



Laboratory Handbook

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5 North Court, The Courtyard, Woodlands, Bradley Stoke,
BS32 4NQ

Revision History

Date	Previous Revision	New Revision	Sections	Details
Jun 2023	N/A	1.0	All	Document creation and publication
Jan 2024	1.0	1.1	Sections 10 and 14	Acceptability criteria and records retention updated

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1. Purpose

This laboratory handbook provides our users and employees with details on the activities we undertake, the processes we perform to ensure a fair, unbiased, and quality continued service, how to make the best use of our services and to outline the best ways to contact us.

2. Introduction

Zoma Fungal Diagnostics Ltd has been trading since 2023 and was founded by scientists with over 20 years' frontline experience of working in diagnostic clinical microbiology, specialising in mycology. We offer expert training, diagnostic testing and fungal identification for microbiology laboratories and their staff. Our goal is to provide a specialist service to help microbiologists achieve best practice and excellent standards in mycological investigations.

Zoma Fungal Diagnostics Ltd is committed to providing expert education in the expanding, yet widely neglected, speciality of mycology for all healthcare providers. We aim to achieve this by offering an innovative, balanced, and inspiring range of support to ultimately improve outcomes for patients. We can provide the assurance of expertise and specialist knowledge which many microbiology laboratories are unable to provide within this discipline.

Our core services include:

- Teaching and training of scientific and medical staff. This includes on-site practical examination of fungal cultures, best practice for fungal diagnostics and bespoke training at source to suit the needs of your laboratory.
- Diagnosis of fungal infection in skin, hair and nail samples including processing, fluorescence microscopy, culture, and identification.

3. Contacts

Our team is always happy to help with information of advice.

Name	Job Title	HCPC registration	Email address
Dr Mark Fraser BSc MSc PhD	Director and Clinical Scientist	CS17526	mark.fraser@zomafungal.com

General Enquires info@zomafungal.com

Where to find us

The laboratory is located at 5 North Court, The Courtyard, Woodlands, Bradley Stoke, BS32 4NQ.

We are conveniently located off junction 16 on the M5 at the Almondsbury interchange. There are two dedicated parking spaces on site (these will require prior notification for booking) and a limited number of visitor spaces.

The nearest train station is Bristol Parkway, which is a 15-minute taxi ride away, or a 25-minute bus journey (Number 73 Citylines operated by First Bristol, Bath and West, every 30 minutes, required stop is Foxfield Avenue).



Opening Times

Monday – Thursday 08:00 – 16:00

Friday – Sunday Closed

Other contact details

Telephone number: 0117 462 1485

Email: info@zomafungal.com

Website: www.zomafungal.com

4. Quality Commitments

Zoma Fungal Diagnostics Ltd is working under ISO 15189 standards pending UKAS accreditation. We are fully committed to provide a consistent, quality service and have an excellent quality management system in place to ensure standards are met throughout the whole of our service. We participate in EQA evaluation schemes and operate IQA regularly for all the key services we provide. Further information is outlined in our Quality Statement and Manual (ZOMA.POL2) Quality Statement:

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<https://zomafungal.sharepoint.com/sites/ZomaFungalDiagnosticsLtd-Setup/Shared%20Documents/General/Document%20Management/Laboratory%20Documents/Policies/ZOMA.POL02%20Quality%20Statement.pdf>

and ZOMA.POL3 Quality Manual:

<https://zomafungal.sharepoint.com/sites/ZomaFungalDiagnosticsLtd-Setup/Shared%20Documents/General/Document%20Management/Laboratory%20Documents/Policies/ZOMA.POL03%20Quality%20Manual.pdf>

However, the core parameters include:

- The operation of a holistic quality management system encompassing organisation, procedures, processes, and resources whilst working to provide continuous service improvement through evaluation and review.
- Provide quality objectives as based on key performance indicators to implement the quality policy with the use of a defined document management system and a dedicated quality manager.
- Undertake periodic review of the laboratory quality management system and processes with the implementation of action plans as necessary for improvement.
- A commitment to health and safety throughout the team as outlined in our health and safety policy (ZOMA.POL01) Health and Safety:
 - <https://zomafungal.sharepoint.com/sites/ZomaFungalDiagnosticsLtd-Setup/Shared%20Documents/General/Document%20Management/Laboratory%20Documents/Policies/ZOMA.POL01%20Health%20and%20Safety.pdf>.
- Comply with all relevant environmental legislation.
- Undertake full and accountable selection of suppliers with best practice under procurement guidelines for sustainability, environmental and suitability criteria.

