



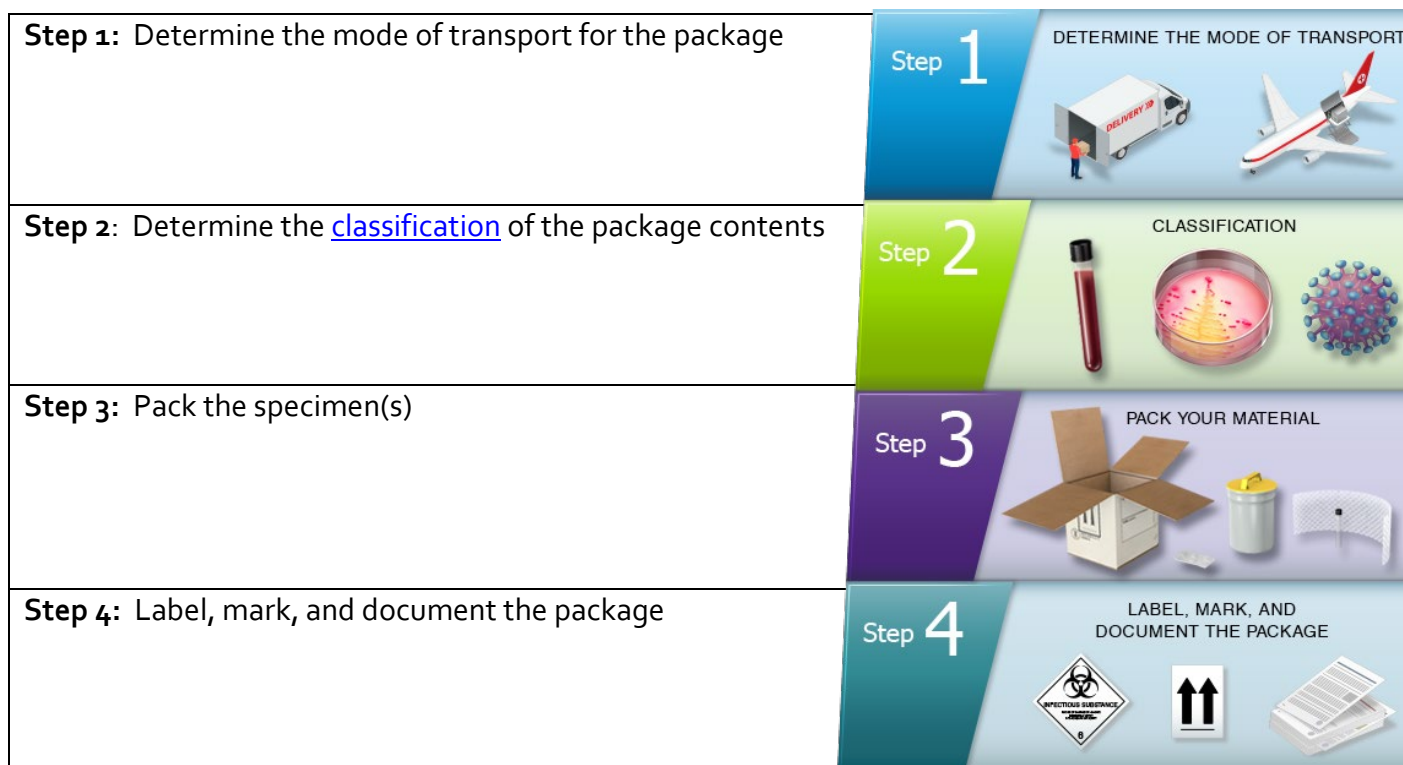
Specimen Storage and Shipping Guidance

Office of the Deputy Director of Infectious Diseases

This job aid defines the criteria to properly ship biological specimens to the Centers for Disease Control and Prevention (CDC). Failure to satisfy these criteria will result in the rejection of submitted specimens by CDC.

