

Pipeline and Hazardous Materials Safety Administration 1200 New Jersey Avenue, SE Washington, DC 20590

# DOT-SP 21051 (FIRST REVISION)

**EXPIRATION DATE: 2026-05-31** 

(FOR RENEWAL, SEE 49 CFR 107.109)

1. <u>GRANTEE</u>: Lab Vendor, LLC

Stamford, CT

#### 2. PURPOSE AND LIMITATION:

- a. This special permit authorizes the transportation in commerce of certain Division 6.2 infectious substances and biological substances packaged in alternative packagings (freezers) in a dedicated truck by highway. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
- b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
- c. No party status will be granted to this special permit.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. <u>REGULATIONS FROM WHICH EXEMPTED</u>: 49 CFR §§ 173.196(a) and (b) and 173.199 in that packaging requirements are waived; and 178.609 in that test requirements for packagings are waived, except as specified herein.
- 5. <u>BASIS</u>: This special permit is based on the application of Lab Vendor, LLC dated March 20, 2022, submitted in accordance with § 107.109.

Tracking Number: 2022034664

# 6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Infectious substances, affecting animals only	6.2	UN2900	N/A
Infectious substances, affecting humans*	6.2	UN2814	N/A
Biological substance, Category B	6.2	UN3373	N/A

<sup>\*</sup>Infectious substances for which effective treatments and preventive measures are not usually available are not allowed under this special permit.

### 7. SAFETY CONTROL MEASURES:

#### a. PACKAGING:

- (1) Infectious substances and biological substances, as listed in Paragraph 6, must be packed as follows:
  - (i) Primary receptacle Cryo-vials containing not more than 5 mL of substance when transported by mechanical freezer or 2 mL when transported by liquid nitrogen freezer and sealed with threaded cap and silicone washer.
  - (ii) Secondary packaging Closed boxes, capable of withstanding cryogenic storage, containing primary receptacles and securely stacked in metal racks. Up to 100 cryo-vials may be placed in a secondary container, secured in individual cells. Sufficient absorbent material must be placed between the primary and secondary packaging to absorb the entire contents of all primary receptacles in case of a vial breakage or leakage. Not more than sixteen (16) secondary packagings when transported by mechanical freezer or fifteen (15) when transported by liquid nitrogen freezer are further placed in a heat-sealed plastic bag.
  - (iii) Outer packaging Portable, mechanical (-20 °C and -80 °C) freezers, and liquid nitrogen freezers. Not more than thirty (30) plastic bags may be packed in a mechanical freezer with a capacity not more than 0.8 cubic meters (28 cubic feet) and not more than sixty (60) plastic bags

must be packed in a liquid nitrogen freezer with a capacity not more than 1.3 cubic meters (46.5 cubic feet).

- (iv) When transported via mechanical freezer, not more than 48,000 vials are authorized per outer packaging. When transported via liquid nitrogen freezer, not more than 90,000 vials are authorized per outer packaging.
- (v) Outer packagings must be tightly closed and secured to prevent movement of the vials during transport.
- (vi) A single shipment is limited to a combination of 12 cryogenic shippers (mechanical or liquid nitrogen freezers) transported on one truck.
- (2) The outer packagings are sturdily constructed with a stainless steel inner lining.
- (3) The substances within the outer packaging must be kept frozen within the operating temperature range of -20 °C to -85 °C using mechanical refrigeration or -190 °C using liquid nitrogen.
- (4) All outer packagings must be secured against movement in the transport truck.

### b. <u>OPERATIONAL CONTROLS</u>:

- (1) This special permit authorizes the transport of packages containing infectious substances and biological substance using a specially designed dedicated refrigerated truck. The transport vehicle must be operated by Lab Vendor LLC. The loading of the substances must be performed by trained company employees.
- (2) An itemized list of contents must be securely attached to the outside of each outer packaging.
- (3) Emergency equipment necessary to mitigate a spill must accompany each transport vehicle.
- (4) The motor vehicles must be equipped with two independently-operated generators supplying power to the freezers. Each freezer must be equipped with an independent temperature monitoring system that will alert the driver if the temperatures exceed -20°. Empty backup freezers must be maintained at temperature, and the driver shall transfer material from a failing freezer to the backup freezers.

- (5) When transporting liquid nitrogen freezers, a back-up liquid nitrogen supply tank containing no more than 233 L of liquid nitrogen (to keep the substances within the operating temperature range for at least twice the estimated travel time) must be included on the transport vehicle. This supply tank must be secured against movement during transportation.
- (5) When transporting infectious materials described in 172.800(b)(13), a security plan conforming with 172.800 must be in place.
- (6) The cargo area of the transport vehicle must be locked at all times during transportation.

### 8. SPECIAL PROVISIONS:

- a. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package and it is reoffered for transportation in conformance with this special permit and the HMR.
- b. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
- 10. <u>MODAL REQUIREMENTS</u>: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 <u>et seq</u>:
  - o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
  - o Persons operating under the terms of this special permit 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 special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

June 24, 2022

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

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)— "The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. <u>REPORTING REQUIREMENTS</u>: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:

for William Schoonover

Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-13, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at <a href="https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search">https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search</a>. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

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