


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL <b>8605</b>  Accredited to <b>ISO 15189:2022</b>	<b>University Hospitals of Leicester NHS Trust</b>	
	Issue No: 018 Issue date: 29 January 2026	
	<b>Clinical Microbiology</b> University Hospitals of Leicester NHS Trust Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	<b>Contact: Daxa Patel</b> Tel: +44 (0) 116 258 6646 E-Mail: <a href="mailto:daxa.patel11@nhs.net">daxa.patel11@nhs.net</a> Website: <a href="http://www.leicestershospitals.nhs.uk">http://www.leicestershospitals.nhs.uk</a>
<b>Activities performed by the Organisation at the locations specified below</b>		

### Locations covered and their relevant activities

Location Details	Activity	Location Code
<b>Address</b> Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	<b>Local contact</b> Daxa Patel	Microbiology Mycology Parasitology Virology Molecular
Department of Pathology Glenfield Hospital Groby Road Leicester LE3 9QP	Daxa Patel	Molecular



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DETAIL OF ACCREDITATION

Activity	Examination / Procedure Performed	Equipment / Techniques Used	Location Code
HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on related UK Standards for Microbiology Investigations (UKHSA SMIs):	
Aspirates Cellular and fluid material contained on swabs, cannulae, Faeces Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine CSF Respiratory samples	General isolation of micro-organisms of clinical significance	Manual inoculation followed by culture using SOPs: PR3449 PR3436 PR3444 PR3445 PR3623	A
Rectal swabs	General isolation of micro-organisms of clinical significance	Manual inoculation of chromogenic agar and screening for carbapenamase producers – SOP PR3567	A
Whole blood	General isolation of micro-organisms of clinical significance	Automated culture using BacTAlert Virtuo PR3451	A
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Automated urine analysis using Atellica UAS 800 PR3623  Manual microscopy IN5741	A
CSF	Quantification of white and red blood cells and bacteria	Microscopy (inc. Giemsa stain) using SOP: PR3449	A
Swabs Urine Sputum Endotracheal Aspirates	MRSA Screening	Manual culture using: PR3447	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Respiratory samples, including tissues and fluids Urine CSF</p> <p>Blood Bone Marrow</p> <p>Skin, Nail, BAL</p> <p>Cultures isolated in house from the above</p> <p>Bacterial cultures isolated in house from the above</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Microscopy, isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)</p> <p>Microscopy, general isolation and characterisation of clinically significant fungi</p> <p>Identification of clinically significant bacteria and fungi</p> <p>Antimicrobial susceptibility testing of clinically significant bacteria</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (UKHSA SMI):</p> <p>Manual culture, automated MGIT 960 and microscopy using PR3434</p> <p>Automated screening (BDBactec FX40) and manual culture SOP PR3434</p> <p>Manual culture and fluorescent microscopy using calcofluor stain using SOP: PR3863 PR3444</p> <p>Automated Matrix-assisted laser desorption/ionisation (MALDITOF) using: SOP PR3913 Biomerieux Vitek MS</p> <p>Biochemical profile determination using: Biomerieux Vitek 2 Compact SOP PR3453</p> <p>Biomerieux Vitek 2 Compact SOP PR3453</p> <p>Manual disc diffusion and/or automated methods using EUCAST methodology: SOP PR3595</p> <p>Determination of MIC of organisms using gradient strips or broth microdilution SOP PR3514</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (UKHSA SMI):	
Bacterial cultures isolated in house from the above	Antimicrobial susceptibility testing against Colistin	Colistin Strip Mueller Hinton Broth, DensiCHEK plus. Broth microdilution (BMD) and Bruker UMIC MIC-Strip. Interpretation following EUCAST guidelines. SOP PR3986	A