Submitters should also refer to guidance and federal regulatory standards external to this procedure for the transport of biological specimens (e.g., IATA, DOT, etc.). Per International Air Transport Association (IATA) regulation, a dangerous goods certificate of training is required for any person who submits dangerous goods to a public carrier for transportation.

For all information about the storage of samples prior to shipment, refer directly to the Test Directory and test-specific guidance.



Step 1: Determine the Mode of Transport for the Package

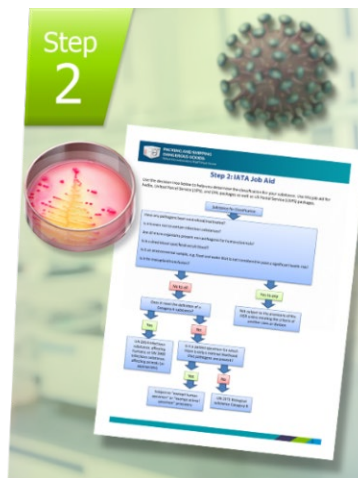
The mode of transport will dictate the federal transport regulations that should be followed. Submitters should review federal regulatory standards external to this procedure for the transport of biological specimens (e.g., IATA, DOT, USPS, etc.).

Specimens should be shipped with overnight shipping when possible or if required for the specific testing requested.



Step 2: Determine the Classification of the Package Contents

Submitters should reference external regulatory standards if they are uncertain of specimen classification. There are three classifications for biological specimens: Category A, Category B, and Exempt Specimen.



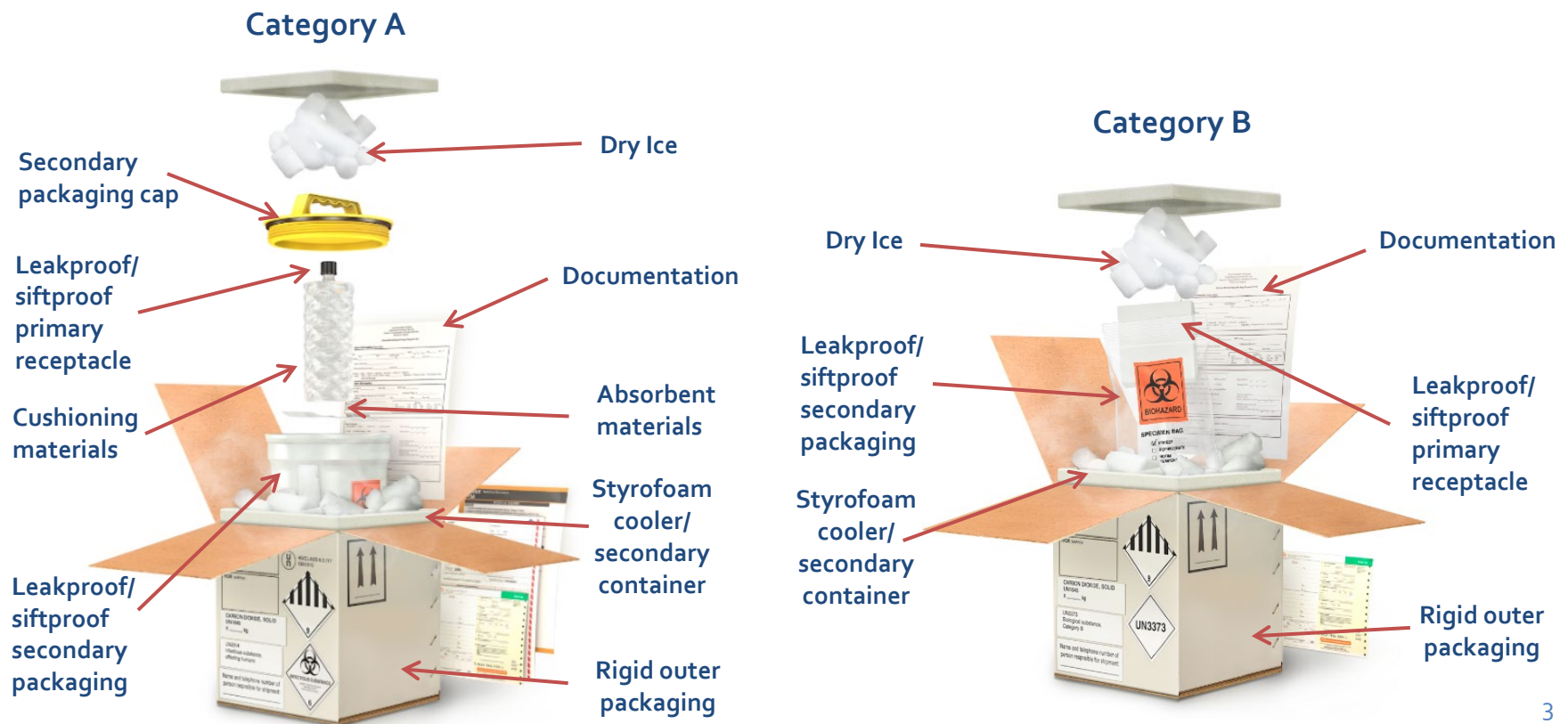
Step 3: Pack the Specimen(s)

