

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 10196</p> <p>Accredited to ISO 15189:2012</p>	<p>Manchester University NHS Foundation Trust</p> <p>Issue No: 006 Issue date: 10 May 2024</p>	
	<p>Mycology Reference Centre Manchester</p> <p>Education and Research Centre Wythenshawe Hospital Manchester M23 9LT United Kingdom</p>	<p>Contact: Dr Caroline Moore</p> <p>Tel: +44 (0) 161 291 2124</p> <p>E-Mail: caroline.moore@mft.nhs.uk</p> <p>Website: www.mrcm.org.uk</p> <p>www. https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/mycology/</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 BODY FLUIDS AND TISSUES</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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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cultures of yeast from in-house culture and referred cultures</p> <p>Cultures of yeast from in-house culture and referred cultures</p> <p>Serum, bronchial alveolar lavage fluid</p> <p>CSF, serum</p>	<p><u>Mycology examinations for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Identification of yeasts of clinical significance</p> <p>Antimicrobial susceptibility testing of yeasts</p> <p>Detection of <i>Aspergillus</i> galactomannan antigen</p> <p>Detection of cryptococcal antigen</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>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;</p> <p>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 MRCM-PR-EX18 <i>C. dubliniensis</i> Identification test MRCM-PR-EX20 ChromAgar</p> <p>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</p> <p>Manual ELISA using Bio-Rad Platelia <i>Aspergillus</i> kit, MRCM-PR-EX13 Platelia™ <i>Aspergillus</i> Ag Galactomannan ELISA</p> <p>IMMYCryptococcal antigen lateral flow assay kit MRCM-PR-EX26 Detection of <i>Cryptococcus</i> species complex using cryptococcal antigen lateral flow assay</p>



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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 colourimetric 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 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 Pyrosequencing (if applicable) and Sanger Sequencing by External source'	Extraction, amplification and purification of fungal DNA using MCRM-PR-EX22 -Identification of fungal species and triazole resistance by Sanger sequencing and the following: DNA extraction PCR using Eurofins Genomics primers, Qiagen HotStar Plus Taq DNA 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>DNA Sanger sequence supplied by Eurofins Genomics</p> <p>Fungal cultures and extracted DNA (potentially from sputum, bronchoalveolar lavage and bronchial washing) using the methods above</p>	<p><u>Mycology examinations for the purposes of clinical diagnosis</u> (cont'd)</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>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>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 ITS databases, using MCRM-PR-EX22 Identification of fungal species and triazole resistance by Sanger sequencing. Analysis of DNA sequences using reference strain comparison and MRCM-PR-EX22</p> <p>Pyrosequencing using Qiagen PyroMark Q24 PCR instrument followed by molecular analysis using Pyromark Design Software. MRCM-PR-EX25 Detection of antifungal resistance in <i>Aspergillus fumigatus</i> by pyrosequencing, MRCMPR-EQ36 PyroMark Q24 Instrument - Equipment SOP, MRCM-PR-EQ37 PyroMark Vacuum workstation - Equipment SOP. MRCM-PR-EQ38 Use of PyroMark Design Software</p>
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