Transport of Specimens to the Laboratory

There is a legal responsibility and a duty of care on anyone who dispatches clinical material (diagnostic specimens) to the Belfast Trust Laboratories, (by whatever means, including hospital van, courier, taxi, post, internal portering, or pneumatic chute).

For transportation of clinical specimens via pneumatic tube please refer to C-17 Pneumatic tube transport of clinical specimens.

For safe packaging and transportation of known or suspect COVID-19 samples please refer to the following posters ;

- C-494 Instructions for packaging all laboratory specimens in a UN3373 BAG for known/suspected COVID-19 patients
- C-495 Instructions for packaging all laboratory specimens in a UN3373 BOX for known/suspected COVID-19 patients

Even when there is a laboratory on your hospital site, centralization and rationalization means different specimens and request types may be sorted close to source and be forwarded by road to other sites bypassing the local laboratory altogether. This means that the person who leaves a specimen out to be collected is regarded legally as the 'Shipper' of an item which under road transport regulations are classed as 'dangerous goods'.

The legal responsibility is to ensure that the specimens are packaged and labelled in compliance with the relevant road transport regulations (ADR/CDG).

Since clinical materials may contain infectious agents there is a further legal responsibility under COSHH regulations, to ensure that the materials do not leak or injure anyone involved in the transportation or the wider public and environment.

The duty of care (to the patient) is to ensure that the transport conditions do not damage the material being sent for testing or otherwise interfere with the validity of the test results, and to ensure the specimen reaches the laboratory in good condition within an appropriate time frame for good clinical management of the case.
This requires:

- Submission of the correct type of specimen, in the correct container for the test required.
- Correct addressing of the specimen/request to the correct laboratory on the correct form.
- Not unnecessarily requesting multiple tests on the on same specimen which may result in specimens having to be shared across different laboratories & sites.

- Full matching PID details on specimen and form.
- A clear statement of the test required.
- Indicate if an unusual or fragile organism is suspected as the causal agent, these may not be isolated by normal testing protocols and may require special media, special isolation conditions and prolonged incubation.
- A clear statement of the nature/site of the specimen.
- A clear statement of the relevant clinical details and history.
- Details of the patient location (where results are to be sent to).

If any of the above are missing this may result in snagging, which may delay transport to the correct lab, may cause wrong tests to be performed, may result in delays in reporting.

In addition the following transport related factors may cause delays or impact the quality of results

- All container tops must be firmly and properly closed, leakage adversely affects not only that specimen but other specimens sharing the transit.
- Only laboratory approved, CE marked, in vitro devices IVDs, must be used as primary specimen containers, no substitutes or improvised containers.
- The date and time of collection should be clearly stated (24 hour clock) because some fragile organisms must reach the lab and be plated within a short timeframe if there is to be a chance of isolating them e.g. *Neisseria meningitidis* or *N. gonorrhoeae*.
- Specimens must be kept in a cool room awaiting despatch, not in the sunlight or near a radiator.
- If specimens cannot be shipped until the next day they should be stored in a fridge at 2-8°C with a max/min monitor to ensure this range is maintained. Specimens must not touch cooling plates which may frost the specimen.
- URT specimens must be stored in a cool room 10-16°C because some of the significant URT pathogens will die off at 2-8°C.
- Transit to the laboratory should be prompt and specimens must not be left in uncontrolled vehicles (hot/cold) for any prolonged period.
- The desired situation is that all vehicles used to transport specimens should have adequate active heating/cooling systems in their goods compartment to ensure the temperature range is maintained between 8 to 22°C and this should be considered in any future rounds of transport procurement or service contracts with carriers. In the interim mitigating action should be taken by way of insulation of specimens in transit with or without cool packs.

The laboratories are not responsible for nor do they have any managerial control over the transportation of specimens between the shipper and ourselves. We can only give advice on good practice to those who send (ship) to ourselves.

The strong recommendation by Belfast Trust Microbiology is that all patient Clinical Specimens should be considered as potentially infectious and must therefore be categorised at the very minimum as UN3373 Biological Substance Category B and be packed and labelled according to Packing Instruction P650 in the ADR/CDG regulations.

If fully compliant with P650 then the package, the transport vehicle and the driver are not subject to further specific requirements under ADR.
THIS EXEMPTION MUST ALWAYS BE USED.
If the packaging is not P650 compliant then there is no exemption from the full ADR/CDG regulations, and the shipper and the driver may be found in breach of a number of transport regulations and liable to prosecution.