The mode of transport and the specimen classification determine the packing requirements. Submitters may reference IATA's packing instructions (PI), which are followed by most submitting laboratories. Regardless of classification, all specimen submissions must include a primary receptacle, secondary packaging, a secondary container, and rigid, outer packaging. The submitter should reference CDC-defined temperature ranges for specimen storage to decide on proper specimen shipping conditions and materials relative to ambient, room-temperature, refrigerated, or frozen specimens.



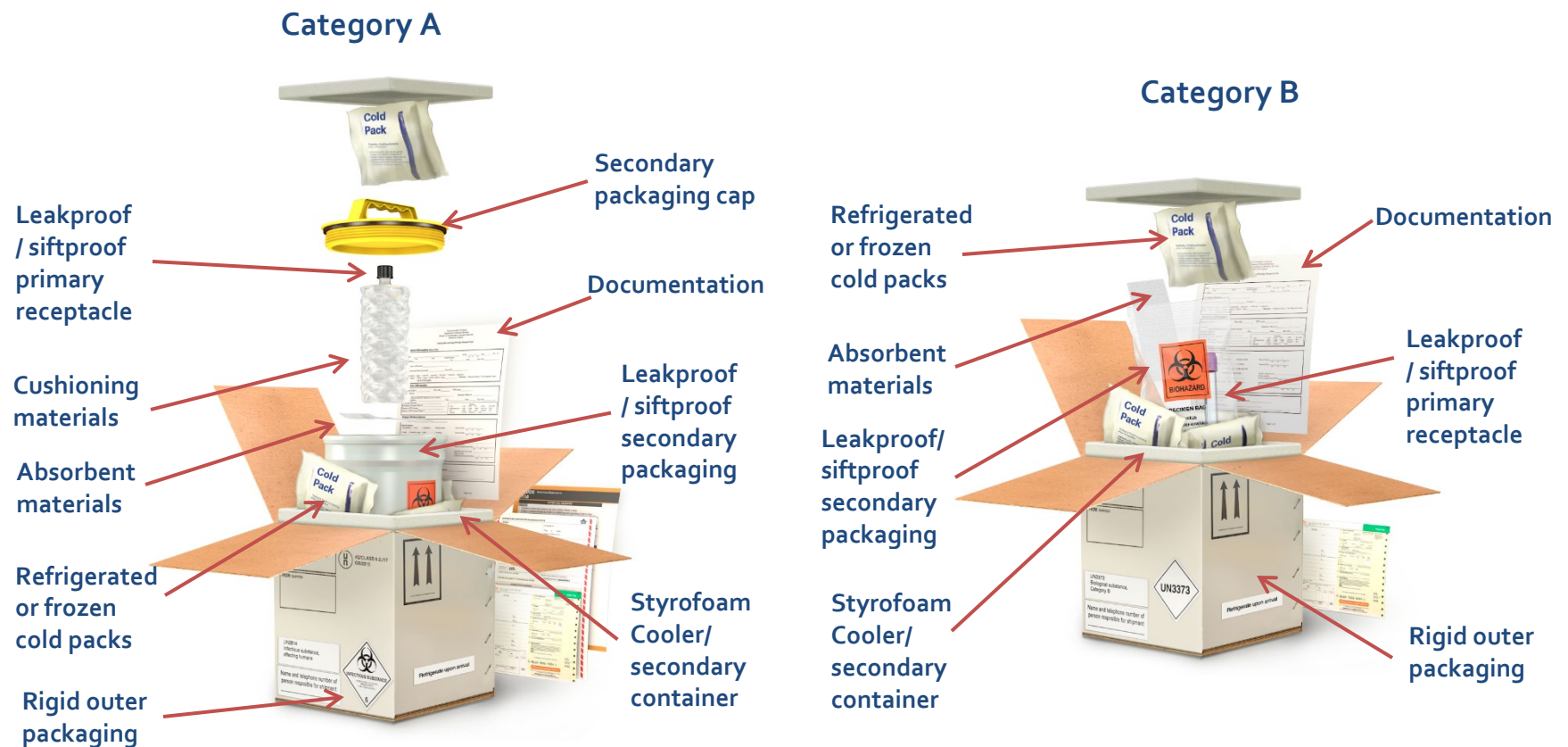
Packing Frozen Specimens:

