic PCR for HSV 1/2, Varicella zoster virus, Parechovirus, Enterovirus, Adenovirus	EMC-VMP-006 – Nucleic Acid Extraction. EMC-VMP-008 - Amplification and Detection by real-time PCR
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis:</u>	In house documented methods based on related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.
Nasal and throat swabs, nasopharyngeal swabs, nasopharyngeal aspirate, tracheal aspiration, bronchial washing and bronchoalveolar lavage	Detection of SARS-CoV-2 RNA: ORF1 gene ORF8 gene	Nucleic Acid Extraction using Qiagen QiaSymphonySP Amplification and Detection by real-time PCR using AusDiagnostics HighPlex SOPs: EMC-VMP-006 EMC-VMP-019
Nose and throat swabs in VTM, Nasopharyngeal aspirate	Qualitative detection of SARS-CoV-2 RNA: Two conserved regions of the ORF1ab gene	Hologic Panther DTS System using Transcription Mediated Amplification (NAATs) following: EMC-VMP-020
Urine, saliva, blood, CSF, Amniotic fluid	Detection of CMV DNA	Real-time PCR assay using ELITech ELITE InGenius analyser following: EMC-VMP-016
CSF	Detection of meningitis pathogen nucleic acid	Real-time PCR MV, MV2 and MB MBG assays using ELITech ELITE InGenius analyser following: EMC-VMP-016
END		