


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
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|  <p>UKAS MEDICAL 9612</p> <p>Accredited to ISO 15189:2022</p> | <h3>NHS Highland</h3> <p>Issue No: 010 Issue date: 13 February 2026</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>Human samples including swabs, fluids, tissues.</p> <p>Bacterial and Yeast cultures (isolated in-house)</p> | <p><u>Microbiological examination activities for the purposes of clinical diagnosis</u></p> <p><u>General Bacteriology</u></p> <p>General detection and characterisation of micro-organisms of clinical significance</p> <p>Identification and antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC) of bacteria and yeasts</p> <p>Identification and antimicrobial susceptibility testing</p> | <p>In House documented methods based on PHE UK SMIs Standards for Microbiology Investigations</p> <p>Manual culture and microscopy including use of Gram stain (MCP011)</p> <p>Identification and susceptibility testing using SOP MCP066 and MCP070 (VITEK 2 automated antimicrobial testing system); SOP MCP082 (Identification of bacterial and yeast isolates using API products); SOP MCP032 and MCP033 (Determination of disc sensitivity and minimum inhibitory concentration (MIC) Sensitivity Procedures using manual methods with EUCAST guidelines)</p> <p>SOP MCP098 (Detection of ESBL production using SOP MCP098)</p> <p>Broth microdilutions of cultured bacteria using Bioconnections Merlin Micronaut Colistin MIC MBD strips SOP MCP105</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 methods based on PHE UK SMIs Standards for Microbiology Investigations |
| Blood cultures | General Bacteriology (cont'd) Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance | Detection of growth in cultures of blood and other fluids using BACTEC FX – SOP MCP015 |
| Cannulae and catheter tips | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP MCP028 |
| CAPD | General isolation and characterisation of micro-organisms of clinical significance | Manual culture and enrichment using BACTEC FX: SOPS MCP085, MCP015 |
| CSF | General isolation and characterisation of micro-organisms of clinical significance | Manual culture and microscopy using SOP MCP077, MCP051 |
| Faeces | General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> O157, <i>Vibrio</i> species and other enteric pathogens | Manual culture methods using selective agar and SOP: MCP007 and MCP008 |
| Faeces | General isolation and characterisation of <i>Clostridioides difficile</i> | Manual culture using selective agar using SOP MCP037 |
| Fluids and tissues from normally sterile sites | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP MCP022 and MCP076 (blood transfusion packs). |
| Fluids from CSF, Ascitic and CAPD fluids | Quantification of white and red blood cells and WBC differential | Manual microscopy using SOPs MCP051, MCP077, MCP085 |
| Genital swabs | Isolation and identification of Group B Streptococci | Manual culture using selective agar – SOP MCP005 |
| Respiratory and other specimens | AAFB | Manual microscopy using phenol auramine SOP: MCP046 |



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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 methods based on PHE UK SMIs Standards for Microbiology Investigations |
| Respiratory fluids (including sputum, tracheal aspirates, bronchial alveolar washings) | General Bacteriology (cont'd) General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP:MCP038. |
| Swabs including 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 and microscopy using SOPs: MCP005, MCP018, MCP021, MCP023, MCP024, MCP041, MCP060 (includes Hays criteria for bacterial vaginosis MCP100) |
| Swabs from rectum and faeces | Isolation and identification of Vancomycin Resistant Enterococcus | Manual culture on chromogenic agar using SOP MCP026 |
| Swabs from various body sites | Isolation of carbapenem resistant Gram negative rods | Screening for and confirmation of carbapenem resistant Gram negative rods using SOP MCP006 |
| Swabs including nose, perineum, wound sites and urine. | Isolation of MRSA | Manual culture on chromogenic agar using SOP MCP042 |
| Urine | Quantification of white and red blood cells, bacteria, yeast and epithelial cells | Manual microscopy using SOP: MCP051 |
| Urine | General isolation and characterisation of micro-organisms of clinical significance | Manual culture using SOP MCP030 |
| Urine | Detection of <i>Legionella pneumophila</i> serogroup 1 antigen and detection of <i>Streptococcus pneumoniae</i> antigen | Detection of <i>Legionella</i> and <i>Streptococcus pneumoniae</i> urinary antigen using Immuvue urinary antigen test - SOP MCP084 |



