


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9096 Accredited to ISO 15189:2012</p>	<p>University Hospitals of Derby and Burton NHS Foundation Trust trading as Derbyshire Pathology</p> <p>Issue No: 004 Issue date: 29 November 2022</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 TISSUES AND FLUIDS</p> <p>Routine samples:</p> <p>Cellular and fluid material contained on swabs, catheter tips and IUCDs Aspirates Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine</p> <p>Swabs , Fluids, urines, tips and sputum</p> <p>Urine</p>	<p><u>Microbiological examination activities performed for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p> <p>Isolation of MRSA</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p>	<p>In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation, incubation and culture using:</p> <p>CRHMIC-LP-GB030, GB033</p> <p>CRHMIC-LP-GEN02, GB004, CBM06, GB013, GB034, CRHMIC-LP-UR001 GB003,GB014, GB002, GB015, GB002, GB016,</p> <p>Manual culture on chromogenic agar/broths using SOP CRHMIC-LP-AST06</p> <p>Automated urinalysis, image capture and recognition using: SOP CRHMIC-LP-UR001, in conjunction with equipment manual using UF1000i, UR003</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Blood	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	Liquid media culture using SOP CRHMIC-LP-BC003 in conjunction with manufacturers instructions for BD BACTEC FX automated system BC004, BC005
CSF / Ascitic	General isolation and characterisation of micro-organisms of clinical significance	Manual microscopy and manual inoculation and media culture using SOPs CRHMIC-LP-GB016, CBM06, GB034
Respiratory specimens :	General isolation and characterisation of micro-organisms of clinical significance	Manual media culture using SOPs CRHMIC-LP-RB003, CBM06, CL302, GB034
Sputum Bronchoalveolar lavage Bronchial aspirate, brushings and washings Cellular material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid		
Faeces	General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157	Manual culture and using selective agar with SOPs CRHMIC-LP-EB004, GB004, EB003, EB011
Faeces and bowel contents	Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B	Immunochromatographic assay using SOP CRHMIC-LP-EB010 in conjunction with manufacturers instructions using C. difficile Quik Chek complete.
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Immunochromatographic technique using SOP CRHMIC-LP-EB008 and Proflow H pylori kit



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Bacterial cultures (isolated in-house)	Identification and characterisation of micro-organisms	Manual and/or automated identification methods using : SOPs CRHMIC-LP-CBM15, CBM01, CBM16, CBM02, CBM05, CBM17 GB001, CBM03, CBM09, CBM13, CBM11, CBM06, AST11, UR001, AM001, CBM08, EB004, CBM12 with Automated methods using Vitek 2
Bacterial cultures (isolated in-house)	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	SOP CRHMIC-LP-AST10, 04, 11, 03, CBM01, BC004, UR001 by manual disk diffusion using BSAC guidelines and MIC determination using E-Tests and Vitek 2
Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: SOPs CRHMIC-LP-EB005
Faeces	Detection of Cryptosporidium	Fluorescent microscopy method (auramine stain) and confirmation using Cold ZN incident-light microscopic examination
Skin, Hair and nail clippings	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: SOP CRHMIC-LP-MYC013



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Sputum, fluid, urine, tissue and swabs	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Liquid culture, auramine phenol staining and incident-light fluorescence microscopy and confirmation ZN staining using light microscopy using: CRHMIC-LP-RB005, CL302, EB009 in conjunction with BD TB MGIT, RB001
Faeces	Detection of Norovirus	Immunochromatographic assay SOP CRHMIC-LP-EB007 using Ridascreen Norovirus kit
Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues CSF Ascitic fluids	Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae	Staining (inc. Gram) and microscopic examination using:
Urine	Detection of Legionella urinary antigen	Immunochromatographic assay using SOP CRHMIC-LP-SE044 and Alere Binax NOW for legionella Ag detection
Urine	Detection of <i>S.pneumoniae</i> urine antigen	Immunochromatographic assay using SOP CRHMIC-LP-SE053 and Alere Binax NOW for <i>s.pneumoniae</i> Ag detection
Blood	All Malarial Parasites known to cause human disease	CRHMIC-LP-GB005 using light microscopy and Giemsa stain
Blood	Malarial Parasites to include: <i>Plasmodium falciparum</i> Pan malarial antigen	Immunochromatographic assay using CRHMIC-LP-GB005 and Binax NOW malaria kit.



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Cervix/Urethral/Vaginal swabs and urine	Detection of Chlamydia trachomatis and Neisseria gonorrhoea DNA NAAT testing	Strand Displacement Amplification (SDA) using SOP CRHMIC-LP-SE119 in conjunction with manufacturers instructions using BD VIPER RT PCR using BD Max and SOP CRHMIC-LP-GB035 in conjunction with manufacturer's instructions
Cervix/Urethral/Vaginal swabs and urine	Confirmation of Neisseria gonorrhoea DNA	
Faeces	tcdB gene in C.difficile DNA	
Faeces	Molecular detection of DNA of: Salmonella species Shigella/EIEC Campylobacter STEC	
Nose/throat swabs, NPA samples	Identification of DNA from the following viruses: Influenza A/B RSV	RT PCR using Nanosphere and SOP CRHMIC-LP-GB031
	<u>Serological examination activities performed for the purpose of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Serum	Detection of Antistreptolysin O antibody	SOP CRHMIC-LP-SE007 by manual latex agglutination using Rheumajet ASO



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities performed for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)
Urine	Detection of HCG	<p>Immunochromatographic assay SOP CRHMIC-LP-SE123 in conjunction with manufacturers instructions using Biosign RC hCG serum/urine pregnancy test using Dxpess reader</p> <p>In-house procedures in conjunction with manufacturers instructions using Roche COBAS C8000 e801/e802 (testing performed in blood sciences)with reference to CRHMIC-LP-SE133</p>
Serum	Hepatitis A IgM Hepatitis B Surface antibody Hepatitis B Core IgG and IgM Hepatitis B Surface antigen Rubella IgG Hepatitis C antibody HIV 1 & 2 antibody and p24antigen Treponema IgG and IgM	
END		