



# Laboratory Handbook

Document Number: ZOMA/LH1

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
Jun 2024	1.1	1.2	All	Various text amendments, addition of review due date, DX details updated.
Jul 2024	1.2	2.0	Sections 3, 9, 10, 12, 15,	Change of opening hours. Limitations of use added. Viability of specimens. Moved sections around. Added details to specimen collection. Added our services to complaints. Incident reporting added.
Dec 2024	2.0	3.0	Sections 10.1, 13, 15	Details about rejection criteria and process, retention of positive cultures, and complaints process added.

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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 specimens including processing, fluorescence microscopy, culture, and identification.

### 3. Contacts

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

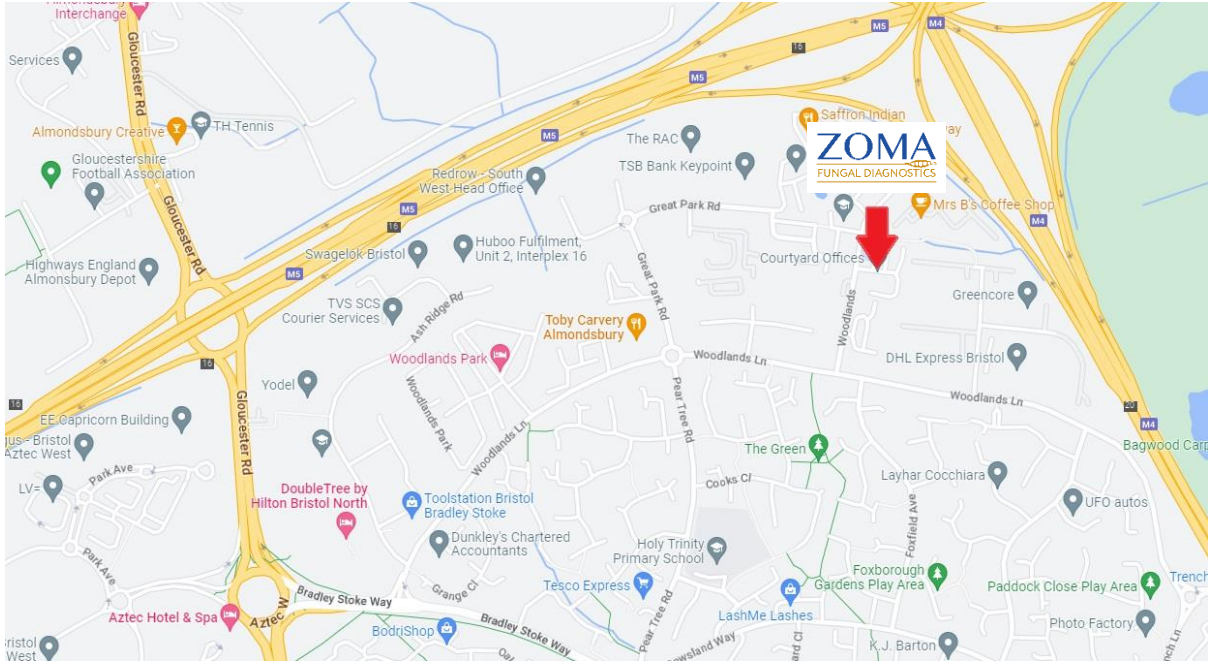
Name	Job Title	HCPC registration	Email address
Dr Mark Fraser BSc MSc PhD	Director and Clinical Scientist	CS17526	<a href="mailto:mark.fraser@zomafungal.com">mark.fraser@zomafungal.com</a>
Zoe Patterson BSc MSc MIBMS	Director and Biomedical Scientist	BS40970	<a href="mailto:zoe.patterson@zomafungal.com">zoe.patterson@zomafungal.com</a>
General Enquiries			<a href="mailto:info@zomafungal.com">info@zomafungal.com</a>

#### 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).



### Laboratory Opening Times

Monday – Friday 08:00 – 16:00

Saturday – Sunday Closed

### Other contact details

Telephone number: 0117 462 1485

Email: [info@zomafungal.com](mailto:info@zomafungal.com)

Website: [www.zomafungal.com](http://www.zomafungal.com)

## 4. Quality Commitments

Zoma Fungal Diagnostics Ltd is working under ISO 15189:2022 standards pending UKAS accreditation. We are fully committed to the provision of 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:

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

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 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. 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.
- 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.

