


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8721</p> <p>Accredited to ISO 15189:2012</p>	<b>University Hospitals Coventry and Warwickshire NHS Trust</b>	
	<b>Issue No: 009 Issue date: 16 September 2021</b>	
	<b>Coventry and Warwick Pathology Service</b> Department of Microbiology Clifford Bridge Road Walsgrave Coventry CV2 2DX	<b>Contact: Dr. Peter Munthali</b> Tel: +44 (0)2476 965 472 E-Mail: peter.munthali@uhcw.nhs.uk Website: <a href="http://www.uhcw.nhs.uk/for-gps/pathology-services">http://www.uhcw.nhs.uk/for-gps/pathology-services</a>
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address</b>                      Department of Microbiology                      University Hospitals Coventry and Warwickshire NHS Trust                      Clifford Bridge Road                      Walsgrave                      Coventry                      CV2 2DX</p> <p><b>Local contacts</b>                      Mandip Hira                      Laboratory Manager                      Tel: 02476 965467</p> <p>Tina Wotherspoon                      Molecular Pathology Manager                      Tel: 02476965488                      Email:                      Tina.Wotherspoon@uhcw.nhs.uk</p>	Bacteriology Virology Molecular testing	A
Integrated Sexual Health Service (ISHS) Coventry Health Centre Coventry CV4 4FH	Detection of bacteria of clinical significance for purposes of sexual health screen	B
<p>Blood Sciences Laboratory                      George Eliot Hospital                      College Street                      Nuneaton                      CV10 7DJ</p> <p><b>Local Contact</b>                      Nigel Blease                      Haematology Manager                      02476 865033</p>	Virology Molecular testing	C
<p>Blood Sciences Laboratory                      South Warwick Hospital                      Lakin Road                      Warwick</p> <p><b>Local Contact</b>                      Nigel Blease                      Haematology Manager                      01926 495321</p>	Virology Molecular testing	D



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Faeces, Tissues, Fluids (joint fluids, CSF, CAPD fluid), swabs (ear, nose, throat, eye, mouth, genital, wound), line tips sputum, broncho-alveolar lavage, pleural fluid, plates inoculated in GUM clinic</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)</p> <p>Manual culture using prepared manufacturers agar plates</p> <p>Identification using Bruker MALDI-TOF system. Supplementary tests and kits used to aid selection of colonies requiring MALDI (e.g. oxidase) or for confirmation or clarification of MALDI result (e.g. API 20E)</p> <p>SOP numbers:</p> <ul style="list-style-type: none"> <li>• MI LPR52</li> <li>• MI LPR5</li> <li>• MI LPR39</li> <li>• MI LPR34</li> <li>• MI LPR12</li> <li>• MI LPR13</li> <li>• MI LPR14</li> <li>• MI LPR39</li> <li>• MI LPR53</li> </ul>	A
<p>MRSA swab</p>	<p>MRSA screening</p>	<p>Manual culture using prepared manufacturers chromogenic media agar plates</p> <p>Identification using Staph latex. Positives are confirmed by MALDI-TOF</p> <p>SOP numbers: MI LPR24</p>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)	
Sputum, bronchoalveolar lavage, bronchial washing, trap sputum, Endotracheal tubes, Pleural fluid, ascitic fluid, aspirates, Lung tissue, lymph nodes, Curettings, Gastric lavage, Laryngeal swab, Urine, Faeces, Swabs, Bone marrow.	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Using BD MGIT system for liquid culture  Using manufactured agar (LJ slopes) for solid culture  Manual Ziehl-Neelsen staining using Kinyoun cold stain method  Manual auramine staining  SOP number: • MI LPR33	A
