

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8043

Accredited to
ISO 15189:2022

UK Health Security Agency, An Executive Agency of the Department of Health and Social Care

Issue No: 016

Issue date: 25 March 2025

Infection Sciences Laboratory
Pathology Building
Southmead Hospital
Southmead Road
Westbury on Trym
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BS10 5NB
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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Infection Sciences Laboratory Pathology Building Southmead Hospital Southmead Road Westbury on Trym Bristol BS10 5NB	Local contact Deborah Williams Diagnostic testing	A
Satellite laboratory Royal United Hospital Bath NHS Trust Combe Park Bath	Local contact Deborah Williams Diagnostic testing	B
Pathology Laboratory Bristol Royal Infirmary Marlborough Street Bristol BS2 8HW	Local Contact Deborah Williams Incubation and reporting of negative blood cultures	C
UNITY Sexual Health Clinic Tower Hill, Bristol BS2 0JD	Local Contact: Deborah Williams Molecular detection of Chlamydia, gonorrhoea and Trichomonas	D



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE/FLUIDS	<u>Microbiology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and UK Standards for Microbiology Investigations (SMIs) as relevant.	
	<u>General Bacteriology</u>		
Urines, cellular and fluid material contained on swabs from genital sites and for infection screening	Isolation and identification of organisms of clinical significance	Semi-automated inoculation and incubation of non-selective selective, differential and chromogenic agar plates and liquid enrichment broth using the BD Kiestra system together with Visual analysis of culture plate images through digital imaging technology allowing the detection of microbial growth IS/BAC/AUTOBSOP003	A
Cellular and fluid material contained on swabs, catheter tips Fluids Tissues	Isolation and identification of organisms of clinical significance	Manual inoculation and incubation of non-selective selective, differential and chromogenic agar plates and liquid enrichment broth	A, B
Skin and soft tissue		IS/BAC/WOUBSOP011	A
Pus and deep-seated infections		IS/BAC/WOUBSOP014	A
sputum, BAL and associated specimens		IS/BAC/RESPBSOP057	A
MRSA screening		IS/BAC/XIBSOP029	A
Genital samples		IS/BAC/GENBSOP028	A
Mouth swabs		IS/BAC/WOUBSOP004	A
Ear swabs		IS/BAC/WOUBSOP001	A
Eye swabs and associated specimens		IS/BAC/WOUBSOP002	A



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HUMAN TISSUE/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and UK SMIs as relevant:	
Fluids		IS/BAC/BCBSOP026 IS/BAC/WOUBSOP025 IS/BAC/WOUBSOP015	A
Tissues		IS/BAC/WOUBSOP017 IS/BAC/RESPBSOP057	A, B
Pleural fluids		IS/BAC/BCBSOP026 IS/BAC/RESPBSOP057	A
Pernasal swabs		IS/BAC/WOUBSOP006	A
Nose swabs		IS/BAC/WOUBSOP005	A
Throat swabs		IS/BAC/WOUBSOP009	A
CSF		IS/BAC/BCBSOP038 IS/BAC/BCBSOP022 IS/BAC/BCBSOP023	A, B
Human Skin, Hair, Nails	Identification of yeasts and fungal pathogens of clinical significance	IS/BAC/MYCBSOP001 IS/BAC/MYCBSOP002 IS/BAC/MYCBSOP005 IS/BAC/MYCBSOP006	A
Urine	Detection, identification & quantification of: White blood cells Red blood cells Bacterial cells	Automated fluorescence flow cytometric urinalysis using: Sysmex UF-5000 IS/BAC/URBSOP041	A
Urine	Detection of: <i>S. pneumoniae</i> soluble antigen <i>Legionella pneumophila</i> serotype 1 antigen	Abbott BinaxNOW <i>Streptococcus pneumoniae</i> Antigen Card IS/BAC/URBSOP042 Abbott BinaxNOW <i>Legionella</i> Urinary Antigen Card IS/BAC/URBSOP043	A