Shippers Responsibility for Transport

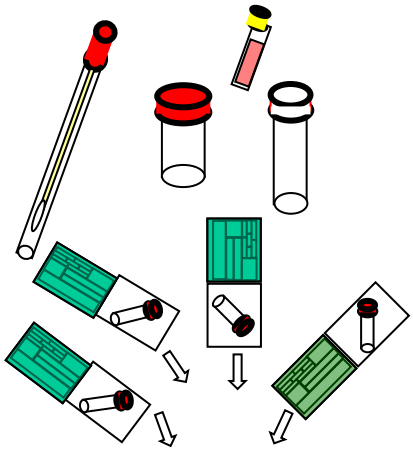
Any Unit, Hospital, Clinic, GP Practice or Trust transporting specimens by road (which includes postal services) should take professional advice and guidance on the packaging and labelling of any materials they hand over for transportation because they are technically the shipper and are therefore legally responsible for compliance. Any staff involved in the packaging and shipment of Clinical Specimens should be appropriately trained for their role and this training should be documented.
Specimens transported on public roads are subject the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2019 (CDG 2019) and the European agreement ("Accord européen relatif au transport international des marchandises Dangereuses par Route", (known as ADR) (ADR 2019) which together regulate the carriage of dangerous goods by road.
Specimen transport is also subject to further guidance issued by the competent authority for the UK, the Department for Transport, the key document is 'Transport of Infectious Substances (DfT) 2012: A guidance document produced by the Department for Transport, the Civil Aviation Authority and the Maritime and Coastguard Agency' Guidance note reference 17/2012[REV.7]

Individual couriers such as the Post Office may issue their own additional requirements and restrictions, which must be complied with.

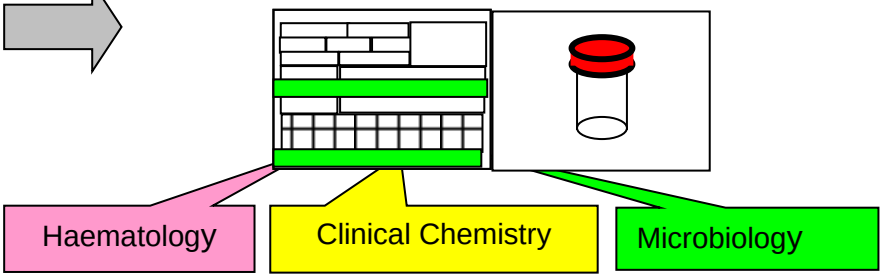
Overview of Packing Instruction P650

Users MUST consult the full packing instruction, this is only an overview. The packaging standard comprises 3 layers, two leak-proof layers, and a third outer rigid layer which provides protection against impact.

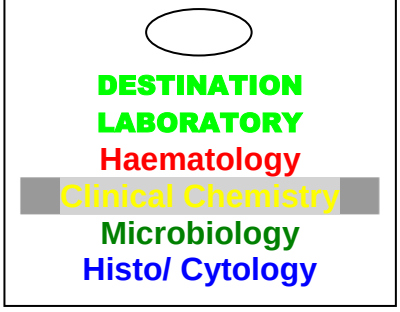
1. PRIMARY CONTAINER (LAYER #1)
Rigid, leak-proof, lid tightened.
In Vitro Diagnostic Device (CE marked)



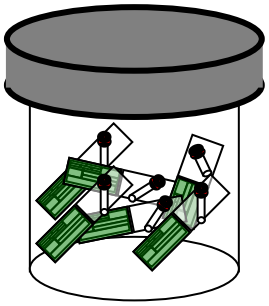
2. REQUEST FORM POUCH
Individual, Clear plastic envelope, attached to appropriate colour coded form, sealed. This device does not meet the criteria for a leak-proof container. It is a device to direct the specimen to the correct destination and keep specimen and request together.

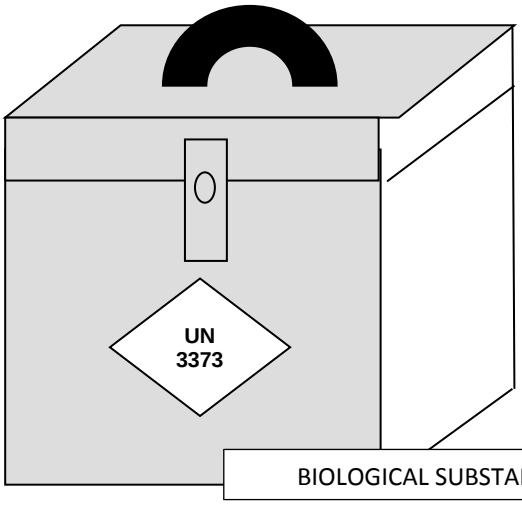


3. OPAQUE/CLEAR SPECI-BULK BAG (optional)
Where large numbers of specimens are being sent samples are sorted at source and streamed by colour code into pre addressed and colour coded bags supplied by the laboratory. Sorting and streaming at source speeds specimens through reception areas. For road transport purposes this does not meet the criteria of a leak-proof layer.