Whole blood	Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance	Using BacTAlert analyser, CO2 detection system.  SOP number • MI LPR26	A
Urine	Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance	MAST Uri-system for culture/sensitivity  Further identification using API system and Bruker MALDI-TOF  SOP number • MI LPR29	A
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Sysmex UF5000 for urine microscopy  SOP number • MI LPR80	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMLs)	
Faeces	Detection of rota/adenovirus	Biotec Certest immunochromatographic kit  SOP number: • MI LPR21	A
Faeces	Detection of H pylori antigen	Using Oxoid Amplified IDEIA StAR kit on DS2  SOP number • MI LPR64	A
Faeces	Detection of Clostridium difficile toxin and Clostridium difficile GDH	Using GDH and Toxin A/B ELISA on DS2  Confirmation of positives by Cepheid PCR  SOP number • MI LPR65	A
CSF, CAPD fluids, ascitic fluids, joint fluids	Detection and quantification of red cells and white cells	Manual cell counts and light microscope  SOP numbers • MI LPR13 • MI LPR14 • MI WI98	A
Any genital sample, most commonly High vaginal or cervical swab.	Detection and identification of Trichomonas Vaginalis	Using manufacturer's trichomonas media followed by inverted microscopy  SOP number • MI LPR39	A



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Sterile fluids and tissues (joint fluids, pus, placental swabs, peritoneal fluids, maxillo-facial specimens) and any other specimen we receive from a normally sterile site. CSF, Ascitic and CAPD fluids Blood cultures that flag positive from the BactALERT analyser Pleural fluids/tissue specimens and lymph nodes. Genital specimens requesting Bacterial vaginosis. Pre-inoculated eye slides from the eye department. (corneal scrapes).</p> <p>Genital samples- HVS, endo-cervical, penile, and urethral.</p> <p>Faeces</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of bacteria of clinical significance for purposes of sexual health screen</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)</p> <p>Manual gram stain</p> <p>SOP number</p> <ul style="list-style-type: none"> <li>MI WI121</li> </ul>	A
	<p>Detection of bacteria of clinical significance for purposes of sexual health screen</p>	<p>Manual gram stain</p> <p>SOP number</p> <ul style="list-style-type: none"> <li>MI WI121</li> </ul>	B
	<p><u>Parasitology examination activities for the purpose of clinical diagnosis</u></p> <p>Detection and identification of helminths, nematodes, flukes, parasitic larvae, protozoa, ova, amoebae and cysts of clinical significance</p>	<p>In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)</p> <p>Midi Parasep®SF concentration method</p> <p>Modified Ziehl Neelsen stain for cryptosporidium</p> <p>SOP number</p> <ul style="list-style-type: none"> <li>MI LPR11</li> </ul>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Mycology examination activities for the purpose of clinical diagnosis</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)	
Skin, nails, hair	Isolation and identification of fungi of clinical significance.	Manual culture using prepared manufacturers agar plates  Identification by macroscopic examination of colonies by eye and microscopic examination of colonies using calcofluor white and brightfield microscopy using the Nikon Ci-L microscope  SOP number <ul style="list-style-type: none"> <li>MI LPR18</li> </ul>	A