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HUMAN TISSUE/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and UK SMIs as relevant:	
Lower respiratory tract samples (Sputum, BAL) Tissue, Pus	Isolation and identification of mycobacterial species	Becton Dickinson MGIT Fluorometric growth detection and manual culture and microscopy using Ziehl Neelsen and auramine stains IS/BAC/RESPBSOP040	A
Respiratory samples Early morning urine (EMU) Gastric aspirates Fluids Tissues Pus Fine needle aspirates (FNA) Cerebrospinal fluid (CSF) Faeces	Detection of: <i>Mycobacterium tuberculosis</i> DNA Rifampicin-resistance genes	Cepheid GeneXpert multiplex, real-time PCR IS/BAC/RESPBSOP040	A
Urine	Identification of white blood cells, red blood cell, epithelial cells	Manual microscopy. IS/BAC/URBSOP041	A
Urine	Isolation and identification of organisms of clinical significance	Manual Culture IS/BAC/URBSOP041	A
Blood Cultures	Detection of microbial growth in blood	BD BACTec FX system; colorimetric sensor IS/BAC/BCBSOP037	A, B
Blood cultures	Detection of microbial growth with subsequent analysis of positive samples at site A (Southmead Hospital) Reporting of negative samples	BD BACTec FX system; colorimetric sensor IS/BAC/BCBSOP039	C



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HUMAN TISSUE/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and UK SMIs as relevant:	
Faeces	Isolation and identification of organisms of clinical significance	Manual culture IS/BAC/FXBSOP030	A
Faeces, slides, aspirates and pus	Microscopy for the detection and identification of ova, cysts and parasites	Manual methods using Parasep concentrators and light microscopy IS/BAC/FXBSOP031	A
Saline swabs	Detection and identification of ova of Enterobius vermicularis	Light Microscopy IS/BAC/FXBSOP031	A
Faeces	Detection of Clostridioides difficile Toxins A & B	Tech Lab QuikChek Complete IS/BAC/FXBSOP035	A
Faeces	Detection of Helicobacter pylori antigen	Dynex DS2 EIA IS/BAC/FXBSOP033 IS/BAC/FXBSOP047	A



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HUMAN TISSUE/FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions and UK SMIs as relevant:	
Cultures isolated in house from routine and blood samples listed above	Identification of organisms of clinical significance	Brucker MALDI-ToF Biotyper system IS/BAC/OTHBSOP060	A
Cultures isolated in house from routine and blood samples listed above	Identification of organisms of clinical significance	Biomerieux Vitex2XL IS/BAC/SENBSOP045	A
Cultures isolated in house from routine and blood samples listed above	Identification of organisms of clinical significance	Manual biochemical and enzymatic tests IS/BAC/OTHBSOP070 IS/BAC/OTHBSOP064	A
Pure culture of isolates of clinical significance from the samples listed above	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	VITEK 2XL (A) and VITEK 2 Compact (B) utilising EUCAST breakpoint guidelines IS/BAC/SENBSOP045	A, B
		Manual disc diffusion method utilising EUCAST breakpoint guidelines IS/BAC/SENBSOP046	A, B



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<p>HUMAN TISSUE/ FLUIDS (cont'd)</p> <p>Serum, plasma (unless stated otherwise)</p> <p>Serum only</p>	<p><u>Virology examinations for the purposes of clinical diagnosis</u></p> <p>Detection of: HIV HT (high throughput): HIV-1 & HIV-1 antibodies and HIV-1 p24 antigen* Hepatitis B surface antigen* Treponemal total antibodies* Borrelia IgG/IgM Helicobacter IgG Hepatitis A total antibodies Hepatitis A IgM Hepatitis B core total antibodies Hepatitis B core IgM Hepatitis B surface antibody Hepatitis B e antigen Hepatitis B e antibody Hepatitis C ab Measles IgG and IgM Mumps IgG Rubella IgG and IgM Toxoplasma IgG HSV type 1/2 IgG HTLV 1 & 2 antibodies Parvovirus IgG and IgM CMV IgG and IgM CMV avidity EBNA IgG EBV VCA IgG and IgM C. trachomatis IgG B. pertussis IgG Varicella-zoster IgG</p>	<p>In-house documented procedures based on equipment manuals and UK SMLs as relevant. (cont'd)</p> <p>Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the laboratory QA evidence requirements' (targets marked *)</p> <p>Diasorin Liaison XL serology analyser using chemiluminescence IS/VIR/AUTOVSOP001</p>	<p>A</p>



