


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8099</p> <p>Accredited to ISO 15189:2012</p>	<h3>North Bristol NHS Trust</h3> <p>Issue No: 002 Issue date: 14 April 2020</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS	<u>Microbiology examination activities for the purpose of clinical diagnosis:</u>	Documented In house methods in conjunction with manufacturer's instructions
Serum/plasma	Therapeutic drug monitoring: Gentamicin Vancomycin Tobramycin Amikacin Teicoplanin	Thermo Scientific Indiko Plus immunoassay platform MISOP/NBT/ASSAY085 MISOP/NBT/ASSAY085 MISOP/NBT/ASSAY085 MISOP/NBT/ASSAY085 MISOP/NBT/ASSAY085
Serum/Plasma	Streptomycin Itraconazole Posaconazole Voriconazole	Sciex ABI3000 LC MS-MS Tandem Mass Spectroscopy MISOP/NBT/ASSAY057 – LCMS SOP 13 and 14 MISOP/NBT/ASSAY052 - LCMS SOP 10 MISOP/NBT/ASSAY053 - LCMS SOP 11 MISOP/NBT/ASSAY054 - LCMS SOP 12
Serum/Plasma	Colistin Isavuconazole	MISOP/NBT/ASSAY079 LC-MS/MS MISOP/NBT/ASSAY088 LC-MS/MS



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Documented in-house procedure– in conjunction with manufacturer's instructions:
Serum/Plasma	Fluconazole	MISOP/NBT/ASSAY089
	Ethambutol	MISOP/NBT/ASSAY107
	Isoniazid	MISOP/NBT/ASSAY109
		<u>HPLC UV Absorption</u> <u>Autosamplers:</u> Gynotek Gina50, Dionex Gina 50, TSP AS300, Rheodyne 7125, Shimadzu SIL20AC <u>Detectors:</u> UV Dionex Ultimate 3000, 170u UVD, 170 UV, RF2000, 0200-9060 SP Linear 120-000, Shimadzu SPD 20A, SPD 20A, TSP UV150 <u>Pumps:</u> Gilson 307, MSI Concept ASII, Shimadzu LC 20AB MISOP/NBT/ASSAY001 MISOP/NBT/ASSAY005
Serum/plasma	Acyclovir	MISOP/NBT/ASSAY007 - SOP 7
	CMMG (Acyclovir metabolite)	MISOP/NBT/ASSAY100 HPLC
	Chloramphenicol	MISOP/NBT/ASSAY012 - SOP12
	Ciprofloxacin	MISOP/NBT/ASSAY013 - SOP 13
	Co-trimoxazole (Sulphamethoxazole + Trimethoprim)	MISOP/NBT/ASSAY028 – SOP 28
	Cycloserine	MISOP/NBT/ASSAY 014 - SOP 14



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Serum/Plasma</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>Daptomycin</p> <p>Flucloxacillin</p> <p>Flucytosine</p> <p>Ganciclovir</p> <p>Levofloxacin</p> <p>Linezolid</p> <p>Meropenem</p> <p>Moxifloxacin</p> <p>Piperacillin</p> <p>Rifabutin</p> <p>Rifampicin</p>	<p>Documented in-house procedure– in conjunction with manufacturer's instructions:</p> <p><u>HPLC</u> <u>Autosamplers:</u> Gynotek Gina50, Dionex Gina 50, TSP AS300, Rheodyne 7125, Shimadzu SIL20AC <u>Detectors:</u> UV Dionex Ultimate 3000, 170u UVD, 170 UV, RF2000, 0200-9060 SP Linear 120-000, Shimadzu SPD 20A, SPD 20A, TSP UV150 <u>Pumps:</u> Gilson 307, MSI Concept ASII, Shimadzu LC 20AB</p> <p>MISOP/NBT/ASSAY036 - SOP 36</p> <p>MISOP/NBT/ASSAY015 - SOP 15</p> <p>MISOP/NBT/ASSAY016 - SOP 16</p> <p>MISOP/NBT/ASSAY018 - SOP 18</p> <p>MISOP/NBT/ASSAY022 - SOP 22</p> <p>MISOP/NBT/ASSAY031 - SOP 31</p> <p>MISOP/NBT/ASSAY020 - SOP 20</p> <p>MISOP/NBT/ASSAY034 - SOP 34</p> <p>MISOP/NBT/ASSAY025 - SOP 25</p> <p>MISOP/NBT/ASSAY026 - SOP 26</p> <p>MISOP/NBT/ASSAY027 – SOP 27</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Urines, cellular and fluid material from genital and infection screening sites</p> <p>Cellular and fluid material contained on swabs, catheter tips Fluids Tissues</p> <p>Skin and soft tissue</p> <p>Pus and deep-seated infections</p> <p>Sputum, BAL and associated specimens</p> <p>MRSA screening</p> <p>Genital samples Mouth swabs Ear swabs Eye swabs and associated specimens</p> <p>Fluids</p> <p>Tissues</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>Isolation and identification of organisms of clinical significance</p> <p>Isolation and identification of organisms of clinical significance</p>	<p>In-house documented procedures based on manufacturer's instructions and PHE SMI as relevant:</p> <p>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 and manual inoculation. IS/BAC/AUTOBSOP003</p> <p>Manual inoculation and incubation of non-selective selective, differential and chromogenic agar plates and liquid enrichment broth</p> <p>IS/BAC/WOUBSOP011</p> <p>IS/BAC/WOUBSOP014</p> <p>IS/BAC/RESPBSOP057</p> <p>IS/BAC/XIBSOP029</p> <p>IS/BAC/GENBSOP028 IS/BAC/WOUBSOP004 IS/BAC/WOUBSOP001 IS/BAC/WOUBSOP002</p> <p>IS/BAC/BCBSOP026 IS/BAC/WOUBSOP025 IS/BAC/WOUBSOP015</p> <p>IS/BAC/WOUBSOP017 IS/BAC/RESPBSOP057</p>



