


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8760</p> <p>Accredited to ISO 15189:2012</p>	<p>University Hospitals Birmingham NHS Foundation Trust</p> <p>Issue No: 014 Issue date: 13 September 2024</p>	
	<p>Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham B15 2WB</p>	<p>Contact: Catherine Swann E-Mail: catherine.swann@uhb.nhs.uk Website: www.uhb.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Laboratory locations:

Location details	Activity	Location code
<p>Address Microbiology Department Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham B15 2WB</p> <p>Local Contact Catherine Swann</p>	<p>Bacteriology Parasitology Mycology Serology Molecular Biology</p>	A
<p>Address Biochemistry Department Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham B15 2WB</p> <p>Local Contact: Catherine Swann</p>	<p>Automated examinations in support of bacteriology and serology</p>	B
<p>Address Department of Genito-Urinary Medicine Whittal Street Clinic Whittal Street Birmingham B4 6DH</p> <p>Local Contact: Catherine Swann</p>	<p>Bacteriology in support of a GUM Clinic</p>	C



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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
<p>HUMAN TISSUES AND FLUIDS</p> <p>Cellular and fluid material contained on swabs from eyes, ears and throat, skin, sites, wounds, burns, ulcers and abscesses</p> <p>Catheter tips, drainage fluids, bile and pus</p> <p>Tissues, biopsies, specimens from central nervous system</p> <p>Tissues from patients with blast or other traumatic injury</p> <p>Sinus aspirates and antral washouts</p> <p>Cellular fluid material contained on swabs from the Genito-urinary Tract .</p> <p>Tissue from endoprosthetic revision, vertebral discs and associated aspirates and swabs.</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual or automated Kiestra inoculation of selected culture media using in-house procedures:</p> <p>MAA_S036 Manual inoculation of culture media.</p> <p>MRS_S024 Routine General Bench Microbiology</p> <p>MRS_S025 Processing Specimens on the Priority Section</p> <p>MRS_S013 Genital specimens</p>	<p align="center">A</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Blood, fluids, aspirates, (pre-inoculated bottles)</p> <p>Transfused blood and blood products; stem cell and bone marrow concentrates.</p> <p>Cellular and fluid material contained on swabs</p> <p>Cellular and fluid material contained on rectal swabs, faecal specimens, wound swabs, sputum and urine specimens</p> <p>Faeces</p> <p>Sputum, pleural fluid, broncho-alveolar lavage</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Isolation and characterisation of microorganisms of clinical significance (cont'd)</p> <p>Screening for Methicillin-Resistant Staphylococcus aureus (MRSA)</p> <p>Screening for bacteria with carbapenem hydrolysing β lactamases (carbapenemases)</p> <p>Isolation and characterisation of enteric pathogens: Salmonella, Shigella, Campylobacter, E.coli O157 and Vibrio spp.</p> <p>Isolation and characterisation of microorganisms of clinical significance, (excluding <i>Mycobacterium tuberculosis</i>)</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs):</p> <p>MBC_S001 BacT/Alert Blood Cultures</p> <p>MBC_S003 Investigation of adverse reactions associated with transfusions of blood and blood products.</p> <p>Manual or automated Kiestra inoculation, incubation and imaging of chromogenic culture media as above and using: MAA_S042 The Kiestra system. MRS_S014 MRSA screening</p> <p>Manual or automated Kiestra inoculation of selected chromogenic culture media using in-house procedures: MAA_S050 Organism Screening</p> <p>Solid and enrichment culture: MET_S001 Enteric pathogens</p> <p>ML3_S001 Sputum, Pleural fluid, Broncho-alveolar lavages and associated specimens</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<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 (SMIs):	
Cellular and fluid material contained on swabs from the Genito-urinary tract.	Examination for the presence of Neisseria gonorrhoea, Trichomonas vaginalis, Candida and diagnosis of Bacterial vaginosis	Light microscopy, fluorescent microscopy, and culture: Acridine orange stain. MRS_S013 Genital Specimens MRS_S006 Bright Field and Fluorescence Microscopy (including Gram & Acridine Orange Staining)	A
Cerebro-spinal fluid (CSF). Ascitic fluid. Peritoneal dialysis fluid.	Isolation and characterisation of microorganisms of clinical significance by Gram's stain	Light Microscopy (Gram stain) and culture: MRS_S006 Bright Field and Fluorescence Microscopy (including Gram & Acridine Orange Staining) MRS_S025 Processing specimens on priority section	A
Synovial fluid and joint aspirates	Detection of crystals.	Polarising microscopy, light microscopy. MRS_S025 Processing specimens on the Priority section	A