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HUMAN TISSUE/ FLUIDS (cont'd)	<u>Virology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals and UK SMLs as relevant. (cont'd)	
Serum, plasma	HIV-1 & HIV-2 antibodies and HIV-1 p24 antigen Hepatitis B surface antigen Hepatitis B core total antibodies	BioMérieux VIDAS 3 immunoassay IS/VIR/AUTOVSOP005	A
Serum	Detection of:	Manual ELISA using:	A
	T. pallidum IgM	Syphilis Mikrogen Recomwell IgM IS/VIR/MSVSOP021	A
Serum	Detection of:	Particle agglutination tests using IS/VIR/MSVSOP017	A
	ASO antibody		A
	Rapid plasma reagin	ASI RPR Card, macroscopic nontreponemal flocculation test IS/VIR/MSVSOP018	A
Serum	Detection of Treponema pallidum IgG	Fujirebio INNO-LIA Syphilis Score Line Immunoblot IS/VIR/MSVSOP027	A
Serum	Detection of antibodies to HIV 1 and HIV 2	Geenius HIV1/2 line assay, IS/VIR/MSVSOP002	A
	Detection of:	PCR using Qiagen Symphony extraction platform and ABI 7500*, or Dyad*** amplification	A
Blood	Adenovirus *DNA	IS/VIR/BMVSOP011	
Urine, plasma	Polyoma (BK) virus* DNA	IS/VIR/BMVSOP007	
Blood	CMV* DNA	IS/VIR/BMVSOP004	
Blood	EBV* DNA	IS/VIR/BMVSOP015	
Serum, plasma	Hepatitis C genotype***	IS/VIR/BMVSOP003	
Serum, plasma	Hepatitis C* RNA	IS/VIR/BMVSOP002	
Serum, plasma	Parvovirus* DNA	IS/VIR/BMVSOP006	
Serum plasma	Human Herpes Virus 6 DNA*	VSOP 123/VSOP 124/VSOP 135	



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HUMAN TISSUE/ FLUIDS (cont'd)	<u>Virology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals and UK SMLs as relevant. (cont'd)	A
Eye Faeces	Adenovirus* DNA Adenovirus* DNA	IS/VIR/BMVSOP009 IS/VIR/BMVSOP011	
Amniotic fluids, CSF, LRT CSF CSF, faeces respiratory CSF Swabs CSF*	Cytomegalovirus* DNA Epstein Barr* DNA Enterovirus* RNA Human Herpes type 6* DNA HSV type 1&2*** DNA HSV type 1&2* DNA	IS/VIR/BMVSOP004 IS/VIR/BMVSOP015 IS/VIR/BMVSOP009 IS/VIR/BMVSOP015 IS/VIR/RMVSOP004 IS/VIR/BMVSOP005	A
Amniotic fluids	Parvovirus*DNA	IS/VIR/BMVSOP015	
CSF, swabs (skin etc)	Varicella Zoster virus* DNA	IS/VIR/RMVSOP001	



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<p>HUMAN TISSUE/ FLUIDS (cont'd)</p> <p>Upper respiratory tract samples</p>	<p><u>Virology examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Qualitative detection of nucleic acids from:</p> <p>Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), specific gene sequences S and M Human Metapneumovirus Human Rhinovirus Human Enterovirus Influenza A subtypes: H1, H3, H1-2009 Influenza B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus <i>Bordetella parapertussis</i> (IS1001) <i>Bordetella pertussis</i> (ptxP) <i>Chlamydia pneumoniae</i> <i>Mycoplasma pneumoniae</i></p>	<p>Multiplex PCR using: BioFire Film Array Torch system & Respiratory panel 2.1 plus IS/VIR/RMVSOP016</p>	<p>A</p>