Yeast cultures isolated in house from the above	Antifungal MIC testing of yeasts	YeastOne Sensititre – ThermoFisher PR4092  Vizion plate reader – ThermoFisher PR4090	A
Cultures isolated in house from the above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci	Pro-Lab Strep grouping kit IN5361	A
Bacterial cultures isolated in-house	Testing of Staphylococcus for coagulase	Prolex Staph latex ultra kit IN8045	A
Cultures isolated in house from the above	Serotyping of <i>Salmonella</i> polyvalent 'O' (PSO) and <i>Salmonella</i> polyvalent 'H' (PSH); <i>Campylobacter</i> species; <i>Shigella</i> species; <i>Vibrio</i> species and <i>E.coli</i> 0157	Manual Culture and detection SOP PR3436 <i>Salmonella</i> – PR3439 <i>Vibrio</i> – PR3430 <i>Shigella</i> – PR3428 <i>Campylobacter</i> PR3429 <i>E coli</i> 0157 – PR3437	A
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration by Parasep and light microscopic examination using: SOP – PR3443	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (UKHSA SMLs):	
Faeces	Qualitative detection of <i>Salmonella enterica</i> spp. DNA, <i>Shigella</i> spp. DNA, STEC/VTEC DNA, <i>Yersinia enterocolitica</i> DNA, <i>Vibrio cholerae/Vibrio parahaemolyticus</i> DNA, <i>Campylobacter</i> ( <i>C. jejuni</i> , <i>C. coli</i> , <i>C. lari</i> ) DNA, <i>Giardia lamblia</i> DNA, <i>Cryptosporidium parvum/Cryptosporidium hominis</i> DNA, <i>Entamoeba histolytica</i> DNA	SeroSep EntericBio Dx assay PCR Multiplex RT-PCR Roche LightCycler 480 II and automated analysis of fluorescence data using the FastFinder software with a specific Dx plug-in PR4142	A
Faeces	Detection of <i>Yersinia</i> species	Manual culture protocol onto CIN agar PR3431	A
Urine	Detection of <i>Schistosoma haematobium</i> ova	Concentration and light microscopic examination using: SOP – PR3443	A
Clear adhesive tape slides Peri-anal swabs	Detection of threadworms	Light microscopic examination using SOP PR3443	A
Faeces	Detection of <i>C. difficile</i> toxin A and B and GDH antigen	EIA by DS2 SOP PR3440 SOP PR3442	A
Whole blood	Detection of <i>M. tuberculosis</i> IFN- $\gamma$ test	QuantiFERON-TB Gold test by EIA on DS2 SOP PR3433 SOP PR3442 SOP PR3427	A
Faeces	Detection of <i>Cryptosporidium</i> and <i>Giardia</i>	EIA by DS2 SOP PR3440 SOP PR3442	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (UKHSA SMLs):	
Serum	Detection of Beta 1,3 Glucan	Fungitell® assay using SOP PR 3883 Semi Automated using BioTek ECx808iu ultra microplate reader SOP PR3883	A
Serum Plasma	Serological examination activities for the purpose of clinical diagnosis  Detection of:  HIV 1&2 AgAb (CHIV) HBsAg (HBsII) and confirmation (Conf) HBc IgM (aHBcM) AntiHBc Total Ab (HBcT2) AntiHBs Ab (aHBs2) HBeAg (HBeAg) AntiHBe (aHBe2) HCV Ab (aHCV) Syphilis Ab (Syph) Rubella IgM (RubM) Rubella IgG (RubG) Hepatitis A IgM (aHAVM) Hepatitis A Total Ab (aHAVT)	Documented in house methods incorporating manufacturers' instructions where relevant  Diasorin Liaison XL SOP PR3864	A
Dried Blood Spot (DBS) samples	HIV 1&2 AgAb (CHIV) HBsAg (HBsII) and confirmation (Conf)  HCV Ab (aHCV)	Diasorin Liaison XL SOP PR3864	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL, SOP PR3864	A
Serum, Plasma	EBV EBNA IgG EBV VCA IgG EBV VCA IgM CMV IgG CMV IgM Toxoplasma IgG Toxoplasma IgM	SOP PR3490	A
Serum Serum, Plasma	Parvovirus B19 IgG Parvovirus B19 IgM VZV IgG HSV IgG Mumps IgG Mumps IgM Measles IgG HTLV 1&2 Ab HCV Ag/Ab <i>Borrelia burgdorferi</i> IgG	SOP PR3989 SOP PR3478 SOP PR3571	A A A
Serum, Plasma	CMV IgG avidity HEV IgG HEV IgM		
Serum, BAL	Detection of Galactomannan antigen	DS2 SOP PR3489	A
Serum	Qualitative detection of <i>Aspergillus</i>	Olm Diagnostics AspLateral Flow Device SOP PR3985	A