5. Workforce

Zoma Fungal Diagnostics Ltd work hard to maintain a dedicated, committed, engaged, professional and supported workforce in order to provide the highest level of service to our users. Through prescribed recruitment, induction, and continuous training our employees are encouraged to take responsibility for the work that they perform in line with the quality policy, the health and safety policy and good working practices.

We aim to support all our employees equally and inclusively and we strive to provide an open and honest working environment where our employees are free to be themselves.

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Further details are outlined in our Equality and Diversity policy (ZOMA.POL04 Equality and Diversity) which can be supplied upon request.

Competency assessments and regular appraisals are used to ensure the continual development and enhancement of our employee's needs. Our workforce is motivated by an open and honest workplace environment, where they are encouraged to provide input into the continual improvement of the services we provide.

6. Assessment and Monitoring

Quality and competency are continually monitored against the output of the laboratory. Key performance indicators such as turnaround time, EQA/IQA performance and trend analysis are reviewed regularly to ensure that the laboratory is providing the most efficient and accurate service for our users.

A process of annual internal audits is undertaken to ensure the conformity with the quality policy across all areas of the business, from the technical processes in the laboratory to the wider application of the quality management system.

Non-conformances are recorded and reviewed including the assessment of root cause analysis to ensure that any necessary corrective action is undertaken to address the cause of any incidence. All employees are encouraged to raise their concern or notify senior management about potential issues at the earliest opportunity.

7. Health and Safety

Zoma Fungal Diagnostics Ltd recognises and accepts its health and safety duties for providing a safe and healthy working environment (as far as is reasonably practicable) for all its workers (paid or volunteer) and other visitors to its premises under the Health and Safety at Work Act 1974, the Fire Precautions (Workplace) Regulations 1997, the Management of Health and Safety at Work Regulations 1999, other relevant legislation, and common law duties of care.

Throughout this Statement, terms such as 'staff', 'workers', 'employees', include both paid and volunteer workers.

It is the policy of Zoma Fungal Diagnostics Ltd (the Organisation) to promote the health and safety of the directors, volunteers, staff, and any visitors to the organisation's premises and to that intent to:

- Take all reasonably practicable steps to safeguard the health, safety, and welfare of all personnel on the premises.

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- Provide adequate working conditions with proper facilities to safeguard the health and safety of personnel and to ensure that any work which is undertaken produces no unnecessary risk to health or safety.
- Encourage persons on the premises to co-operate with the Organisation in all safety matters, in the identification of hazards which may exist and in the reporting of any condition which may appear dangerous or unsatisfactory.
- Ensure the provision and maintenance of plant, equipment and systems of work that are safe.
- Maintain safe arrangements for the use, handling storage and transport of articles and substances.
- Provide sufficient information, instruction, training, and supervision to enable everyone to avoid hazards and contribute to their own safety and health.
- Provide specific information, instruction, training, and supervision to personnel who have health and safety responsibilities (e.g., a person appointed as Health and Safety Officer).
- Make, as reasonably practicable, safe arrangements for protection against any risk to health and safety of the general public or other persons that may arise for the Organisation's activities.
- Make specific assessment of risks in respect of new or expectant mothers and young people under the age of eighteen.
- Provide information to other employers of any risks to which those employer's workers on the Organisation's premises may be exposed.

This policy statement and/or the procedures for its implementation may be altered at any time by the Organisation's directors. The statement and the procedures are reviewed annually by the directors.

Further information can be found in the Health and Safety Policy (ZOMA.POL01 Health and Safety Policy) and this can be supplied upon request.

8. Confidentiality

Under the General Data Protection Regulation (GDPR), we have both a contractual and a legal obligation for the processing and storage of data. We may be obligated to share your data if requested with law enforcement or other authorities. We have designed our bespoke laboratory software to utilise and collect only the minimal amount of essential data required for the processing of our tests.

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We do not directly hold personal data from patients who have submitted samples. We currently only collect relevant clinical information such as travel history, animal contact, occupation, and recreational activities, where appropriate for the test requested, details of the requesting healthcare provider such as address and contact information and information which is necessary to process invoices such as referral centre numbers, financial, bank and credit card information for the primary user, the healthcare provider. The personal information we process is provided by the healthcare provider who is our primary user. The data we use allows us to process tests for diagnostic purpose and to issue invoices to the requesting healthcare provider.

Our bespoke laboratory software (Caspio) has been designed to allow submission of samples and retrieval of results in the most efficient and effective way for our users. Any stored data is stored on secure servers within the UK which are monitored by a highly reputable ISO 27001 IT service provider, ensuring data will always be kept secure.

