



Shipping recommendations for saliva samples collected with Oragene™

Summary of recommendations

For saliva samples not expected to be pathogenic, the following packaging is recommended for shipping the Oragene vial:

- Capped Oragene vial (with or without secondary rigid plastic container)
- A liquid-tight bag with biohazard logo to hold the capped Oragene vial
- Absorbent material in the liquid-tight bag sufficient to soak up at least 4 mL of liquid
- An outer mailing envelope labeled with the words “Exempt Human Specimen”

This complete kit is available for purchase from DNA Genotek, including all relevant labels and instructions. Please ask for Product #MO-2.

Background

Air transportation of diagnostic specimens is governed under authority of the International Civil Aviation Organization (ICAO) and its regulations are published by the International Air Transport Association (IATA). Since courier services designated as “ground” may involve an air transport segment, the IATA publications are broadly applicable to both air and ground shipment.

The IATA Dangerous Goods Manual was revised on January 1, 2005, and most recently amended according to Addendum III, issued on July 5, 2005. This Addendum introduces the following guidance:

3.6.2.2.3.6 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate. The packaging must meet the following conditions:

- (a) The packaging must consist of three components:
 - (1) a leak-proof primary receptacle(s);
 - (2) a leak-proof secondary packaging; and
 - (3) 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 × 100 mm;
- (b) 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 the outer packaging and will not compromise the integrity of the cushioning material;
- (c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

NOTE:

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That 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 this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); 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 and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

For those collecting samples which may not fit the definition above, more stringent requirements for transportation apply. These include the use of a rigid outer container, application of UN2814 (Category A pathogens) or UN3373 (Category B pathogens) labels, and demonstration of compliance with pressure tests. More information is available upon request from DNA Genotek, directly from IATA, or possibly from your local carrier.