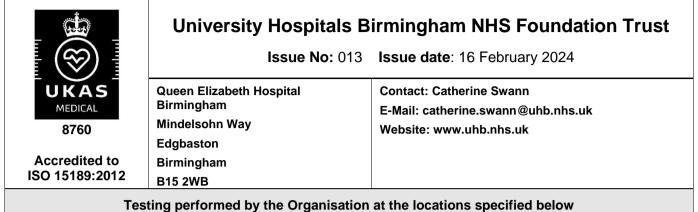
Schedule of Accreditation

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United Kingdom Accreditation Service

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



Laboratory locations:

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



ISO 15189:2012

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University Hospitals Birmingham NHS Foundation Trust

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Testing performed by the Organisation at the locations specified

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

DETAIL OF ACCREDITATION



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



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological</u> <u>examination activities for</u> <u>the purpose of clinical</u> <u>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</u> <u>examination activities for</u> <u>the purpose of clinical</u> <u>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, tropozoites) of clinical significance:	Auramine phenol staining and incident-light fluorescence, Giemsa, Ziehl-Neelsen, iodine staining as appropriate: MET_S002 Parasitology	А
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	С
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	С
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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Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd):	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 micro- organisms 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, proprionibacteria 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</u> <u>examination activities for</u> <u>the purpose of clinical</u> <u>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
		MVS_S036 Dynex DS2 instrument	
	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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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis (cont'd):	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	
Serum	Anti-HTLV I/II		В
	Hepatitis A IgG (Total) Antibody (HAVAb IgG)		
	Hepatitis A IgM Antibody (HAVAb IgM)		
	Hepatitis B Surface Antibody (HBsAb)		
	Hepatitis B Surface Antigen (HBsAg)		
	Hepatitis B Core Antibody Total (HBcTotal)		
	Hepatitis B Core IgM Antibody (HBcIgM)		
	Hepatitis B e Antibody (HBeAb)		
	Hepatitis B e Antigen (HBeAg)		
	Hepatitis C Antibody (anti-HCV)		
	Human Immunodeficiency Virus I & II, (HIV) Antigen/Antibody Combo (Ab to types 1 & 2 and p24 antigen)		
	Cytomegalovirus (CMV IgG)		
	Syphilis TP (antibodies to Treponema pallidum)		



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HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis (cont'd):	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)/ manufacturers instructions:	
Serum		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:	
	Toxoplasma gondii (Tox IgG)		В
	Rubella (Rubella IgG)		В
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	Qualititative 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)	Molecular examination activities for the purpose of clinical diagnosis:	In-house documented procedures with reference to manufacturers' instructions:	
Urine	Detection of Legionella pneumophilia 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	A
		ML3_S009 Cepheid GeneXpert	

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis:	In-house documented procedures with reference to manufacturers' instructions:	
Bacterial isolates from samples.	Detection of bacteria with carbapenem hydrolysing β lactamases (carbapenemases)	Nucleic acid amplification using GeneXpert (Cepheid) and Xpert CARBA-R cartridge: MAA_S050 Organism Screening ML3_S009 Cepheid GeneXpert	A
		END	1