

Shipping Category B Diagnostic Samples

Safety Advisory Notice on Transporting COVID-19 Diagnostic Samples



U.S. Department of Transportation
Pipeline and Hazardous Materials
Safety Administration

"To protect people and the environment by advancing the safe transportation of energy
and other hazardous materials that are essential to our daily lives."



Disclaimer: These slides are informational and DOT always advises you use the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) when determining compliance




Agenda

- **Applicability**
- **Triple Packaging System**
- **Package Capability Requirements**
- **Air Packaging and Quantities**
- **Required Markings**
- **Emergency Response Information**
- **Closure Instructions**



Resource Materials


 U.S. Department of Transportation
 Pipeline and Hazardous Materials Safety Administration

1002 NEW JERSEY AVENUE, SE
 WASHINGTON, DC 20590


Safety Advisory Notice for the Transportation of COVID-19 Diagnostic Samples
 U.S. Department of Transportation
 Pipeline and Hazardous Materials Safety Administration
 Office of Hazardous Materials Safety

The U.S. Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) plays a leading role in ensuring the safe transportation of hazardous materials in commerce throughout the United States. Because of the ongoing Coronavirus Disease 2019 (COVID-19) public health emergency, there have been shipments of COVID-19 diagnostic samples (e.g., nasal swabs, sputum, and other related items) that are classified as a Category B infectious substance (Division 6.2) hazardous material under the Hazardous Materials Regulations (HMR, 49 CFR Parts 171-180).


Investigators from PHMSA's Office of Hazardous Materials Safety (OHMS) recently conducted compliance inspections and found several instances of improperly marked or packaged diagnostic samples that were offered for transportation, which included sample vials packaged without rigid outer packaging. In response, PHMSA has developed this Safety Advisory Notice to provide information on the HMR related to offering and transporting these materials.

Guide to Packaging Category B Diagnostic Samples
 You can learn more about the packaging system and its components by following these 1-2-3 Packaging Instructions*.

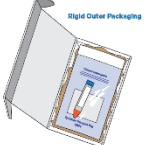
STEP 1: Primary Receptacle
 Package primary receptacle
 - Leakproof the liquid or air proof (for solids).


 Primary Receptacle

STEP 2: Secondary Packaging
 Pack primary receptacle into secondary packaging (leakproof or 95%PA specimen bag). Pack in such a way to prevent breakage, punctures, or leakage of primary receptacle.
 - Wrap or separate each fragile primary receptacle to prevent contact with one another.
 - Include sufficient absorbent material to absorb all liquids should the primary receptacle leak or break.
 - Liquids by air require 95%PA capability for primary receptacle or secondary packaging.


 Secondary Packaging
 Leakproof or 95%PA specimen bag
 Primary Receptacle
 Absorbent material


STEP 3: Rigid Outer Packaging
 Secure secondary packaging into rigid outer packaging.
 - Include suitable cushioning material to fill void spaces and reduce possibility of packaging failure (e.g., leaks and breaks).


 Rigid Outer Packaging


NOTE: A carrier provided shipping bag or box (e.g., overpack) is not a substitute for rigid outer packaging.
 * Always follow the exact instructions on filling and closing a package used to transport a Category B infectious substance provided by the packaging manufacturer.

The Hazardous Materials Regulations (HMR, 49 CFR Parts 171-180) help ensure the safe transportation of hazardous materials, including Category B infectious substances. When packaging a Category B diagnostics sample, always follow the exact instructions for filling and closing the packaging used to transport a Category B infectious substance provided by the packaging manufacturer. The packaging requirements in the HMR (found in §172.203) specify a triple packaging system designed, constructed, maintained, filled, and closed so that under conditions normal to transportation, there is no release of the hazardous material.

Hazard Communication
 - Apply UN3373 marking and proper shipping name: "Biological Substance, Category B" marking.
 - Apply Name and Telephone number of person responsible for providing emergency response information. Alternatively, this information can instead be included on a written document, such as a bill of lading.
 - When packages are overpacked (e.g., shrink wrapped, consolidated or placed in additional outer packaging, such as a carrier provided shipping envelope), all required markings must be clearly visible or reproduced on the outside of the overpack.


