


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	University Hospitals Coventry and Warwickshire NHS Trust	
	Issue No: 015 Issue date: 11 February 2025	
	Coventry and Warwick Pathology Service Department of Microbiology Clifford Bridge Road Walsgrave Coventry CV2 2DX	Contact: Dr. Peter Munthali Tel: +44 (0)2476 965 472 E-Mail: peter.munthali@uhcw.nhs.uk Website: http://www.uhcw.nhs.uk/for-gps/pathology-services
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Department of Microbiology University Hospitals Coventry and Warwickshire NHS Trust Clifford Bridge Road Walsgrave Coventry CV2 2DX Local contacts Mandip Hira Laboratory Manager Tel: 02476 965467 Tina Wotherspoon Molecular Pathology Manager Tel: 02476965488 Email: Tina.Wotherspoon@uhcw.nhs.uk	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
Blood Sciences Laboratory George Eliot Hospital College Street Nuneaton CV10 7DJ Local Contact Nigel Blease Haematology Manager 02476 865033	Virology - Serology Molecular testing	C
Blood Sciences Laboratory South Warwick Hospital Lakin Road Warwick Local Contact Nigel Blease Haematology Manager 01926 495321	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, Positive Blood Culture</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) and use of the Sepsityper on Positive Blood Cultures for Rapid Identification</p> <p>SOP numbers:</p> <ul style="list-style-type: none"> • MI LPR52 • MI LPR5 • MI LPR39 • MI LPR34 • MI LPR12 • MI LPR13 • MI LPR14 • MI LPR39 • MI LPR53 • MI LPR71 	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' (SMLs)	
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' (SMIs)	
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>HUMAN BODY FLUIDS AND TISSUES (cont'd)</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><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 • MI W1121</p>	A
<p>Genital samples- HVS, endo-cervical, penile, and urethral.</p>	<p>Detection of bacteria of clinical significance for purposes of sexual health screen</p>	<p>Manual gram stain</p> <p>SOP number • MI W1121</p>	B
<p>Faeces</p>	<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 • MI LPR11</p>	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Skin, nails, hair	<u>Mycology examination activities for the purpose of clinical diagnosis</u> Isolation and identification of fungi of clinical significance.	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs) 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 • MI LPR18	A



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<p>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</p> <p>FFPE tissue sections, FFPE punch biopsies lung, colorectal and skin tissue, sputums, broncho-alveolar lavages, nose / throat swabs, nasopharyngeal aspirate</p>	<p><u>Molecular diagnostic activities for the purpose of clinical diagnosis</u></p> <p>DNA/RNA extraction</p>	<p>Documented in-house methods using analysers specified</p> <p>Qiagen EZ1 Advanced XL (magnetic bead extraction system) using EZ1 virus mini kit and DSP virus kit ABBOTT M2000 extraction system</p> <p>SOP numbers</p> <ul style="list-style-type: none">• MD LPR16• MD LPR24 <p>Promega Maxwell 16 system Promega Maxwell 16 LEV DNA Blood Kit Promega Maxwell RSC extraction system using Promega Maxwell RSC Blood DNA kit</p> <p>SOP numbers</p> <ul style="list-style-type: none">• MD LPR50• MD WI82	<p>A</p>



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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 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
Nose and Throat Swab	Detection of Influenza A, Influenza B, Respiratory Syncytial (RSV), and SARS-CoV-2 virus RNA (specific gene sequences E and N2)	Real-time RT-PCR using Xpert Xpress CoV-2/Flu/RSV Plus Multiplex PCR on the Cepheid GeneXpert System SOP MD LPR73	A, C, D
Plasma/Serum	HIV-1 Viral Load	Real-time RT-PCR using Xpert HIV-1 Viral Load PCR on the Cepheid GeneXpert System SOP MD LPR74	A
Plasma/Serum	Hepatitis B Viral Load	Real-time RT-PCR using Xpert HBV Viral Load PCR on the Cepheid GeneXpert System SOP MD LPR74	A
Plasma/Serum	Hepatitis C Viral Load	Real-time RT-PCR using Xpert HCV Viral Load PCR on the Cepheid GeneXpert System SOP MD LPR74	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 targets: CMV EBV BK	Real-time PCR using Qiagen Rotorgene Q and Qiagility SOP numbers • MD LPR22 • MD LPR40 • MD WI45 • MD WI46	A
Faeces	Argene respiratory virus markers (DNA/RNA targets) Norovirus	SOP number • MD LPR26 Cepheid Genexpert System using Expert Norovirus PCR kit SOP number • MD LPR 62	A A
Rectal swabs and Isolates	Detection of Carbapenamase resistance genes: KPC, NDM, VIM, IMP-1, and OXA-48	Rapid, real-time RT-PCR using the Xpert Carba-R rapid molecular test on the Cepheid GeneXpert System SOP number SOP LPR75	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
DNA extracted in-house from Nose and Throat Swabs, NPAs, and Sputum	Detection of Respiratory Viruses: Influenza A, Influenza B, Respiratory Syncytial Virus, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Bocavirus, Human Coronavirus, and Human Parainfluenza Virus	Extraction using the Promega Maxwell RSC Extraction Equipment followed by RT-PCR on the Qiagen Rotorgene using BiomeriueX Argene Respiratory Multiplex PCR Assay SOP numbers MD LPR 89 & MD LPR 26	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"> • JAK2 V617F mutation (JK2) • Prothrombin gene mutation (PGM) • Factor V Leiden mutation (FVL) • AAG • HFE 	Real time PCR using Roche Lightcycler 2.0 SOP numbers <ul style="list-style-type: none"> • MD LPR1 • MD LPR2 • MD LPR3 • MD LPR4 • MD LPR11 • MDLPR 55 • MD LPR56 • MD LPR 52 	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"> • MD LPR53 	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"> • MD LPR50 	A



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	Serological diagnostic activities for the purpose of clinical diagnosis	Documented in-house methods using analysers specified	
		'Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy screening programme 2024 as defined in the laboratory QA evidence requirements: tests demarcated with an * are involved in the screening programme accreditation	
Serum	HIV-1 and HIV-2	Siemens Atellica: Immunoassay HIV Ag/Ab Combo Assay *	C
Serum	Hepatitis B Surface Antigen (HbsAg)	Siemens Atellica: Immunoassay HBsII Assay *	C
Serum	<i>Treponema pallidum</i> (Syphilis) combined IgG and IgM antibodies	Siemens Atellica: Immunoassay Syph *	C
Serum	<i>Treponema pallidum</i> (Syphilis) IgM	Mikrogen Immunoassay	C
Seru,	<i>Treponema pallidum</i> Haemagglutination Assay	Fortress Diagnostics Haemagglutination Assay	C
Serum	Rapid Plasma Reagin	ASI Latex Agglutination Assay	C
Urine	Legionella Antigen	Binax Enzyme-Linked Immunoassay	C
Urine	Legionella Antigen (Confirmation)	BinaxNOW Immunochromatographic Assay	C
Serum	Anti-Streptolysin O	Biokit Latex Agglutination Assay	C
Serum	Cryptococcal Antigen	Alpha Labs Latex Agglutination Assay	C
END			