


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8675</p> <p>Accredited to ISO 15189:2012</p>	<p>Great Ormond Street Hospital for Children NHS Foundation Trust</p> <p>Issue No: 003 Issue date: 31 May 2019</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 (unless specified)</p> <p>Wound swabs, surface swabs, biopsies and tissues, implants, tips, sterile body fluids.</p> <p>Bacterial cultures and yeasts isolated in house</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>General Bacteriology</p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>General identification of micro-organisms of clinical significance</p> <p>Quantification of white and red blood cells and bacteria) Isolation and characterisation of micro-organisms of clinical significance</p>	<p>Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:</p> <p>In house documented procedures which follow current PHE SMIs</p> <p>Culture onto selected media with reference to BSOP B0052 BSOP B0013 A BSOP B0075 BSOP B0055 BSOP B0079 BSOP B0080</p> <p>In house documented procedures using traditional, routine biochemical and identification test methods below BSOP B0017 BSOP B0032 BSOP B0044 BSOP B0072 (Maldi ToF)</p> <p>Manual microscopy using an inverted microscope. Culture on selected media. BSOP B0047</p>



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HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:
Body fluids including CSF	General Bacteriology (cont'd) Bacterial and fungal antigens <i>BHS group B</i> <i>N. meningitidis A, C, Y, W135,</i> <i>N. meningitidis B</i> <i>E. coli K1,</i> <i>Strep pneumo,</i> <i>H. influenzae Pittman type B</i>	In house documented procedures which follow current PHE SMIs BSOP B0056 using Wellcogen Bacterial Antigen Kit
Faeces, rectal swabs, duodenal fluids	General isolation and characterisation of enteric pathogens of clinical significance	Culture onto selected media and manual microscopy with reference to BSOP B0024 BSOP B0077
Faeces	<i>Clostridium difficile</i>	Culture onto selective media BSOP B0074
Faeces, rectal swabs, duodenal fluids	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Wet prep, faecal concentration and manual microscopy BSOP B0024 BSOP B0077 BSOP B0081
Nose, throat, skin, site and other specimens as required	MRSA screening	BSOP B0032 Using Chromogenic agar (Oxoid Brilliance MRSA II medium)
Whole blood, peritoneal dialysis fluid, gene therapy fluid, other sterile fluids	Detection of microbial growth and general isolation of micro-organisms of clinical significance	BD Bactec FX400 and FX200 using colorimetric detection BSOPB0016
All specimens considered appropriate after clinical assessment, including respiratory samples sputum, bronchoalveolar lavage, tissue and CSF	Detection and isolation of microbial growth and isolation of <i>Mycobacteria</i> sp.	Using ZN microscopy, LJ Slopes and automated culture using BD Bactec MGIT 320 BSOP B0046 BSOP B0004



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HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:
Clinical isolates from human tissue and body fluids	General Bacteriology (cont'd) Antimicrobial susceptibility	In house documented procedures which follow current PHE SMIs Testing by disc diffusion following EUCAST guidelines and confirmation by MICE or Etest BASC/MICE BSOP B0002 BSOP B0003
Respiratory specimens, including nose, throat, tracheostomy, sputum, endo-tracheal aspirate, nasopharyngeal aspirate and eye swabs if indicated.	Culture for significant bacterial and fungal pathogens	Culture onto selected media BSOP B0040 BSOP B0004 BSOP B0076 BSOP B0078
Plasma, CSF	Therapeutic Drug Monitoring (TDM) Amikacin Gentamicin Tobramycin Vancomycin	Assay using Indiko Plus by photometric, monochromatic, bichromatic absorbance measurement BSOP B0068
Hair, skin scrapings and nails	Mycology General isolation and characterisation of fungi of clinical significance	Culture and Microscopy BSOP B0026A BSOP B0026B BSOP B0053
Serum	Serology Serological testing Antistreptolysin O and antiDNAase B titres (aka ASOT/DNAase) Syphilis screening	Separation and storage of sera BSOP B0064 Using BNII Nephelometer BSOP B0015 Using lateral flow device, ESPLINE® TP by FUJIBREBIO INC BSOP B0070