 UN3373
 Biohaz. PHMSA Diagnostic Substances Category B

For additional information contact:
The Hazardous Materials Info Center
 1-800-HMR-4922
 (1-800-467-4922)
 E-mail: info@hazmat.gov
 https://www.phmsa.dot.gov


 U.S. Department of Transportation
 Pipeline and Hazardous Materials Safety Administration



TRANSPORTING INFECTIOUS SUBSTANCES SAFELY


 U.S. Department of Transportation
 Pipeline and Hazardous Materials Safety Administration

WWW.PHMSA.DOT.GOV

Publication:

- <https://www.phmsa.dot.gov/news/phmsa-safety-advisory-transportation-covid-19-diagnostic-samples>
- <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting%20Infectious%20Substances%20Safely.pdf>

Regulations: <https://www.ecfr.gov>



Why is this important?



Background



Applicability

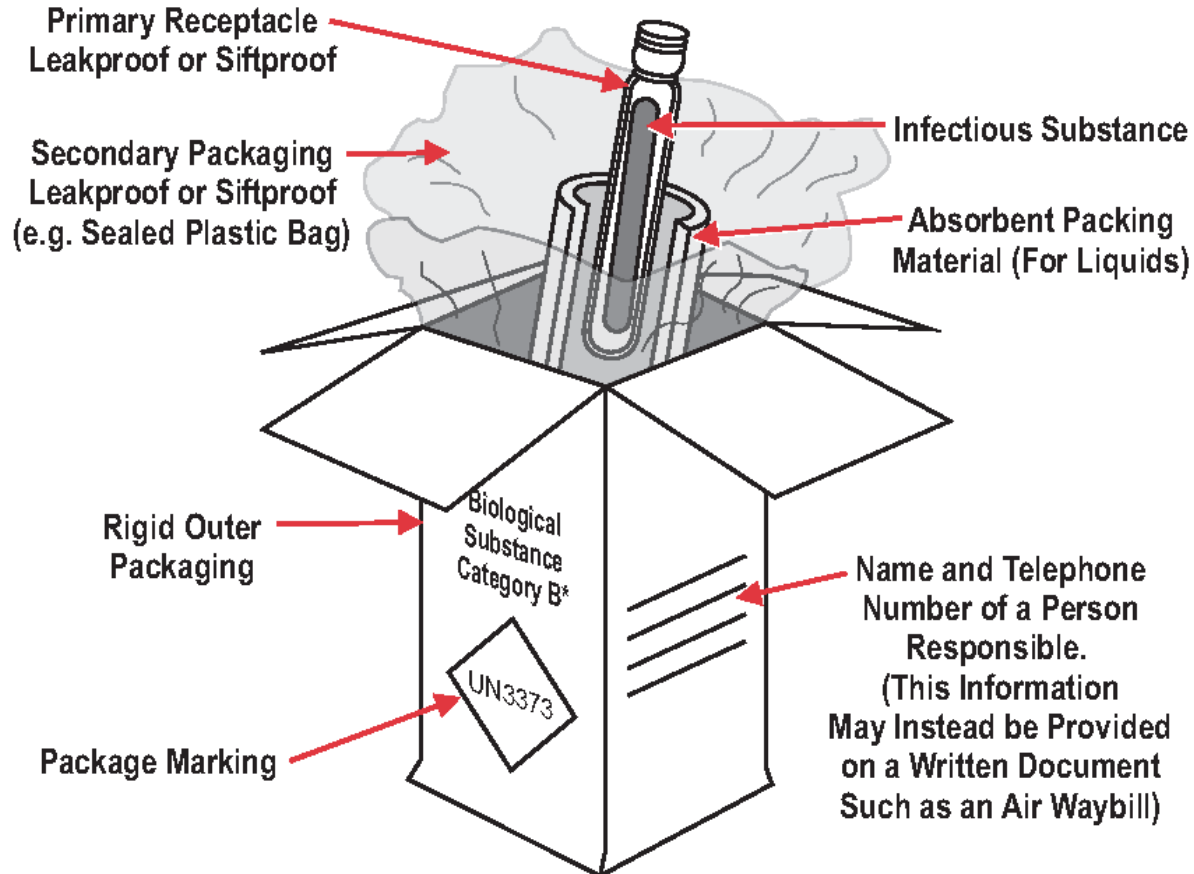
Human and animal specimen samples that are used to test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) should be classed and described as:

