

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189: 2022

Norfolk and Norwich University Hospitals NHS Foundation Trust trading as Eastern Pathology Alliance

Issue No: 007 Issue date: 19 February 2025

Microbiology
Norwich Research Park Innovation
Centre (NRPIC)
Colney
Norwich
NR4 7GJ

Contact: Fiona Butcher
Tel: +44 (0) 1603 286900
E-Mail: Fiona.Butcher@nnuh.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | Activity | Location code |
|---|--|-----------------------------------|
| Address Norwich Research Park Innovation Centre (NRPIC) Colney Norwich NR4 7GJ | Local contact John Hayward Tel: +44 (0)1603 288577 | Microbiology A |
| Norfolk and Norwich University Hospital Colney Lane Norwich NR4 7UY | Local contact Sharon Gooch Tel: +44 (0)1603 286946 George Bailey Tel: +44 (0)1603 646651 | Microbiology – Blood culture B |
| James Paget University Hospital Lowestoft Road Gorleston-on-Sea Great Yarmouth NR31 6LA | Local contact Sarah Swallow Tel: +44 (0)1493 452101 Annie Chileshe Tel: +44 (0)1493 452829 | Microbiology – Blood culture C |
| Queen Elizabeth Hospital Gayton Road Kings Lynn PE30 4ET | Local contact Nicola Pearman Tel: +44 (0)1553 613771 Agnieszka Pieterse Tel: +44 (0)1553 613345 | Microbiology – Blood culture D |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|--|--|---|---------------|
| <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><u>Microbiology examination activities for the purposes of clinical diagnosis:</u></p> <p>Isolation of bacterial isolates of clinical significance.</p> | <p>In house documented procedures following current UK 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> | A |
| <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>Isolation of bacterial isolates of clinical significance.</p> | <p>Manual inoculation and culture: Using EMC-BSOP-025, EMC-BSOP-026,</p> | A |



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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 procedures following current UK 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 | A |
| 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 | A |
| Blood | Culture, isolation and identification of bacterial isolates of clinical significance. | Automated blood culture using colorimetric methodology on the Biomerieux Virtuo Blood Culture Machine, A units and B units. SOP EMC-BSOP-037. | A |
| Blood | Detection of microbial growth with subsequent analysis of positive samples at Location A Reporting of negative samples only | Automated blood culture using colorimetric methodology on the Biomerieux Virtuo Blood Culture Machine, A units and B units. SOP EMC-BSOP-037. | B, C, D |
| Swabs | Screening specimens for MRSA | Manual culture using EMC-BSOP-012 | A |
| 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 | A |
| Sputum, Bronchoalveolar lavage, pleural fluid, swabs | Isolation of clinically significant bacteria and fungi | Manual culture EMC-BSOP-003 | A |



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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 procedures following current UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant. | |
| 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 | A |
| Bacterial and fungal isolates cultured in house from above. | Identification of bacterial isolates of clinical significance. | Manual: Direct latex agglutination: Strep PathoDextra (Oxoid) PROLEX STAPH XTRA LATEX KIT (Prolab) | A |
| | | 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 | A |
| Bacterial and fungal isolates cultured in house from above. | Identification of bacterial isolates of clinical significance. | 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 | A |



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| 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 | A |
| Faeces | Microbiological examination for <i>Salmonella</i> and <i>Shigella</i> spp <i>Campylobacter</i> spp <i>Escherichia coli</i> 0157:H7 <i>Yersinia enterocolitica</i> <i>Vibrio</i> spp <i>Plesiomonas</i> | EntericBio PCR - EMC-BSOP-040 run on Roche Light Cyclor Confirmations by manual culture using EMC-BSOP-029 | A |
| Sellotape anal impression slide | Microscopy for Enterobius ova | Direct light microscopy EMC-BSOP-030 | A |
| Faeces | Detection of OCP including Cryptosporidium oocysts and Giardia lamblia trophozoites | EMC-BSOP-030 Cryptosporidium/Giardia by EntericBio PCR EMC-BSOP-040 run on Roche Light Cyclor | A |
| 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 | A |
| Laboratory isolates | Susceptibility testing | Automated antimicrobial susceptibilities: using EUCAST guidelines VITEK 2 Systems, EMC-BSOP-008 Cepheid EMC-BSOP-034 | A |



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| 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 | A |
| | <u>Serological examination activities for the purposes of clinical diagnosis:</u> | In house documented procedures following current UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant. | |
| Serum | Detection of Bartonella | EMC-VSP-010 – IFA IgG (Focus Diagnostics) | A |
| Serum | Detection of Streptococci | ASO: EMC-VSP-016 - Latex agglutination (Biokit) ADB: EMC-VSP-017 - Neutralisation immunoassay (bioMérieux) | A |
| Serum | Detection of: | bioMérieux VIDAS using ELFA measurement: | A |
| | EBV | IgG: EMC-VSP-002 App 5 IgM: EMC-VSP-002 App 5 | A |
| | CMV | IgG: EMC-VSP-002 App 3 IgM: EMC-VSP-002 App 3 Avidity: EMC-VSP-002 App 4 | A |



