

# 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: 008 Issue date: 16 July 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](mailto: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 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|---------------|
| <b>Address</b><br>Norwich Research Park Innovation Centre (NRPIC)<br>Colney<br>Norwich<br>NR4 7GJ<br><br><b>Local contact</b><br>John Hayward<br>Tel: +44 (0)1603 288577                                                 | Microbiology                 | A             |
| Norfolk and Norwich University Hospital<br>Colney Lane<br>Norwich<br>NR4 7UY<br><br><b>Local contact</b><br>Sharon Gooch<br>Tel: +44 (0)1603 286946<br>George Bailey<br>Tel: +44 (0)1603 646651                          | Microbiology – Blood culture | B             |
| James Paget University Hospital<br>Lowestoft Road<br>Gorleston-on-Sea<br>Great Yarmouth<br>NR31 6LA<br><br><b>Local contact</b><br>Sarah Swallow<br>Tel: +44 (0)1493 452101<br>Annie Chileshe<br>Tel: +44 (0)1493 452829 | Microbiology – Blood culture | C             |
| Queen Elizabeth Hospital<br>Gayton Road<br>Kings Lynn<br>PE30 4ET<br><br><b>Local contact</b><br>Nicola Pearman<br>Tel: +44 (0)1553 613771<br>Agnieszka Pieterse<br>Tel: +44 (0)1553 613345                              | Microbiology – Blood culture | D             |



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| <p align="center"><b>Schedule of Accreditation</b><br/>issued by<br/><b>United Kingdom Accreditation Service</b><br/>2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK</p> |  |
| <p><b>Norfolk and Norwich University Hospitals NHS Foundation Trust trading as Eastern Pathology Alliance</b></p>                                                                       |  |
| <p><b>Issue No: 008   Issue date: 16 July 2025</b></p>                                                                                                                                  |  |
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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><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Specimens from genital tract<br/>CAPD fluid<br/>ENT specimens (ear, nose, per nasal, nasopharyngeal, throat &amp; mouth swabs &amp; sinus aspirate)<br/>Canalicular Pus, Intraocular Fluids<br/>Skin &amp; superficial wounds, post-op wounds, tissues, fluids &amp; bile<br/>Sterile tissues and fluids<br/>Orthopaedic Samples<br/>Intravascular cannulae<br/>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<br/>EMC-BSOP-019, EMC-BSOP-025, EMC-BSOP-026</p> | A             |
|                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>Isolation of bacterial isolates of clinical significance.</p>                                                                                           | <p>Manual inoculation and culture:<br/>Using<br/>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: (cont'd)</u>                                                    | 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<br>White blood cells<br>Red blood cells<br>Squamous epithelial cells<br>Bacterial cells<br>Casts | Automated microscopy by UF 5000 (Sysmex)<br>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.<br>SOP EMC-BSOP-037.                | A             |
| Blood                                                | Detection of microbial growth with subsequent analysis of positive samples at Location A<br>Reporting of negative samples only                 | Automated blood culture using colorimetric methodology on the Biomerieux Virtuo Blood Culture Machine, A units and B units.<br>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<br>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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| 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<br>WBC differential by Toluidine Blue<br>Cryptococcus antigen detection by IMMY CrAg lateral flow procedure<br>EMC-BSOP-014 | A             |
| Bacterial and fungal isolates cultured in house from above. | Identification of bacterial isolates of clinical significance.                                  | Manual:<br>Direct latex agglutination:<br>Strep PathoDextra (Oxoid)<br>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:<br>EMC-BSOP-010<br>PREVI-Color Gram EMC-BSOP-027<br>VITEK 2 Systems EMC-BSOP-008<br>VITEK MS (MALDI-TOF): EMC-BSOP-028<br>EntericBio EMC-BSOP-040                                                                                             | A             |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)               | <u>Microbiology examination activities for the purposes of clinical diagnosis: (cont'd)</u>                                                                                                                    | In house documented procedures following current UK 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<br>Culture by BD MGIT 960 MP and LJ slopes<br>EMC-BSOP-006<br>Dagatron staining EMC-BSOP-039 | A             |
| Faeces                                               | Microbiological examination for <i>Salmonella and Shigella spp</i><br><i>Campylobacter spp</i><br><i>Escherichia coli 0157:H7</i><br><i>Yersinia enterocolitica</i><br><i>Vibrio spp</i><br><i>Plesiomonas</i> | EntericBio PCR - EMC-BSOP-040 run on Roche Light Cycler<br><br>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<br>Cryptosporidium/Giardia by EntericBio PCR EMC-BSOP-040 run on Roche Light Cycler                                                                                     | 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<br>VITEK 2 Systems, EMC-BSOP-008<br>Cepheid EMC-BSOP-034                                                           | A             |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiology examination activities for the purposes of clinical diagnosis: (cont'd)</u> | In house documented procedures following current UK 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:<br>Mastdiscs combi – ESBL & AmpC Detection<br>Following EUCAST - Disc Sets (MAST) EMC-BSOP-024<br>Mastdiscs combi – Carbapenemase Detection<br>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)<br>ADB: EMC-VSP-017 - Neutralisation immunoassay (bioMérieux)                                                                                                                                                                                                                          | A             |
| Serum                                  | Detection of:                                                                               | bioMérieux VIDAS using ELFA measurement:                                                                                                                                                                                                                                                                                               | A             |
|                                        | EBV                                                                                         | IgG: EMC-VSP-002 App 5<br>IgM: EMC-VSP-002 App 5                                                                                                                                                                                                                                                                                       | A             |
|                                        | CMV                                                                                         | IgG: EMC-VSP-002 App 3<br>IgM: EMC-VSP-002 App 3<br>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<br>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)<br>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:<br>EMC-VSP-003<br>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<br>EMC-BSOP-040 run on Roche Light Cycler<br><br>Toxin detection by Rapid EIA with TechLab Cl.difficile Tox A/B QuickChek<br>EMC-BSOP-041<br>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:<br>EMC-BSOP-034<br>EMC-BSOP-034 Appendix 11                                                                              | A             |
| Faeces, rectal swabs                           | Norovirus 1&2 RNA                                                                          | EMC-VMP-006 – Nucleic Acid Extraction.<br>EMC-VMP-005 - Real-Time PCR on RIDAGene                                                                               | A             |