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HUMAN BODY TISSUE AND FLUIDS AS SWABS OR LIQUID SWABS	<u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Pleural fluids		IS/BAC/BCBSOP026 IS/BAC/RESPBSOP057
Per nasal swabs		IS/BAC/WOUBSOP006
Nose swabs	Isolation and identification of organisms of clinical significance	IS/BAC/WOUBSOP005
Throat swabs		IS/BAC/WOUBSOP009
CSF		IS/BAC/BCBSOP038 IS/BAC/BCBSOP022 IS/BAC/BCBSOP023 Manual inoculation and incubation of non-selective selective, differential plates
Human Skin, Hair, Nails	Isolation and Identification of yeasts and fungal pathogens of clinical significance	IS/BAC/MYCBSOP001 IS/BAC/MYCBSOP002 IS/BAC/MYCBSOP003 IS/BAC/MYCBSOP004 IS/BAC/MYCBSOP005 IS/BAC/MYCBSOP006
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
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



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HUMAN BODY TISSUE AND FLUIDS AS SWABS OR LIQUID SWABS (Cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Urine	Identification and quantification of white blood cells, red blood cell, epithelial cells, casts	Menarini SediMax automated and manual microscopy method IS/BAC/URBSOP041
Blood Cultures	Detection of bacterial growth in blood	Biomerieux BacT/ALERT 3D Culture System; colorimetric sensor IS/BAC/BCBSOP037
Faeces	Isolation and identification of organisms of clinical significance	Manual Inoculation and culture S/BAC/FXBSOP030
Faeces	Detection and identification of ova, cysts and parasites	Manual method using Parasep concentrator and light microscopy IS/BAC/FXBSOP031
Faeces	Detection of cryptosporidium oocysts	Auramine phenol staining and fluorescence microscopy using IS/BAC/FXBSOP031
Saline swabs	Detection and identification of ova of Enterobius vermicularis	Light Microscopy IS/BAC/FXBSOP031
Faeces	Detection of: C. difficile glutamate dehydrogenase (GDH)	Dynex DS2 EIA and Premier C.difficile GDH IS/BAC/FXBSOP034
Faeces	Detection of: Clostridium difficile toxins A & B (CDT)	Dynex DS2 EIA and Premier Toxins A&B IS/BAC/FXBSOP035



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HUMAN BODY TISSUE AND FLUIDS AS SWABS OR LIQUID SWABS (Cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis: (cont'd)</u>	In-house documented procedures based on manufacturer's instructions and PHE SMIs as relevant:
Faeces	Confirmation of anomalous CDT and GDH results from EIA assays	Techlab QuikChek Immunochematographic assay IS/BAC/FXBSOP035
Faeces	Helicobacter pylori antigen	Dynex DS2 EIA and Premier Platinum HpSA PLUS IS/BAC/FXBSOP033
Faeces	Isolation and identification of C. difficile	Manual Culture IS/BAC/FXBSOP010
Faeces	Cryptosporidium parvum and Giardia lamblia	Dynex DS2 EIA and IVD Research IS/BAC/FXBSOP032 (screen)
Faeces	Confirmation of reactive samples in Crypto/Giardia EIA assay	TechLab QuikChek Immunochematographic assay IS/BAC/FXBSOP044
Cultures isolated in house from routine and blood samples listed above	Identification of organisms of clinical significance	Brucker Matrix Assisted Laser Desorption Ionisation Time of Flight MALDI-ToF Biotyper system IS/BAC/OTHBSOP060 Biomerieux Vitex 2XL IS/BAC/SENBSOP045 Manual biochemical and enzymatic tests IS/BAC/OTHBSOP070 IS/BAC/OTHBSOP064
Pure culture of isolates of clinical significance from the samples listed above	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	VITEK 2XL utilising EUCAST breakpoint guidelines IS/BAC/SENBSOP045 Manual disc diffusion method utilising EUCAST breakpoint guidelines IS/BAC/SENBSOP046
END		