**“UN3373, Biological substance,
Category B, 6.2”**



Triple Packaging

DIAGRAM OF CATEGORY B PACKAGE

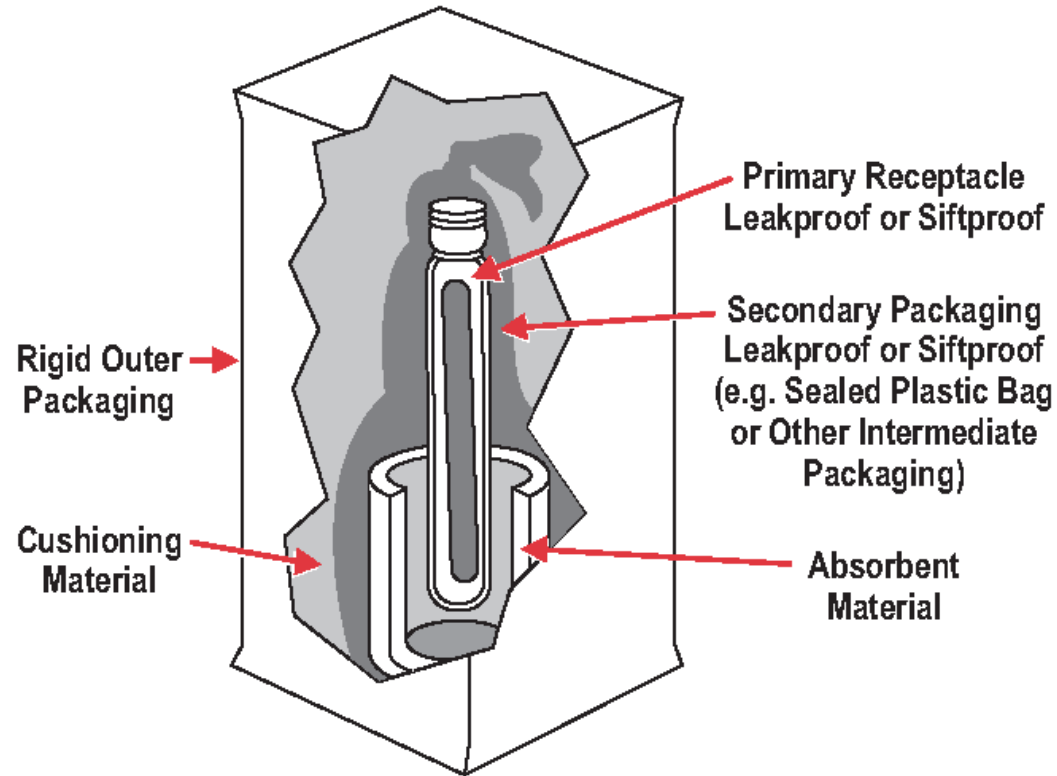


Regulatory reference: 49 CFR, 173.199



Triple Packaging

CROSS SECTION OF CLOSED PACKAGE



Regulatory reference: 49 CFR, 173.199



Package Capability Requirements



- **MUST** be capable of passing the drop test at a drop height of at least 1.2 meters (3.9 feet).
- **MUST** be no leakage from the primary receptacle, which **MUST** remain protected by the absorbent material in the secondary packaging – when required.

Regulatory reference: 49 CFR, 178.609 (d)



Air Packaging

The primary receptacle or the secondary packaging must be capable of preventing leak by withstanding an internal pressure of not less than 95kPa (0.95 bar, 14 psi).