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| CSF, swabs, fluids (vesicle, vitreous)                                                                                                   | Systemic PCR for HSV 1/2, Varicella zoster virus, Parechovirus, Enterovirus, Adenovirus  | EMC-VMP-006 – Nucleic Acid Extraction.<br>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:<br>ORF1 gene<br>ORF8 gene                                   | Nucleic Acid Extraction using Qiagen QiaSymphonySP<br>Amplification and Detection by real-time PCR using AusDiagnostics HighPlex<br>SOPs:<br>EMC-VMP-006<br>EMC-VMP-019 | A             |
| Urine, saliva, blood, CSF, Amniotic fluid                                                                                                | Detection of CMV DNA                                                                     | Real-time PCR assay using ELITech ELITE InGenius analyser following:<br>EMC-VMP-016                                                                                     | A             |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd)                                                                                             | <u>Molecular examination activities for the purposes of clinical diagnosis: (cont'd)</u>                                                                                            | In house documented procedures following current UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant. | A             |
| CSF                                                                                                                                | Detection of meningitis pathogen nucleic acid<br><br>HSV1<br>HSV2<br>VZV<br>EV<br>Parechovirus<br>hAdv<br>N. meningitidis<br>S. pneumoniae<br>H. influenzae<br>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)<br>Faeces specimens (sterile universal)<br>Tissue samples (sterile universal) | Viral (12 well) panel<br>HSV-1<br>HSV-2<br>VZV,<br>HeV (includes types A, B, C and D),<br>HPeV,<br>hAdV (includes species B, B, E and some A, D; excludes hAdV 21)                  | Aus Diagnostics – MT PCR PROCESSER<br>Aus Diagnostics – MT PCR ANALYSER<br>EMC-VMP-026 AusDiagnostics<br>Viral (12 Well)                                        |               |
| Plasma                                                                                                                             | Viral Loads on NeumoDx<br>CMV viral load<br>EBV viral load<br>HBV viral load<br>HCV viral load                                                                                      | NeuMoDx 96 Molecular System<br><br>EMC-VMP-027 Qiagen NeuMoDx Quant Assays                                                                                      |               |



10296  
Accredited to  
ISO 15189: 2022

|                                                                                                                                                                                         |  |
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| <p align="center"><b>Schedule of Accreditation</b><br/>issued by<br/><b>United Kingdom Accreditation Service</b><br/>2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK</p> |  |
| <p align="center"><b>Norfolk and Norwich University Hospitals NHS Foundation Trust trading as Eastern Pathology Alliance</b></p>                                                        |  |
| <p align="center"><b>Issue No: 008 Issue date: 16 July 2025</b></p>                                                                                                                     |  |
| <p align="center"><b>Testing performed by the Organisation at the locations specified</b></p>                                                                                           |  |

| Materials/Products tested                                                                                                             | Type of test/Properties measured/Range of measurement                                                                                                                                                                                                                                                         | Standard specifications/ Equipment/Techniques used                                                                                                                                                                                                                                                                         | Location Code |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Nasal swab, Throat swab, Bronchoalveolar lavage, nasopharyngeal aspirate, sputum</p> | <p><u>Molecular examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p>Molecular detection of respiratory viruses:</p> <p>Influenza A (including H1N1 typing),<br/>Influenza B,<br/>Parainfluenza<br/>RSV<br/>hMPV<br/>Adenovirus<br/>Rhinovirus<br/>Coronavirus (HKU1, NL40)</p> | <p>In house documented procedures following current UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant.</p> <p>EMC-VMP-029 Respiratory Pathogen PCR (AusDiagnostics 24-well) using Aus Diagnostics – MT PCR PROCESSER and Aus Diagnostics – MT PCR ANALYSER</p> | A             |
| END                                                                                                                                   |                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                            |               |