- Ensure that specimens are frozen at the required temperature (e.g., -20°C , -70°C) prior to packing.
- Within the secondary container, place sufficient dry ice to surround the sealed secondary packaging, and add further insulation. It is important to note that surrounding the secondary packaging on all sides with the dry ice has shown to improve the length of time the specimen remains frozen during transit. Dry ice:
 - Should not come in direct contact with the primary receptacle.
 - Should not be used as a substitute for padding, as it will dissipate during transport.
 - Must not adversely affect the specimen(s) being shipped.
 - Will sublimate at a rate of 5-10 pounds every 24 hours; therefore 5-10 pounds of dry ice is required in an overnight shipment.
- Secondary packaging must be surrounded by an outer, secondary container (i.e., a Styrofoam cooler) with walls that are, at minimum, two inches thick.



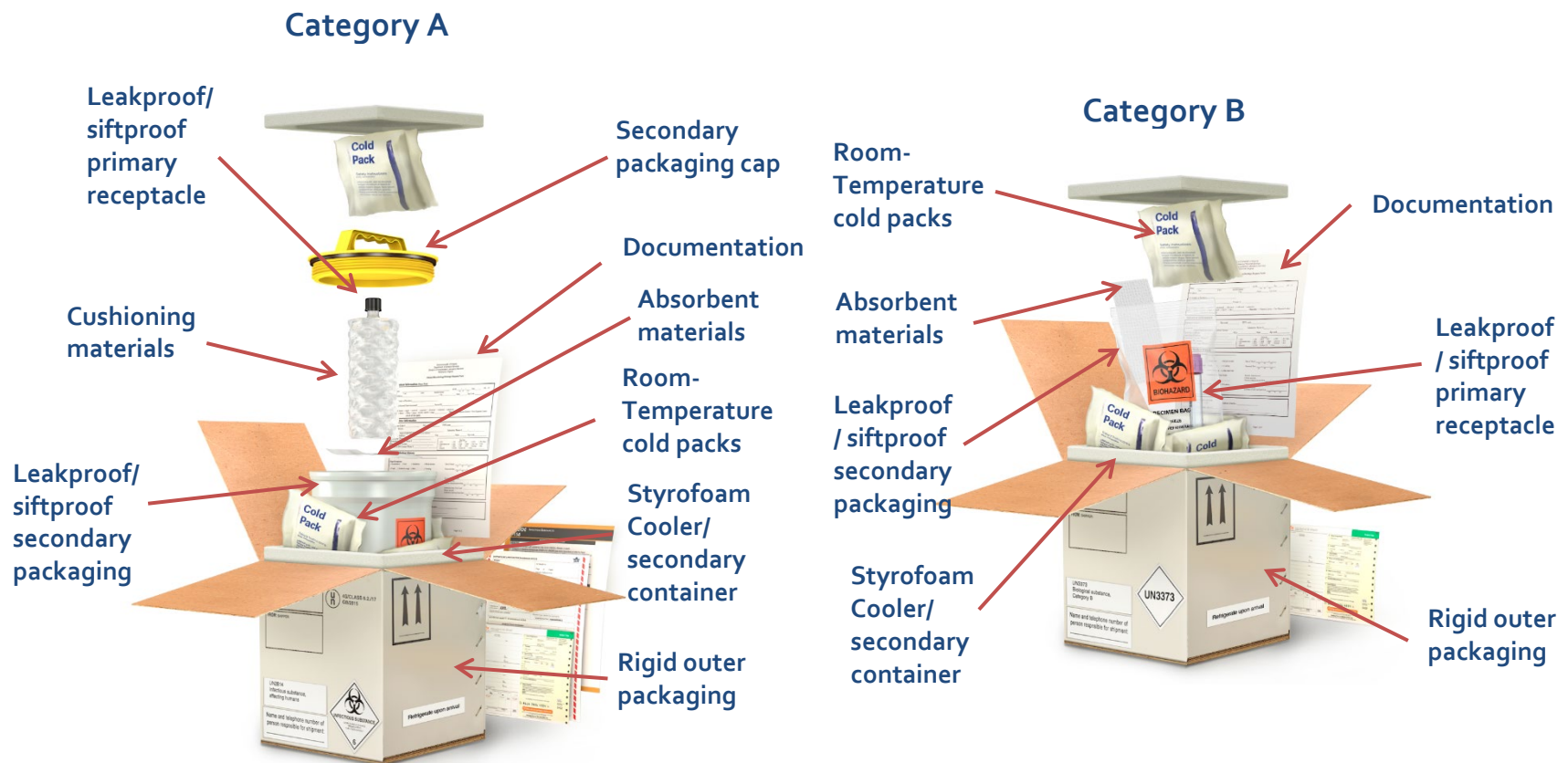
Packing Refrigerated Specimens:

- Ensure that specimens are at 2-8°C prior to shipment.