Maximum Quantity by Air

Liquid Category B, infectious substance

Inner Package

maximum quantity = **may not exceed 1 L (34 ounces)**

Outer Packaging

maximum quantity = **may not exceed 4 L (1 gallon)**



Maximum Quantity by Air – cont.

Solid Category B, infectious substance

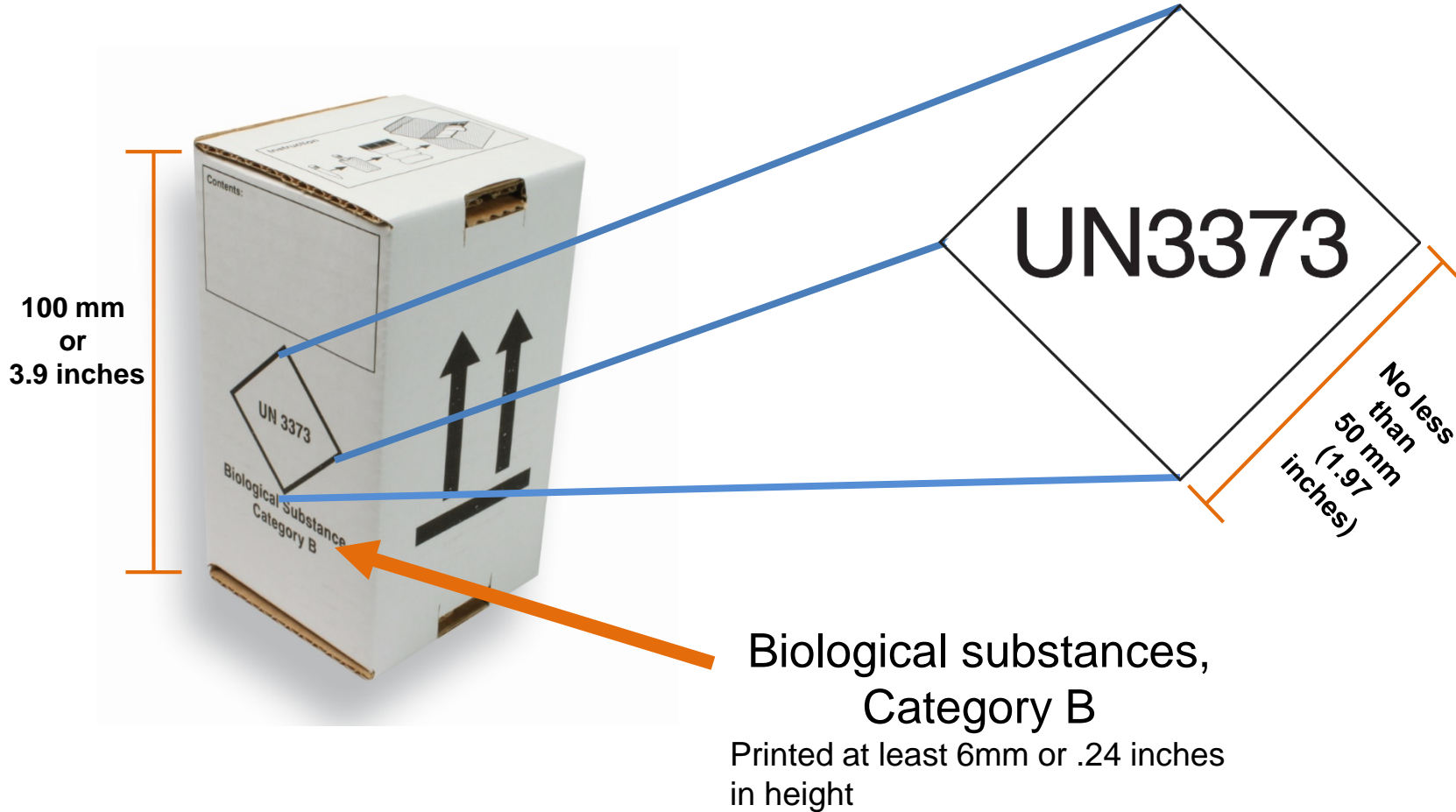
Outer Packaging

maximum quantity = **may not exceed 4 kg (8.8 lbs)**

NOTE: Does not apply to ice, dry ice or liquid nitrogen when used to maintain integrity of the sample