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HUMAN BODY FLUIDS AND TISSUES (unless specified)	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Serology (cont'd)</p> <p>Qualitative detection of:</p> <p>CMV IgG Antibody CMV IgM Antibody Hepatitis A IgM Antibody Anti-Hepatitis A total antibody Hepatitis B Surface Antigen Anti-HBs total antibody HIV-1 Antigen/Antibody and HIV-2 Lyme IgG and IgM Rubella IgG Toxoplasma Gondii complete antibody VZV IgG antibody EBV VCA IgG Antibody EBV VCA IgM Antibody Hepatitis B core antibody Measles IgG Hepatitis B e Antigen/Antibody</p> <p>Mycoplasma PPA HSV IgG Antibody Hepatitis C Antigen/ Antibody</p> <p>Virology</p> <p>Interferon Gamma testing</p>	<p>Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:</p> <p>In house documented procedures which follow current PHE SMIs</p> <p>Manufacturer's instructions for Biomerieux Vidas (ELFA) in conjunction with in house documented methods:</p> <p>VIDAS and VIDAS PC VSOP W0021 VSOP S0034 VSOP S0035 VSOP S0036 VSOP S0037 VSOP S0038 VSOP S0040 VSOP S0041 VSOP S0044 VSOP S0046 VSOP S0048</p> <p>VSOP S0049 VSOP S0058 VSOP S0059 VSOP S0063 VSOP S0042 VSOP S0053</p> <p>Manual EIA using kits from various manufacturers VSOP S0002 (Mast) VSOP S0030 (Bio-Rad) VSOP S0052 (Bio-Rad)</p> <p>Quantiferon QTB gold VSOP S0060 VSOP S0061</p>
Serum		
Stool	Pancreatic Elastase	Manual EIA-Pancreatic elastase 1 EIA – Schebo tech VSOP S0029



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HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:
Stool	Virology (cont'd) Clostridium difficile toxin A and B gene Clostridium difficile glutamate dehydrogenase (GDH) C difficile toxins A and B	In house documented procedures which follow current PHE SMIs Clostridium difficile cell toxicity (toxin genes) by PCR using in house method VSOP P0036 Gene positives tested by Quick Chek Complete (EIA) VSOP I0033
Sputum, BAL, Biopsy	<i>Pneumocystis jiroveci</i> formerly known as <i>Pneumocystis carinii</i>	PCR method VSOP P0026
EDTA blood spun down to plasma	Blood borne virus <ul style="list-style-type: none"> • HIV • Hepatitis B • Hepatitis C 	QIAGEN Qiasymphony PCR method SP/AS/RGQ and QIAGEN artus kits VSOP P0025 VSOP W0073 VSOP W0074
Respiratory secretions NPA, BAL, Nose and throat swabs, Biopsy	Virology Respiratory panel <ul style="list-style-type: none"> • RSV A • RSV B • Parainfluenza 1, 2 & 3 • Flu A • Flu B • Flu A H1N1 • human metapneumo 	Nucleic acid and PCR set up via QIAGEN Qiasymphony SP/AS Assays run on the ABI 7500. Primers/Probes in-house, Controls in house. VSOP I0028 VSOP P0026 VSOP W0073 VSOP W0037 VSOP P0007 VSOP P0008 VSOP P0009 VSOP D0007
Respiratory secretions NPA	Extended respiratory panel <ul style="list-style-type: none"> • Rhinovirus • Coronavirus • Enterovirus 	Nucleic acid and PCR set up via QIAGEN Qiasymphony SP/AS Assays run on the ABI 7500. Primers/Probes in-house, Controls in house. VSOP P0026