All paper generated in the laboratory is held for the duration of time as laid out in our retention policy, and routine disposal is undertaken via a responsible confidential waste management company.

Your data protection rights

Under data protection law, you have the right to:

- Access – You have the right to ask us for copies of any personal information we may hold about you.
- Rectification - You have the right to ask us to rectify personal information you think is inaccurate or complete information you believe to be incomplete.
- Data portability – You have the right to ask that we transfer the personal information you gave us to another organisation in certain circumstances.

There is no charge for exercising your right to access your personal data. If you make a request, we have one calendar month to reply.

Please contact us at info@zomafungal.com if you wish to make a request or have any further questions regarding your data security.

9. Test Repertoire

- Specialist teaching and training in the identification of pathogenic fungi
- The processing of skin, hair, and nails for the diagnosis of fungal infection, including fluorescent microscopy and culture.
 - Sample type: Skin scrapings, nail clippings and hair plucks.
 - Sample stability: When samples are kept dry and contained, their stability is assured for several months.
 - Turnaround time:
 - **Direct microscopy** – we **guarantee** this diagnostic result **within 48 hours** of receipt of sample into our laboratory.
 - **Culture Analysis** – a final report will usually be issued 7 days after sample processing, however where there are specific requests additional incubation time may be required.

10. How to request tests

All requests for teaching and training should be first submitted via email to info@zomafungal.com.

For diagnostic assessment of dermatological samples, all requests must be made electronically using our bespoke client portal on our website (www.zomafungal.com). There is a requirement to register in the first instance, but once this is complete tests and samples can be submitted, status reviewed, and reports accessed exclusively online. The primary healthcare provider holds all the data pertaining to the patient/client and none of this data is transmitted to or held by Zoma Fungal Diagnostics Ltd. Our system only requires sample specific details which must include:

- Unique sample identifier (Healthcare provider reference number)
- Specimen type
- Anatomical Site of specimen
- Date of collection

Relevant clinical details especially travel history, occupation, recreational activities, and animal contacts. All of these criteria must be met to be able to request a test. If samples are not labelled appropriately with their reference number, then they will not be tested and will be discarded.

11. Payment for Services

11.1 Terms of Payment

Invoices are issued at the end of each month and work is completed on the basis of an undertaking by the Client to ensure payment within 30 working days (6 weeks) from the date of the invoice.

11.2 Acceptable Methods of Payment

BACs is the preferred method of payment.

12. Sample Collection

Dermatological Samples (Skin, Hair, and Nails)

- a. Sample collection:
 - i. **Skin.** Using a curved scalpel blade, scrape across the inflamed margin of the lesion into the apparently healthy tissue. The removal of dry, scaly skin flakes is recommended.
 - ii. **Nail.** Discoloured, dystrophic or brittle areas should be sampled using nail clippers. If the distal edge is not involved, scrape the affected area using A sterile scalpel blade to remove nail tissue.
 - iii. **Hair.** Infected hair should never be cut but removed by plucking with epilating forceps.

13. Specimen transportation

Most samples can be sent via Royal Mail (we recommend recorded delivery) or using the first-class prepaid address labels provided on request by us, or via courier. We can accommodate those healthcare providers who utilise the DX delivery system, please contact us at info@zomafungal.com to discuss this method further.

We recommend the use of MycoTrans™ (Mycotrans Limited, PO Box 1172, Biggar, Lanarkshire, ML12 6NN) for the collection and transport of dermatological samples for mycological investigation. Place specimen in centre of fully opened receptacle. Close by re-folding and seal by removing backing strip. For additional security place MycoTrans in outer bag and seal.

Alternatively, heavy weight paper or card (preferably black), sterile universal containers, or other suitable medical sample containers may be used.

The transport of patient samples by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations.

14. Retention of Pathological Specimens

In accordance with the guidance from The Royal College of Pathologists and the Institute of Biomedical Science for the retention and storage of pathological records and specimens 2015, we have set the following retention periods:

For skin, hair, and nails, where whole sample is not used in processing, and diagnostic testing, samples will be discarded after 2 weeks.

All records will be held indefinitely in our cloud storage.

15. How to Complain

If there are any concerns about our use of personal information a complaint can be made to us at:

info@zomafungal.com

Alternatively, please contact the laboratory via telephone and ask to speak to a Laboratory Director on 0117 462 1485.

Complaints can also be made to the Information Commissioner's Office (ISO):

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Helpline number: 0303 123 1113

Website: <https://www.ico.org.uk>