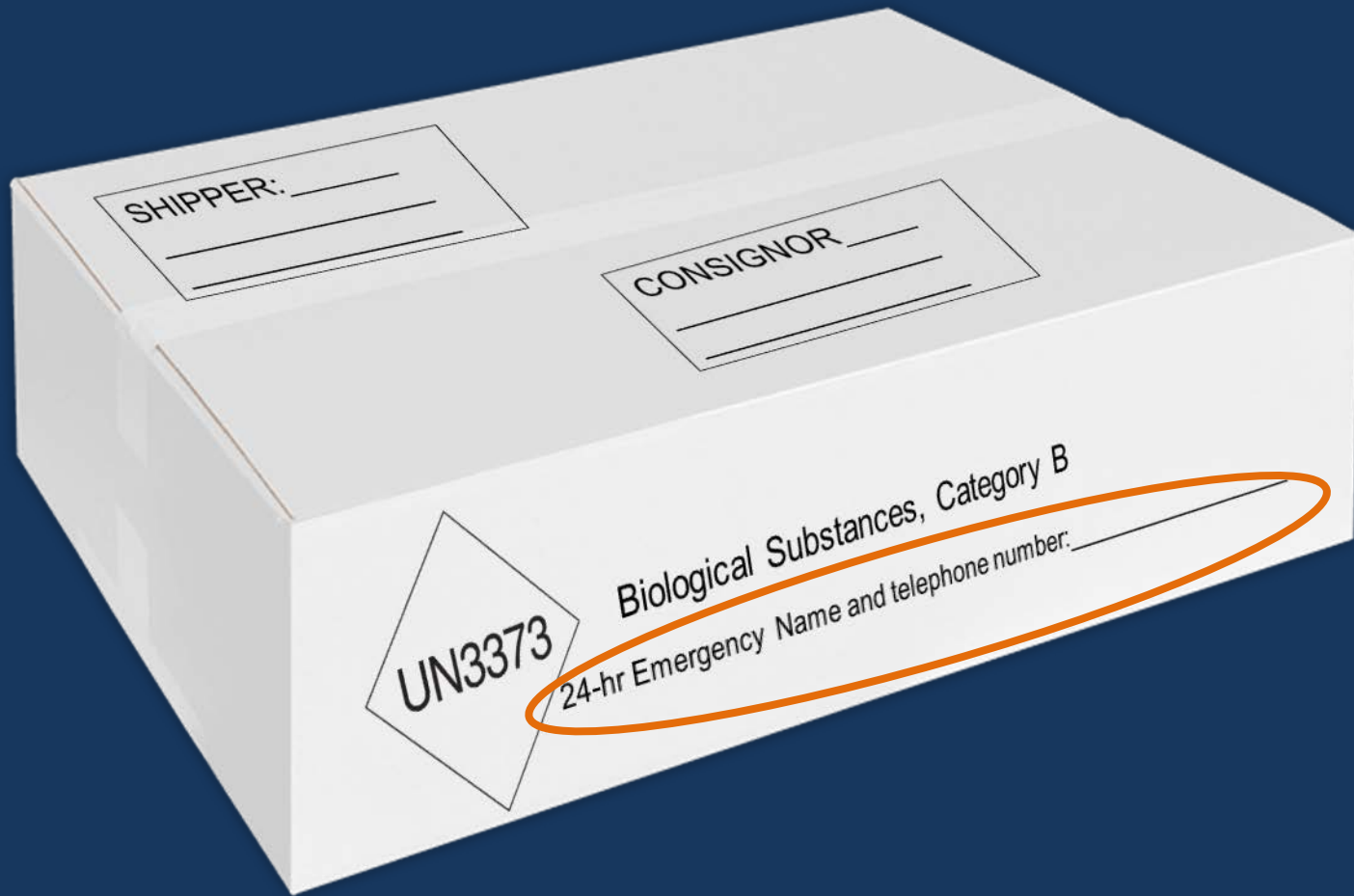
Required Markings



Regulatory reference: 49 CFR, 173.199 (a) 4-5