Faeces	Detection of rotavirus and adenovirus antigen	ProLab ROAD DUAL lateral flow device assay SOP PR 3491	A
Faeces	Detection of Norovirus antigen	RIDA Quick Norovirus Lateral flow device SOP PR3884	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Urine	Detection of <i>Legionella pneumophila</i> serotype 1 Antigen <i>S.pneumonia</i> antigen	Manual serology method using Immuvue kit SOP PR 3840, PR 3486	A
Urine	Legionella urinary antigen and pneumococcal antigen	BinaxNOW Lateral Flow device SOP PR3486	A
Serum	Cryptococcal Antigen	IMMY lateral flow assay, immunochromatography SOP PR3488	A
Serum	ASO titres	Latex particle agglutination assays using a variety of cards + PR3591 (ASO)	A
Serum	RPR (syphilis confirmation)	Latex particle agglutination assays using a variety of cards + PR3485 (RPR)	A
Serum	Detection of <i>T. pallidum</i> -specific antibodies (TPHA)	Manual assay, NewBio TPHA kit, latex agglutination assay SOP IN4369, PR3485	A
Serum, Plasma	HIV Ag/Ab (confirmation)	Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL SOP PR3864	A
Serum	Detection and typing of HIV 1&2 antibody	Immuno-chromatographic detection of HIV1 and HIV2 using the BioRad Geenius card system SOP IN4349	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum Plasma</p> <p>Serum</p> <p>Plasma</p> <p>Plasma</p> <p>Serum</p>	<p><u>Serological activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of:</p> <p>HIV 1&amp;2 antibody and antigen (CHIV)* HBsAg (HBsII)* and confirmation (Conf) Syphilis Ab* (Syph)</p> <p>RPR (syphilis confirmation)*</p> <p>Quantitative assays for BKV DNA</p> <p>Quantitative assays for CMV DNA</p> <p>Quantitative assays for EBV DNA</p> <p>HIV Ag/Ab</p>	<p>Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy (IDPS) screening programme(s) as defined in the Laboratory QC evidence requirements (relevant tests marked with *);</p> <p>Siemens Atellica (PR4113) testing procedures:</p> <p>Latex particle agglutination assays using a variety of cards PR3591</p> <p>Hologic Panther and Fusion BKV Quant assay kit PR4154</p> <p>Hologic Panther and Fusion CMV Quant assay kit PR4154</p> <p>Hologic Panther and Fusion EBV Quant assay kit PR4154</p> <p>Lateral flow device with immunochromatographic methodology SteriLab Multisure HIV 1&amp;2 Rapid Test IN7985 PR3473</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
CSF, eye swabs, skin swabs, meningeal swabs, EDTA blood	Extraction for further analysis	Extraction using the QIASymphony SOP PR3459	A
Nucleic amplification from CSF, eye swabs, skin swabs, tissue, respiratory samples, EDTA blood	Viral PCR panel: HSV1 & 2 VZV Enterovirus Parechovirus CMV EBV HHV6 HHV7 Adenovirus	Semi-automated qualitative PCR by AusDiagnostics HighPlex System SOP PR3931	A
Genital swabs	Detection of HSV 1 and 2	Automated transcription-mediated amplification (TMA) using Hologic Panther SOP PR 3847	A
Endocervical swabs, vaginal swabs, male/female urine, vulval swabs, urethral swabs, throat, rectal and eye swabs	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA, including GC confirmation testing	Automated transcription-mediated amplification (TMA) using Hologic Panther SOP PR3847	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
EDTA Blood (Plasma and serum)	Detection of HIV-1 RNA and quantification of HIV viral load Qualitative result only for serum	Automated quantitative RT-PCR using Hologic Panther system SOP PR 3846	A
Blood (Serum from clotted blood)	Detection of HBV DNA	SOP PR3846	A
Blood (Serum from clotted blood preferred and Dried Blood Spot (DBS) samples)	Detection of HCV RNA Qualitative result only for DBS	SOP PR3846	A
Rectal swabs, dual Swab of rectal, peri-rectal	Direct CRO Screening	Carbapenemase PCR screening by Cepheid GeneXpert Infinity SOP PR3567	A
Isolates	Detection of <i>blaKPC</i> , <i>blaNDM</i> , <i>blaVIM</i> , <i>blaOXA-48</i> , and <i>blaIMP-1</i> gene sequences	Carbapenemase PCR by Cepheid GeneXpert Infinity SOP PR 3567	A
