Casing Scientific

5015 Addison Circle
Addison, Texas 75001
800 358 6866 Fax 888 661 9606 Digital 214 995 1132
www.casingcorp.com Email: casing@prodigy.net

SUMMARY OF EXEMPT PATIENT SPECIMEN RULES

Exempt Human or Animal Specimens

Summary of Patient Specimen Exemptions: Under IATA DGR 2005, Amendment III permits certain types of diagnostic specimens to be shipped with reduced documentation, labeling, and packaging if the specimens meet the standards for the exemption. Specimens that meet the following definitions and other criteria are qualified for the exemption; specimens that fail to meet the definition and other criteria must continue to be meet the 2007 rules:

1. Specimen must meet the following definition:

Specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta blood and its components, tissue and tissue fluid, swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment, and prevention.

2. Minimal likelihood that he specimen contains a pathogen:

A patient or animal specimen is considered exempt if there is a minimal likelihood that pathogens are present. In determining whether a patient or animal specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt. This judgment should be based on the known medical history, symptoms, and individual circumstances of the source, human or animal, and endemic local conditions.

Examples of specimens which may be transported under the exemption include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, PSA tests, tests required to monitor organ function such as heart, liver, or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes, biopsies to detect cancer; and antibody detection in humans or animals

Patient or animal specimens, with minimal likelihood that pathogens are present, may utilize the exemption provided that the specimen is packaged in a packaging which will prevent any leakage. The packaging must meet the following conditions:

1. <u>The packaging must consist of three components:</u>

(a) a leak-proof primary receptacle (s);
(b) a leak-proof secondary packaging, and
(c) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm.

2. For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that during transport, any release or leak of a liquid substance will not reach he outer packaging and will not compromise the integrity of the cushioning material.

3. When multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.

<u>Documentation</u>:

- Do not mark "Diagnostic Specimen, UN3373" on the air bill.

- If dry ice is used as a refrigerant, continue to mark "Dry ice, 9, UN1845, III on the air bill (check the dry ice on the FedEx air bill).

- Continue to check the "no" checkbox on the FedEx air bill in response to the question: "Does this shipment contain Dangerous Goods"

- Mark the outside of the outer container with the words "Exempt human specimen" or "Exempt animal specimen" as appropriate.

- Do not place the "Diagnostic specimen, UN3373 label on the outer box

- If dry ice is used as a refrigerant continue to follow the Packing Instruction 904 packaging requirements