


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |  |
|---|---|--|
|  <p><b>UKAS</b><br/>MEDICAL<br/>8844</p> <p>Accredited to<br/>ISO 15189:2012</p> | <h3>NHS Fife</h3> <p><b>Issue No:</b> 012    <b>Issue date:</b> 15 September 2023</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   |
|---|---|--|
| HUMAN BODY TISSUES/FLUIDS                               | <p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> | <p>In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate</p> |
| CSF   |   | <p>Culture and Light Microscopy<br/>ESOP008 and ESOP 068 Investigation of CSF</p>  |
| Genital samples   |   | <p>ESOP009 Investigation of genital tract and associated specimens</p>   |
| Mouth swabs   |   | <p>ESOP012 Investigation of mouth swabs</p>  |
| Nasal samples   |   | <p>ESOP013 Investigation of nasal samples</p>  |
| Throat swabs  |   | <p>ESOP015 Investigation of throat swabs</p>   |
| Bronchoalveolar lavage, Sputum and associated specimens |   | <p>ESOP016 Investigation of Bronchoalveolar lavage, Sputum and associated specimens</p>  |
| Tissues and biopsies                                    |   | <p>ESOP017 Investigation of tissues and biopsies<br/>ESOP221 Orthopaedic Implants/prosthetic joints associated with infection samples</p>  |



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| HUMAN BODY TISSUES/FLUIDS (cont'd)               | <u>Microbiology examination activities for the purpose of clinical diagnosis</u>            | In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA)) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate  |
| Bone   | General isolation and characterisation of micro-organisms of clinical significance (cont'd) | ESOP020 Investigation of bone and soft tissue associated with osteomyelitis   |
| Ear swabs and associated specimens               |   | Culture and Light Microscopy of wet preps and Gram stains<br>ESOP023 Investigation of ear swabs and associated specimens  |
| Eye swabs and canaliculi pus                     |   | ESOP024 Investigation of eye swabs and canalicular pus  |
| Skin, and wound swabs, cyst and abscess material |   | ESOP025 Investigation of swabs, skin and superficial soft tissue infection<br>ESOP 026 investigation of abscesses post operative and deep seated wound infections (pus and exudate)<br>ESOP 028 Investigation intervascular cannular and associated specimens |
| Urine  |   | ESOP 010 Investigation of Urine   |
| Bile   |   | ESOP027 Investigation of Bile<br><br>Traditional Culture and Microscopy of wet preps and Gram stains  |
| CAPD fluid                                       |   | ESOP030 Investigation of CAPD fluid   |



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| HUMAN BODY TISSUES/FLUIDS (cont'd)       | <u>Microbiology examination activities for the purpose of clinical diagnosis</u>                     | In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate |
| Joint, ascitic pericardial fluid         |  | ESOP031 Investigation of fluids from normally sterile sites/ESOP 221 Investigation of Orthopaedic implants/prosthetic joint associated infection  |
| Intraocular fluids and corneal scrapings |  | ESOP033 Investigation of intraocular fluids and corneal scrapings   |
| Nasal, groin, perineum swabs             | MRSA   | ESOP032 Investigation of specimens for MRSA screening   |
| Sputum                                   | Detection of <i>Mycobacterium tuberculosis</i> complex and detection of Rifampicin resistance genes. | ESOP278. Detection using GeneXpert and MTB/RIF Ultra.   |
| Urine                                    | Detection of Legionella pneumophila serogroup 1 urinary antigen                                      | ESOP 189, By the Sofia Legionella Fluorescent Immunoassay. (FIA)  |
| Skin, hair and nails                     | Mycoses  | ESOP072 Investigation of dermatological specimens for superficial mycoses using culture and Lactophenol blue wet mounts   |
| Faeces                                   | Enteric Pathogens  | Investigation of faeces for enteric pathogens ESOP021   |
| Faeces                                   | Helicobacter pylori  | ESOP107 Investigation of Helicobacter pylori (Antigen detection by ELISA on DS2)  |



