


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	University Hospitals of Leicester NHS Trust Issue No: 015 Issue date: 10 February 2025	
	Clinical Microbiology University Hospitals of Leicester NHS Trust Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Contact: Daxa Patel Tel: +44 (0) 116 258 6504 E-Mail: daxa.patel@uhl-tr.nhs.uk Website: http://www.leicestershospitals.nhs.uk
Activities performed by the Organisation at the locations specified below		

Locations covered and their relevant activities

Location Details	Activity	Location Code
Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Microbiology Mycology Parasitology Virology Molecular	A
Department of Pathology Glenfield Hospital Groby Road Leicester LE3 9QP	Molecular	B



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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 SMLs):	
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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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 SMIs):	
Respiratory samples Urine CSF	Microscopy, isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)	Manual culture, automated MGIT 960 and microscopy using PR3434	A
Blood Bone Marrow		Automated screening (BDBactec FX40) and manual culture SOP PR3434	
Skin, Nail, BAL	Microscopy, general isolation and characterisation of clinically significant fungi	Manual culture and fluorescent microscopy using calcofluor stain using SOP: PR3863 PR3444	A
Cultures isolated in house from the above	Identification of clinically significant bacteria and fungi	Automated Matrix-assisted laser desorption/ionisation (MALDITOF) using: SOP PR3913 Biomerieux Vitek MS	A
Bacterial cultures isolated in house from the above	Antimicrobial susceptibility testing of clinically significant bacteria	Biochemical profile determination using: Biomerieux Vitek 2 Compact SOP PR3453	
		Biomerieux Vitek 2 Compact SOP PR3453	A
		Manual disc diffusion and/or automated methods using EUCAST methodology: SOP PR3595 Determination of MIC of organisms using gradient strips or broth microdilution SOP PR3514	



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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):	
Bacterial cultures isolated in house from the above	Non-fastidious resistant isolates	Thermo Scientific Sensititre Susceptibility plate (DensiCHEK) SOP PR4003	A
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 Biomerieux Vitek 2 Compact SOP PR3453	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
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):	
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-γ test	QuantiFERON-TB Gold test by EIA on DS2 SOP PR3433 SOP PR3442 SOP PR3427	A
Serum	Detection of Beta 1,3 Glucan	Fungitell® assay using SOP PR 3883 Semi Automated using BioTek ECx808iu ultra microplate reader SOP PR3883	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u>	Documented in-house methods incorporating manufacturers' instructions where relevant Using the Siemens Atellica DLi (PR4113) and Dried Blood Spot (DBS) testing (PR3493) procedures:	
Serum Plasma	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)		A
Dried Blood Spot (DBS) samples	HIV 1&2 AgAb (CHIV) HBsAg (HBsII) and confirmation (Conf) HCV Ab (aHCV)		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 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	A
	CMV IgG avidity	SOP PR3478	A
Serum, Plasma	HEV IgG HEV IgM	SOP PR3571	A
		Documented in house semi-automated methods incorporating manufacturers' instructions where relevant	
Serum, BAL	Detection of Galactomannan antigen	DS2 SOP PR3489	A
Serum, BAL	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 Latex particle agglutination assays using a variety of cards +	A
Serum	ASO titres	PR3591 (ASO)	A
Serum	RPR (syphilis confirmation)	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	Immunochromatographic detection of HIV1 and HIV2 using the BioRad Geenius card system – SOP IN4349	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 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 *);	
Serum Plasma	Detection of: HIV 1&2 antibody and antigen (CHIV)* HBsAg (HBsII)* and confirmation (Conf) Syphilis Ab* (Syph)	Siemens Atellica (PR4113) testing procedures:	A
Serum, Plasma	HIV antibody and antigen (confirmation)	Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL SOP PR3864	A
Serum	DHIV 1 and HIV 2 detection and typing	Immunochromatographic detection of HIV1 and HIV2 using the BioRad Geenius card system – SOP IN4349	A
Serum	RPR (syphilis confirmation)*	Latex particle agglutination assays using a variety of cards PR3591	A
Serum	Detection of <i>T. pallidum</i> -specific antibodies (TPHA)	Manual assay, NewBio TPHA kit, latex agglutination assay SOP IN4369, PR3485	A



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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:	
EDTA blood samples (for whole blood or plasma assays), Urine (qualitative only), BAL (qualitative only)	Extraction for further analysis on the CMV/EBV DNA screen	Extraction using the QIA Symphony SOP PR3465	A
Nucleic acid from EDTA blood (Whole) Urine Respiratory samples	Detection / quantification of CMV DNA	Semi-automated quantitative RT-PCR by QIA Symphony SP/AS and rotorgene SOP PR3465	A
Nucleic acid from EDTA blood (Whole)	Quantification of EBV DNA	SOP PR3465	A
CSF, eye swabs, skin swabs, meningeal swabs, EDTA blood	Extraction for further analysis	Extraction using the QIA Symphony 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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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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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 QIAAsymphony 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</i> (PCP)</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>	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:	
Nucleic Acid amplification from respiratory samples	Detection of: Influenza A (incl. typing for influenza A H1N1pdm09 and influenza A H3) Influenza B Respiratory Syncytial Virus RSV Types A & B Human Metapneumovirus Types A & 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 & ORF8 genes)	Semi-automated qualitative PCR using AusDiagnostics Easy-Plex/High-Plex System SOP PR3523	A
END			