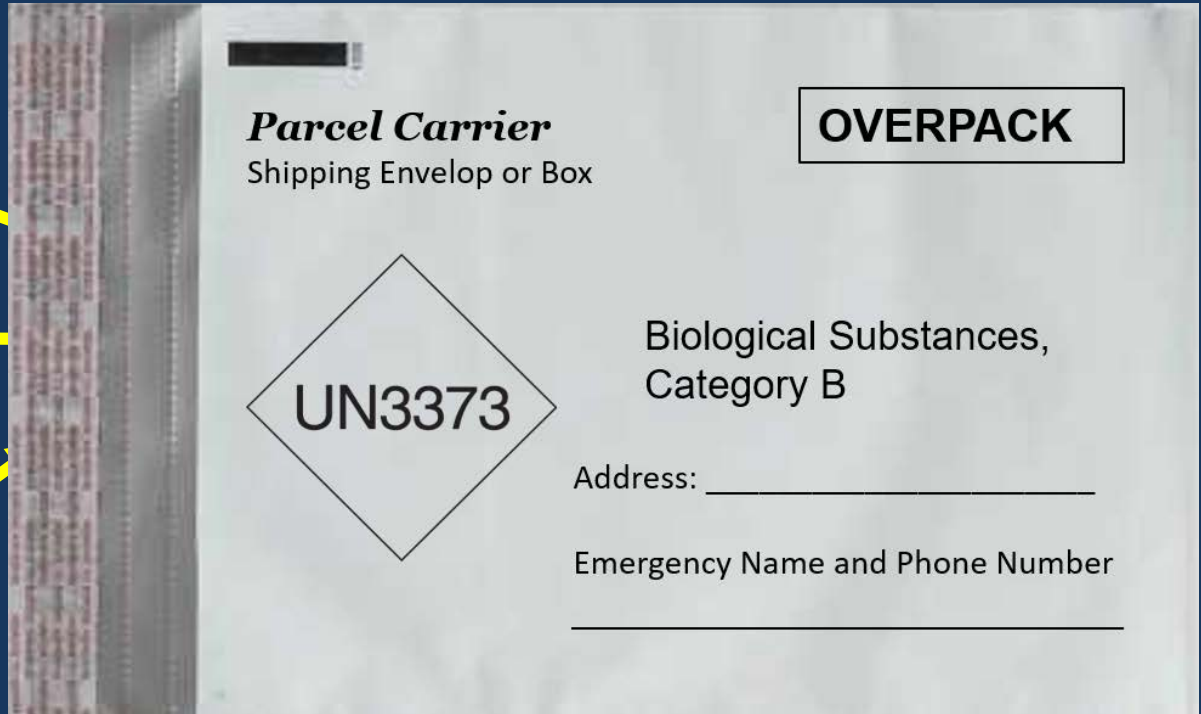
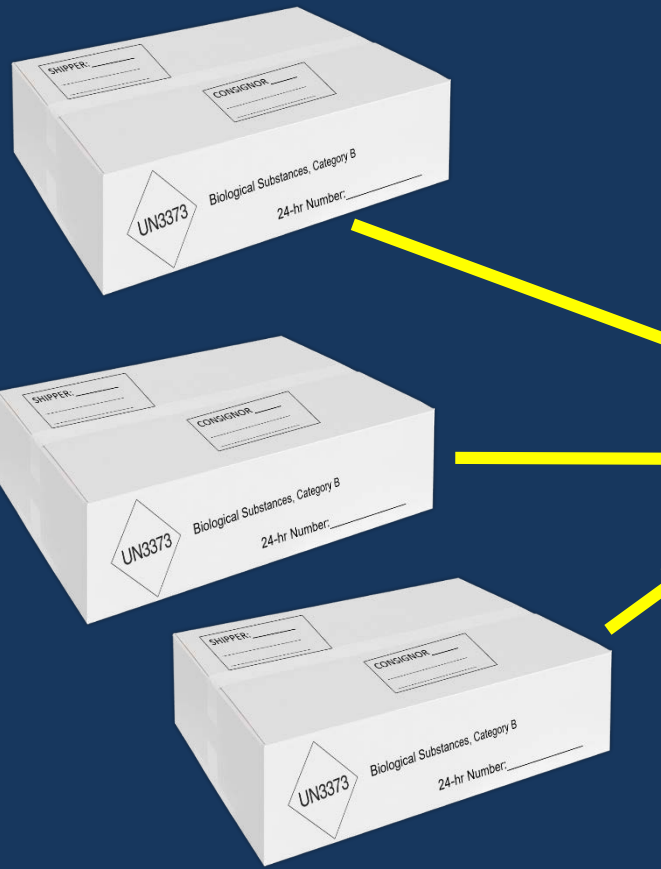
Emergency Response Information