4. SECONDARY LEAKPROOF CONTAINER (LAYER #2)



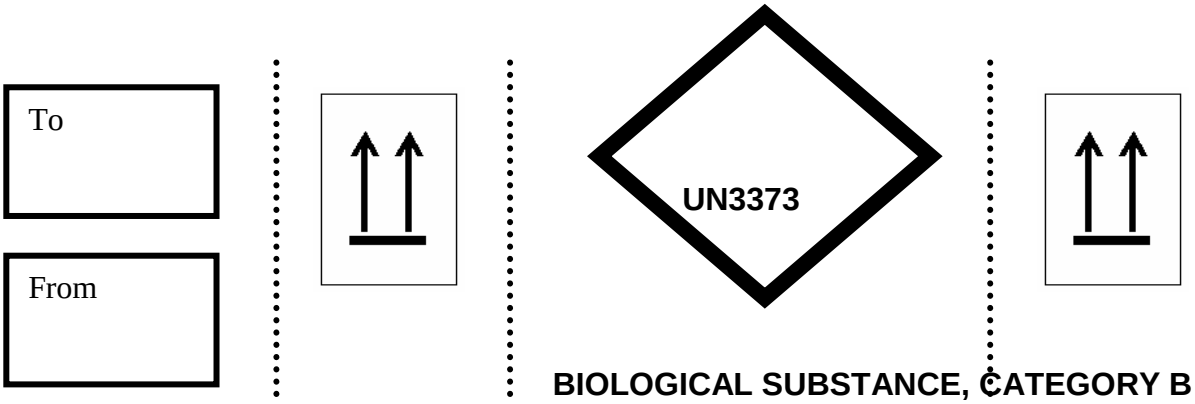


5. TERTIARY RIGID OUTER (LAYER #3)
Road transport outer box.
Each specimen does not have to be individually packaged in its own separate three layer system. Several specimens or multiple specimens can be packed together in a bulk transport system provided the above model of the three layer configuration is complied with.

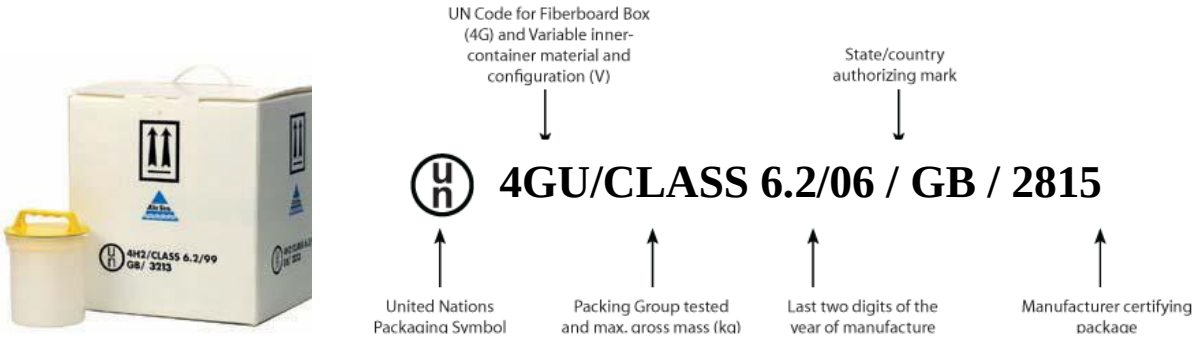
BIOLOGICAL SUBSTANCE, CATEGORY B

Note that we are in transition from colour coded plastic forms, as in the diagram above, to plain white forms printed by Cyberlab with patient details and test details, to which a colour coded bag rather than a clear bag will be attached but the general principles of the above diagram stay the same.

There should be sufficient absorbent material between the leak-proof layers to absorb the leakage of one of the containers.
There should be sufficient padding to ensure specimens do not rattle around loose inside the package and that multiple specimens are cushioned against knocking against each other.
The outer container should be marked with the details of the shipper and consignee and the following symbol and shipping name should be on the outer layer as well as two sets of this way up arrows on opposite surfaces. Four faces of box shown below:



For road transport the packaging systems must be certified by the maker/ issuer to be compliant with the ADR/CDG standards for road transport of UN3373 and must be used with all the components, and only those components, tested and stipulated by the maker / issuer as meeting compliance. Alternately the higher standard UN type approved packaging for Class 6.2 Dangerous goods can be used, these are independently tested and marked in the style of:



Some trusts use self-approved, home designed, bulk transport systems in vehicles, these are suitable if they are properly risk assessed as such but it must be pointed out that leak-proof means through 360^0, and with liquid in contact with the access

point/lid. A common misunderstanding is that a loose lidded container, essentially a trough or bucket is leak-proof, this is not leak-proof within the road transport regulations.

