

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9018

Accredited to
ISO 15189:2012

Royal Devon University Healthcare NHS Foundation Trust

Issue No: 011 Issue date: 05 June 2024

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Pus/ Swabs/ Tissues/ fluids, genital samples, faeces, respiratory samples , urine	Isolation and characterisation of microorganisms of clinical significance	Manual inoculation and culture using in-house procedures: MLPBZ021 - Inoculation of culture media
Swabs, non-sterile tissues, fluids		MLPBZ049 – main bench guide
Sterile tissues and fluids		MLPBM101 – sterile tissues and fluids bench guide
Blood culture and CSF		MLPBB006
Urine		MLPBU008 – urine bench guide
Genital samples		MLPBG003
Respiratory samples		MLPBR010 (Culture of Non- Mycobacterial spp.)
Faeces	Isolation of bacterial enteric pathogens including: <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Escherichia coli</i> O157 <i>Campylobacter</i> spp.	Manual culture using: MLPBM048 <i>E coli</i> 0157 Prolab MLPBF151
Cellular and fluid material contained on swabs from nose, throat & groin/perineum	Screening for: Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual chromogenic culture MLPBM022



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMLs) and incorporating relevant manufacturers' instructions
Blood	Isolation of clinically significant bacteria and fungi	Remote unit FX40 in Blood Sciences MLPVMB057
Blood	Mycobacterium liquid culture	BD-MGIT MLPBR015
Bacterial & fungal isolates cultured in-house from the above	Identification/ Biological classification	Automated identification using: Bruker MaldiTof MLPBZ305
Sputum	Detection of TB	Fluorescent Microscopy MLPBR001
Bacterial isolates cultured in-house from the above	Antibiotic susceptibility testing	Automated using: Beckman Microscan MLPBM107 Manual using: EUCAST sensitivity testing MLPBZ063, MLPBZ044, MLPBZ064, MLPBZ066
Faeces	Detection of ova, cysts & parasites (OCP)	Wet Microscopy MLPBF008 Midi Parasep concentration followed by Microscopic analysis MLPBF011
Faeces	<i>Giardia lamblia</i> / <i>Cryptosporidium</i>	Microscopy: MLPBF003 – modified ZN stain
Faeces	<i>Giardia lamblia</i> / <i>Cryptosporidium</i>	Automated: MLPBF016 Alere EIA MLPBZ054 DS2 automation



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HUMAN TISSUES AND FLUIDS	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMLs) and incorporating relevant manufacturers' instructions
Faeces	<i>Giardia lamblia</i> / <i>Cryptosporidium</i>	Immunochromatographic kit: MLPBF017 Alere Quick check
Faeces	<i>Helicobacter</i> antigen	Bioline antigen test MLPVS028
Faeces	<i>C. difficile</i> GDH Antigen	GDH EIA – Alere MLPBZ055
Faeces	<i>C. difficile</i> toxin A and B	QUIK CHEK complete - Alere MLPBF014
Faeces	<i>C. difficile</i> toxin gene	Realtime PCR using Cepheid Gene Xpert MLPBF015
Urine	White blood cells Bacteria All small particles (ASP)	Manual microscopy MLPBU004
Urine	<i>Legionella</i> Antigen: <i>L. pneumophila</i> serogroup 1 antigen	Binax membrane immunochromatographic assay MLPBU001
Urine	<i>Streptococcus pneumoniae</i> soluble antigen	Binax membrane immunochromatographic assay MLPBU002
Sputum	Detection of Acid-Alcohol Fast Bacilli	Fluorescent Microscopy Leica DMLB Auramine MLPBR001 ZN MPLBR003
Genital samples	<i>Trichomonas vaginalis</i> Bacterial vaginosis Presence of white cells and yeasts	Wet prep, Gram stain, Microscopy MLPBG001
Skin, Hair, Nails	Isolation and identification of fungi of clinical significance	Macroscopic & microscopic analysis and culture MLPBM001 – Mycological examination of skin, hair and nails
Swab or Culture	CPE	Cepheid Gene Xpert MLPBLFD265