Skin, hair, nails	General isolation and characterisation of fungi and yeasts of clinical significance	Light Microscopy (Calcofluor white stain) and culture: MMY_S001 Mycology	A
Faeces Sellotape slide Perianal swab Urine	Detection of ova, cysts and parasites (OCP)	Light microscopy (unstained and iodine stain), and/or Formol-ether faecal concentration: MET_S002 Parasitology	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<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 (SMIs):	
Bile Duodenal aspirates Jejunal aspirates	Examination for the presence of parasites (ova, cyst, trophozoites) of clinical significance:	Auramine phenol staining and incident-light fluorescence, Giemsa, Ziehl-Neelsen, iodine staining as appropriate: MET_S002 Parasitology	A
Slides prepared from cellular and fluid material contained on swabs from the Genito-urinary tract.	Examination for the presence of Neisseria gonorrhoeae, Yeasts, and diagnosis of Bacterial vaginosis	Using Ison Hay criteria, gram stain for purposes of sexual health screen: MGU_S003 Whittall Street Clinic	C
Slides prepared from cellular and fluid material contained on swabs from the Genito-urinary tract.	Examination for the presence of Trichomonas vaginalis.	Wet films for detection of TV for purposes of sexual health screen: MGU_S003 Whittall Street Clinic	C
Ascitic fluid, peritoneal dialysis fluid, CSF	Detection and quantification of white blood cells, red blood cells, epithelial cells and bacteria. Differential of white blood cells	Light microscopy: MRS_S025 Processing specimens on the Priority section. MRS_S006 The Gram stain and light microscopy Bright field and fluorescence microscopy (including gram & Acridine orange staining).	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<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 (SMIs)/ manufacturers instructions:	
Blood, fluids, aspirates	Isolation and characterisation of microorganisms of clinical significance	MBC_S001 BacT/Alert Blood Cultures	A
Urine	Detection and quantification of white blood cells, red blood cells, epithelial cells and bacteria. Isolation and characterisation of microorganisms of clinical significance	Differential cell count (flow cytometry) using UF-1000 (Sysmex). Culture and digital imaging using Kiestra Laboratory Automation. MUR_S001 Urines The Sysmex UF1000i Urine Analyser MUR_S003 Urine culture	A
Cultures isolated in-house from the samples listed above.	Identification of microorganisms of clinical significance.	Manual biochemical and/or automated methods: MAA_S008 Identification methods MAA_S025 Identification of anaerobes (& Actinomyces, Nocardia, propionibacteria and Eikenella) MBC_S001 BacT/Alert Blood Cultures MSN_S004 Vitek identification and susceptibility testing.	A
Cultures isolated in-house from the samples listed above.	Identification of bacteria and yeasts of clinical significance.	Matrix assisted laser desorption ionization: MSN_S006 The BioMerieux Vitek MS-Maldi-TOF instrument	A
Cultures isolated in-house from the samples listed above.	Antimicrobial susceptibility testing of clinically significant bacteria	Manual sensitivity testing: MSN_S003 Antibiotic susceptibility testing - EUCAST method. Automated sensitivity testing: MSN_S004 Vitek identification and susceptibility testing.	A
Neisseria gonorrhoea cultures isolated in-house from samples.	Antibiotic susceptibility testing of Neisseria gonorrhoea	Manual sensitivity testing: MSN_S007 Neisseria gonorrhoea susceptibility testing – EUCAST E-test methodology	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<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 (SMIs)/ manufacturers instructions:	
Faeces	Detection of Clostridium difficile GDH	MET_S006 Detection of Clostridium difficile GDH on DS2 using Meridian Premier C.difficile GDH EIA test	A
	Detection of Clostridium difficile toxin A & B	MET_S005 Detection of Clostridium difficile Toxin A & B on DS2 using Meridian Premier Toxin A & B EIA test.	
Serum	Serological detection of;	Dynex DS2 using enzyme immunoassay (EIA):	A
	HTLV I+II Ab	MVS_S042 HTLV ELISA on DS2	
	VZV IgG	MVS_S039 Varicella zoster ELISA on DS2	
	Measles IgG	MVS_S040 Measles ELISA on DS2	
Faeces	H.pylori stool antigen	Dynex DS2 analyser using enzyme immunoassay (EIA): MVS_S047 H.pylori Stool Antigen on the DS2 MVS_S036 Dynex (DS2) Instrument	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum</p>	<p><u>Serological examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Anti-HTLV I/II</p> <p>Hepatitis A IgG (Total) Antibody (HAVAb IgG)</p> <p>Hepatitis A IgM Antibody (HAVAb IgM)</p> <p>Hepatitis B Surface Antibody (HBsAb)</p> <p>Hepatitis B Surface Antigen (HBsAg)</p> <p>Hepatitis B Core Antibody Total (HBcTotal)</p> <p>Hepatitis B Core IgM Antibody (HBcIgM)</p> <p>Hepatitis B e Antibody (HBeAb)</p> <p>Hepatitis B e Antigen (HBeAg)</p> <p>Hepatitis C Antibody (anti-HCV)</p> <p>Human Immunodeficiency Virus I & II, (HIV) Antigen/Antibody Combo (Ab to types 1 & 2 and p24 antigen)</p> <p>Cytomegalovirus (CMV IgG)</p> <p>Syphilis TP (antibodies to Treponema pallidum)</p>	<p>In house documented procedures based on equipment manuals and CITS.S200 Abbott Alinity ci series Standard Operating Procedure and CITS.S073 Serology Standard Operating Procedure</p>	<p>B</p>