The primary specimen container must be a CE marked 'in vitro device' IVD approved by the laboratory for the particular test requested, not a substitute nor an alternate improvised container. Other containers may not be sufficiently leak-proof or robust enough to withstand the rigors of transport and will invalidate the compliance of the packing system.

Users must be mindful that if the lid of the primary container is not properly secured then it is not leak-proof and the entire packing system is not compliant for road transport. Users must make sure lids are firmly tightened and not rely on patients having done so when they collect their own specimens.

The transport packaging system must be adequately secured within the vehicle against the normal rigors of road transport or minor road traffic accidents. It must not be transported in the passenger compartment of the vehicle.

Transport of High Risk UN2814 Infectious substance affecting humans, Category A

There is an important exception to the above general rule where a specimen is transported from a patient suspected or known to have a highly infectious disease, one identified as a Containment Level 4 agent by the Advisory Committee on Dangerous Pathogens. An example is Ebola virus or any VHF.

These high risk specimens must not be transported to Belfast Trust Microbiology or any other Trust Laboratory or premises without first consulting with Microbiology or Virology.

Cat A specimens must not even be transferred internally by portering or other hospital staff without consultation, instruction and authorization by senior laboratory staff.

These are extremely rare events and our most recent experience with Ebola illustrates that the algorithms and protocols in such events will be continuously revised, it is therefore essential to check with the laboratory on every occasion when such material is transported to the laboratory. This is to ensure that the most current procedure is followed and that suitably trained and equipped laboratory staff are ready to receive and process the material

Case by case and day by day risk assessments of patients and their specimens will be made in liaison with consultants in IDU, Microbiology, and the Imported Fever Service IFS at Porton Down.

These will be highly infectious viruses and will require a specialist courier for road transfer, they must not be transported by post, hospital van or taxi.

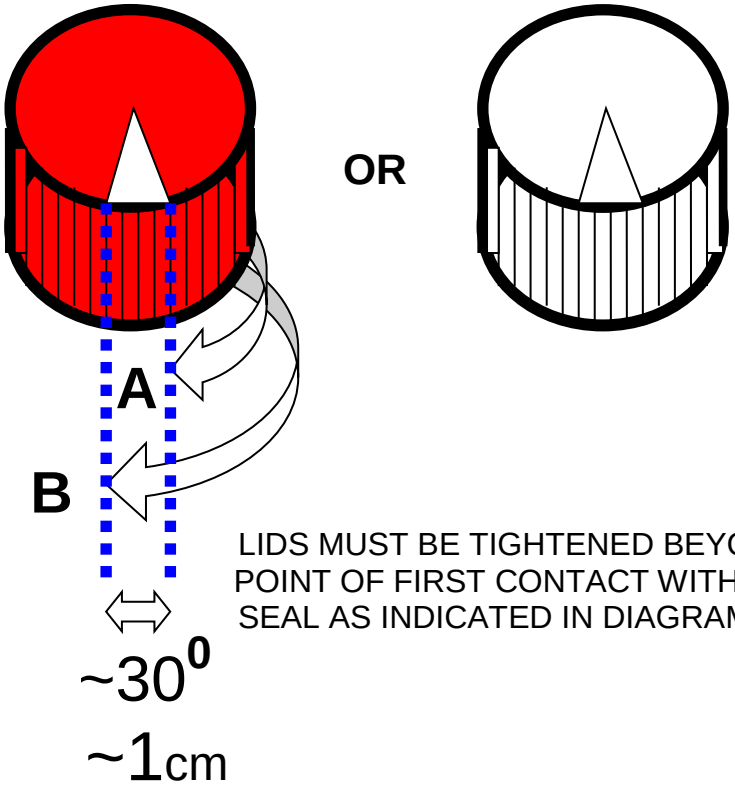
Technical Note for Laboratories wanting to transfer Cultures of suspect or known Hazard Group 3 (CL3) organisms to Belfast Trust Laboratories

For laboratories shipping cultures of CL3 organisms to the Belfast Trust Laboratories for further testing, many of these cultures should be shipped as UN2814 but some have derogations to be shipped instead as UN3373. It is the responsibility of the shipping laboratory to consult the relevant regulations, DfT guidance, and take advice from a DGSA before shipping any cultures.

Securing the lids of screw top 30 ml Universal Containers before Transporting

A = point at which bottle first touches rubber seal
B = point where lid is securely locked and sealed

URINES & BODY FLUIDS



LIDS MUST BE TIGHTENED BEYOND POINT OF FIRST CONTACT WITH LID SEAL AS INDICATED IN DIAGRAM

FAECES

Blue lidded faeces containers have a different type of sealing mechanism.

The Distance from first bite point to securely closed is shorter, an angle of 15^0 or 0.5cm