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| HUMAN BODY TISSUES/FLUIDS<br>(cont'd) | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> | In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate |
| Faeces                                | <i>Clostridium difficile</i> Glutamate dehydrogenase                             | Enzyme immunoassay for the detection of <i>C.difficile</i> glutamate dehydrogenase (GDH) on DS2. Qualitative  |
|                                       | Toxins A & B   | Immunocard Toxin A&B kit. By horizontal flow EIA<br>ESOP196 and ESOP 215  |
|                                       | Detection of <i>Clostridium difficile</i> Glutamate dehydrogenase and Toxins A&B | ESOP215 using Techlab C.Diff Quik Check Complete  |
|                                       | Rotavirus  | ESOP 021 (Coris Lateral Flow)   |



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| HUMAN BODY TISSUES/FLUIDS (cont'd)  | Microbiology examination activities for the purpose of clinical diagnosis | In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA)) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate  |
| Faeces, Intestinal fluid, bile, CSF, liver & spleen aspirates, clear adhesive tape slides, sputum & tissue biopsies | Detection of parasites of clinical significance.                          | Concentration of and Traditional Microscopy using ESOP022 Investigation of specimens other than blood for parasites   |
| Faeces  | Cryptosporidium oocysts   | Cold Ziehl Neelsen and microscopy ESOP 021 and ESOP117  |
| Blood   | Bacterial growth detection  | Automated incubation and bacterial growth detection by BD Bactec Fx ESOP 007 -investigation of blood cultures   |
| Cultured isolates   | Identification of micro-organisms   | Automated identification using Vitek 2 and ESOP071 and manual identification tests<br><br>MALDI-TOF Identification ( VITEK MS)<br>ESOP 255 and 256  |
| Bacterial Isolates  | Antimicrobial susceptibility testing                                      | Determination of antimicrobial susceptibility by disc diffusion read manually (ESOP083) or on SIRscan i2a 2000, Gradient Mic strip (ESOP080) and Automated broth microdilution using VITEK 2 (ESOP 163). Interpretation of breakpoints and zone sizes based on EUCAST |



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| <p>HUMAN BODY TISSUES/FLUIDS (cont'd)</p> <p>Serum/plasma</p> <p>Serum</p> <p>Serum/plasma</p> | <p><u>Serology examination activities for the purpose of clinical diagnosis</u></p> <p>HIV antibody/antigen combination</p> <ul style="list-style-type: none"> <li>• Anti Hbs</li> <li>• Hep B Core</li> <li>• Hep B sAg</li> <li>• Rubella IgG</li> <li>• Syphilis</li> </ul> <p>Antibody / Antigen Detection for:</p> <ul style="list-style-type: none"> <li>• Hepatitis B antibody</li> <li>• Hepatitis B surface antigen</li> <li>• HIV antigen/antibody</li> <li>• Syphilis antibody</li> <li>• Hepatitis C antibody</li> </ul> <ul style="list-style-type: none"> <li>• CMV IgM and IgG</li> <li>• Measles IgG</li> <li>• Hep A IgM and IgG</li> <li>• Toxoplasmosis IgG</li> <li>• Parvovirus B19</li> <li>• EBV IgM/EBV IgG/EBNA</li> <li>• VZ IgG</li> </ul> | <p>In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA)) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate</p> <p>Antibody and Antigen detection by electrochemiluminescence immunoassay (ECLIA) on Cobas 8000/e602 ESOP 101 and QMS 696</p> <ul style="list-style-type: none"> <li>• ESOP 112</li> <li>• ESOP102</li> <li>• ESOP102</li> <li>• ESOP105</li> <li>• ESOP104</li> </ul> <p>Antibody / Antigen detection by electrochemiluminescence immunoassay ECLIA on Cobas8000/e602</p> <ul style="list-style-type: none"> <li>• ESOP 112</li> <li>• ESOP 102</li> <li>• ESOP 101</li> <li>• ESOP 104</li> <li>• ESOP 097</li> </ul> <p>Detection by Chemiluminescence immunoassay (CLIA) on Liaison XL</p> <p>ESOP106<br/>ESOP113<br/>ESOP103 and 157<br/>ESOP115<br/>ESOP174 and QMSP698<br/>ESOP173<br/>ESOP116</p> |