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<p>HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)</p> <p>Stool</p> <p>EDTA whole blood/bone marrow (other sample types are validated for qualitative testing CSF, swabs, urine)</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Virology (cont'd)</p> <p>Virology Gastro panel</p> <ul style="list-style-type: none"> • Adeno • Sapo • Astro • Rota • Noro I and II <p>Virology</p> <ul style="list-style-type: none"> • CMV • EBV • Adenovirus 	<p>Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:</p> <p>In house documented procedures which follow current PHE SMIs</p> <p>Nucleic acid and PCR set up via QIAGEN Qiasymphony SP/AS Assays run on the ABI 7500. Primers/Probes in-house, Controls in house.</p> <p>VSOP I0030 VSOP P0031 VSOP W0073 VSOP W0037 VSOP P0007 VSOP P0008 VSOP P0009 VSOP D0007</p> <p>Nucleic acid and PCR set up via QIAGEN Qiasymphony SP/AS Assays run on the ABI 7500. Primers/Probes in-house, Controls in house, in house Quantitative PCR</p> <p>VSOP P0032 VSOP I0001 VSOP W0073 VSOP W0037 VSOP P0007 VSOP P0008</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)</p> <p>EDTA whole blood, Urine & Swabs, CSF</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Virology (cont'd)</p> <p>Virology</p> <ul style="list-style-type: none"> • VZV • HSV • BK • JC • Parvo • Entero • Parecho • HHV6 <p>VZV viral load</p> <p>VZV vaccine/wildtype differentiation</p> <p>VZV TK sequencing (Acyclovir resistance)</p> <p>VZV Serology Quantitative IgG</p>	<p>Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:</p> <p>In house documented procedures which follow current PHE SMIs</p> <p>Nucleic acid and PCR set up via QIAGEN Qiasymphony SP/AS Assays run on the ABI 7500. Primers/Probes in-house, Controls in house, in house Qualitative PCR</p> <p>VSOP P0033 VSOP W0073 VSOP W0037 VSOP P0007 VSOP P0008 VSOP I0001 VSOP I0032 VSOP I0031</p> <p>ABI 7500 Real-time PCR VSOP P0033</p> <p>Conventional PCR and Sanger sequencing using PCR Thermocycler and ABI 3130 Genetic Analyser VSOP VZRL006</p> <p>Manual ELISA VaccZyme™ VZV glycoprotein IgG Low Level Enzyme Immunoassay Kit; (Binding Site) Plate washer and Plate reader VSOP VZRL009</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (unless specified) (cont'd)</p> <p>Any sample from a normally sterile site (BAL, NPA, sputum, pernasal swabs, nose and throat swabs)</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Virology (cont'd)</p> <p>Bacterial targets</p> <p><i>Staphylococcus aureus</i> <i>Streptococcus pyogenes</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus agalactiae</i> <i>Neisseria meningitidis</i> <i>Kingella kingae</i> <i>Mycobacteria</i> <i>Tropheryma whippelii</i> <i>Enterobacteriaceae</i> <i>Bordetella pertussis</i></p>	<p>Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:</p> <p>In house documented procedures which follow current PHE SMIs</p> <p>ABI 7500 Real-time PCR Qiagen QiaSymphony BSOP P0005 BSOP P0013 BSOP P0015 BSOP P0017 BSOP P0018 BSOP P0019 BSOP P0020 BSOP P0021 BSOP P0022 BSOP P0023 BSOP P0024 BSOP P0026 BSOP B0027 VSOP W0073 VSOP P0007</p>
<p>Any sample from a normally sterile site</p>	<p>Broad-range 16S rDNA PCR</p>	<p>PCR using Thermal cyclers ABI 3130 BSOP P0001 BSOP P0005 BSOP P0004 BSOP P0009 BSOP P0014 VSOP W0073 VSOP P0007</p>
<p>Any sample from a normally sterile site</p>	<p>Broad-range fungal targets</p>	<p>PCR using Thermal cyclers BSOP P0002 BSOP P0005 BSOP P0004 BSOP P0009 BSOP P0014 VSOP W0073 VSOP P0007</p>

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