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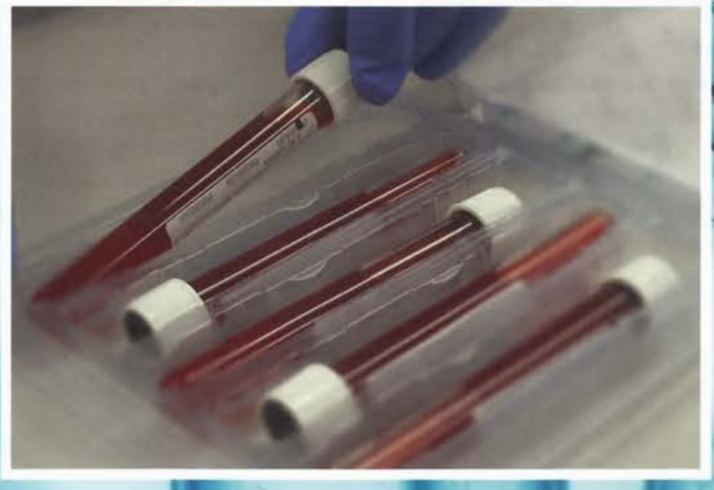
The responsibility of sample packaging 34

Are you compliant with the latest biological sample packaging regulations?



SAMPLE TRANSPORT

Just pack it in...

Are you UN3373 compliant? Understanding your biological sample packaging responsibilities is vital says **Sue Fletcher**

Medical laboratory and clinical personnel have always needed to transport biological samples from the patient source, between clinics and laboratories, or to centres offering expertise in a particular type of test. However, what is relatively new is the appearance of on-line health testing companies offering a range of assays to the general public. Ensuring that clinical samples reach their destination safely, securely, and at the right temperature is crucial as any element of the diagnostic testing process.

Transport of biological samples is also strictly controlled under the Dangerous Goods Act due to the potential risk of infection the specimens pose. The Dangerous Goods Regulations were introduced in recognition of the need to transport hazardous substances on a global scale. Its aims are to enable these goods to be transported relatively easily, in a consistent, recognisable manner. This ensures that all such parcels, and their contents, reach their destination in good condition, whilst not endangering the environment or anyone who comes into contact with them during their journey.

The United Nations created a set of model instructions from which the governing bodies for Air, Sea, Rail and Road transport each developed their own version of the Dangerous goods regulations. The regulations vary dependant on the mode of transport.

Possible prosecution

Compliance with the dangerous goods regulations is a legal requirement when transporting human or animal samples. Non-adherence to the packaging instructions can lead to prosecution, resulting in fines or even imprisonment.

The general guideline from the WHO is that samples such as blood, tissue, excreta, secreta etc. from humans or animals (which are not assigned to Category A, Infectious Substances), are considered to be Category B Biological Substances. These samples are then assigned to UN3373 and must be packaged according to the Dangerous Goods IATA or ADR Packing Instruction 650 for transport.

There is a third category, which is not generally used, but often causes the most confusion. Samples described as "has minimal likelihood that pathogens are present" can be classified as exempt. Many people think that exemption means that no special packaging is required, but this is not the case. Exempt samples also require a three layer packaging system to be compliant with the legislation.

The consequences of non-compliance can be costly. For the patient this could result in a delay in diagnosis or treatment, and the inconvenience of having to repeat samples. For the labs this could mean delays in receipt of samples, loss of data and costs to repeat the patient tests. For laboratory staff it could result in additional workload for clean ups and re-tests. For courier staff handling the package during transit, there could be ill health and time off work. For the laboratory packaging the sample there could be fines, and in the worst case scenario, the person who packaged the sample could be jailed. Yes that's right, ultimately the person responsible for the parcel, is the person who packaged it!

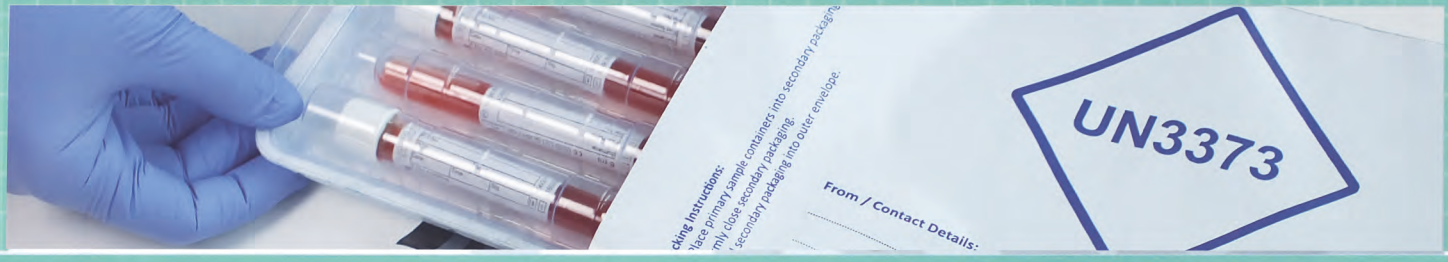
Laboratory personnel are trained to handle human or animal samples correctly, to keep themselves and others safe. But, when it comes to sample transport the legislation can be difficult to interpret and costly to implement, both in terms of time and money.

Sample specifics

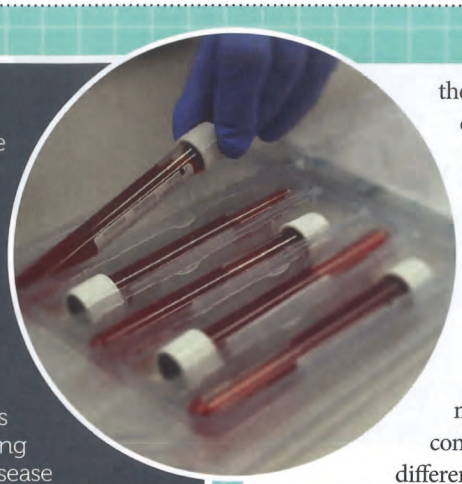
When samples are being sent as 'Category B', the packaging must meet certain minimum conditions. Principally it must consist of three components: the leak-proof primary receptacle (blood tube/universal container), a secondary packaging (e.g. sealed plastic bag or rigid container), plus an outer packaging (cardboard box or mailing envelope).