Serum	<u>Serology examination activities for the purpose of clinical diagnosis</u>  Hepatitis B surface antibody, Hepatitis B core antibody, Hepatitis B e antigen, Hepatitis B e antibody, Hepatitis B core IgM antibody  Hepatitis A IgG antibody Hepatitis A IgM antibody  Hepatitis C antibody  CMV IgG & IgM antibody  Rubella IgG & IgM antibody  Hepatitis B surface antigen  HIV p24 antigen/antibody (HIV1/2)  Syphilis total IgG & IgM antibody	Documented in-house methods using analysers specified  ROCHE E170 -Chemiluminescent Assay  SOP numbers <ul style="list-style-type: none"> <li>VI LPR12 Hepatitis Serology</li> <li>VI LPR13 HIV Serology</li> <li>VI LPR4 RUBELLA Serology</li> <li>VI LPR5 Syphilis serology</li> <li>VI LPR 60 CMV serology</li> </ul> Documented in house methods to meet the requirements of IDPS screening programme as defined in the July 2018 'Infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Serum	Hepatitis E IgG and IgM	Fortress solid phase optical density EIA  SOP number <ul style="list-style-type: none"><li>Hepatitis E SOP Ref: VI LPR50</li></ul>	A
Serum	Parvovirus IgG & IgM antibody  Toxoplasma gondii IgG antibody  Varicella-zoster IgG antibody  Measles IgG antibody  Herpes simplex 1 & 2 IgG antibody  EBV EBNA/VCA IgG/IgM  Mumps IgG serology  HIV-1 group O, HIV1 and HIV 2 antibody confirmation  Hepatitis B surface antigen confirmation  Hepatitis B core antibody confirmation  CMV IgG avidity	DIASORIN X LIAISON – Chemiluminescent Assay  SOP number <ul style="list-style-type: none"><li>VI LPR45 Parvovirus B19 serology</li><li>VI LPR44 Toxoplasma serology</li><li>VI LPR43 VZG serology</li><li>VI LPR42 Measles serology</li><li>VI LPR46 HSV Serology</li><li>VI LPR47 EBV serology</li><li>VI LPR 51 Mumps</li><li>VI LPR 52 HIV1/2</li><li>VI LPR 53 HBsAg</li><li>VI LPR 54 HBcAb</li><li>VI LPR4 Rubella</li><li>VI LPR 60 CMV serology</li></ul>	A
Serum	ASO antibody	BIOKIT – Latex agglutination  SOP number <ul style="list-style-type: none"><li>VI LPR1 ASO Serology</li></ul>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified (cont'd)	
Serum	Cryptococcal antigen	ALPHA LABS – Latex agglutination  SOP number • VI LPR16 Cryptococcal serology	A
Urine	Detection of legionella urinary antigen	ALERE Enzyme-linked immunoassay using the LAUNCH ELX50 EIA WASHER & LAUNCH ELX800 EIA READER  SOP number • VI LPR3 Legionella Antigen Detection	A
Urine	Legionella urinary antigen confirmatory assay	ALERE Immunochromatographic assay  SOP number VI LPR3 Legionella Antigen Detection	A
Serum	Syphilis RPR	AXIS-SHIELD – Flocculation method  SOP number • VI LPR5 Syphilis serology	A
Serum	Syphilis Total Antibody	MAST – Particle Agglutination method  SOP number • VI LPR5 Syphilis serology	A
Serum	Syphilis IgM antibody	Manual MIKROGEN immunoassay using the LAUNCH ELX50 EIA WASHER & LAUNCH ELX800 EIA READER  SOP number • VI LPR5 Syphilis serology	A





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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified (cont'd)	
Serum	HIV 1/2 Antibody	HIV1/2 Immunochromographic test (Geenius)  SOP number <ul style="list-style-type: none"> <li>VI LPR40 Geenius HIV 1/2 confirmation</li> </ul>	A
Blood, faeces, fluids, swabs, sputum/lavage samples, vomit, oral mouth swab, CSF, EDTA plasma samples, coagulation tube samples, oropharyngeal swabs, sputums, broncho-alveolar lavages, nose / throat swabs, nasopharyngeal aspirate	<u>Molecular diagnostic activities for the purpose of clinical diagnosis</u>	Documented in-house methods using analysers specified	
