

# Schedule of Accreditation

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## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 10196</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Manchester University NHS Foundation Trust</b></p> <p>Issue No: 007 Issue date: 21 February 2025</p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY FLUIDS AND TISSUES</b></p> <p>Genital, oral and wound swabs, and respiratory samples</p> <p>Cultures of mould from in-house culture and referred cultures</p>	<p><u>Mycology examinations for the purposes of clinical diagnosis</u></p> <p>Isolation and characterisation of yeasts and moulds of clinical significance</p> <p>Identification of moulds of clinical significance</p> <p>Antimicrobial susceptibility testing of moulds</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Manual inoculation and media culture using MRCM-PR-EX19 Fungal Culture</p> <p>Phenotypic assessment based on microscopic and gross morphology using MRCM-PR-EX4 Czapek Dox ID Test and MRCM-PR-EX9 Lactophenol Cotton Blue Mount</p> <p>Minimum inhibitory concentration and minimum effective concentration using microdilution plate methodology, using EUCAST guidelines and MRCM-PR-EX17 Mould Susceptibility Testing</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)  Cultures of yeast from in-house culture and referred cultures	<u>Mycology examinations for the purposes of clinical diagnosis</u> (cont'd)  Identification of yeasts of clinical significance	In-house documented procedures based on equipment manuals as relevant  Phenotypic assessment based on microscopic and gross morphology. Identification using biochemical tests, Matrix assisted laser desorption ionisation time of flight (MALDI – TOF) Mass Spectrometry and the following procedures;  MRCM-PR-EX34 Yeast Identification by Bruker MALDI-TOF MRCM-PR-EX11 Wet Preparation MRCM-PR-EX6 Germ Tube Test MRCM-PR-EX3 APIWEBMRCM-PR-EX7 API ID 32C MRCM-PR-EX4 Czapek DoxID MRCM-PR-EX8 India Ink Mount MRCM-PR-EX10 Nitrate Test
Cultures of yeast from in-house culture and referred cultures	Antimicrobial susceptibility testing of yeasts	Minimum inhibitory concentration using microdilution plate methodology, using EUCAST guidelines, and disc diffusion tests and MRCM-PR-EX2 Flucytosine Disc Sensitivity Test for Yeasts and MRCM-PR-EX16 Yeast Susceptibility Testing
Serum, bronchial alveolar lavage fluid	Detection of <i>Aspergillus</i> galactomannan antigen	Manual ELISA using Bio-Rad Platelia <i>Aspergillus</i> kit, MRCM-PR-EX13 Platelia™ <i>Aspergillus</i> Ag Galactomannan ELISA
CSF, serum	Detection of cryptococcal antigen	IMMYCryptococcal antigen lateral flow assay kit MRCM-PR-EX26 Detection of Cryptococcus species complex using cryptococcal antigen lateral flow assay



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Mycology examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant
Serum	Detection of fungal (1-3)-B-D glucan	Manual colorimetric assay using MRCM-PR-EX15 Fungitell® Assay-Serum Test for (1-3)-B-D-Glucan
Serum	Quantitative antifungal assay for therapeutic drug monitoring: Flucytosine	In-house bioassay method using MRCM-PR-EX1 Flucytosine Antifungal Drug Level
Hair, skin and nails	Isolation and characterisation of yeasts and moulds of clinical significance	Investigation of superficial mycology specimens by microscopy for fungal elements and fungal culture, using MRCM-PR-EX21 Investigation of Superficial Mycology Specimens (Hair, Skin and Nails)
Respiratory samples	Molecular detection of <i>Aspergillus</i> spp. genomic DNA which includes <i>Aspergillus fumigatus</i> , <i>A. flavus</i> , <i>A. niger</i> , <i>A. terreus</i> , <i>A. nidulans</i> , <i>A. versicolor</i> , and <i>A. glaucus</i>	Extraction, amplification and purification of fungal DNA by quantitative PCR using MRCM-PR-EX28 Automated DNA extraction and <i>Aspergillus</i> species quantification using the InGenius System, which describes the procedure for automated DNA extraction and quantitative PCR using the ELITech InGenius system and the ELITech <i>Aspergillus</i> species ELITe MGB® Kit
Fungal culture isolates – primary samples and as produced by methods above	Production of extracted, amplified and purified DNA for the purposes of subsequent identification by Sanger Sequencing by External source and Pyrosequencing (if applicable)	Extraction, amplification and purification of fungal DNA using MRCM-PR-EX41 -Identification of fungal species and triazole resistance by Sanger sequencing (AllTaq) and the following: DNA extraction PCR using Eurofins Genomics primers, Qiagen AllTaq PCR kit and endpoint Thermal Cycler. Purification of DNA using agarose gel electrophoresis and Qiagen QIAquick PCR purification kit Quantification of DNA using Nanodrop spectrophotometer



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Fungal culture isolates – primary samples and as produced by methods above</p> <p>DNA Sanger sequence supplied by Eurofins Genomics or Source Bioscience</p>	<p><u>Mycology examinations for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Production of extracted, amplified and purified DNA for the purposes of subsequent identification of triazole resistance in <i>Aspergillus fumigatus</i>, <i>Aspergillus niger</i> and <i>Aspergillus flavus</i> by Sanger Sequencing by External source and Pyrosequencing (if applicable)</p> <p>DNA sequence identification of yeasts and moulds. DNA sequence analysis to detect triazole resistance in <i>Aspergillus fumigatus</i>, <i>Aspergillus niger</i> and <i>Aspergillus flavus</i> by detection of DNA polymorphisms within the cyp51A gene</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Extraction, amplification and purification of fungal DNA using MCRM-PR-EX41 Identification of fungal species and triazole resistance by Sanger sequencing (AllTaq) and the following: DNA extraction PCR using Eurofins Genomics primers, Qiagen AllTaq PCR kit and endpoint Thermal Cycler. Purification of DNA using agarose gel electrophoresis and Qiagen QIAquick PCR purification kit Quantification of DNA using Nanodrop spectrophotometer</p> <p>Analysis of DNA sequences and final identification of fungal species using publicly available sequence databases (including but not limited to NCBI, Westerdijk Institute and ISHAM Barcoding databases), using MCRM-PR-EX41 Identification of fungal species and triazole resistance by Sanger sequencing (AllTaq). Analysis of DNA sequences for determination of cyp51-based <i>Aspergillus fumigatus</i> azole resistance using reference strain comparison and MRCM-PR-EX41 Identification of fungal species and triazole resistance by Sanger sequencing (AllTaq).</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Fungal cultures and extracted DNA (potentially from sputum, bronchoalveolar lavage and bronchial washing) using the methods above</p>	<p>Mycology examinations for the purposes of clinical diagnosis (cont'd)</p> <p>Detection of triazole resistance in <i>Aspergillus fumigatus</i> using identification of DNA polymorphisms in gene cyp51A</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Pyrosequencing using Qiagen PyroMark Q24 Advanced instrument followed by molecular analysis using PyroMark Design Software.</p> <p>MRCM-PR-EX25 Detection of antifungal resistance in <i>Aspergillus fumigatus</i> by pyrosequencing,</p> <p>MRCMPR-EQ36 PyroMark Q24 Instrument - Equipment SOP,</p> <p>MRCM-PR-EQ37 PyroMark Vacuum workstation - Equipment SOP.</p> <p>MRCM-PR-EQ38 Use of PyroMark Design Software</p>
<p>END</p>		