


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>9562</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Warrington and Halton Teaching Hospitals NHS Foundation Trust</b></p> <p>Issue No: 007    Issue date: 13 January 2022</p>	
	<p>Microbiology Department Warrington Hospital Lovely Lane Warrington WA5 1QG</p>	<p>Contact: Steve Acton Tel: +44 (0)1925 275592 E-Mail: <a href="mailto:s.acton1@nhs.net">s.acton1@nhs.net</a> Website: <a href="http://www.whh.nhs.uk/ServiceCatInfo.asp?id=31">www.whh.nhs.uk/ServiceCatInfo.asp?id=31</a></p>
<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
<p>HUMAN TISSUES AND FLUIDS as specified below:</p> <p>Aspirates Cellular and Fluid material contained on swabs Cannulae Corneal Scrapes/Contact lens fluid Faeces Fluids Genital Samples Pus Samples from sterile sites Tissues Urine CSF</p> <p>Whole Blood</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p> <p>General isolation of micro-organisms of clinical significance</p>	<p>In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMI's)</p> <p>Manual inoculation (SOP MF131 – Inoculation of culture media for bacteriology) followed by culture using SOP's: MF49 – sterile sites MF50 – cannulae MF51 – skin/superficial soft tissue MF57 – faeces MF83 – bacterial eye infections MF85 – genital tract MF86 – MRSA screen MF88 – urine MF90 – CSF MF107 – respiratory samples MF110 – pus and exudates MF111 – Intra-operative tissue MF127 – Ear MF128 – Nasal MF129 – Superficial mouth MF130 - Throat</p> <p>Automated blood culture using the BacTAlert analyser.</p> <p>SOP's: ME2 – Blood Culture registration MF26 – Investigation of Blood Cultures</p>



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HUMAN TISSUES AND FLUIDS as specified below:	<u>Microbiology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMI's)
Skin/Nail	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic and microscopic examination (stained and unstained) SOP: MF117 – Dermatological specimens for superficial mycosis
Urine	Quantification of White Blood Cells, Red Blood Cells and Bacteria	Sysmex UF 5000 – Flow cytometry using automated urine analysers x2 SOP's: MF88 – Urine Culture (including automated cell count and manual culture where required)
Aspirates Corneal Scrapes Eyes Fluids Tissues	<u>Microscopy</u> Detection of Bacteria, Yeast cells and fungal hyphae	Microscopic examination using: MF114 – Staining Procedures
Cerebral Fluid Samples	Quantification of white blood cells and red blood cells	Microscopic examination using: MF90 – CSF
Faeces	Detection of ova, cysts and parasites	Unstained and iodine stained direct microscopic examination and/or formol ether faecal concentration and microscopic examination using: MF41 – Investigation of specimens other than blood for parasites Modified Cold Ziehl-Neelsen using MF 114 – Staining Procedures
Faeces	Detection of oocysts of Cryptosporidium	Unstained and iodine stained direct microscopic examination and/or formol ether faecal concentration and microscopic examination by Modified Cold Ziehl-Neelsen using SOP: MF 114



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Ascitic Fluid	<u>Microscopy (cont'd)</u> Investigation for Spontaneous Bacterial Peritonitis Quantification and differential of white blood cells	Microscopic examination using: SOP: MF58 – Specimen Microscopy – Ascitic Fluid
Genital Tract	Examination of genital specimens for the presence of Gonococci, Yeast, Bacterial vaginosis and Trichomonas vaginalis	Gram stained microscopic examination by manual methods or semi -automated method using Polystainer using SOP: MF126
Cultures isolated in-house from all samples previously listed.	Identification of microorganisms of clinical significance	Manual and/or automated methods using: VITEK MS (Matrix-Assisted Laser Desorption/Ionisation) using SOP's: MF121 – VITEK MS MF122 – VITEK MS instrument management  VITEK 2 Compact (x2) using colorimetric reactions from individual wells containing test substrate.  SOP's: MF46 – Automated organism identification  MF118 – VITEK 2 Compact instrument management



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<p>HUMAN TISSUES AND FLUIDS as specified below:</p> <p>Bacterial cultures isolated in-house from all samples previously listed:</p> <p>Enterobacteriaceae isolates from urine only</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>Antibiotic Sensitivity Testing of clinically significant bacteria</p>	<p>In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMI's)</p> <p>Manual and/or automated antimicrobial susceptibility testing by EUCAST guidelines</p> <p>VITEK 2 Compact (x2)—analysis of microbial growth in microwells with varying concentration of antibiotic</p> <p>VITEK XL – analysis of microbial growth in microwells with varying concentration of antibiotic</p> <p>SOP: MF46 – Vitek 2 systems (Compact and XL)-Automated Organism Identification and Antibiotic Sensitivity testing.(</p> <p>Manual techniques using SOP's: MF120 – Antibiotic Sensitivity Testing with Semi-Automated technique using Mastascan Elite (limitations include where difficult to read sensitivity tests prepared on ISA and NAD media, the plates will be removed from the analyser and measured using UKAS calibrated callipers). MF29 – Carbapenemase producers MF62 – Detection of ESBL's</p>



