Schedule of Accreditation

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Royal Devon University Healthcare NHS Foundation Trust

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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	Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current United Kingdom Health Security Agency (UKHSA 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		– M-BSOP-3 - main bench guide
Sterile tissues and fluids (including microscopy and crystals) and CSF		M-BSOP-5 – Sterile tissues and fluids bench guide
Blood culture		M-BSOP- 8 Blood culture
Blood		Remote unit FX40 in Blood Sciences M-BSOP-8
Cellular and fluid material contained on swabs from nose, throat & groin/perineum	Screening for: Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Manual chromogenic culture M-BSOP-6
Respiratory Tissue, fluids	Mycobacterium liquid culture	BD-MGIT M-BSOP-7
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Bacterial isolates cultured in-house from the above	Detection of carbapenemases (KPC, OXA-48-like, VIM, IMP and NDM)	NG-Test CARBA 5 lateral flow immunochromatographic assay M-BSOP-12
Bacterial isolates cultured in-house from the above	Antibiotic susceptibility testing	Automated using: Beckman Microscan M-BSOP-9 Manual using: EUCAST sensitivity testing MLPBZ063, MLPBZ044, MLPBZ066
Faeces	Isolation of bacterial enteric pathogens including: *Salmonella* sp. *Shigella* spp. *Vibrio* spp. *Yersinia* spp. *Escherichia coli* O157 *Campylobacter* spp.	Manual culture using: M-BSOP-13 *E coli* 0157 Prolab MLPBF151
Faeces	Detection of ova, cysts & parasites (OCP)	MBSOP-14 Microscopy Midi Parasep concentration followed by Microscopic analysis Modified ZN stain
Faeces	*Giardia lamblia / Cryptosporidium*	Automated: MLPBF016 Alere EIA MLPBZ054 DS2 automation
Faeces	*Giardia lamblia / Cryptosporidium*	Immunochromatographic kit: MLPBF017 Alere Quick check
Faeces	*Helicobacter* antigen	Bioline antigen test MLPVS028
Faeces	*C. difficile* GDH Antigen	GDH EIA – Alere MLPBZ055
Faeces	*C. difficile* toxin A and B	QUIK CHEK complete - Alere MLPBF014

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Faeces	*C. difficile* toxin gene	Realtime PCR using Cepheid Gene Xpert MLPBF015
Urine	Isolation and characterisation of microorganisms of clinical significance	MLPBU008 – Urine bench guide
Urine	White blood cells	Manual microscopy MLPBU004
Urine	*Legionella* Antigen: *L. pneumophila* serogroup 1 antigen	Binax membrane immunochromatographic assay MLPBU001
Respiratory samples	Isolation and characterisation of microorganisms of clinical significance	M-BSOP-2 Culture of Non-Mycobacterial spp.
Sputum	Detection of Acid-Alcohol Fast Bacilli	Fluorescent Microscopy Leica DMLB Auramine MLPBR001 ZN MLPBR003
Genital samples	Isolation and characterisation of microorganisms of clinical significance	M-BSOP-1 Genital bench
Genital samples	*Trichomonas vaginalis* Bacterial vaginosis and yeasts	Wet prep, Gram stain, Microscopy M-BSOP-1
Skin, Hair, Nails, Isolates from culture	Isolation and identification of fungi of clinical significance	Macroscopic & microscopic analysis and culture M-BSOP-4 – Mycological examination of skin, hair and nails
Swab or Culture	CPE	Cepheid Gene Xpert MLPBFLFD265

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HUMAN TISSUES AND FLUIDS	Serological examination activities for the purpose of clinical diagnosis	Documented in-house methods to meet the requirements of the NHS *Infectious Diseases in Pregnancy Screening (IDPS):: 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 IgM CMV IgG CMV IgM VZV IgG EBNA VCA IgG VCA IgM Rubella IgG Rubella IgM Measles IgG Lyme serology – IgG, IgM	Biomerieux VIDAS 3 ELFA MLPV036

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	Serological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using the following equipment and SOPs:
Blood	Anti-streptolysin O titre (ASOT)	Manual latex agglutination Rheumajet biokit MLPVS021
Blood	HIV antigen/ antibody	Geenius assay (manual) MLPVS032
Blood	Inteferon γ release (*Mycobacterium tuberculosis tuberculosis* infection)	Enzyme immuno-assay technique. Quantiferon Gold using Dynex DS2 MLPV038
Blood	Rapid Plasma Reagin (*Treponema pallidum* infection)	ASI RPR latex MLPVS043

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	Molecular diagnostic examination activities for the purpose of clinical diagnosis	Extraction, PCR amplification and detection using equipment and procedures stated below
Genital swabs/urine Genital Dry swabs	*Chlamydia trachomatis*	Roche COBAS 6800 RT PCR MLPVM065
Genital swabs/urine Genital Dry swabs	*Neisseria gonorrhoeae*	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	Roche COBAS 6800 RT PCR MLPVM068
Faeces	Norovirus	Realtime PCR using Cepheid Gene Xpert MLPVM086
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 EliTech BeGenius MLPVM097/098/099
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
Respiratory samples, BW/BAL	PJP	Elitech Elite MLPVM070

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