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| Serum | Detection of: | bioMérieux VIDAS using ELFA measurement: | A |
| | <i>Borrelia burgdorferi</i> (lyme Disease) IgG | EMC-VSP-002 App 9 | A |
| | Hepatitis B anti-HBc IgM | EMC-VSP-002 App 6 | A |
| | Human immunodeficiency virus (HIV) confirmation | EMC-VSP-002 App 8 | A |
| | Toxoplasma IgG | EMC-VSP-002 App 11 | A |
| | Hepatitis C confirmation | EMC-VSP-002 App 7 | A |
| | Rubella Serology | IgM: EMC-VSP-002 App 10 | A |
| | | 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 *) | |
| Serum | Detection of: | Abbott Architect using CMIA: | A |
| | Hepatitis A Serology | IgG: EMC-VSP-001 App 6 IgM: EMC-VSP-001 App 7 | A |
| | Hepatitis B anti-HBc (Total) | EMC-VSP-001 App 4 | A |
| | Hepatitis B anti-HBe | EMC-VSP-001 App 11 | A |
| | Hepatitis B anti-HBs | EMC-VSP-001 App 5 | A |
| | Hepatitis B e antigen | EMC-VSP-001 App 11 | A |
| | Hepatitis B surface antigen (HBsAg)* | Screen: EMC-VSP-001 App 3 | A |



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| Serum (cont'd) | Detection of: (cont'd) | Abbott Architect using CMIA: | A |
| | Hepatitis B surface antigen (HBsAg) confirmation | EMC-VSP-001 App 10 - Murex HBsAg confirmatory kit (neutralisation) | A |
| | Hepatitis C Serology | Screen: EMC-VSP-001 App 2 | A |
| | * HIV-1 & HIV-2 Antibodies and HIV1 p24 Antigen* | Screen: EMC-VSP-001 App 1 | A |
| | Rubella | IgG: EMC-VSP-001 App 8 | A |
| Serum | Syphilis total Antibody* | Screen: EMC-VSP-001 App 9 - Immunoassay (CMIA) on Abbott Architect | A |
| Serum | Hepatitis E Serology | IgG: EMC-VSP-013 – EIA (Fortress Diagnostics) IgM: EMC-VSP-013 – EIA (Fortress Diagnostics) | A |
| Serum | Human immunodeficiency virus (HIV) typing | Typing: EMC-VSP-005 Geenius HIV 1/2 Confirmatory Assay (ICT) | A |
| Serum | Detection of Measles IgG | EMC-VSP-019 - NovaLisa Measles virus IgG (ELISA) | A |



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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 | A |
| Blood | Varicella zoster virus IgG | EMC-VSP-003 App 4 – ORGENTEC Alegria ELISA | A |
| Faeces | Adenovirus Antigen | EMC-VSP-020 - EIA (Oxoid ProSpecT) | A |
| Faeces | <i>Clostridioides difficile</i> antigen and toxin detection | Screening for toxin gene by EntericBio PCR EMC-BSOP-040 run on Roche Light Cycler 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) | A |
| Faeces | Detection of <i>Helicobacter pylori</i> Antigen | EMC-VSP-012 App 1 – EIA (Premier Platinum HpSA PLUS) | A |
| Faeces | Detection of Rotavirus Antigen | EMC-VSP-021 - EIA (Oxoid ProSpecT) | A |
| Urine | Detection of Legionella urinary antigen | EMC-VSP-006 - Bartels EIA | A |
| Urine | Detection of <i>Streptococcus pneumoniae</i> urinary antigen test | EMC-VSP-024 - Immunoassay, Meridian TRU | A |



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| Serum | Detection of antibodies to Treponema pallidum by TPHA | EMC-VSP-023 ASI TPHA Test | |
| Serum | Rapid Plasma Reagin (RPR) | EMC-VSP-022 ASI RPR Card Test for Syphilis | |
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Molecular examination activities for the purposes of clinical diagnosis:</u> | In house documented procedures following current UK 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) | A |
| Urine, swabs (endocervical, urethral, vaginal) | Detection of Trichomonas vaginalis (TV) DNA | Hologic Panther DTS System using Transcription Mediated Amplification (NAATs) following: EMC-VMP-007 | A |
| Bacterial isolates | Molecular detection of MRSA | PCR using Cepheid GeneXpert following: EMC-BSOP-034 EMC-BSOP-034 Appendix 11 | A |
| Faeces, rectal swabs | Norovirus 1&2 RNA | EMC-VMP-006 – Nucleic Acid Extraction. EMC-VMP-005 - Real-Time PCR on RIDAGene | A |



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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 | A |
| 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 | A |
| 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 | A |
| Urine, saliva, blood, CSF, Amniotic fluid | Detection of CMV DNA | Real-time PCR assay using ELITech ELITE InGenius analyser following: EMC-VMP-016 | A |



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| CSF | Detection of meningitis pathogen nucleic acid HSV1 HSV2 VZV EV Parechovirus hAdv N. meningitidis S. pneumoniae H. influenzae H. influenzae type B | Real-time PCR MV, MV2 and MB MBG assays using ELITech ELITe InGenius analyser following: EMC-VMP-016 | |
| CSF, swabs (dry and VTM), fluids (sterile universal) Faeces specimens (sterile universal) Tissue samples (sterile universal) | Viral (12 well) panel HSV-1 HSV-2 VZV, HeV (includes types A, B, C and D), HPeV, hAdV (includes species B, B, E and some A, D; excludes hAdV 21) | Aus Diagnostics – MT PCR PROCESSER Aus Diagnostics – MT PCR ANALYSER EMC-VMP-026 AusDiagnostics Viral (12 Well) | |
| Plasma | Viral Loads on NeumoDx CMV viral load EBV viral load HBV viral load HCV viral load | NeuMoDx 96 Molecular System EMC-VMP-027 Qiagen NeuMoDx Quant Assays | |
| END | | | |