How to Send Clinical Diagnostic Samples to Zoma Fungal Diagnostics Ltd

Sample Types and Recommendations for Sampling

As outlined in the laboratory handbook, Zoma Fungal Diagnostics Ltd offers a full diagnostic service for the diagnosis of superficial fungal infections of skin, hair, and nail.

Skin: Edges of lesions should be scraped with a blunt scalpel blade into a folded paper envelope. If insufficient sample 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.

Nail: A targeted sampling of areas of discoloration, malformation or brittleness should be attempted. Nail clippings should be taken through the entire thickness of the nail, and any crumbly or powdery material should be included.

Hair: Samples must include hair roots and shafts, plucked strands are desired with no more than 1cm of hair attached to the root are preferred. Scalp scrapings can be removed from the site in the same manner as for skin, from visible lesions or flakes.

Please note: Cut hair is NOT appropriate for direct examination of infection.

All samples should be kept at ambient temperature, transported, and processed as soon as practicable. However, provided the samples remain dry and sealed, the fungus should remain viable for several months.

Samples from associated sites i.e. toenails and skin from the toes/feet should be sent as separate samples in individual packets with their own testing request.

Specimen Containers

Sample specimen containers must conform with the requirements outlined in the EU *in vitro* Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) which states **"the design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen"**.

We recommend the use of CE marked leak proof containers or sealed paper envelopes such as those provided by Mycotrans™ or Dermapak®.

Packaging

All clinical diagnostic samples should be packaged in accordance with UN 3373 Biological Substance, Category B. The requirements for the road transport of UN 3373 are specified in

Packing Instruction 650 of the ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road, 64th Edition, January 2023).

Packaging must consist of three components:

a) A primary receptacle such as a universal or a Mycotrans™ envelope.
b) A secondary packaging such as a marsupial bag, a travel container, or an envelope.
c) A rigid outer packaging such as a box.

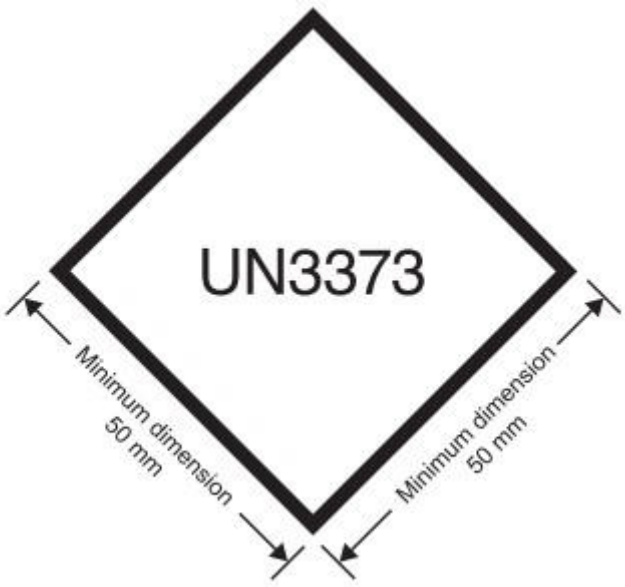
Primary receptacles must be packed in secondary packaging so that under normal conditions of transport they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Both primary and secondary packaging must be impermeable to dry contents so that particles cannot be released from the package during transportation.

If multiple primary receptacles are placed in a single secondary packaging, the must be individually wrapped or separated to prevent contact between them.

An itemised list of contents must be enclosed between the secondary and outer packaging.

Transportation

For transportation, the mark illustrated below MUST be displayed on the external surface of the outer packaging. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm. The width of the outer line must be at least 2 mm and the letters and numbers contained in the mark should be at least 6 mm high. The entire mark must be visible on one side of the package. The proper shipping name "**Biological Substance, Category B**" must be marked on the outer packaging adjacent to the mark in letters at least 6 mm high.



Infectious substances assigned to UN 3373 which are packed and marked in accordance with the instructions specified in Packing Instruction 650 are NOT subject to any other requirements of the regulation except for the following:

a) The name and address of the shipper and sender must be provided on each package.
b) The name and telephone number of a person responsible must be provided on the package.
c) The classification must be in accordance with 3.6.2 of ADR 2023
d) The incident reporting requirements in 9.6.1 and 9.6.2 of ADR 2023 must be met.
e) The inspection for damage or leakage requirements in 9.4.1 and 9.4.2 of ADR 2023.

Postage

Deliveries can only be accepted Monday-Friday during working hours. Samples should be addressed to:

Zoma Fungal Diagnostics Ltd

5 North Court, The Courtyard

Woodlands

Bristol, BS32 4NQ

We recommend using the secure, guaranteed overnight courier provided by Hayes **DX network** using the following details:

Zoma Fungal Diagnostics Ltd

DX number: 433601

DX exchange: BRISTOL 99 BS

Alternatively, we recommend the use of the Royal Mail Tracked delivery service. This service requires a signature upon receipt and is usually delivered by 1pm on the next working day.

Please note: It remains the client's responsibility to check their chosen carrier's individual requirements for the transportation of biological substances.

References

ADR 2023 – Agreement concerning the International Carriage of Dangerous Goods by Road, applicable from 01/03/2023. United Nations, 2022 ADR 2023 - Agreement concerning the International Carriage of Dangerous Goods by Road | UNECE

Packaging and transport requirements for patient samples – UN3373, 26/03/2020 Packaging and transport requirements for patient samples – UN3373 - GOV.UK (www.gov.uk)

Packing Instruction 650 DGR-64-EN-RGB (iata.org)

Mycotrans Specimen Transport System Mycotrans Home

UK Standards For Microbiology Investigations B39 Investigation of Dermatological Specimens for Superficial Mycoses UK Standards for Microbiology Investigations (UK SMI): general information - GOV.UK (www.gov.uk)

Directive 98/79/EC of the European Parliament on in vitro diagnostic medical devices Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (legislation.gov.uk)