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HUMAN TISSUE/FLUIDS (cont'd)	<u>Virology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals and UK SMLs as relevant. (cont'd)	
Tissues	Manual extraction protocol	PCR using manual extraction and ABI7500	A
Tissues	Cytomegalovirus DNA	IS/VIR/MOLVSOP012	
Tissues	HSV type 1 and 2 DNA	IS/VIR/BMVSOP015	
	Parvovirus DNA	IS/VIR/BMVSOP005	
		IS/VIR/BMVSOP015	
	Detection of:	Transcription Mediated Amplification (TMA) using Hologic Panther	A, D
Urine	Chlamydia trachomatis DNA	IS/VIR/NAATVSOP001	
Urethral, cervical, vaginal swabs	Neisseria gonorrhoeae DNA		
Endocervical swabs, vaginal swabs	Trichomonas vaginalis DNA	Transcription Mediated Amplification (TMA) using Hologic Panther and in-house method: IS/VIR/NAATVSOP001	D
Swabs (Nose &/or Throat), NPA, BAL, Sputum	Detection of: Influenza A RNA Influenza B RNA Human Metapneumovirus RNA Adenovirus DNA RSV RNA Rhinovirus RNA Parainfluenza virus (1, 2, 3 & 4) RNA	PCR and Transcription Mediated Amplification using Hologic Panther Fusion and in-house method:	A
Nasopharyngeal / oropharyngeal swabs, combined throat and nose swabs and upper respiratory tract aspirates in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; ORF1ab gene	IS/VIR/RMVSOP013	
		Transcription Mediated Amplification (TMA) using Hologic Panther, Aptima assay and in-house method: IS/PH/CoV SOP003	A



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Nose, Throat and pernasal swabs	Bordetella spp. DNA	In house method on Hologic Panther Fusion using PCR and TMA and in-house method: IS/VIR/RMVSOP013	A
Plasma only (EDTA)	Detection and quantification of: Hepatitis B DNA HIV RNA	Qiagen NeumoDX 288 Fluorescence based real time PCR and in-house method: IS/VIR/BMVSOP014	A
Serum and Plasma (EDTA or ACD)	Hepatitis C RNA		
HUMAN TISSUE/FLUIDS (cont'd)	<u>Mycology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals and UK SMLs as relevant. (cont'd)	
fluids, tissues, swabs	Isolation and identification of moulds and yeasts	Fluorescence microscopy using calcofluor. Bright field microscopy using Indian ink using IS/MRL/MYCSOP001-4	A
Yeast and mould isolates	Identification of yeast and mould isolates	Manual culture using IS/MRL/MYCSOP001-4 Culture and microscopy and analysis using Bruker Maldi-tof mass spectrometer and SOP IS/MRL/MYCSOP011, IS/MRL/MYCSOP012 Yeast - MALDI ID IS/MRL/MYCSOP013 MALDI	A



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		Yeast identification by PCR and sequencing of nuclear ribosomal regions using IS/MRL/MYCSOPPCR001	A
		Mould identification by PCR and sequencing of regions of the genomic DNA of filamentous fungi using IS/MRL/MYCSOPPCR002, IS/MRL/MYCSOPPCR003	A
Quantitative anti fungal assay results received from UKAS accredited laboratory 8099	Reporting of quantitative assays for: Fluconazole Flucytosine Itraconazole Voriconazole Posaconazole Isavuconazole	IS/MRL/MYCSOP105	A
Yeast and mould isolates	Anti-fungal antibiotic sensitivity testing	Minimum inhibitory concentration by manual microdilution and E test using SOP IS/MRL/MYCSOP34, 36,37	A
Blood, serum, CSF	Antibody detection to the following: Coccidioides species Histoplasma species Blastomyces species Paracoccidioides species	Manual Ouchterlony double diffusion using IS/MRL/MYCSOP026	A



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Blood, serum, CSF	Antibody detection to the following: Aspergillus species Candida species	Manual counter current immunoelectrophoresis using IS/MRL/MYCSOP021	A
Blood, serum, CSF	Antigen detection of the following: Aspergillus species Candida species	Manual ELISA method using Platelia kit IS/MRL/MYCSOP024 IS/MRL/MYCSOP028	A
	Cryptococcus neoformans	IMMY Cryptococcus antigen latex kit and IMMY Cryptococcus lateral flow kit using IS/MRL/MYCSOP023 and 29	A
	Beta-1,3 glucan	Manual ELISA using Fungitell kit and IS/MRL/MYCSOP025	A
END			