- Surround sealed secondary packaging (e.g., sealed biohazard bag) with refrigerated or frozen cold packs and further insulation (and do not use damaged or leaking cold packs or wet ice).
 - **Note:** It will be crucial for the submitter to consider the distance and expected duration of travel, as well as the season/outdoor temperature, to decide whether refrigerated or frozen cold packs should be used (e.g., where overnight shipping is not available, and/or during summer months, submitters may opt to include frozen cold packs).
- Ensure that secondary packaging is surrounded by an outer, secondary container (i.e., a Styrofoam cooler) with walls that are, at minimum, two inches thick.



Packing Room-Temperature Specimens:

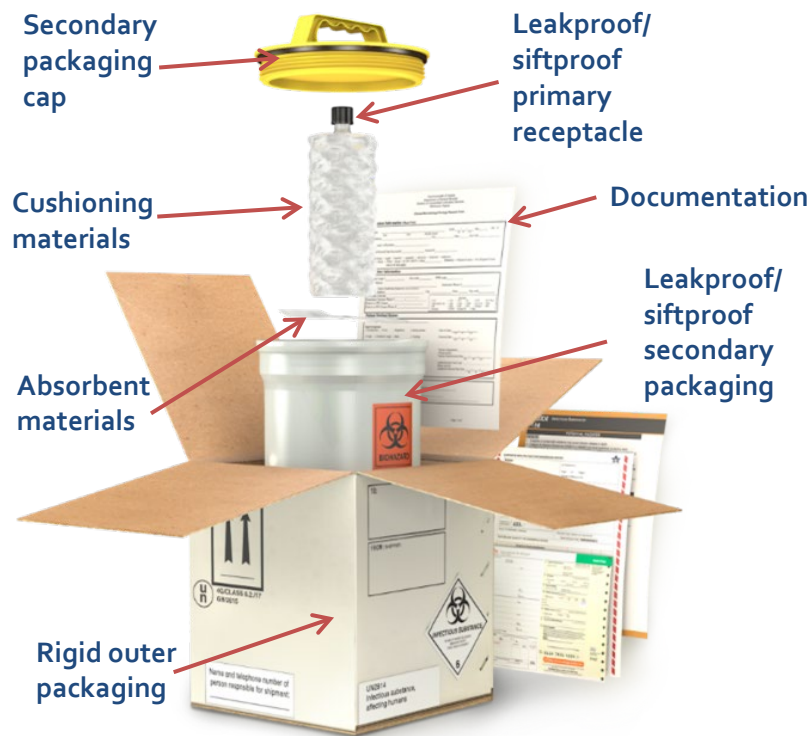
- Ensure that specimens are at 15-25°C prior to shipment.
- Include room-temperature cold packs to maintain proper temperature within the secondary container and add adequate cushioning material.
- Ensure that secondary packaging is surrounded by an outer, secondary container (i.e., a Styrofoam cooler) with walls that are, at minimum, two inches thick. For dried samples (e.g., blood slides, swabs), a secondary container may be omitted.