We do not directly hold personal data from patients who have submitted specimens. 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 specimens 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](mailto: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.
  - Specimen type: Skin scrapings, nail clippings and hair plucks.
  - Specimen stability: When specimens 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 specimen into our laboratory.
    - **Culture Analysis** – a final report will usually be issued 7 days after specimen processing, however where there are specific requests additional incubation time may be required, up to 21 days.

### 9.1 Limitations of Dermatology Testing:

- It is not uncommon to obtain negative results from culture of nail specimens from patients with dermatophytosis. One reason for this is that good specimens are often difficult to obtain and may require sampling by a technician.
- A positive microscopy result does not always result in isolation of the causative organism. This could be due to quality of specimen or if the patient has already started treatment.
- Positive microscopy is not an indication that the causative organism is viable. The test used to determine infection cannot differentiate living from dead fungal organisms.

## 10. How to request tests

All requests for teaching and training should be first submitted via email to [info@zomafungal.com](mailto:info@zomafungal.com).

For diagnostic assessment of dermatological specimens, all requests must be made electronically using our bespoke client portal on our website ([www.zomafungal.com](http://www.zomafungal.com)). There is a requirement to register in the first instance, but once this is complete, tests and specimens can be submitted, status reviewed, and reports accessed exclusively online

either via the webpage link or directly at [clientportal.zomafungal.com](http://clientportal.zomafungal.com) . 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 specimen specific details; however, it is mandatory to provide a minimum of 2 unique specimen identifiers. Each specimen entered on the Client Portal from testing should also be accompanied by the following information which **MUST** include:

- **2 of 3 Unique specimen identifiers** (These must be present on the specimen)
  - Referring Centre Reference Number (Laboratory Number)
  - Date of Birth
  - Additional Reference (such as NHS number or Clinic/Hospital Number)
- Specimen type
- Anatomical Site of specimen
- Date of collection
- Relevant clinical details especially travel history, occupation, recreational activities, and animal contacts

All these criteria must be met to be able to request a test. Appropriate guidance is provided in the Sample Submission form in the form of pop-up boxes to alert the user if there is insufficient data provided.

If specimens are not labelled appropriately with their unique identifiers reference, they will not be tested and will be discarded.

For more detailed information on how to request tests please request a copy of our bench guide ZOMA/BENCH08 External User Guide for the Zoma Fungal Diagnostic Laboratory Information Management System (LIMS) or find it on our website.

## 10.1 Rejection Criteria for Specimens

### 10.1.1 Specimen Labelling

The Zoma Fungal Diagnostics Ltd Client LIMS interface has been designed to not accept specimens for testing without a minimum of 2 unique identifiers. As such, specimens which are entered incompletely will not appear on the Zoma Fungal Diagnostics Ltd Laboratory specimen receipt list. If incomplete specimens are received, a member of the Zoma Fungal Diagnostics Ltd team will contact the Client by their preferred method of communication, generally email, to request that the missing information is provided.

Specimens received which are not clearly labelled with 2 identifiers matching those entered onto the Client Portal will be marked as rejected. As they cannot securely be identified and processed with any provided data. A comment detailing the issue is added

to the specimen record and the report is issued immediately as “Rejected Specimen”. The specimen will be discarded in accordance with local policies.

If the specimen does have unique identifiers on it, but they have been incorrectly entered onto the Client Portal, Client’s will have the opportunity to amend or provide the required information within the Order details. All specimens in an Order remain editable until specimens are marked as received in the Zoma Fungal Diagnostics Ltd laboratory. Where possible, a member of the Zoma Fungal Diagnostics Ltd laboratory team will contact the Client by email to notify and request these changes are made.

**It remains the sole responsibility of the Client to ensure that all data entered onto the Client portal directly matches the labelling present on each specimen referred for testing and that the data is pertinent to the tests requested.**

#### 10.1.2 Specimen packaging

Specimens should be securely packaged and wrapped for transport and delivery to Zoma Fungal Diagnostics Ltd. If the integrity of a specimen package is compromised or damaged in such a way as to make the specimen unusable, unsuitable, or inappropriate for testing, all reasonable attempts will be made to salvage specimens. However, in cases where this is not possible the specimen will be rejected and marked as discarded, and a report and appropriate comment will be issued.

For guidance on the best practice for the transportation of specimens please refer to ZOMA/BENCH10 How to send samples to Zoma.