FFPE tissue sections, FFPE punch biopsies lung, colorectal and skin tissue, sputums, broncho-alveolar lavages, nose / throat swabs, nasopharyngeal aspirate	DNA/RNA extraction	Qiagen EZ1 Advanced XL (magnetic bead extraction system) using EZ1 virus mini kit and DSP virus kit ABBOTT M2000 extraction system  SOP number <ul style="list-style-type: none"> <li>MD LPR16</li> <li>MD LPR24</li> </ul> Promega Maxwell 16 system Promega Maxwell 16 LEV DNA Blood Kit Promega Maxwell RSC extraction system using Promega Maxwell RSC Blood DNA kit  SOP number <ul style="list-style-type: none"> <li>MD LPR50</li> <li>MD WI82</li> </ul>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular diagnostic activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
Paraffin wax slides, tissue	DNA extraction	Promega Maxwell system (magnetic bead extraction)  SOP number MD WI 82	A
Nose swab Throat swab Nasopharyngeal aspirate	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences RdRp and N genes	Extraction and PCR using Abbott m2000sp and Abbott m2000rt using Abbott Real-time SARS-CoV2 assay  SOP number • SOP LPR72	A
Nose swab Throat swab Nasopharyngeal aspirate	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences RdRp and N and E genes	Extraction and PCR using Seegene STARlet IVD using Seegene Allplex 2019 n-COV assay  SOP number • SOP LPR76	A
Nose swab Throat swab Nasopharyngeal aspirate	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences E and N2	Rapid, real-time RT-PCR using the Xpert Xpress SARS-CoV-2 rapid molecular test on the Cepheid GeneXpert System  SOP number • SOP LPR73	A, C, D
Genital swabs Urine samples Eye swabs (validated separately) As list below	CT/GC/HSV identification	BD Viper system (automated DNA extraction and PCR)  SOP number • MD LPR21 • MD LPR20	A



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Urine, Endocervial swabs, patient collected vaginal swabs, rectal swabs, eye swabs and urethral swabs	Chlamydia trachomatis (CT) and or Neisseria gonorrhoea (NG) genomic DNA differentiation profiles	Cepheid CT/GC confirmation testing using Cepheid GeneXpert real time PCR.  SOP number • MD LPR51	A
DNA extracted in-house using methods above	Identification of the following targets:  CMV EBV BK	Real-time PCR using Qiagen Rotorgene Q and Qiagility  SOP numbers • MD LPR22 • MD LPR40 • MD WI45 • MD WI46	A
RNA extracted as above	Argene respiratory virus markers (DNA/RNA targets)	SOP numbers • MD LPR26	A
	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences R-gene	Argene R-gene SARS-CoV-2 kit  SOP number • MD LPR 69	
Faeces	Norovirus	Cepheid Genexpert System using Expert Norovirus PCR kit  SOP MD LPR 62	A
DNA extracted in-house using methods above	Quantification of viral load (HIV/HCV/HBV)	Real time PCR using Abbott M2000RT  SOP number • MD LPR24	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular diagnostic activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods using analysers specified	
DNA extracted in-house using methods above	Identification of the following genetic mutations: <ul style="list-style-type: none"> <li>• JAK2 V617F mutation (JK2)</li> <li>• Prothrombin gene mutation (PGM)</li> <li>• Factor V Leiden mutation (FVL)</li> <li>• AAG</li> <li>• HFE</li> </ul>	Real time PCR using Roche Lightcycler 2.0  SOP numbers <ul style="list-style-type: none"> <li>• MD LPR1</li> <li>• MD LPR2</li> <li>• MD LPR3</li> <li>• MD LPR4</li> <li>• MD LPR11</li> <li>• MDLPR 55</li> <li>• MD LPR56</li> <li>• MD LPR 52</li> </ul>	A
FFPE tissue sections	EGFR. KRAS. NRAS & BRAF mutations	Biocartis Idylla system. Amplification refractory mutation system (ARMS), and target sequences are detected by means of fluorescence.  SOP number <ul style="list-style-type: none"> <li>• MD LPR53</li> </ul>	A
DNA extracted in house using methods above	EGFR. KRAS. NRAS & BRAF mutations	TaqMan Low Density Array (TLDA) Amplification on ViiA7Dx and using TaqMan® PCR (castPCR™) technology  SOP number <ul style="list-style-type: none"> <li>• MD LPR50</li> </ul>	A
END			