


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9612</p> <p>Accredited to ISO 15189:2012</p>	<p style="text-align: center;">NHS Highland</p> <p style="text-align: center;">Issue No: 008 Issue date: 18 March 2025</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;"> Microbiology Department Zone 3 Raigmore Hospital Old Perth Road Inverness IV2 3UJ United Kingdom </td><td style="width: 50%;"> Contact: Dr Susan Mcdonagh Tel: +44 (0) 1463704206 Fax: +44 (0) 1463704109 E-Mail: susan.mcdonagh@nhs.scot </td></tr> </table> <p style="text-align: center;">Testing performed at the above address only</p>	Microbiology Department Zone 3 Raigmore Hospital Old Perth Road Inverness IV2 3UJ United Kingdom	Contact: Dr Susan Mcdonagh Tel: +44 (0) 1463704206 Fax: +44 (0) 1463704109 E-Mail: susan.mcdonagh@nhs.scot
Microbiology Department Zone 3 Raigmore Hospital Old Perth Road Inverness IV2 3UJ United Kingdom	Contact: Dr Susan Mcdonagh Tel: +44 (0) 1463704206 Fax: +44 (0) 1463704109 E-Mail: susan.mcdonagh@nhs.scot		

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 SMI 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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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



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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 SMI Standards for Microbiology Investigations
	<u>General Bacteriology</u> (cont'd)	
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
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



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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 SMI Standards for Microbiology Investigations
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 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	<u>Parasitology</u> 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
	Cryptosporidium and Cyclospora oocysts	Auramine Phenol Microscopy and Modified Ziehl Neelsen
Genital swabs	Detection of <i>Trichomonas vaginalis</i>	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.



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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 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



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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: <i>Helicobacter pylori</i> IgG Hepatitis E IgG Hepatitis E IgM Measles IgG Parvovirus B19 IgG Parvovirus B19 IgM VZV IgG HEV IgM	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) MSP050(HEV IgM)
Serum/plasma/	Lyme <i>Borrelia burgdorferi</i>	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)
	<i>Borrelia burgdorferi</i> IgG <i>Borrelia burgdorferi</i> IgM	Automated techniques (Diasorin Liaison XL analyser (CLIA))
	<i>Borrelia burgdorferi</i> IgG <i>Borrelia burgdorferi</i> IgM	Mikrogen CarL immunoblot processor)
CSF	<i>Borrelia burgdorferi</i> IgG and IgM	Automated techniques (Diasorin Liaison XL analyser (CLIA)) SOP's MSP046 (Carl Immunoblot) MSP048 & ME069 (Liaison) MSP040 (reporting comments)



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Serum/plasma/	<p>Toxoplasma IgG avidity t</p> <p>Toxoplasma IgM Western blot (LDBio)</p> <p>Toxoplasma total antibody</p> <p>Toxoplasma IgG</p> <p>Toxoplasma IgG avidity</p> <p>Toxoplasma IgM</p>	<p>Manual, semi-automated and automated techniques using manufacturer's documentation and</p> <p>Manual Immunoblot</p> <p>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>



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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Examination activities for the purposes of clinical diagnosis (cont'd)</u> <u>Molecular Biology</u>	In-house documented procedures based on PHE UK SMIs
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,



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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
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>SARS-CoV-2</u> <u>FLU A</u> <u>FLU B</u> <u>RSV</u>	<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><u>Examination activities for the purposes of clinical diagnosis (cont'd)</u></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>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>Vesicle, lesion, skin and ulcer swabs, fluids and crusts, throat swabs, genital swabs</p>	<p>HSV 1, HSV 2.</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>Urines and swabs</p>	<p>Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i></p>	<p>Real-time PCR using the Cepheid GeneXpert in conjunction with manufacturer's instructions and SOP: MMP011</p>
<p>Urines and swabs</p>	<p>Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i></p>	<p>SDA using the BD Viper in conjunction with manufacturer's instructions and SOPs: MMP014</p>



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<p>HUMAN SAMPLES AND TISSUES (cont'd)</p> <p>Nose and throat swabs/Lower tract respiratory specimens including endotracheal aspirate and tracheal aspirate</p>	<p><u>Examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of SARS-CoV-2 RNA (N and ORF targets)</p>	<p>In-house documented procedures</p> <p>Nose and Throat (On board lysis) TRA/ETA (Off board lysis)</p> <p>Manufacturer's automated DNA extraction platform (eMAG and EasyMag)</p> <p>SOP ME070</p> <p>Viasure Assay on ABI 7500 using real-time PCR technology: SOP MMP022</p>
<p>Endotracheal Aspirates/Bronchoalveolar Lavage</p>	<p>Detection of Pneumocystis Jirovecii</p>	<p>Manufacturer's automated DNA extraction platform (eMAG and EasyMag)</p> <p>SOP MMP022</p> <p>Viasure Assay on ABI 7500 using real-time PCR technology: SOP MMP022</p>
<p>CSF/Lesion Swabs/Throat Swabs</p>	<p>Detection of Enterovirus</p>	<p>Manufacturer's automated DNA extraction platform (eMAG and EasyMag)</p> <p>SOP MMP022</p> <p>Viasure Assay on ABI 7500 using real-time PCR technology: SOP MMP022</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
Nose and throat swabs/Nasopharyngeal aspirate	Detection of SARS-CoV-2 and respiratory pathogens	PCR using ePlex analyser and Respiratory Pathogen Panel 2 SOP MMP020
Nose and throat swabs/Lower tract respiratory specimens including endotracheal aspirate	Detection of SARS-CoV-2 (N, RdRp, S and E targets)	Seegene Allplex assay on Nimbus analyser, using real-time PCR technology: - SOP ME071
Nose and throat swabs/Lower tract respiratory specimens including endotracheal aspirate	Detection of SARS-CoV-2 (N, RdRp, S and E targets)	Seegene Allplex assay on STARlet analyser using real-time PCR technology: - SOP ME071 - 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	Reagent 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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HUMAN SAMPLES AND TISSUES (cont'd)	<u>Examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures
<u>Immunology</u>		
Serum/Plasma	Detection of antibodies to: Alpha-1-antitrypsin C1-esterase C3 C4 Haptoglobin IgA IgG IgM Rheumatoid Factor	Siemens BN Prospec – detection of immune complexes by nephelometry - SOP MSP033
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/Urine	Immunofixation	Helena Biosystems SAS-1+ and SAS-2 to perform gel electrophoresis and protein staining - SOP MSP041
Urine	Bence Jones Proteins	Helena Biosystems SAS-1+ and SAS-2 to perform gel electrophoresis and protein staining - 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>Immunology (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> <p>- SOP MSP036</p>



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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>Immunology (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> <p>- SOP MSP036</p>



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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	
END		