## 11. Specimen Collection

Dermatological Specimens (Skin, Hair, and Nails)

- a. Specimen 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. If insufficient specimen can be obtained in this way, sticky tape can be pressed directly onto the lesion and transferred to a clean glass slide, which should then be transported in an appropriate container.
  - 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. Nail clippings should be taken through the entire thickness of the nail, and any crumbly or powdery material should be included.

- iii. **Hair.** Specimens must include hair roots and shafts, plucked strands are desired. Cut hair is **NOT** appropriate for direct examination of infection. Scalp scrapings can be removed as for skin from visible lesions or flakes.
- b. Specimen storage:
  - i. All specimens should be collected into folded paper/card, secured and placed in a plastic bag or in commercially available packets designed specifically for the collection and transport of skin, hair, and nail specimens.
  - ii. Specimens should be kept at room temperature, transported, and processed as soon as practicable. However, provided the specimens remain dry and sealed, the fungus should remain viable for several months.
- c. Specimen labelling:
  - i. Specimens **MUST** be labelled with the primary Healthcare Providers reference number, failure to do so will result in the Specimen being rejected.
  - ii. Specimen details including specimen type, anatomical site, and date of collection, **MUST** be recorded when requesting Specimens (see ZOMA/BENCH09 External User Guide for Zoma LIMS).
- d. Informed consent
  - i. The primary Healthcare Provider is responsible for obtaining NAD verifying consent for testing requested. Consent for testing is inferred from referral of the specimen to a specialised service provider.

## 12. Specimen transportation

Most specimens can be sent via Royal Mail or specialist courier. We recommend Royal Mail Tracked service for an overnight, signed for traceable delivery. Specimens should be sent to the following address:

Zoma Fungal Diagnostics Ltd  
5 North Court, The Courtyard  
Woodlands, Bradley Stoke  
BS32 4NQ

We also operate within the **Hayes DX transport system** and specimens may be sent using the following details:

**Zoma Fungal Diagnostics Ltd**

**DX number: 433601**

**DX exchange: BRISTOL 99 BS**

We recommend the use of MycoTrans™ specimen envelopes (Mycotrans Limited, PO Box 1172, Biggar, Lanarkshire, ML12 6NN) for the collection and transport of dermatological specimens 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 an outer bag and seal.

Alternatively, heavy weight paper or card (preferably black), sterile universal containers, or other suitable medical specimen containers may be used. Sellotape strippings may be sent attached to glass microscope slides. These **MUST** be contained within an appropriate plastic microscope slide transport box, within an outer bag and sealed.

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

For more information on how to send specimens please request a copy of our bench guide ZOMA/BENCH10 How to send diagnostic clinical specimens to Zoma Fungal Diagnostics Ltd.

### 12.1 Incident Reporting

Following an incident with the transportation of your specimens, which could include but is not limited to:

- Incorrect specimens in package
- Incorrect address label on package
- Delivery issues with courier

It is important to contact the laboratory as soon as possible by emailing us at [n](mailto:n) or calling us on 0117 462 1485.

## 13. 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 specimen is not used in processing, and diagnostic testing, specimens will be discarded after 2 weeks. Positive cultures will be retained for a minimum of 14 working days after the final report is issued. This is deemed sufficient time for Clients to contact the laboratory should they require additional testing or referral of cultures to specialist centres.

All requests for additional work should be made via email to [info@zomafungal.com](mailto:info@zomafungal.com). Isolates which are sent to referral labs will be stored for an additional 3 months following referral subject to facilities. Additional charges for specimen referral may apply.

All records will be held indefinitely within our Client Portal's cloud storage, they will always be accessible to all Clients through their unique log in.

## 14. Payment for Services

### 14.1 Terms of Payment

Invoices for diagnostic work are issued at the end of each month, and invoices for training will be issued once the training has been completed. Work is undertaken based on good faith and the understanding by the Client that our standard payment terms are 30 days from invoice issuance. Late payment charges are applicable as laid out in our Terms and Conditions. We may stop performing diagnostic testing for laboratories who persistently miss the payment date. All Clients will be given a written warning one month in advance of this happening. It therefore remains the Client's sole responsibility to ensure payment is fulfilled within 30 working days from the date of the invoice, or within the terms of any existing and active service level agreement (SLA).

### 14.2 Acceptable Methods of Payment

Direct bank transfer (BACs) is the preferred method of payment. Other methods of payment must be agreed with the company before work is undertaken.

