


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9612</p> <p>Accredited to ISO 15189:2012</p>	<h3>NHS Highland</h3> <p>Issue No: 005 Issue date: 22 September 2021</p>	
	<p>Microbiology Department Zone 3 Raigmore Hospital Old Perth Road Inverness IV2 3UJ United Kingdom</p>	<p>Contact: Dr David Ashburn Tel: +44 (0) 1463 704108 Fax: +44 (0) 1463 705648 E-Mail: david.ashburn@nhs.scot</p>
<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>



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 **Issue date:** 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Blood cultures	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



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
CSF	General Bacteriology (cont'd) 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>Clostridium 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
Respiratory fluids (including sputum, tracheal aspirates, bronchial alveolar washings)	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



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
Swabs from various body sites	General Bacteriology (cont'd) 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
Human samples including faeces and urine as specified	Parasitology Examination activities for the purposes of clinical diagnosis	In-house documented procedures based on PHE SMIs
Faeces, Urines, sellotape slides and rectal swabs	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Screening for and identification of enteric parasites using Midi Parasep system SOP MCP004
Genital swabs	Cryptosporidium and Cyclospora oocysts Detection of <i>Trichomonas vaginalis</i>	Auramine Phenol Microscopy and Modified Ziehl Neelsen Wet preparations using SOP MCP060
Urine	Detection of schistosome ova	Screening for and identification of urinary tract parasites using SOP MCP004 using concentration and manual microscopy.



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN SAMPLES AND TISSUES (cont'd)	<u>Examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on PHE UK SMIs
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 PHE SMIs
Skin scrapings, hair and nail clippings	General isolation and characterisation of fungi of clinical significance	Detection of pathogenic fungi using SOP MCP052 including direct microscopy of KOH digested samples and culture on non-chromogenic selective media.
Faeces	<u>Antigen detection</u> Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	Screening for C difficile GDH and toxins using SOP ME013 (DS2) and MCP016
Faeces	Detection of Rotavirus and Adenovirus	Immunochromatographic antigen detection using manufacturers documentation and SOP MCP048
Serum/ Plasma	<u>Serology</u> Anti-streptolysin-O (ASO)	Slide agglutination test in conjunction with manufacturer's documentation and SOP MSP029
Serum/plasma	Detection of: CMV IgG CMV IgM EBV EBNA IgG EBV VCA IgG EBV VCA IgM Hepatitis A IgM Hepatitis B anti-HBs Hepatitis B core antibody Hepatitis B surface antigen Hepatitis C antibody HIV antibody/antigen combination Rubella IgG Syphilis antibody	Antibody and Antigen detection by chemiluminescent microparticle immunoassay (CMIA) on Abbott Architect in conjunction with, manufacturer's documentation and SOPs: SOPs: ME026 and MSP020



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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: <i>Helicobacter pylori</i> IgG Hepatitis E IgG Hepatitis E IgM Measles IgG Parvovirus B19 IgG Parvovirus B19 IgM VZV IgG	Manual or automated ELISA Liaison XL analyser and Diasorin kits in conjunction with manufacturer's documentation and SOPs: ME069 (Liaison)MSP005(H.pylori), MSP037(HEV) MSP038 (Measles), MSP008 (VZV), MSP011(Parvo IgM), MSP017(Parvo IgG)
Serum/plasma/	Lyme Borrelia burgdorferi	Manual, semi-automated and automated techniques using manufacturer's documentation and SOPs: ME013 (DS2) ME028 (Recom scan) MSP002 (ELISA IgG) MSP015 (Immunoblot) MSP040 (reporting comments)
	Borrelia burgdorferi IgG Borrelia burgdorferi IgM	Automated techniques (Diasorin Liaison XL analyser (CLIA))
	Borrelia burgdorferi IgG Borrelia burgdorferi IgM	Mikrogen CarL immunoblot processor)
CSF	Borrelia burgdorferi IgG and IgM	Automated techniques (Diasorin Liaison XL analyser (CLIA)) SOP's MSP046 (CarL Immunoblot) MSP048 & ME069 (Liaison) MSP040 (reporting comments)



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Serum/plasma/	<p>Toxoplasma IgG avidity t Toxoplasma IgM Western blot (LDBio) Toxoplasma total antibody</p> <p>Toxoplasma IgG Toxoplasma IgG avidity</p> <p>Toxoplasma IgM</p>	<p>Manual, semi-automated and automated techniques using manufacturer's documentation and</p> <p>Manual Immunoblot LD Bio Western Blot</p> <p>Dye Test</p> <p>Auto (Diasorin Liaison XL analyser (CLIA & Mikrogen CarL Immunoblot processor)</p> <p>(Diasorin Liaison XL analyser (CLIA) and ISAGA</p> <p>SOPs: MSP022 (Dye Test) MSP024 (ISAGA) MSP026 (LDBio WIB) MSP015 (Immunoblot)</p> <p>MSP046 (CarL) MSP048 & ME069 (Liaison)</p> <p>MSP040 (reporting comments)</p>



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 **Issue date:** 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 <i>C. difficile</i>	Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011
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
CSF, joint fluid, whole blood/buffy coat and human tissue (mainly skin biopsies)	Detection of <i>Borrelia burgdorferi</i>	Extraction by Biomerieux easyMag or Qiacube amplification and detection by ABI 7500 SOPs: ME067 ME014, ME015, ,MMP006,



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 Issue date: 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
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	Influenza A Influenza B respiratory syncytial virus	Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011
Respiratory specimens (Sputum)	TB PCR	Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011



9612
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 005 **Issue date:** 22 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN SAMPLES AND TISSUES (cont'd) Nasal swabs, nasopharyngeal aspirates, respiratory swabs, throat swabs	<u>Examination activities for the purposes of clinical diagnosis</u> (cont'd) Detection of respiratory pathogens; <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 	In-house documented procedures based on PHE UK SMIs Amplification and detection by 'Genmark ePlex' and in conjunction with manufacturer's instructions and SOP;-MMP020
Vesicle, lesion, skin and ulcer swabs, fluids and crusts, throat swabs, genital swabs	HSV 1, HSV 2.	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)
Urines and swabs	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011
Urines and swabs	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	SDA using the BD Viper in conjunction with manufacturer's instructions and SOPs: MMP014
END		