Schedule of Accreditation

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United Kingdom Accreditation Service

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Accredited to ISO 15189:2022

University Hospitals Birmingham NHS Foundation Trust

Issue No: 019 **Issue date:** 10 September 2026

Queen Elizabeth Hospital Birmingham **Mindelsohn Way** **Edgbaston** **Birmingham** **B15 2WB**	**Contact: Catherine Swann** **E-Mail: catherine.swann@uhb.nhs.uk** **Website: www.uhb.nhs.uk**

Testing performed by the Organisation at the locations specified below

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	B
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	C

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS Cellular and fluid material contained on swabs from eyes, ears and throat, skin, sites, wounds, burns, ulcers and abscesses Catheter tips, drainage fluids, pleural fluids, bile and pus Tissues, biopsies, specimens from central nervous system Tissue from endoprosthetic revision, vertebral discs and associated aspirates and swabs. Tissues from patients with blast or other traumatic injury Sinus aspirates and antral washouts Cellular fluid material contained on swabs from the Genito-urinary Tract	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> Isolation and characterisation of microorganisms of clinical significance	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) Manual inoculation of selected culture media using in-house procedures: MIC.S005 Manual inoculation of culture media. MIC.S008 Routine General Bench Microbiology MIC.S013Processing Specimens on the Priority Section MIC.S010 Genital specimens	A

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) Transfused blood and blood products; stem cell and bone marrow concentrates.	Isolation and characterisation of microorganisms of clinical significance (cont'd)	MIC.S029 BacT/Alert 3D Blood Cultures MIC.S030 Investigation of adverse reactions associated with transfusions of blood and blood products.	A
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant Staphylococcus aureus (MRSA)	Manual inoculation, incubation and imaging of chromogenic culture media as above and using: MIC.S009 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 inoculation of selected chromogenic culture media using in-house procedures: MIC.S028 Organism Screening	A
Faeces	Isolation and characterisation of enteric pathogens: Salmonella, Shigella, Campylobacter, E.coli O157 and Vibrio spp.	Solid and enrichment culture: MIC.S021 Enteric pathogens	A
Sputum,, broncho-alveolar lavage	Isolation and characterisation of micro-organisms of clinical significance, (excluding *Mycobacterium tuberculosis*)	MIC.S027 Sputum, Broncho-alveolar lavages and associated specimens	A

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):	
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: MIC.S010Genital Specimens MIC.S011 Bright Field and Fluorescence Microscopy (including Gram Stain)	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: MIC.S011 Bright Field and Fluorescence Microscopy (including Gram Stain) MIC.S013 Processing specimens on priority section	A
Synovial fluid and joint aspirates	Detection of crystals.	Polarising microscopy, light microscopy. MIC.S011, MIC.S013 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: MIC.S012 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: MIC.S022 Parasitology	A
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: MIC.S022 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: MIC.S026 Whittall Street Clinic	C

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):	
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: MIC.S026 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: MIC.S013 Processing specimens on the Priority section. MIC.S011 The Gram stain and light microscopy Bright field and fluorescence microscopy (including gram stain).	A
Blood, fluids, aspirates	Isolation and characterisation of microorganisms of clinical significance	MIC.S029 BacT/Alert 3D 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-5000 (Sysmex). MIC.S019 Urines The Sysmex UF5000Urine Analyser MIC.S020 Urine culture	A
Cultures isolated in-house from the samples listed above.	Identification of microorganisms of clinical significance.	Manual biochemical and/or automated methods: MIC.S006 Identification methods MIC.S029 BacT/Alert 3D Blood Cultures MIC.S015 Vitek 2 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: MIC.S016 The BioMerieux Vitek MS-Maldi-TOF instrument	A