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| <p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Human samples including faeces and urine as specified</p> <p>Faeces, Urines, sellotape slides and rectal swabs</p> <p>Genital swabs</p> | <p><u>Microbiological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><u>Parasitology</u></p> <p>Examination activities for the purposes of clinical diagnosis</p> <p>Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance</p> <p>Cryptosporidium and Cyclospora oocysts</p> <p>Detection of <i>Trichomonas vaginalis</i></p> | <p>In House documented methods based on PHE UK SMIs Standards for Microbiology Investigations</p> <p>In-house documented procedures based on PHE SMIs</p> <p>Screening for and identification of enteric parasites using Midi Parasep system SOP MCP004</p> <p>Auramine Phenol Microscopy and Modified Ziehl Neelsen</p> <p>Wet preparations using SOP MCP060</p> |
| <p>HUMAN SAMPLES AND TISSUES (cont'd)</p> <p>Human samples including skin scrapings, hair and nail clippings</p> <p>Skin scrapings, hair and nail clippings</p> <p>Faeces</p> <p>Serum/ Plasma</p> | <p><u>Examination activities for the purposes of clinical diagnosis</u></p> <p><u>Mycology</u></p> <p>Examination activities for the purposes of clinical diagnosis</p> <p>General isolation and characterisation of fungi of clinical significance</p> <p><u>Antigen detection</u></p> <p>Detection of Rotavirus and Adenovirus</p> <p><u>Serology</u></p> <p>Anti-streptolysin-O (ASO)</p> | <p>In-house documented procedures based on PHE UK SMIs</p> <p>In-house documented procedures based on PHE SMIs</p> <p>Detection of pathogenic fungi using SOP MCP052 including direct microscopy of KOH digested samples and culture on non-chromogenic selective media.</p> <p>Immunochromatographic antigen detection using manufacturers documentation and SOP MCP048</p> <p>Slide agglutination test in conjunction with manufacturer's documentation and SOP MSP029</p> |



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| HUMAN SAMPLES AND TISSUES (cont'd) | <u>Examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures based on PHE UK SMIs |
| Serum/plasma | Serology (cont'd) Detection or confirmation of: | Manual or automated ELISA Liaison XL analyser and Diasorin kits in conjunction with manufacturer's documentation and SOPs: |
| | Helicobacter pylori IgG Hepatitis E IgG Hepatitis E IgM Measles IgG Parvovirus B19 IgG Parvovirus B19 IgM VZV IgG HEV IgM | ME069 (Liaison)MSP005(H.pylori), MSP037(HEV) MSP038 (Measles), MSP008 (VZV), MSP011(Parvo IgM), MSP017(Parvo IgG) MSP050(HEV IgM) |
| Serum/plasma/ | Lyme Borrelia burgdorferi | Manual, semi-automated and automated techniques using manufacturer's documentation and SOPs: |
| | Borrelia burgdorferi IgG | ME013 (DS2) ME028 (Recom scan) MSP002 (ELISA IgG) MSP015 (Immunoblot) MSP040 (reporting comments) |
| | Borrelia burgdorferi IgM | Automated techniques (DiasorinLiaison XL analyser (CLIA)) |
| | Borrelia burgdorferi IgG | Mikrogen CarL immunoblot processor) |
| | Borrelia burgdorferi IgM | |



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| CSF | Serology (cont'd) Borrelia burgdorferi IgG and IgM | Automated techniques (Diasorin Liaison XL analyser (CLIA) SOP's MSP046 (Carl Immunoblot) MSP048 & ME069 (Liaison) MSP040 (reporting comments) |
| Serum/plasma | Toxoplasma IgG avidity t Toxoplasma IgM Western blot (LDBio) Toxoplasma total antibody | Manual, semi-automated and automated techniques using manufacturer's documentation and Manual Immunoblot LD Bio Western Blot Dye Test |
| | Toxoplasma IgG Toxoplasma IgG avidity | Auto (Diasorin Liaison XL analyser (CLIA & Mikrogen CarL Immunoblot processor) |
| | Toxoplasma IgM | (Diasorin Liaison XL analyser (CLIA) and ISAGA SOPs: MSP022 (Dye Test) MSP024 (ISAGA) MSP026 (LDBio WIB) MSP015 (Immunoblot) MSP046 (CarL) MSP048 & ME069 (Liaison) MSP040 (reporting comments) |
| Serum | CMV IgG | Diasorin Liaison XL and Diasorin Kits (CLIA) ME069 |
| | CMV IgM EBV VCA IgG EBV VCA IgM EBV EBNA IgG Hepatitis A IgM Hepatitis B core antibody Hepatitis B surface antigen Hepatitis C Ab HIV antigen/antibody Rubella IgG Syphilis total Ab | |