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Serum	Toxoplasma gondii (Tox IgG)	In house documented procedures based on equipment manuals and CITS.S200 Abbott Alinity ci series Standard Operating Procedure and CITS.S073 Serology Standard Operating Procedure:	B
Serum	Rubella (Rubella IgG)		B
Serum	Confirmatory testing for syphilis by detection of Treponema pallidum antibodies	Non-specific antibodies in blood samples (RPR). Indirect particle agglutination assay (TPPA) for the detection and titration of treponemal antibodies: MVS_S029 Axis-Shield Rapid Plasma Reagin (RPR) test. MVS_S030 SERODIA-TP-PA test	A
Serum, plasma, CSF	Qualitative or semi-quantitative detection of capsular polysaccharide antigens of Cryptococcus species complex	Immy Latex-Cryptococcus Antigen Test: MVS_S048 Immy Lateral Flow Cryptococcal Antigen Assay	A
Serum	Confirmatory testing for: HIV (inc P24) Ab/Ag HBsAg	VIDAS (Biomerieux) using enzyme linked fluorescent assay (ELFA): MVS_S045 Processing blood samples on the VIDAS analyser	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis:</u>	In-house documented procedures with reference to manufacturers' instructions:	
Urine	Detection of Legionella pneumophila serotype 1 antigen	BinaxNow (Alere) Antigen Card, a rapid assay for the qualitative detection of legionella pneumophila serogroup 1 antigen: MVS_S028 BinaxNOW Legionella urinary antigen test.	A
Plasma	Viral Load Molecular monitoring – HIV, Hepatitis B, Hepatitis C and CMV	Abbott m2000 using real-time PCR amplification: MMO_S001 Abbott m2000sp analyser MMO_S002 Abbott m2000rt instrument	A
Whole Blood	Viral Load Molecular monitoring - EBV	Abbott m2000 using real-time PCR amplification: MMO_S001 Abbott m2000sp analyser MMO_S002 Abbott m2000rt instrument	A
Genital and non-genital Aptima liquid swabs. Urine	Molecular detection of <i>C. trachomatis</i> , <i>N. gonorrhoea</i> and <i>T. vaginalis</i> RNA	GenProbe Panther (Hologic) using nucleic acid amplification: MMO_S004 GenProbe Panther analyser	A
Sputum	Molecular detection of FluA, FluB and RSV RNA	Nucleic acid amplification using GeneXpert (Cepheid) ML3_S009 Cepheid GeneXpert	A
Faeces	Molecular detection of Clostridium difficile DNA	Nucleic acid amplification using GeneXpert (Cepheid). ML3_S009 Cepheid GeneXpert	A
Faeces	Molecular detection of Norovirus RNA	Nucleic acid amplification using GeneXpert (Cepheid) ML3_S009 Cepheid GeneXpert	A
Nose swab in VTM, throat and nose swab in VTM, Sputum, Bronchoalveolar lavage	Detection of SARS-CoV-2 RNA (Covid-19). Specifically, E and N2 gene targets	Nucleic acid amplification using GeneXpert (Cepheid) and Xpert Xpress SARS-CoV-2 cartridge ML3_S009 Cepheid GeneXpert	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Bacterial isolates from samples.</p> <p>Nose and Throat Swabs in Virus Transport Media</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis:</u></p> <p>Detection of bacteria with carbapenem hydrolysing β lactamases (carbapenemases)</p> <p>Detection/Identification of respiratory viruses and bacteria: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, SARS-CoV-2, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, <i>Bordatella pertussis</i>, <i>Bordatella pertussis</i>, <i>Chlamydia pneumoniae</i>, <i>Mycoplasma pneumoniae</i></p>	<p>In-house documented procedures with reference to manufacturers' instructions:</p> <p>Nucleic acid amplification using GeneXpert (Cepheid) and Xpert CARBA-R cartridge: MAA_S050 Organism Screening ML3_S009 Cepheid GeneXpert</p> <p>Nucleic acid amplification and detection using the BioFire FilmArray RT-PCR methodology and Respiratory 2.1 and 2.1+ Panels MAA_S058 BioFire FilmArray</p>	<p>A</p> <p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd) CSF Fluid	Molecular examination activities for the purpose of clinical diagnosis: Detection/Identification of bacteria, viruses and yeast: <i>Haemophilus influenzae</i> , <i>Listeria monocytogenes</i> , <i>Neisseria meningitides</i> , <i>Streptococcus agalctiae</i> , <i>Streptococcus pneumoniae</i> , Cytomegalovirus, Human herpesvirus 6, Human parechovirus, Varicella zoster virus, Enterovirus, Herpes simplex virus 1, Herpes simplex virus 2, <i>Cryptococcus neoformans/gattii</i>	In-house documented procedures with reference to manufacturers' instructions: Nucleic acid amplification and detection using the BioFire FilmArray RT-PCR methodology and Meningitis/Encephalitis (ME) Panel MAA_S058 BioFire FilmArray	A
END			