


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 8605 Accredited to ISO 15189:2012	University Hospitals of Leicester NHS Trust Issue No: 009 Issue date: 11 May 2022	
	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 Daxa Patel	Microbiology Mycology Parasitology Virology Molecular	A
Department of Pathology Glenfield Hospital Groby Road Leicester LE3 9QP Daxa Patel	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 (PHE SMI):	
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 PR3428 PR3429 PR3430 PR3438 PR3436 PR3440 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 and; PR3451	A
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Automated urine analysis using Atellica UAS 800 urine machine: PR3623 IN5743	A
Cerebral fluid samples	Quantification of white and red blood cells and bacteria	Manual microscopy IN5741 Microscopy (inc. Giemsa stain) using SOP: PR3449	A



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Activity	Examination / Procedure Performed	Equipment / Techniques Used	Location Code
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 (PHE SMIs):	
Swabs Urine Sputum Endotracheal Aspirates	MRSA Screening	Manual culture using: PR3447	A
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 (Biomerieux Bactec 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 Equipment: Biomerieux Vitek MS Biochemical profile determination using: Biomerieux Vitek 2 Compact SOP PR3453	A



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Bacterial cultures isolated in house from the above</p> <p>Bacterial cultures isolated in house from the above</p> <p>Bacterial cultures isolated in house from the above</p> <p>Yeast cultures isolated in house from the above</p> <p>Cultures isolated in house from the above</p>	<p>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</p> <p>Antimicrobial susceptibility testing of clinically significant bacteria</p> <p>Non-fastidious resistant isolates</p> <p>Antimicrobial susceptibility testing against Colistin</p> <p>Antimicrobial susceptibility testing of clinically significant Yeast</p> <p>Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):</p> <p>Biomerieux Vitek 2 Compact SOP PR3453</p> <p>Manual disc diffusion and/or automated methods using EUCAST methodology: SOP PR3595 Determination of MIC of organisms using gradient strips or broth microdilution SOP PR3513 Beta Lactamase detections using Oxoid ID sticks. SOP PR3511</p> <p>Thermo Scientific Sensititre Susceptibility plate (DensiCHEK) SOP PR4003 Colistin Strip Mueller Hinton Broth, DensiCHEK plus. Broth microdilution (BMD) and MICRONAUT MIC-Strip. Interpretation following EUCAST guidelines. SOP PR3986</p> <p>Yeast One Sensititre Kit – Manual Method SOP IN4275 – MIC determination in yeast Isolates SOP IN4277 – Guidelines for MIC interpretation for yeast</p> <p>Pro-Lab Strep grouping kit IN5361</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMI):	
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 and light microscopic examination using: SOP – PR3443	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>Cryptosporidium</i> oocysts and <i>Giardia</i>	EIA by DS2 and modified ZN staining for <i>Cryptosporidia</i> and Microscopy for <i>Giardia</i> using: SOP PR3442	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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Activity	Examination / Procedure Performed	Equipment / Techniques Used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Clotted (Serum) EDTA blood (Plasma) Dried Blood Spot (DBS) samples</p> <p>Clotted and/or EDTA Blood</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Serological activities for the purpose of clinical diagnosis</u></p> <p>HIV Ag/Ab HBsAg AntiHBc AntiHBs HBeAg AntiHBe HBcIgM HCV Ab HAV IgM HAV total Ab Rubella IgG Rubella IgM Syphilis Ab</p> <p><u>Serological activities for the purpose of clinical diagnosis</u></p> <p>EBV EBNA IgG EBV VCA IgG EBV VCA IgM</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMI):</p> <p>Documented in house Methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant Using ADVIA Centaur XP (PR3502):</p> <p>SOPs: Dried Blood Spot (DBS) testing PR3493</p> <p>IN4348 IN4346 IN4341 IN4345 IN4343 IN4344 IN4342 IN4350 IN4352 IN4353 IN4363 IN4364 IN4370</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL</p> <p>SOPs:PR3864</p>	<p style="text-align: center;">A</p> <p style="text-align: center;">A</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL SOPs:PR3864	A
Clotted and/or EDTA Blood (cont'd)	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		
Serum Plasma	Detection of Borrelia burgdorferi Ig G	Diasorin Liaison XL (CLIA) SOP PR3684 SOP PR3989	A
		Documented in house semi-automated methods incorporating manufacturers' instructions where relevant using Siemens BEP2000 contd: SOPs: PR 3503	A
	HEV total antibody HEV IgG HEV IgM	IN5101 IN5102 IN5103	
Clotted Blood	Detection of Galactomannan antigen	Documented in house semi-automated methods incorporating manufacturers' instructions where relevant using DS2 SOP PR3489	A
Serum BAL	Qualitative detection of Aspergillus	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



