

Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Manchester University NHS Foundation Trust	
	Issue No: 002 Issue date: 20 August 2019	
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Testing performed at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	Mycology examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant
Genital, oral and wound swabs, and respiratory samples	Isolation and characterisation of yeasts and moulds of clinical significance	Manual inoculation and media culture using MRCM-PROC139 Fungal Culture
Cultures of mould from in-house culture and referred cultures	Identification of moulds of clinical significance	Phenotypic assessment based on microscopic and gross morphology using MRCM-PROC26 Czapek Dox ID Test and MRCM-PROC49 Lactophenol Cotton Blue Mount
	Antimicrobial susceptibility testing of moulds	Minimum inhibitory concentration and minimum effective concentration using microdilution plate methodology, using EUCAST guidelines and MRCM-PROC136 Mould Susceptibility Testing
Cultures of yeast from in-house culture and referred cultures	Identification of yeasts of clinical significance	Phenotypic assessment based on microscopic and gross morphology. Identification using biochemical tests and the following procedures: MRCM-PROC17 Wet Preparation MRCM-PROC41 Germ Tube Test MRCM-PROC9 APIWEBMRCM-PROC44 API ID 32C MRCM-PROC26 Czapek Dox ID MRCM-PROC46 India Ink Mount MRCM-PROC54 Nitrate Test MRCM-PROC137 C. dubliniensis Identification test (using ELITex Bicolor Kit) MRCM-PROC156 ChromAgar Candida



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HUMAN BODY FLUIDS AND TISSUES (CONT'D)	Mycology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant
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-PROC2 Flucytosine Disc Sensitivity Test for Yeasts and MRCM-PROC134 Yeast Susceptibility Testing
Serum, bronchial alveolar lavage fluid	Detection of <i>Aspergillus</i> galactomannan antigen	Manual ELISA using Multiscan FC plate reader and Bio-Rad Platelia <i>Aspergillus</i> kit, MRCM-PROC109 Platelia™ <i>Aspergillus</i> Ag Galactomannan ELISA
CSF, serum	Detection of cryptococcal antigen	IMMY latex agglutination kit and MRCM-PROC28 Latex-Cryptococcus Antigen Detection
Serum	Detection of fungal (1-3)-B-D glucan	Manual colourimetric assay using Bio-Tek Instruments ELx809 Ultra Microplate Reader and MRCM-PROC118 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-PROC1 Flucytosine Antifungal Drug Level
Hair, skin and nails	Isolation and characterisation of yeasts and moulds of clinical significance (primarily dermatophytes)	Investigation of superficial mycology specimens by microscopy for fungal elements and fungal culture, using MRCM-PROC157 Investigation of Superficial Mycology Specimens (Hair, Skin and Nails)



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<p>HUMAN BODY FLUIDS AND TISSUES (CONT'D)</p> <p>Respiratory samples</p> <p>Fungal culture isolates – primary samples and as produced by methods above</p> <p>DNA Sanger sequence supplied by Eurofins Genomics</p>	<p>Mycology examinations for the purposes of clinical diagnosis (cont'd)</p> <p>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></p> <p>Production of extracted, amplified and purified DNA for the purposes of subsequent Pyrosequencing (if applicable) and Sanger Sequencing by External source'</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>PCR using MRCM-PROC159 Automated Nucleic Acid Extraction from Respiratory Specimens, MRCM-PROC160 Quantification of <i>Aspergillus</i> Species by Quantitative PCR and the following: Pre-extraction using ELITech pre-lysis kit Automated DNA extraction using ELITech Star and ELITech ELITe STAR 200 extraction kit Quantitative PCR using ABI 7500 Fast DX thermal cycler and ELITech <i>Aspergillus</i> Species ELITe MGB kit</p> <p>Extraction, amplification and purification of fungal DNA using MCRM-PROC158-Identification of fungal species and triazole resistance by Sanger sequencing and the following: DNA extraction using Thermo Fisher UltraPrepMan PCR using Eurofins Genomics primers, Qiagen HotStar Plus Taq DNA kit and Hain 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 NCBI, Westerdijk Institute and ISHAM ITS databases, using MCRM-PROC158 Identification of fungal species and triazole resistance by Sanger sequencing. Analysis of DNA sequences using reference strain comparison and MRCM-PROC158</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 <i>cyp51A</i></p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Pyrosequencing using Qiagen PyroMark Q24 PCR instrument followed by molecular analysis using Pyromark Design Software. MRCM-PROC176 Detection of antifungal resistance in <i>Aspergillus fumigatus</i> by pyrosequencing, MRCM-PROC178 PyroMark Q24 Instrument - Equipment SOP, MRCM-PROC179 PyroMark Vacuum workstation - Equipment SOP. MRCM-PROC180 Use of PyroMark Design Software</p>
<p>END</p>		