


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|--|
|  Accredited to ISO 15189:2022 | NHS Tayside Issue No: 017 Issue date: 10 July 2025 | |
| | Medical Microbiology Ninewells Hospital Ninewells Avenue Dundee DD1 9SY | Contact: Alisson McPherson Tel: +44 (0)1382 660111 ext. 36718 E-Mail: alisson.mcpherson@nhs.scot Website: http://www.nhstayside.scot.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 Microbiology Department Ninewells Hospital Ninewells Avenue Dundee DD1 9SY | Local contact As above | Bacteriology Mycology Enteric Parasitology Virology Serology Molecular Microbiology |
| Address Sexual and Reproductive Health Clinic Ninewells Hospital Ninewells Avenue Dundee DD1 9SY | Local contact As above | Plate inoculation and microscopy |



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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 |
|--|--|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> | In-house documented procedures based on UKHSA UK SMIs | |
| | <u>General Bacteriology</u> | | |
| Human samples including swabs, fluids, tissues, urine. | Detection and characterisation of micro-organisms of clinical significance | Use of Gram stain and SOP: NB029 Microscopy and Identification | A |
| Human samples including swabs, urine | Detection and characterisation of micro-organisms of clinical significance | Use of Gram stain and SOP: NB029 Microscopy and Identification | B |
| Swabs from eyes, wounds, mouth, nose, throat, ears, genital sites and intrauterine contraceptive devices | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOPs: NB002 Exudates Manual NB036 Genital Swabs NB039 Acute Bench | A |
| CSF | Detection of cryptococcus | Use of India Ink stain and SOP: NB039 Acute Bench | A |
| Inoculated plates from Site B | General isolation and characterisation of micro-organisms of clinical significance | Processing of inoculated plates using SOPs: NB010 Sexual and Reproductive Health Clinic NB036 Genital Swabs | A |
| Respiratory fluids (sputum, bronchial washings) | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP: NB003 Respiratory Specimens | A |
| Swabs from nose, perineum and wound sites | Isolation of MRSA | Manual culture on chromogenic agar using SOP: NB040 Resistant Organism Screens | A |
| Swabs from rectum and faeces | Isolation of Vancomycin Resistant Enterococcus | Manual culture on chromogenic agar using SOP: NB040 Resistant Organism Screens | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures based on UKHSA UK SMIs | |
| Swabs from various body sites | <u>General Bacteriology</u> (cont'd) Isolation of carbapenem resistant Gram negative rods | Screening for and confirmation of carbapenem resistant Gram negative rods using SOPs: NB030 Carbapenem Resistance Confirmation in GNR NB040 Resistant Organism Screens NB072 Use and Maintenance of the Cepheid GeneXpert | A |
| Intravenous catheters | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOPs: NB039 Acute Bench | A |
| Fluids and tissues from normally sterile sites | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOPs: NB038 Orthopaedic Specimens NB039 Acute Bench | A |
| Fluids from CSF and CAPD fluids | Quantification of white and red blood cells and WBC differential | Manual microscopy using SOPs: NB029 Microscopy and Identification NB039 Acute Bench | A |
| Urine | Quantification of white and red blood cells, bacteria and epithelial cells | Manual microscopy using SOP: NB007 Urine Manual | A |
| Urine | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP: NB007 Urine Manual | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures based on UKHSA UK SMIs | |
| | <u>General Bacteriology</u> (cont'd) | | |
| Faeces | General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> O157 and other enteric pathogens | Manual culture methods using selective agar and SOP: NB300 Molecular faeces specimen triage and setup NB301 Molecular faeces confirmation | A |
| Faeces | Detection of <i>Clostridioides difficile</i> GDH antigen and toxins A & B | Screening for C diff GDH and toxins using SOP: NB073 C difficile/H pylori antigen in conjunction with manufacturer's instructions using DS2 analyser (GDH) and VIDAS (Toxin) | A |
| Faeces | Detection of <i>Helicobacter pylori</i> | Screening for <i>H pylori</i> faecal antigen using SOP: NB073 C difficile/ <i>Helicobacter pylori</i> antigen in conjunction with the manufacturer's instructions for Amplified IDEIA HpStAR on DS2 analyser. | A |
| Blood cultures | Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance | Detection of growth in cultures of blood using SOP: NB001 Blood Cultures in conjunction with manufacturer's instructions for automated system BacT/Alert. | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures based on UKHSA UK SMIs | |