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| HUMAN SAMPLES AND TISSUES (cont'd) | <u>Examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures based on PHE UK SMIs |
| | <u>Molecular Biology</u> | |
| Bacterial isolates and fluid from blood culture bottles | SA / MRSA PCR | Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |
| Faeces | Norovirus GI and GII | Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |
| | <i>C. difficile</i> | |
| Faeces, swabs | CPE | Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |
| Amniotic fluid, whole blood/buffy coat., CSF, ocular fluid, human tissues | Detection of <i>Toxoplasma gondii</i> | Extraction by Biomerieux easyMag or Qiacube amplification and detection by ABI 7500 QIACube whole blood/buffy coat, tissue EasyMag CSF and amniotic and eye fluids SOPs: ME067 ME014, ME015, MMP006 |
| Blood, CSF | Detection of <i>Cytomegalovirus</i> | Extraction by Biomerieux easyMag or Qiacube amplification and detection by ABI 7500 SOPs: ME067 ME014, ME015, MMP006,ME016 |
| CSF | Detection of: Herpes Simplex Virus 1 & 2 Varicella Zoster Virus | Extraction by Biomerieux easyMag or Qiacube amplification and detection by ABI 7500 (SOP ME014, ME015), using commercial kits - Launch Fast Track Diagnosis (FTD) SOP MMP019 ME016 |



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| | <u>Molecular Biology</u> (cont'd) | |
| CSF, joint fluid, whole blood/buffy coat and human tissue (mainly skin biopsies) | Detection of <i>Borrelia burgdorferi</i> | Extraction by Biomerieux easyMag or Qiagubeamplification and detection by ABI 7500 SOPs: ME067 ME014, ME015, ,MMP006, |
| Eye swabs | Detection of: Varicella zoster Herpes simplex virus 1 & 2, Adenovirus | Extraction by Biomerieux easyMag amplification and detection by ABI 7500 SOPs: ME014, ME015, , , MMP006, |
| Faeces | Norovirus GI and GII | Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |
| Lower respiratory tract samples | Detection of <i>Pneumocystis jiroveci</i> | Extraction by Biomerieux easyMag amplification and detection by ABI 7500 SOPs: ME014, ME015, |
| Respiratory specimens (Sputum) | TB PCR | Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |
| Upper respiratory tract swabs (nose, throat, perinasal) | <u>FLU A</u> FLU B RSV | <u>Cepheid Combined SARS-CoV-2/FLU A/FLUB/RSV PLUS assay by</u> Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011 |



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| <p>HUMAN SAMPLES AND TISSUES (cont'd)</p> <p>Nasal swabs, nasopharyngeal aspirates, respiratory swabs, throat swabs</p> <p>Vesicle, lesion, skin and ulcer swabs, fluids and crusts, throat swabs, genital swabs</p> <p>Urines and swabs</p> | <p><u>Examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Molecular Biology (cont'd)</p> <p>Detection of respiratory pathogens;</p> <ul style="list-style-type: none"> • Adenovirus • Human Bocavirus • <i>Bordetella pertussis</i> • <i>Chlamydia pneumonia</i> • Coronavirus (229E, HKU1, NL63, OC43) • Human Rhinovirus/Enterovirus • Influenza A • Influenza B • <i>Legionella pneumophila</i> • Human Metapneumovirus • Middle East Respiratory Syndrome Coronavirus (MERS) • <i>Mycoplasma pneumoniae</i> • Parainfluenza 1,2,3,4 • Respiratory Syncytial Virus A and B <p>HSV 1, HSV 2.</p> <p>Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i></p> | <p>In-house documented procedures based on PHE UK SMIs</p> <p>Amplification and detection by 'Genmark ePlex' and in conjunction with manufacturer's instructions and SOP;-MMP020</p> <p>Extraction by Biomerieux easyMag or Qiacube amplification ME067 and detection by ABI 7500 (SOPs ME014, ME015 ME 016), using in-house methods (SOPs MMP001, MMP002)</p> <p>Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011</p> |



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| Endotracheal Aspirates/Bronchoalveolar Lavage | Molecular Biology (cont'd) Detection of Pneumocystis Jirovecii | Manufacturer's automated DNA extraction platform (eMAG and EasyMag) SOP MMP022 Viasure Assay on ABI 7500 using real-time PCR technology: SOP MMP022 |
| CSF/Lesion Swabs/Throat Swabs | Detection of Enterovirus | Manufacturer's automated DNA extraction platform (eMAG and EasyMag) SOP MMP022 Viasure Assay on ABI 7500 using real-time PCR technology: SOP MMP022 |
| Urine, Swabs (Genital swabs, Oropharyngeal (throat) swab, Anorectal swabs and Eye swabs) | Qualitative detection of: Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Mycoplasma genitalium | Seegene Allplex Assay on STARlet analyser using real-time PCR technology - SOP ME072 |
| Serum/Plasma | Detection of SARS-CoV-2 IgG antibodies | Diasorin Liaison XL analyser using CLIA technology and SARS-CoV-2 S1/2 and SARS-CoV-2 TrimericS IgG assays: - SOP MSP048 - SOP ME069 |
| Faeces | Detection of Helicobacter pylori faecal antigen | Diasorin Liaison XL analyser - SOP MSP048 |
| CSF | Detection of CXCL13 for the diagnosis of Lyme neuroborreliosis | Reagentia Reascan CXCL13 Lateral Flow Assay - SOP:MSP050 |
| Faeces | Detection of: Clostridioides difficile glutamate dehydrogenase antigen and Toxins A & B | Clostridioides difficile Alere TechLab Quik Chek Complete GDH/Tox AB Lateral flow kit - SOP:MCP109 |