## 15 Cancellation of Services

### 15.1 Training Courses

Please note that once the Customer has booked a course with us it means that the Company has reserved time in our schedule exclusively for the Customer.

The following cancellation terms apply:

- Cancellation more than 4 weeks before scheduled date a full refund will be given, or the booking may be rescheduled without charge.
- Cancellation between 1 and 4 weeks before scheduled date 50% will be refunded or alternatively the booking may be rescheduled for a re-booking charge of £50.00 per person.
- Cancellation less than 1 week before scheduled no refund will be given.

You can cancel or reschedule an appointment by emailing us at [info@zomafungal.com](mailto:info@zomafungal.com)

### 15.2 Diagnostic Testing

All diagnostic testing should be performed against an agreed and signed service level agreement (SLA). Where there are instances that this is not possible, such as in an ad hoc or one-off testing scenario, testing will be undertaken on good faith by the Company to not delay patient results, this is founded in the assumption that the Client will complete their responsibilities in terms of due diligence and invoice payment as laid out in Section 14.

The standard terms of notice for the cancellation of diagnostic testing services where an SLA is in place, is one calendar month. Where no SLA or agreement exists between the Client and the Company, there is no notice period required.

The cancellation of testing of an individual specimen can be done directly by the Client in the Client Portal prior to receipt at Zoma Fungal Diagnostics Ltd. Clients should notify Zoma Fungal Diagnostics Ltd by email if a cancelled specimen has already been dispatched. Once specimens are marked as received, they can no longer be edited or cancelled by the Client. If testing of specimens is no longer required, the Client should notify Zoma Fungal Diagnostics Ltd as soon as possible once the specimen has been sent. This can be done via email to [info@zomafungal.com](mailto:info@zomafungal.com) or by telephone on 0117 462 1485. As Zoma Fungal Diagnostics Ltd guarantees a turnaround time for microscopic evaluation of dermatology testing of 48 hours, it may not always be possible to cancel a specimen test prior to it being processed. All reasonable efforts will be made to fulfil the request of the Client, however if specimens have already been processed, charges will still apply.

## 16. How to Complain

### 16.1 How we handle complaints

The complaint will be investigated by a responsible person who has accountability for the management of complaints, this is usually a director of the company. Appropriate action will be taken to address the issues of concern, determine any remediation actions which may be required and to prevent recurrences where necessary.

- Complaints should be provided in writing, electronically, or verbally.
- All complaints will be acknowledged by a responsible person within 3 working days of receipt.
- We aim to provide a full investigative reply to all complaints within 30 working days.
- All formal complaints will be documented, and a report of follow-up actions returned to the complainant by return of mail or email as per the client's request.

### 16.2 Process for investigation of complaints

Once a complaint had been received, the laboratory will confirm whether the complaint relates to laboratory activities or process for which it is wholly responsible and if so, will seek to resolve the complaint in a timely manner. This may involve the arrangement of a meeting between the complainant and a company director, to gather more information or ascertain the nature of the complaint. An investigation into the nature of the complaint, the likely root causes of the complaint, the potential impact of the situation from which the complaint has arisen, the desired resolution, and steps that may be taken to prevent reoccurrence of events leading to complaints in the future will be undertaken in an unbiased and impartial environment.

Investigations will be conducted within the company by the responsible person who, where possible, does not have any involvement in the subject of the complaint. This person will gather evidence and attempt to understand the root cause of the problem which has arisen. A report will be produced outlining each step of the investigation and this will be shared with the complainant upon completion. The outcome will be reviewed at the next appropriate laboratory meeting, as well as in the Annual Management Meeting. Any corrective actions will be implemented and documented in this way to the whole of the company. All report details will remain confidential, and each investigation will retain impartiality and not result in any form of discriminatory actions.

### 16.3 How to complain about use of personal data

If you have any concerns about our use of personal information or wish to raise a complaint against any aspect of our services, this can be done by emailing:

[info@zomafungal.com](mailto:info@zomafungal.com)

Or by writing a letter to the following address:

Zoma Fungal Diagnostics Ltd  
5 North Court, The Courtyard  
Woodlands, Bradley Stoke  
BS32 4NQ

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>

## 17 References

ZOMA/BENCH08 External user guide for Zoma Fungal Diagnostics laboratory information system (LIMS)

## ZOMA/BENCH10 How to send diagnostic clinical specimens to Zoma Fungal Diagnostics Ltd