| Bacterial cultures (isolated in-house) | <u>General Bacteriology</u> (cont'd) Identification and antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC) of bacteria | Identification and susceptibility testing using VITEK 2 automated antimicrobial testing system and BioMérieux MS Biotyper MALDI-tof and SIRScan SOPs: NB027 Sensitivity Testing NB012 Etest MIC NB013 ESBL Testing NB029 Microscopy and Identification NB030 Carbapenem Resistance NB298 Operation of MS prime NB078 SIRScan | A |
| Yeast cultures (isolated in-house) | Identification of yeasts | Identification of yeasts using VITEK 2 automated testing system and BioMérieux MS Biotyper MALDI-tof | A |
| Bronchoalveolar lavage/washings, sputum | Detection of Mycobacterium Tuberculosis | TBRif Ultra kit via Cepheid PCR, using SOP NB072, NB004 | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures based on UKHSA UK SMIs | |
| Human samples including faeces and urine as specified | <u>Parasitology</u> Examination activities for the purposes of clinical diagnosis | In-house documented procedures based on UKHSA SMIs | |
| Faeces | Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance | Screening for and identification of enteric parasites using SOP: NB300 Molecular faeces specimen triage and setup using concentration where required and manual microscopy. | A |
| Urine | Detection of schistosome ova | Screening for and identification of urinary tract parasites using SOP: NB007 Urine Manual using concentration where required and manual microscopy. | A |
| Human samples including skin scrapings, hair and nail clippings | <u>Mycology</u> Examination activities for the purposes of clinical diagnosis | In-house documented procedures based on UKHSA SMIs | |
| Skin scrapings, hair and nail clippings | General isolation and characterisation of fungi of clinical significance | Detection of pathogenic fungi using SOP: NB006 Mycology manual and direct microscopy of KOH digested samples and culture on non-chromogenic selective media. | A |



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| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum/plasma</p> | <p><u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Serology</u></p> <p>Detection of: Hepatitis A IgM Hepatitis A total antibody Hepatitis B anti-HBs Hepatitis B core antibody Hepatitis B surface antigen Hepatitis C antibody HIV antibody/antigen combination Rubella IgG Syphilis antibody</p> | <p>In house documented procedures based on manufacturer's instructions</p> <p>Serology using the Atellica IM (Siemens)) in conjunction with the manufacturer's instructions & SOPs:</p> <p>NV032 Reporting of HBsAg Positives samples from pregnant women</p> <p>NV033 Hepatitis B Testing and Reporting</p> <p>NV037 Hepatitis A Testing and Reporting</p> <p>NV040 Rubella IgG Testing</p> <p>NV115 HIV Minimum Testing Algorithm</p> <p>NV121 Serological Diagnosis of Syphilis</p> <p>NV136 Handling of HIV Requests in Children <18 months of age</p> <p>NV197 Preparation of Dried Blood Spots</p> <p>NV295 – Operation of the Siemens Atellica Solution</p> | <p>A</p> |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In house documented procedures based on manufacturer's instructions | |
| Serum/plasma | <u>Serology</u> (cont'd) Detection or confirmation of: CMV IgM EBV EBNA IgG EBV VCA IgG EBV VCA IgM Measles IgG Parvovirus B19 IgG Parvovirus B19 IgM VZV IgG | DiaSorin Liaison XL analyser in conjunction with the manufacturer's instructions & SOPs: NV111 Biotrin Parvovirus ELISA NV215 EBV Testing on the Liaison NV217 CMV IgM testing on the Liaison NV227 VZV IgG testing on the Liaison NV252 Measles IgG on the Liaison NV262 Use and Maintenance of the Liaison XL | A |
| Serum/plasma | Detection or confirmation of: CMV IgG Hepatitis B core antibody Hepatitis B core IgM Hepatitis B e antibody Hepatitis B e antigen Hepatitis B surface antigen Hepatitis C antibody HIV antibody/antigen combination Mumps IgG Rubella IgM Toxoplasma IgM Toxoplasma total antibody | Serology using the BioMerieux VIDAS analyser in conjunction with the manufacturer's instructions and SOPs: NV017 Toxoplasma Total Antibody and IgM NV032 Reporting of HBsAg Positives from ANC Patients in Tayside NV033 Hepatitis B Testing and Reporting NV041 VIDAS HBsAg Confirmation Protocol NV102 Mini-Vidas NV103 Hep C Confirmation Reporting Protocol NV042 Mumps and CMV Vidas Protocol NV115 HIV Minimum Testing Algorithm NV122 Rubella IgM Serology NV136 Handling of HIV Requests in Children <18 months of age NV258 Use and Maintenance of the VIDAS 3 analyser | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In house documented procedures based on manufacturer's instructions | |