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| Serum, Plasma | <u>Molecular Biology</u> (cont'd) Detection of: Toxoplasma IgM | Manual ELISA using Biorad Platelia assay - SOP MSP053 |
| Serum/Plasma | <u>Immunology</u> Detection of antibodies: Alpha-1-antitrypsin C3 C4 | Siemens Atellica Nephelometer 630– detection of immune complexes by nephelometry - SOP MSP033 |
| Serum | IgA | |
| Serum | Detection of protein abnormalities. Detection and characterisation of monoclonal proteins | Sebia Capillary Zone Electrophoresis using Sebia Capillarys 2 Flex with Capillarys protein 6 kit or capillarys immunotyping kit - SOP MSP035 |
| Serum | Immunofixation of Immunoglobulins IgG, IgA, IgD, IgE, and IgM | Helena Biosystems Vitrésí SAS-1+ and SAS-2 by gel electrophoresis - SOP MSP041 |
| Urine | Bence Jones Proteins | Helena Biosystems Vitrésí by gel electrophoresis - SOP MSP041 |
| Serum/Plasma | Total IgE Specific IgG: - Aspergillus fumigatus - Avian antibody (pigeon & budgie) - Micropolyspora faeni (farmers lung) Tryptase | Phadia ImmunoCap 250 FEIA by fluorescence detection of strength of antibody/antigen reactions - SOP MSP036 |



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| HUMAN SAMPLES AND TISSUES (cont'd) | <p><u>Examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Immunology</u> (cont'd)</p> <p>Specific IgE allergens:</p> <ul style="list-style-type: none"> - Almond - Apple - Aspergillus fumigatus - Banana - Beef - Bee venom - Blue mussel - Brazil nut - Cacao - Cashew - Cat - Cheese (cheddar) - Chicken - Chickpea - Coconut - Crab - Dog - Egg white - Egg yolk - Fish (Cod) - Garlic - Grape - Guinea pig - Hamster - Hazel nut - Horse - House dust mite - Kiwi - Latex - Lemon - Lentil - Lobster - Maize (corn) - Melon - Milk | <p>In-house documented procedures</p> <p>Phadia ImmunoCap 250 FEIA by fluorescence detection of strength of antibody/antigen reactions</p> <ul style="list-style-type: none"> - SOP MSP036 |



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| <p>HUMAN SAMPLES AND TISSUES (cont'd)</p> | <p><u>Examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Immunology</u> (cont'd)</p> <ul style="list-style-type: none"> - Oat - Onion - Orange - Peanut - Pear - Pineapple - Pork - Potato - Prawn/ shrimp - Rabbit - Rape seed - Rice - Salmon - Scallop - Sesame seed - Sheep - Silver birch pollen - Soya - Strawberry - Tomato - Tuna - Walnut - Wasp venom - Wheat - White bean <p>Allergen mixes:</p> <ul style="list-style-type: none"> - Mixed food (egg white, milk, fish, wheat, peanut, soya) - Mixed nuts (peanut, hazel nut, brazil nut, almond, coconut) - Mixed grass pollen (anthoxanthum odoratum, Lolium perenne, Phleum pratense, Secale cereale, Holcus lantus) | <p>In-house documented procedures</p> <p>Phadia ImmunoCap 250 FEIA by fluorescence detection of strength of antibody/antigen reactions</p> <ul style="list-style-type: none"> - SOP MSP036 |



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| HUMAN SAMPLES AND TISSUES (cont'd) | <u>Examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures |
| Serum/Plasma | Immunology (cont'd) Autoimmunity antibodies to: Cardiolipin CCP CTD dsDNA Extractable nuclear antigen identity (CenpB, Jo-1, La, Ro, RNP, Scl-70, SmD) Extractable nuclear antigen screen GBM Intrinsic Factor MPO PR3 Thyroid peroxidase | Phadia ImmunoCap 250 FEIA by fluorescence detection of strength of antibody/antigen reactions - SOP MSP036 |
| Serum | Anti Tissue Transglutaminase IgG antibodies | |
| Serum | Anti Tissue Transglutaminase IgA antibodies | |
| Serum | Detection of: IgA IgG IgM Rheumatoid Factor | Siemens Atellica CH Analyser by turbidimetry BSL 125 |

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