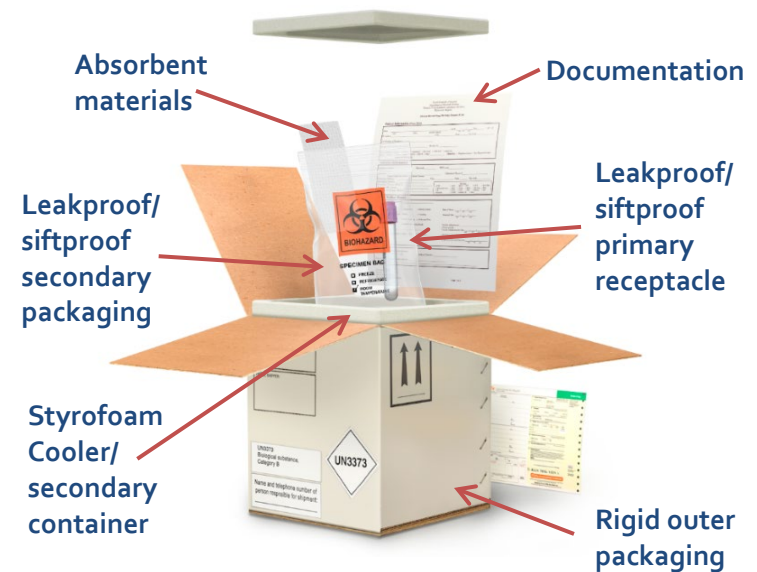
Packing Ambient Specimens:

- Submitters should ensure that specimens are at ambient temperature prior to packing.
- No temperature-maintaining materials (e.g., cold packs) are required.

Category A



Category B



Step 4: Label, Mark, and Document the Package

The mode of transport and the classification, as determined in the previous steps, will determine the proper mode of labeling and marking, as well as documentation needed for the outer packaging.



Definitions

Cold pack: reusable, leakproof, gel or solid refrigerant used to maintain temperature within a shipping container during transit. Cold packs can be frozen, refrigerated, or room temperature.

Ambient: descriptor of any specimen or material that maintains a temperature equal to its surrounding environment and which is not otherwise temperature controlled.

Frozen: descriptor of any specimen or material that is kept at or below -20°C.

Refrigerated: descriptor of any specimen or material that is kept within a range of 2-8°C.

Room-temperature: descriptor of any specimen or material that is kept within a range of 15-25°C.

Primary receptacle: the glass, metal, or plastic, leakproof/siftproof container housing the submitted specimen.

Secondary packaging: the leakproof/siftproof packing material that seals, cushions, and surrounds the primary receptacle(s).

Secondary container: a sealable, Styrofoam cooler that makes up the outermost layer of secondary packaging.

Outer packaging: the rigid, outermost packaging (typically a cardboard box) that houses the primary receptacle(s), secondary packaging, and secondary container.