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HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis</u>	Documented in-house documented procedures to meet the requirements of the *IDPS programme as defined in the April 2019 version of 'Infectious diseases in pregnancy screening: laboratory QA evidence requirements' for antenatal screening using the following equipment and SOPs
Blood	Syphilis antibody IgG/IgM* HIV antigen/ antibody* Hepatitis B sAg* Hepatitis B Anti HBc total* Hepatitis B Anti HBs* HCV antibody HTLV I / II antibody	Cobas e601 ECLIA MLPVS033
Blood	Toxoplasma total antibody HIV antigen/ antibody total Hepatitis A IgG Hepatitis A IgM Hepatitis B sAg Hepatitis B Anti HBc total Ab HCV antibody Hepatitis B 'e' antigen Hepatitis B 'e' antibody Hepatitis E IgG Hepatitis E IgM CMV IgG CMV IgM VZV IgG EBNA IgG VCA/IgM Rubella IgG Rubella IgM Measles IgG Lyme serology – IgG, IgM	Biomerieux VIDAS 3 ELFA MLPV036



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HUMAN TISSUES AND FLUIDS	<u>Serological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures using the following equipment and SOPs:
Blood	Anti-streptolysin O titre (ASOT)	Manual latex agglutination Rheumajet biokit MLPVS021
Blood	Anti-Streptococcal Dnase (ADN)	Manual latex agglutination Anti Dnase B Biomerieux ASD KIT MLPVS006
Blood	HIV antigen/ antibody	Geenius assay (manual) MLPVS032
Blood	Inteferon γ release (<i>Mycobacterium tuberculosis tuberculosis</i> infection)	Enzyme immuno-assay technique. Quantiferon Gold using Dynex DS2 MLPV038
Blood	Rapid Plasma Reagin (<i>Treponema pallidum</i> infection)	ASI RPR latex MLPVS043



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HUMAN TISSUES AND FLUIDS	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u>	Extraction, PCR amplification and detection using equipment and procedures stated below
Genital swabs/urine	<i>Chlamydia trachomatis</i>	Roche COBAS 6800 RT PCR MLPVM065
Genital swabs/urine	<i>Neisseria gonorrhoeae</i>	Roche COBAS 6800 RT PCR MLPVM065 Realtime PCR using Cepheid GeneXpert MLPBG008
Blood	HIV Viral load	Roche COBAS 6800 RT PCR MLPVM066
Blood	HCV viral load	Roche COBAS 6800 RT PCR MLPVM067
Blood/Plasma	HBV Viral load	Cepheid Gene Expert MLPVM079
Faeces	Norovirus	Realtime PCR using Cepheid Gene Xpert MLPVM056
Nasal Swabs	FluA/FluB/RSV/SARS	Realtime PCR using Cepheid Gene Xpert MLPVM047
Blood/Plasma Blood/Plasma Blood	EBV Quantitative CMV Quantitative BK Quantitative	EliTech InGenius MLPVM074/75/76 <u>EliTech BeGenius MLPVM097/098/099</u>
Genital/Mouth Copan Swabs/Skin	HSV1 HSV2	EliTech InGenius MLPVM078 MLPMV083
CSF	Molecular CSF Meningitis Screen: HSV1 HSV2 VZ Enterovirus	Meningitis Viral ELITe MGB® Panel and Meningitis Viral 2 ELITe MGB® Panel EliTech InGenius MLPVM071



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HUMAN TISSUES AND FLUIDS BW/BAL Nose/Throat Swabs	<u>Molecular diagnostic examination activities for the purpose of clinical diagnosis</u> (cont'd) PJP SARS CoV-2 RNA ORF a/b and e gene SARS CoV-2 RNA RdRp, E and N gene	Extraction, PCR amplification and detection using equipment and procedures stated below Elitech Elite Ingenius MLPVM070 Roche Cobas 6800 Analyser Cobas 6800 SARS CoV 2 SOP-MLPVM084 Elitech InGenius analyser using Elitech Gene Finder, Covid 19 SOP using Elitech In Genius-MLPVM080
END		