



Shipping ThinPrep® Solutions and Samples within CONUS 51-500 Vials – Limited Quantity Shipments

FACT SHEET 37-039-0518

This Fact Sheet is applicable for 1-500 vials of Thin Prep but additional exceptions are allowed when shipping between 1-49 vials. If you need to ship greater than 500 vials per package, we suggest you break up the number of vials so that each package you send has a maximum of 500 vials each. This will enable you to use the limited quantity exception allowed by the Department of Transportation (DOT) as well as by the International Air Transport Association (IATA).

- 1. BACKGROUND.** Department of Defense (DoD) medical facilities collect and process specimens to test for cervical cancer using the ThinPrep® PreservCyt® solution made by Hologic Inc. PreservCyt® is a methanol-based, buffered preservative solution and is classified as a hazardous material (HM) due to its low flashpoint (80°F/26.5°C) and must be packaged and shipped in accordance with regulatory requirements governing transport of HMs within the United States. A vial of ThinPrep contains 20 mL of solution.
- 2. TRAINING.** Personnel who package any quantity of ThinPrep® solution must receive training, within 90 days of employment per 49 CFR 172.704 and International Air Transport Association (IATA) Regulations Chapter 1, Section 1.5. All personnel who sign hazardous materials shipping papers for ThinPrep® shipments must be formally trained per DoD Defense Transportation Regulation (DTR), 4500.9-R, Part II, Chapter 204, Section D (https://www.ustranscom.mil/dtr/part-ii/dtr_part_ii_204.pdf). Certification training can be obtained by successfully completing the Transport of Biomedical Material Course given by the Army Public Health Center. Registration for the Transport of Biomedical Material Course is available at <http://phc.amedd.army.mil/Pages/Training.aspx>. This paper is not a substitute for the specialized training required.
- 3. HAZARD CLASSIFICATION.** New vials of PreservCyt® solution as well as those containing a specimen are Hazard Class 3, flammable liquid, based on the manufacturer's Safety Data Sheet. Although PreservCyt® solution contains a biological specimen being sent for purposes of diagnosis, the sample IS NOT classified as a Diagnostic Specimen. PreservCyt® solution contains chemicals that neutralize any infectious agents that might be present. The specimen is therefore excepted from being classified as a Division 6.2 material based on 49 CFR Section 173.134(b)(4) or the IATA Regulation (59th Edition) Chapter 3, Section 3.6.2.2.3.3.
- 4. DESCRIPTION. Basic Description:** UN1993, Flammable liquids, n.o.s., 3, III; **Shipping Description:** UN1993, Flammable liquids, n.o.s. (contains methanol), 3, III
- 5. SHIPMENT AS A LIMITED QUANTITY.** Limited quantity requirements are defined in 49 CFR 172.101, Column 8A and IATA Dangerous Goods Regulations, Chapter 2, Section 2.7. New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity **provided** each inner receptacle (vial) does not contain more than 5 L of solution. Each vial of Thin Prep holds 20 milliliters of solution.

a. **Highway:** The 49 CFR 172.101, Hazardous Materials Table, Column 8A (Exceptions) directs you to the appropriate section under 49 CFR Part 173 that determines the quantity limits and types of packaging that can be used to ship that particular HM as a limited quantity. The proper shipping name "Flammable liquids, n.o.s.," lists three packing groups. ThinPrep is PG III. Column 8A of the Hazardous Materials Table directs you to Section 173.150 for shipping Limited Quantities of Class 3 flammable liquids.

Use of trademarked names does not imply endorsement by the U.S. Army but is intended only to assist in identification of a specific product.

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(1) Packaging: Combination packagings are authorized. Each inner receptacle with a removable closure must be packaged so that closures of the inner containers are upright. The inner receptacles must be securely packed in cushioning material. Strong outer packaging that are able to withstand the rigors of transport must be used. Under 49 CFR 173.150(b), you may ship PreservCyt® solution or specimens as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds). In this case, the number of vials is not the limiting factor but the overall package weight. [49 CFR 171.8, 173.24, 173.24a, 173.150(b)(3)]

(2) Marking and Labeling: The proper shipping name with the technical name [Flammable liquids, n.o.s. (contains methanol)] and UN identification (ID) number are not required to be marked on the package provided it is marked with the white square-on-point limited quantity marking (Figure 1)[49CFR 172.315]. Hazard labels are not required.

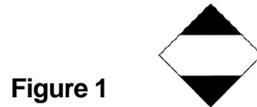


Figure 1

(3) Shipping Papers: No shipping paper required [49 CFR 172.200(b)(3) and 173.150(b)]. No emergency response number required [49 CFR 172.604(d)(1)]. No placards are required.

b. **Commercial Air:** New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity as defined in the IATA Dangerous Goods Regulations, Chapter 2, Section 2.7. Chapter 4, Section 4.2, Column G of the IATA, the Dangerous Goods List, directs you to the proper packing instruction to determine the quantity limits and types of packaging that may be used to ship PreservCyt®.

(1) Packaging: Flammable liquids, n.o.s. (PG III) directs you to Packing Instruction Y344 for limited quantity shipments. The inner receptacles must be securely packed with sufficient cushioning/ absorbent material. Outer packaging must pass the drop and stacking test required under IATA 2.7.6. Under IATA Section 2.7.4.2, you may ship PreservCyt® solution or specimens as a limited quantity as long as the total outer packaging weight does not exceed 30 kg (66 pounds). The maximum quantity permitted in one outer packaging is 10,000 mL (10 L). A maximum of 500 of the 20 mL vials may be shipped in one package as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds).

(2) Marking and Labeling: Mark the proper shipping name (with technical name), UN ID number, and the net quantity of the dangerous goods contained in the package on the outer packaging near the receiver's full name and address (IATA Section 7.1.4). The package must also bear the **Limited Quantities Mark** (Figure 2) (IATA Section 7.1.4.2). Mark the shipper's full name and address on the outer packaging. Labeling is required. Affix a "Hazard Class 3 - Flammable Liquids" (IATA 7.3.8) label to the outer packaging on the same surface as the proper shipping name, near the receiver's address. Package orientation labels are not required (IATA 7.2.4.4). Both the shipper's and receiver's full names and addresses must be marked on the outer package when shipping by commercial air.]



Figure 2

(3) Shipping Papers: A "Shipper's Declaration for Dangerous Goods" and an Air Waybill are required. Complete the "Shipper's Declaration for Dangerous Goods" according to the instructions found in IATA Chapter 8, Section 8.1.6. Complete the Air Waybill per the carrier's instructions.

6. For waste management issues, procedures and regulatory requirements see APHC Fact Sheet, Management of Waste from the ThinPrep® Processor.