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Faeces	<u>Immunoassays</u> Detection of Helicobacter pylori antigen	Automated Dynex DS2 ELISA system to perform Helicobacter pylori antigen testing. SOP: MV18
Faeces	Detection of C.difficile GDH/Toxin A and B	Detection of GDH and toxins A and B using the TechLab® C.Diff Quik Chek Complete rapid membrane enzyme immunoassay. SOP:MF35 – C.difficile toxin testing in faecal specimens.
Urine	Detection of Pneumococcal urinary antigen	The qualitative detection of Streptococcus pneumoniae antigen in urine using an immunochromatographic assay – BinaxNOW. SOP: MV2 – Detection of pneumococcal antigen
Urine	Detection of legionella pneumophila serogroup 1 urinary antigen	The qualitative detection of Legionella pneumophila serogroup 1 antigen in urine specimens using a rapid immunochromatographic assay using BinaxNOW SOP: MV26



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HUMAN TISSUES AND FLUIDS as specified below:	<u>Serological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures following PHE SMI's
Plasma/Serum	<u>Infectious Disease tests</u>  Hepatitis A IgM HBsAg HIV Ab/Ag (combo) Anti-HBs HB Core Ab (Total) HCV ab Rubella IgG Syphilis total Ab	Documented in-housed methods to meet the requirements of the of Infectious Diseases in Pregnancy Screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy Screening Programme: laboratory QA evidence requirements'  Immunoassay using Siemens Centaur analysers (Biochemistry) SOP: MV4/MV5/MV6/MV7/MV8/MV12
Plasma/Serum	Detection of specific antibodies <ul style="list-style-type: none"> <li>• CMV IgG and IgM</li> <li>• EBV EBNA IgG</li> <li>• EBV VCA/EA IgG</li> <li>• EBV VCA IgM</li> <li>• Hep C antibody</li> <li>• Measles IgG</li> <li>• Varicella Zoster IgG</li> </ul>	ELFA (Enzyme Fluorescent Assay) by VIDAS 3 Immuno-analyser using SOP: MV3/MV9/MV10/M24
Plasma/Serum	<u>Miscellaneous activities for the purpose of clinical diagnosis</u>  Procalcitonin	Detection of human procalcitonin using ELFA techniques by VIDAS 3 Immuno-analyser using SOP: MV19
Joint Fluids	Detection of crystals for diagnosis of gout and pseudo gout: <ul style="list-style-type: none"> <li>• Monosodium urate</li> <li>• Calcium pyrophosphate</li> </ul>	Polarised light microscopy SOP: MF25 – Joint fluid microscopy and culture



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HUMAN TISSUES AND FLUIDS as specified below:	<u>Molecular Examination activities for the purpose of clinical diagnosis</u>	In house documented procedures following PHE SMI's
MRSA Screens (Nasal swabs)	Detection of MRSA	Real-time PCR by the GeneXpert (Cepheid) analyser: SOP: MF59
Faeces	Detection of genes for C. difficile toxin b/binary toxin	Real-time PCR by the GeneXpert (Cepheid) analyser SOP: MF35
Nasal swabs	Detection of influenza A & B	SOP: MF138
	Detection of RSV	SOP: MF138
Faeces	Detection of Norovirus	SOP:MF144
Rectal Swabs	Detection of Carbapenemase encoding genes blaVIM, blaNDM, blaOXA, blaKPC and blaIMP	Xpert Carba-R assay SOP: MF143
Nasal, mid-turbinate, nasopharyngeal swabs (in viral transport media)	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences: E, N2	Real-time PCR by the GeneXpert (Cepheid) analyser and Xpert Xpress SARS-CoV-2 assay SOP: MF 147 and MF-59
Faeces	Detection of multiple target sites: <ul style="list-style-type: none"> <li>• Salmonella</li> <li>• Shigella</li> <li>• Campylobacter</li> <li>• C.difficile toxin A and B</li> <li>• Adenovirus</li> <li>• Norovirus</li> <li>• Rotavirus</li> </ul>	Qualitative multiplexed nucleic acid test by FilmArray (Bio Fire) GI panel using SOP: MF125
CSF	Detection of multiple target sites: <ul style="list-style-type: none"> <li>• Neisseria meningitidis</li> <li>• Streptococcus pneumoniae</li> <li>• Haemophilus influenza</li> <li>• Enterovirus</li> <li>• HSV1 and 2</li> <li>• Varicella Zoster</li> <li>• Human Parechovirus</li> </ul>	Qualitative multiplexed nucleic acid test by FilmArray (Bio Fire) ME panel using SOP: MF124
END		