For Road Transport (ADR) the primary or secondary packaging must pass the 95kPa pressure differential test conducted at an ambient temperature. The entire package, with its three layers, must withstand a 1.2m drop test without any damage to the primary container, and either the secondary, or outer layer of packaging, must be rigid. In addition, there must also be sufficient absorbent material included in the package to absorb all of the sample volume. When sending multiple samples in one package, each primary container must be individually wrapped or separated so they do not contact each other directly. Samples being sent under UN3373 Category B, Biological Substance should also display the appropriate symbol.

There are additional stipulations and requirements particularly relating to air transport (IATA). The same 95kPa pressure differential test applies, but the container, whether it is the primary or secondary one, must pass this test at both -40°C and +55°C. Maximum volume (1L) and weight



Assess Your Sample



Under the Dangerous Goods Regulations, there are 9 classes of goods segregated according to the particular risks they pose. Human or Animal Specimens fall into Class 6 – Toxic and Infectious Substances. 6.1 – Toxic Substances. 6.2 Infectious Substances, where these types of samples are assigned

Category A

Pathogens vary greatly in their ability to cause disease and how dangerous those diseases can be. Those which are capable of causing permanent disability, life threatening or fatal disease in humans or animals are categorised as Category A Infectious Substance and a complete list of these organisms is contained within the regulations. Transport of Category A Infectious substances is very strictly regulated and must only be done in UN approved packaging.

Category B

Most pathogens fall into Category B Biological Substances as they may cause disease or illness but it is not usually too serious. Category B has less stringent requirements but never-the-less the packaging instruction detailed in the regulations must be adhered to. The majority of samples transported in the UK fall under UN3373 Biological Samples, Category B.

Exempt Samples

Under Class 6.2 there is a 3rd sub division which causes a great deal of misunderstanding and these are Exempt Samples. Many people think that "exempt" means you don't require any special packaging, but this is not the case. Exempt samples are described as those which have "minimal likelihood that pathogens are present". However, the authorities in some countries believe that unless you are able to categorically say that the sample does not contain pathogens, it should be treated as any other sample containing pathogens. Even when a sample is categorised as "exempt", it still requires a triple layer packaging system to be compliant with the Dangerous Goods Act for Transport.

(1Kg) limits apply to the primary container, and the outer container (4L or 4Kg). The outer packaging layer must be rigid, and must contain an itemised list of contents. The UN3373 diamond symbol must be at least 50mm along each side of the diamond shape, and the outer packaging must be at least 100mm x 100mm in size.

Trying to meet these requirements using standard materials around the laboratory can be a daunting task and lead to variability within the packaging processes. Ideally DIY solutions should be avoided as there are specific tests regarding robustness, absorbency etc. which elements of the packaging must comply with to be considered suitable.

To help provide some packaging consistency there are a range of "off the shelf" materials readily available to assist with compliance, but the choice can be overwhelming and some are overly large and can become costly in terms of transport. It's important to shop around to find the most appropriate and cost effective solution for your particular requirements.

The SpeciSafe range of all-in-one secondary packaging from Alpha Laboratories is one example that provides a consistent, convenient means of compliance. Intended for use with primary containers that have passed the appropriate pressure differential test (for air or road transport), the robust, blister type, leak-proof pack combines an ultra-absorbent gel-based material within the rigid container. It simply encloses the sample container and protects it in the sealed casing.

When transporting your samples by road, you then only need to add an appropriately labelled padded envelope or bag as your outer packaging and your sample is ready for transportation according to UN3373 regulations. SpeciSafe is also suitable for air transport when placed inside a rigid outer box. Custom designed solutions can also be prepared to provide complete sample collection and transport packs for logistics solutions in diagnostic, clinical trials and contract research applications across the pharmaceutical, healthcare and laboratory industries.

Training

When transporting Category A samples, staff must be fully trained and certified in their responsibilities for compliance to transport regulations and how to correctly package samples. This must be achieved through a CAA approved course. People only transporting Category B, UN3373 samples do not have to be certified to such high standards but still require training.

To help support this Alpha Laboratories offers a UN3373 Sample Transport Seminar. This training is provided by a technical expert who is certified in the Carriage of Diagnostic and Infectious Substances by Air, through a CAA approved course.

To find out more about UN3373 compliant packaging or to request a seminar for your laboratory please visit www.un3373.co.uk

Sue Fletcher is Principal Product Manager, Alpha Laboratories

SAMPLE TRANSPORT UN3373 SEMINAR

Benefits

- Seminars are held on-site at your own premises at a time and venue which is convenient to you
- The trainers are Alpha specialists with a wealth of experience, with appropriate training and certificates in the subject area
- Each participant will receive a certificate of attendance for the sessions they attend

Who Should Attend?

Anyone who is packaging biological samples for transport.

On-going Support

Each participant will receive a free 'Journey to Compliance' wallchart showing the routes to compliant packaging for samples, dependent on their classification and the mode of transport. It is a useful tool to hang on your wall for reference.

How to Arrange Your Sample Transport Seminar

All you need is a group of 10 to 16 colleagues who are interested in attending.

You can either complete the on-line form at **www.alphalabs.co.uk/sample-transport-seminars** or contact your local Alpha representative to discuss your needs and make the arrangements.