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| HUMAN BODY TISSUES/FLUIDS (cont'd)  | <u>Molecular diagnostic activities for the purpose of clinical diagnosis</u> | In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA)) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate  |
| Urine, Vulvo-vaginal swab, rectal swab, throat swab, eye swab, urthethral   | Chlamydia trachomatis and Neisseria gonorrhoea                               | Automated extraction, amplification and utilising real-time PCR technology using the Qiagen QIASymphony and Rotor Gene Q ESOP 257 ESOP 258 ESOP056  |
| Respiratory panel only:<br>Throat swab<br>Nasopharyngeal swab<br>Nasopharyngeal aspirate<br>Endotracheal aspirate | Detection of respiratory and/or gastrointestinal targets                     | Flexible Scope for targets detected by real time RT-PCR using QIAstat-DX (QIAstat-Dx Respiratory Panel or QIAstat-Dx Gastrointestinal Panel)<br>Flexible scope protocols:<br>ESOP 198<br>ESOP 266<br>ESOP 267   |
| GI panel only:<br>Faecal swab   |  | Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record  |
| Throat swab<br>Nasopharyngeal swab<br>Nasopharyngeal aspirate<br>Endotracheal aspirate                            | Detection of Respiratory Pathogens   | Flexible Scope for targets detected by Qiagen NeuMoDx 96 Molecular System and NeuMoDx real time PCR Assays<br><br>Flexible scope protocols:<br>ESOP 198<br>ESOP 266<br>ESOP 267<br><br>Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record |



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| Urine, Vulvo-vaginal swab, rectal swab, throat swab, eye swab, urethral swab | Detection Genito Urinary Pathogens   | Flexible Scope for targets detected by Qiagen NeuMoDx 96 Molecular System and NeuMoDx real time PCR Assays<br><br>Flexible scope protocols:<br>ESOP 198<br>ESOP 266<br>ESOP 267<br><br>Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record |
| Serum / Plasma   | Detection of Bloodborne Viruses (qualitative and quantitative)               | Flexible Scope for targets detected by Qiagen NeuMoDx 96 Molecular System and NeuMoDx real time PCR Assays<br><br>Flexible scope protocols:<br>ESOP 198<br>ESOP 266<br>ESOP 267<br><br>Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record |





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| <p>HUMAN BODY TISSUES/FLUIDS (cont'd)</p> <p>Vesicle, lesion and ulcer swabs, fluids and crusts</p> <p>Genital swabs</p> <p>Throat swabs<br/>Nasopharyngeal swabs using eNaat swabs</p> | <p><u>Molecular diagnostic activities for the purpose of clinical diagnosis</u></p> <p>Detection of</p> <ul style="list-style-type: none"> <li>• Herpes Simplex Virus 1 &amp; 2</li> <li>• Varicella Zoster Virus</li> </ul> <p>Detection of Herpes Simplex Virus 1 &amp; 2</p> <p>Detection of RNA targets of :<br/>B-beta coronavirus E gene and S gene</p> | <p>Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus kits<br/>ESOP 257<br/>ESOP 258<br/>ESOP226</p> <p>Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus Kit<br/>ESOP 257<br/>ESOP 258E SOP226</p> <p>Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by RealStar by Altona diagnostics using RT PCR</p> |



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| HUMAN BODY TISSUES/FLUIDS<br>(cont'd)<br><br>Eye swab | <u>Molecular diagnostic activities for the purpose of clinical diagnosis</u><br><br>Detection of <ul style="list-style-type: none"><li>• Varicella zoster</li><li>• Herpes simplex virus 1 &amp; 2,</li><li>• Adenovirus</li></ul> | Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus Kit<br>ESOP 257<br>ESOP 258<br>ESOP226 |
| END   |  |  |