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using Diasorin Liaison XL SOPs:PR3864	A
Faeces	Detection of Norovirus	RIDA Quick Norovirus Lateral flow device SOP IN4413	A
Urine	Detection of Legionella pneumophila serotype 1 Antigen <i>S.pneumonia antigen</i>	Manual serology method using Immuvue kit SOP PR 3840, PR 3486	A
Urine	<u>Legionella urinary antigen and pneumococcal antigen</u>	BinaxNOW Lateral Flow device SOP PR3486	A
Serum	<u>Detection of HEV IgG and IgM</u>	Documented in house methods incorporating manufacturers' instructions where relevant using BioMerieux VIDAS-3 analyser (ELFA) SOP PR3571	A
Serum	Detection and typing of HIV 1 and HIV 2	Documented in house Methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening Immunochromatographic detection of HIV1 and HIV2 using the BioRad Geenius card system – IN4349	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	A
Serum Plasma	<u>Detection of</u> HIV Antigen/Ab	EFLA using VIDAS 3 analyser	A
	Determination of CMV IgG Avidity	Documented In-house Methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening PR 3473 PR 3478	A
CSF, Serum	Cryptococcal Antigen	BioRad RDT CryptoPS lateral flow device SOP PR3488	A
Clotted Blood	ASO titres Syphilis confirmation	Latex particle agglutination assays using a variety of cards PR 3591 Documented in house Methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening IN4369 IN4371	A
	TPPA (syphilis confirmation) RPR (syphilis confirmation)		



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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 (Whole) Urine Respiratory samples	Detection / quantification of CMV DNA	Semi-automated quantitative RT-PCR by QIAAsymphony SP/AS and rotorgene SOP PR3465	A
EDTA blood (Whole)	Quantification of EBV DNA	SOP PR3465	A
CSF, eye swabs, skin swabs tissue, respiratory samples, EDTA blood	HSV1 & 2 VZV Enterovirus Parechovirus CMV EBV HHV6 HHV7 adenovirus	Semi-automated qualitative PCR by AusDiagnostics HighPlex System SOP PR3931	A
Serum BAL	Qualitative detection of Aspergillus DNA	Qualitative PCR on the Rotogene following extraction on the MagnaPure using the Fungiplex Aspergillus IVD Real-Time PCR Kit SOP PR3928	A
Nose Swab, Throat Swab, combined nose / throat swab, NPA, BAL, Sputum, ET aspirate	Detection of RNA from SARS-CoV-2 specifically ORF 1 gene target	Realtime PCR using automated transcription-mediated amplification (TMA) using Hologic Panther SOP PR 3929	A
Genital swabs	Detection of HSV 1 and 2	Automated transcription-mediated amplification (TMA) using Hologic Panther SOP PR 3847	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:	
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		A
EDTA Blood (Plasma and serum)	Detection of HIV-1 RNA and quantification of HIV viral load Qualitative result only for serum	Documented in house Methods to meet the requirements of the IDPS screening programme as defined in the July 2018 'infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening Automated quantitative RT-PCR using Hologic Panther system SOP PR 3846	A
Blood (Serum from clotted blood)	Detection of HBV DNA Qualitative result only for DBS		A
Blood (Serum from clotted blood preferred and Dried Blood Spot (DBS) samples)	Detection of HCV RNA Qualitative result only for DBS		A
Isolates from rectal swabs, dual Swab of rectal, peri-rectal	Direct CRO Screening	Carbapenemase PCR screening by Cepheid Infinity SOP PR3567	A
Direct from rectal swab Isolates from rectal swabs	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 SOP PR 3567	A
Feaces	Detection of <i>Giardia lamblia</i> , <i>Cryptosporidium</i> sp and <i>Entamoeba histolytica</i>	Real time PCR using Amplidiag Easy and Biorad CFX C1000 PCR	A



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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
Oropharyngeal / nasopharyngeal swabs in VTM (nose and throat swabs, NTS), nasal swabs	Detection of RNA from SARS-CoV-2 specifically N and E gene target	Rapid, real-time RT-PCR using the Xpert Xpress SARS-CoV-2 rapid molecular test on the Cepheid GeneXpert / Infinity System SOP PR 3906	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 rapid molecular test on the Cepheid GeneXpert / Infinity System SOP PR 3906	A and B
Nasopharyngeal swabs (nose and throat)	Detection of RNA from SARS-CoV-2 specifically ORF1ab and N genes	Real-time PCR using Rapid Novodiag SARS-CoV-2 SOP PR3932	A and B
Oropharyngeal / nasopharyngeal swabs (nose, throat, nose and throat swabs)	Detection of RNA from SARS-CoV-2 specifically ORF1ab and N genes	Real time PCR using Amplidiag Easy and Biorad CFX C1000 PCR SOP PR3946	A
Sterile sites – tissues, fluids, pus and bacterial isolates	Extraction and Amplification of 16S RNA 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



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Nasopharyngeal aspirate (NPA), Bronchoalveolar lavage (BAL), pleural aspirate, ET aspirate, sputum tracheal aspirate, throat swab, nose swab, respiratory tissues	Detection of RNA from SARS-CoV-2 specifically ORF 1 and ORF 2 gene targets	Extraction using QIASymphony and semi-automated qualitative PCR using AusDiagnostics Easy-Plex/High-Plex System using SARS CoV-2-ORF 1 assay SOP PR 3921	A
Nucleic Acid 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	Semi-automated qualitative PCR using AusDiagnostics Easy-Plex/High-Plex System SOP PR3523	A
Post Mortem Tissue		Extraction of nucleic acid for PCR Pre-Treatment off board and nucleic acid extraction on the QIA symphony IN5428	A
END			