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)/ manufacturers instructions:	
Cultures isolated in-house from the samples listed above.	Antimicrobial susceptibility testing of clinically significant bacteria	Manual sensitivity testing: MIC.S014 Antibiotic susceptibility testing - EUCAST disc diffusion method. Automated sensitivity testing: MIC.S015Vitek identification and susceptibility testing.	A
Neisseria gonorrhoea cultures isolated in-house from samples.	Antibiotic susceptibility testing of Neisseria gonorrhoea	Manual sensitivity testing: MIC.S017 Neisseria gonorrhoea susceptibility testing – EUCAST E-test methodology	A
Faeces	Detection of Clostridium difficile GDH Detection of Clostridium difficile toxin A & B	MIC.S023Detection of Clostridium difficile	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Serological examination activities for the purpose of clinical diagnosis	In house documented procedures based on equipment manuals	
Serum	Serological detection of:	Dynex DS2 using enzyme immunoassay (EIA): MIC.S077 Dynex DS2 instrument	A
	VZV IgG	MIC.S078 Varicella zoster virus IgG on Dynex DS2 using EIA	A
	Measles IgG	MIC.S079 Measles ELISA on DS2	
Faeces	H.pylori stool antigen	Dynex DS2 analyser using enzyme immunoassay (EIA): MIC.S083 H.pylori Stool Antigen on the DS2 MIC.S077 Dynex (DS2) Instrument	A
Serum	Anti-HTLV I/II	CITS.S200 Abbott Alinity ci series Standard Operating Procedure and CITS.S073 Serology Standard Operating Procedure	B
	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)		
Serum	EBV EBNA IgG, VCA IgG & VCA IgM	Abbott Alinity I CITS.S200 v3.5 CITS.S201 v1.8	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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 (cont'd)	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) Toxoplasma gondii (Tox IgG) Rubella (Rubella IgG)		B
Serum	Confirmatory testing for syphilis by detection of Treponema pallidum antibodies	RPR - Qualitative & Semi-Quantitative non-treponemal flocculation test for the detection of reagin antibodies: MIC.S073 ASI Rapid Plasma Reagin (RPR) Test. TPHA - Qualitative & Semi-Quantitative for the presence of IgG & IgM: MIC.S074 ASI TPHA Test.	A
Serum	HIV-1 & 2 typing	BioRad Geenius MIC.S082	A
Serum, plasma, CSF	Qualitative or semi-quantitative detection of capsular polysaccharide antigens of Cryptococcus species complex	Immy Latex-Cryptococcus Antigen Test: MIC.S084 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): MIC.S081 VIDAS 3 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: MIC.S072 BinaxNOW Legionella urinary antigen test.	A
Genital and non-genital Aptima liquid swabs. Urine	Molecular detection of *C. trachomatis,* *N. gonorrhoea* and *T. vaginalis* RNA	Panther (Hologic) using nucleic acid amplification: MIC.S068 Hologic Panther/ Panther fusion analyser	A
	Detection / Identification of M. Genitalium RNA		A
Nose & Throat swabs in virus transport media	Detection / Identification of respiratory virus & bacteria - SARS-CoV-2, Influenza A, Influenza B, Respiratory syncytial virus, Adenovirus, Human metapneumovirus, Rhinovirus, Parainfluenza 1, 2, 3 & 4	Panther Fusion using nucleic acid amplification: MIC.S068 Hologic Panther/ Panther fusion analyser	A
Nose and throat swab in VTM, Sputum, Bronchoalveolar lavage, Endotracheal aspirate (ETA), Nasopharyngeal aspirate (NPA)	Molecular detection of SARS-CoV-2, FluA, FluB and RSV RNA	Nucleic acid amplification using GeneXpert (Cepheid) - Cepheid Xpert Xpress CoV-2/Flu/RSV plus kit MIC.S064 Cepheid GeneXpert assays	A
Faeces	Molecular detection of Clostridium difficile DNA	Nucleic acid amplification using GeneXpert (Cepheid). MIC.S064 Cepheid GeneXpert assays	A
Faeces	Molecular detection of Norovirus RNA	Nucleic acid amplification using GeneXpert (Cepheid) MIC.S064 Cepheid GeneXpert assays	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures with reference to manufacturers' instructions:	
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 MIC.S064 Cepheid GeneXpert assays	A
Bacterial isolates from samples.	Detection of bacteria with carbapenem hydrolysing β lactamases (carbapenemases)	Nucleic acid amplification using GeneXpert (Cepheid) and Xpert CARBA-R cartridge: MIC.S028 Organism Screening MIC.S064 Cepheid GeneXpert assays	A
Nose and Throat Swabs in Virus Transport Media	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 Syncitial Virus, *Bordatella papertussis, Bordatella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae*	Nucleic acid amplification and detection using the BioFire FilmArray RT-PCR methodology and Respiratory 2.1 and 2.1+ Panels MIC.S032 BioFire FilmArray	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis: (cont'd)	In-house documented procedures with reference to manufacturers' instructions:	
CSF Fluid	Detection/Identification of bacteria, viruses and yeast: *Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitides, Streptococcus agalctiae, Streptococcus pneumoniae,* Cytomegalovirus, Human herpesvirus 6, Human parechovirus, Varicella zoster virus, Enterovirus, Herpes simplex virus 1, Herpes simplex virus 2, *Crytococcus neoformans/gattii*	Nucleic acid amplification and detection using the BioFire FilmArray RT-PCR methodology and Meningitis/Encephalitis (ME) PanelMIC.S032 BioFire FilmArray	A
Plasma	HIV	Real-Time PCR using Abbott Alinity m for viral load assays - MIC.SOP.S069 Alinity m HIV Amp Kit	A
Serum, Plasma	HBV	Alinity m HBV Amp Kit	A
Serum, Plasma	HCV	Alinity m HCV Amp Kit	A
Plasma	EBV	Alinity m EBV Amp Kit	A
Plasma	CMV	Alinity m CMV Amp Kit	A

END