



U.S. Department
of Transportation

400 Seventh Street, S.W.
Washington, D.C. 20590

**Research and
Special Programs
Administration**

OCT 18 2004

DOT-E 13321
(SECOND REVISION)

EXPIRATION DATE: April 30, 2006

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Quest Diagnostics, Inc
Collegetown, PA
2. PURPOSE AND LIMITATION:
 - a. This exemption authorizes the transportation in commerce of certain infectious substances in specially designed, reusable textile bags. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.28(b)(3) in that textile bags are not authorized for reuse except as specified herein.
5. BASIS: This exemption is based on the application of Quest Diagnostics, Inc., dated October 29, 2003, and additional information dated March 30, 2004, April 15, 2004, June 22, 2004, and August 30, 2004, submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

OCT 18 2004

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/Division	Identification Number	Packing Group
Diagnostic specimen	6.2	UN3373	N/A
Infectious substances, affecting animals <i>only</i>	6.2	UN2900	N/A
Infectious substances, affecting humans	6.2	UN2814	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - The prescribed packaging is a specially designed UN5L3 textile bag, meeting the description and performance of TEN-E Packaging Services, Inc. Test Report Number: 02-2338 on file with the Office of Hazardous Materials Exemptions and Approvals. The construction of the textile bag is as follows:

(1) An outer bag fabricated from polyester fabric with a PVC backing. The bag is closed with a plastic zipper.

(2) The bag has a removable inner liner coated with PVC and attached to the outer bag with hook and loop (e.g., Velcro®) fasteners.

(3) The outer bag has two vents to permit carbon dioxide to escape from the packaging when dry ice is used as a refrigerating material.

(4) The outer bag has 4 side handles and 1 carrying strap.

(5) The approximate dimensions of the outer bag are: 18-3/4" x 9-7/8" x 16-3/8".

OCT 18 2004

b. OPERATIONAL CONTROLS -

(1) Prior to reuse the outer packaging, including the removable inner liner, must be inspected by the grantee to ensure it is acceptable for continued use, is capable of meeting the design test requirements for an infectious substance packaging and meets the requirements for the initial design type. Each bag must be inspected to ensure that:

(i) All handles are securely fastened to the bag in accordance with the design type; and

(ii) Seams are free from defects in stitching, heat sealing or gluing which would render the packaging unsafe for transporting infectious substances; and

(iii) Fabric used to construct the package is free from cuts, tears and punctures. Additionally, fabric must be free from scoring which may render the package unsafe for transport; and

(iv) Vents are unobstructed and capable of venting carbon dioxide gas, if dry ice is to be used as a refrigerating material.

(2) The liner and textile bag may not be reused if the inner packagings are compromised and release the infectious substances within the packaging.

(3) The zippers on the outer textile bag must be secured with a tamper evident seal after the infectious substances are loaded into the packaging.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this exemption and the HMR.

b. A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.

OCT 18 2004

- c. Quest Diagnostics, Inc. must have a copy of TEN-E Packaging Services, Inc. Test Report Number: 02-2338 and the latest periodic retest report required by § 178.601(e) on file. Test reports must be made available to a DOT representative upon request.
9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, passenger aircraft and cargo aircraft only.
10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each aircraft or motor vehicle used to transport packages covered by this exemption. The shipper must furnish a copy of this exemption to the air carrier before or at the time the shipment is tendered.
11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
- o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
 - o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
 - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

OCT 18 2004

Continuation DOT-E 13321 (2nd Rev.)

Page 5

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (Sections 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued in Washington, D.C.:



fe Robert A. McGuire
Associate Administrator
Hazardous Materials Safety

OCT 18 2004

Date

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590.
Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at <http://hazmat.dot.gov/exemptions> Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: DB/AM