Regulatory reference: 49 CFR, 173.199 (a) (7)



Overpack Markings



Regulatory reference: 49 CFR, 173.199



Closure Instructions

COVID-19 Collection and Shipping to Diagnostic Laboratory

Shipping guidance and packing materials for samples being tested at Diagnostic Laboratory

Collection of Specimen Check expiration date of all kit components before collecting sample.

Collect appropriate sample for type of swab received.

Nasopharyngeal Swab: A dry-tip swab is inserted into one or both nostrils to the NP area and pressed against the nasal wall. Allow a moment to absorb secretions. Rotate the swab 2 or 3 times and withdraw. Place in transport medium. Break off shaft and cap tube.

Nasal Swab: Insert a dry swab into the lower aspect of the nostril under direct vision until the tip is past the external orifice. The swab is then placed in the gutter below the inferior turbinate and allowed to remain there a moment to absorb secretions. Rotate the swab gently over the turbinate surface and the septal surface 2 or 3 times and withdraw. Place in transport medium. Break off shaft and cap tube.

Throat Swab: Depress the tongue with tongue blade and repeatedly swab the posterior pharynx in an up and down motion. Place swab in transport medium. Break off shaft and cap tube.

Storage and Shipment Temperatures

Before collection store media at 5°-25°C
Store refrigerated until shipping 2°-8°C
Ship ambient 20°-25°C

Packaging and Shipping



Break off swab into transport media



Place tube inside bag with absorbent.



Put requisition inside pouch on biohazard bag.



Place contents in box, ensuring snug fit



Close box, check for proper HAZMAT marking, name, phone number and attach shipping label

Refer to 49CFR 173.199 for current regulations on packaging and shipping of Category B infectious substances



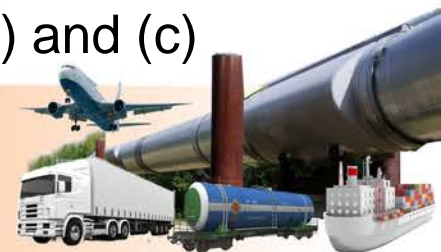
Regulatory reference: 49 CFR, 173.199 (a) 10



Exceptions

- The HMR contain some exceptions from the requirements described above for Category B infectious substances.
- The Shipper is responsible for determining if an exception is relevant and complying with the provisions contained in the exception.

Regulatory reference: 49 CFR, 173.6 (a) (4) and 173.134 (b) and (c)



For additional information contact:

The Hazardous Materials Info Center

1-800-HMR-4922

(1-800-467-4922)

E-mail: infocntr@dot.gov

<https://www.phmsa.dot.gov>

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Questions Moving Forward

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QUESTIONS