| Dried Blood Spots | <u>Serology</u> (cont'd) Detection of: Hepatitis B Hepatitis C HIV | Serology using SOPs: NV197 Preparation of Dried Blood Spots NV218 Dried Blood Spot HIV, HCV, and HBsAg Testing | A |
| Serum | Confirmation of HIV | Serology using SOP NV250 Geenius HIV 1 and 2 Confirmatory Assay | A |
| Serum/plasma | Syphilis confirmation using specific Reagin antibody tests, ASI RPR Reditest | Serology using SOPs: NV014 ASI RPR Reditest NV121 Serological Diagnosis of Syphilis | A |
| Nasopharyngeal swab/aspirate Bronchoalveolar lavage, sputum | Detection of: Panel 1: <ul style="list-style-type: none"> • Influenza virus, • Influenza B, • Flu A-H3, • Flu A-H3, • Flu A-H1pdm09 • RSV A, RSV B. Panel 2: <ul style="list-style-type: none"> • Adenovirus, • Enterovirus, • MPV, • Parainfluenza 1, 2, 3 & 4. Panel 3: <ul style="list-style-type: none"> • Bocavirus, Rhinovirus, CoV OC43, • CoV NL63, CoV 229E Panel 4: <ul style="list-style-type: none"> • M.pneumoniae, • S.pneumoniae, • H.influenzae | Allplex respiratory assays via the Seegene Starlet analyser using SOP NV290 Seegene Allplex Respiratory panel assay using Seegene Starlet NV 303 work instruction for triaging samples for the extended respiratory screen | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) Bloods, CSF, Faeces, Fluids, Respiratory aspirates, Swabs (various sites), Urines | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) <u>Molecular Biology</u> Detection of: Adenovirus Respiratory BK Virus CMV Coronavirus (x4) EBV Enterovirus Hepatitis B Hepatitis C HIV HSV Influenza A and B Influenza Subtyping Measles Metapneumovirus Mumps <i>Mycoplasma pneumoniae</i> Norovirus Parainfluenza (x4) Parechovirus Rhinovirus RSV VZV | In house documented procedures based on manufacturer's instructions Real-time PCR using BioMerieux Easymag and ABI 7500 thermocyclers and SOPs: NV115 HIV Minimum Testing Algorithm NV186 Preparation of Norovirus RNA Control for PCR NV203 Preparation of BK Standard and DNA control for PCR NV204 Preparation of CMV Standard and DNA Control for PCR NV205 Preparation of DNA Control for HSV, VZV and Adenovirus PCR NV225 Non-respiratory IH PCR NV234 Preparation of EBV Standard and EBV Control NV237 Preparation of Nucleic Acid for Parecho-Enterovirus PCR Controls NV255 Preparation of MMR Positive control NV140 Probe titration for Real time PCR NV165 Virus Detection examination Procedure NV163 Preparation of primer/probe mix for inhouse PCR NV266 Preparation of PCR mix for IH PCR NV 146 Use of the ABI 7500 NV 144 Maintenance of the ABI 7500 NV 243 Preparation of internal control for IH PCR NV 257 Verification of Quantitative Standards for PCR NV 254 Preparation of samples for virus Detection SOP NV 35 Quantitative IH PCR | A |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In house documented procedures based on manufacturer's instructions | |
| Plasma | <u>Molecular Biology</u> (cont'd) HCV rRnaViral Load HIV Viral Load HBV Viral Load | Aptima Viral Load assays on the Hologic Panther platform, using Transcription Mediated Amplification (TMA) SOP NV265 HIV, HCV and HBV Viral Load Testing on the Hologic Panther | A |
| Urines and swabs Vaginal/vulvovaginal, Endocervical, urethral, rectal and throat | Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae r RNA</i> | Aptima Combo 2 assay on the Hologic Panther platform using Transcription Mediated Amplification (TMA) SOP NV266 Chlamydia and N gonorrhoeae Testing using the Aptima Combo Assay on the Hologic Panther. NV268 Maintenance of the Hologic panther NV269 Handling samples fro CTNG testing on the Hologic panther | A |
| Nasopharyngeal combined swab | Detection of Sars Cov-2 virus | RT-PCR for qualitative detection via Seegene Starlet using SOP NV285. | A |
| Nasopharyngeal combined swab | Detection of Sars Cov-2 virus | Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification (TMA), and Dual Kinetic Assay (DKA) via Hologic Panther using SOP NV286. | A |



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| Nasopharyngeal combined swab | <u>Molecular Biology</u> (cont'd) Detection of Sars Cov-2 virus and Multiplex assay (Sars Cov-2, FluA, FluB and RSV) | RT-PCR Xpert Xpress SARS-CoV-2 & Multiplex kit for the qualitative detection via the GeneXpert Cepheid analyser using SOP DX POCT 4/ NV294 NV 300 Maintenance of the Cepheid GeneXpert in the Hot lab | A |
| | | Multiplex real-time RT-PCR assay for the simultaneous rapid in vitro qualitative detection via Roche Liat using SOP DX POCT 1 / NV293 | A |
| END | | | |