Faeces	<i>C. difficile</i> toxin	PCR using Cepheid GeneXpert DX SOP PR3441	A
Sputum BAL CSF Tissue Urine	Detection of <i>Mycobacterium tuberculosis</i> complex DNA	Semi-quantitative nested RT-PCR using MTB/RIF Ultra kit on Cepheid GeneXpert SOP PR3435	A
Nasopharyngeal swabs (nose and throat), Nasal swab Nasopharyngeal aspirate (NPA), Bronchoalveolar lavage (BAL), Endotracheal aspirate (ETA)	Detection of SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus	Qualitative, real-time RT-PCR using the Xpert Xpress SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus rapid molecular test on the Cepheid GeneXpert / Infinity System SOP PR 3906	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Nasopharyngeal swabs (nose and throat), Nasal swab	Detection of SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus	Qualitative, real-time RT-PCR using the Xpert Xpress SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus rapid molecular test on the Cepheid GeneXpert SOP PR 3906	B
Nasopharyngeal swabs (nose and throat), Nasal swab, Nasopharyngeal aspirate (NPA), Bronchoalveolar lavage (BAL), Endotracheal aspirate (ETA)	Detection of Influenza A Virus (Matrix gene); Influenza B Virus (Matrix gene); Respiratory Syncytial Virus A/B (Matrix gene); SARS-CoV-2 (ORF1ab gene)	Qualitative, real-time PCR using the Panther Fusion RESP-4 System SOP PR 4084	A
Sterile sites – tissues, fluids, pus and bacterial isolates	Extraction and Amplification of 16S DNA for subsequent cDNA sequencing at a referral sequencing laboratory.	Manual in-house qualitative PCR (extraction by QIAGEN, block PCR, gel electrophoresis. SOP PR3469	A
16S rDNA sequence data	Identification of clinically significant species of bacteria	Analysis and reporting of outsourced DNA sequencing SOP PR3469	A
Nasopharyngeal aspirate (NPA), Bronchoalveolar lavage (BAL), pleural aspirate, ET aspirate, sputum, tracheal aspirate, throat swab, nose swab, respiratory tissues	Extraction for further analysis as below:	Extraction using QIASymphony SOP PR3459	A
Tissues (including heart, spleen, liver, lung, trachea, brain, bowel, placenta/amniotic fluid)		Extraction of nucleic acid for PCR SOP PR3459  Pre-Treatment off board and nucleic acid extraction on the QIA symphony IN5428	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Bronchoalveolar lavage (BAL), Tracheal/Endotracheal aspirate, Sputum</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of Bacterial and Fungal causative agents of pneumonia:</p> <p><i>Mycoplasma pneumoniae</i> <i>Chlamydia pneumoniae</i> <i>Chlamydia psittaci</i> <i>Legionella pneumonia</i> <i>Legionella longbeach</i> <i>Bordetella spp.</i> <i>Pneumocystis jirovecii (PCP)</i></p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Multiplex-tandem PCR (MT-PCR) using AusDiagnostics Atypical Pneumonia 16-Plex Panel. Extraction: QIASymphony SOP PR4014</p>	<p style="text-align: center;">A</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Nucleic Acid amplification from respiratory samples</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of:</p> <p>Influenza A (incl. typing for influenza A H1N1pdm09 and influenza A H3) Influenza B Respiratory Syncytial Virus RSV Types A &amp; B Human Metapneumovirus Types A &amp; B Human Rhinovirus/Enterovirus (hRV/EV) Enterovirus (EV) Human Bocavirus (hBoV) Parainfluenza virus PIV 1, 2, 3, 4 Parechovirus Adenovirus (hAdv) NONO sample adequacy control (human gene target) SPIKE assay process control Human Coronavirus (hCoV, excluding SARS and MERS coronaviruses) SARS-CoV-2 (COVID-19, ORF1 &amp; ORF8 genes)</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Semi-automated qualitative PCR using AusDiagnostics Easy-Plex/High-Plex System SOP PR3523</p>	<p style="text-align: center;">A</p>

END