Northern Plains Laboratory

Specimen Transport Guide 2020

Introduction

Bismarck, North Dakota is the home of Northern Plains Laboratory, LLC (NPL), a full-service clinical laboratory with state-of-the-art robotics and automation ranking it among the top clinical laboratories in the upper Midwest.

NPL offers reference clinical laboratory and consulting services. Anatomic pathology services (surgical pathology, cytology and autopsies) are available through Pathology Consultants, PC (Path PC). Over the past 40+ years Path PC has enjoyed an outstanding reputation for providing a full-spectrum of pathology services to the northern plains region.

NPL's reference laboratory services are customized to meet the needs of our clients. Our spectrum of services include: telecommunication networking with a windows-based electronic order and result return system, information technology consultation, courier services, biomedical/instrument support provided by Kebocom, on-site consultations with pathologists and medical technologists, 24/7 availability (toll-free) of pathologists and medical technologists through NPL's client services department, sales/marketing services, billing/coding consultation, laboratory directorship/technical supervisor functions - per CLIA regulations, and esoteric reference laboratory relationships.

Specimen pickup and transport to Northern Plains Laboratory are managed by the Northern Plains Laboratory (NPL) Client Services Department. Specimens are delivered by US Postal Service or by a representative from a contract courier in the client's service area. In order to optimize specimen integrity, NPL provides supplies to clients for specimen collection, packaging and transport.

Northern Plains Laboratory complies with the shipping regulations for medical specimens as established by the International Air Transport Association (IATA) and the Department of Transportation (DOT).

GENERAL OVERVIEW

A dangerous good is any solid, liquid, or gas that can harm people, other living organisms, property, or the environment.

The public and the workers that handle the specimens throughout the transportation chain must be protected from exposure to biological specimen. This includes send out staff, couriers and people receiving specimens into the laboratory.

Responsibilities – as the shipper you are responsible for the package until it reaches its final destination, including all aspects of packaging the specimen and complete documentation.

According to the regulations, each employee involved in the preparation, handling and transportation of hazardous materials must be trained. Training of shipping requirements are to be completed within 90 days of hire. Until training takes place, new employees need to be under the supervision of a trained employee. On-going training depends on which regulations you are following. Air transportation regulations (IATA) require training every 2 years; ground transportation requires training every 3 years.

The carrier is not responsible for any leaks or accidents that occur to the shipment during transport. The Carriers of dangerous goods have the right to reject packages for improperly completed documentation and/or non-compliant packaging.

The government has developed regulations based on the mode of transport utilized. The regulations provide a schedule of fines that can be levied against the person packing the box, the employer, the carrier, and possibly the recipient of the package if an exposure occurs. Even spelling errors and filling out the shippers declaration incorrectly could result in fines.

- United States Postal Service (USPS) regulation guidelines published in the Domestic Mail Manual
- Department of Transportation (DOT) regulations are found in the 49 Code of Federal Regulation (CFR).
- International Air Transportation Association (IATA) and International Civil Aviation Organization (IACO) regulations follow the dangerous goods regulations. Published packaging instructions are #620 for Infectious Substance, Category A and #650 for Biological Substance, Category B.

When shipping by private vehicle, exceptions apply. Private or contract couriers used exclusively to transport diagnostic specimens are exempt from the DOT regulations. Packages by private vehicle should be packaged the same as if shipping via USPS. If anyone transports specimens via private vehicle, they must be aware that regulations do exist.

SPECIMEN LABELING

To assure positive identification and optimum patient specimen integrity, all specimens submitted to Northern Plains Laboratory must be labeled accurately and appropriately. Two unique identifiers are required for proper specimen identification.

For clients with a NPL Connect (HVR) system, the label generated by the HVR or the client's LIS/EMR must be placed on the transport tube. If NPL determines that there are any name or demographic discrepancies on the specimen, the client will be contacted.

For clients utilizing a manual requisition, clearly label the specimen with the patient's first and last name and another unique identifier such as birthdate or medical record number. It is recommended that the date & time of the collection also be noted on the specimen. If different specimen types are sent to NPL such as serum, plasma and /or urine, please note the specimen type on each appropriate vial.

Northern Plains Laboratory may refuse to accept specimens that are not appropriately labeled with two unique identifiers. In addition, we reserve the right to discard any unlabeled specimens. There are specific mandatory blood bank labeling requirements for those sites that NPL performs type and crossmatch testing. These requirements are available in the Northern Plains Laboratory test catalog.

Place specimen labels vertically on the specimen tube with label being about ¼ inch below the bottom of the lid of tube. If possible do not cover up hand-written information. Avoid placing multiple labels on the specimen tube.

SPECIMEN PREPARATION

For samples that must be frozen, drawn in a non-gel additive tube, or that will not arrive at NPL within 24 hours, a plastic transport tube is available. A few different transport tubes are available. When submitting specimens, it is critical to leave an air space at the top of the tube to allow for expansion and to prevent leakage. Do not overfill tubes. Please make sure caps are securely fastened. Metal-free transport tubes are available for trace element testing. Standard transport tubes are not sterile. Do not use them for infectious disease tests requiring sterile transport. Sterile transport vials are available, if desired. Add preservatives to urine specimens as required.

When submitting frozen samples:

- Leave air space at the top of the tube for expansion when the sample freezes.
- **A separate tube must be submitted for each test ordered**.
- Place frozen sample(s) between two frozen dark blue ice packs with the identification XC-12R. Rubber band the ice packs together tightly with the sample “sandwiched” between the ice packs.

CULTURES

Cultures are the result of a process by which pathogens are intentionally amplified or propagated in order to generate high concentrations. As such, the risk of infection is increased if exposure occurs. **This definition does not include cultures intended for diagnostic and clinical purposes.** Cultures can be classified as Infectious Substance, Category A, or Biological Substance, Category B.

Cultures can be shipped to NPL as Biological Substance, Category B if they aren’t intended for the intentional generation of pathogens and can’t be found in the Category A list in the IATA regulations, Table 3.6 D.

SPECIMEN REJECTION / TEST CANCELLATION

Unacceptable specimens include:

- Syringe with needle attached – if a specimen is submitted in a syringe, the syringe must be plastic and have a fitting so that the cap can be secured.
- Transport tubes secured with parafilm.
- Insufficient volume (including leaked in transit and gross external contamination)
- Improperly labeled specimen (no label or mismatched information)
- Improper specimen transport (expired or incorrect tubes, incorrect storage temperature, incorrect or expired transport medium, thawed in transit, specimen sent in non-sterile transport tube requiring a sterile container)
- Inappropriate specimen type (hemolyzed, clotted)
- Multiple specimen types with source not indicated (urine vs. serum)

If recollection of the sample is impossible or would compromise patient care, it may be possible in some cases to report the result provided you are able to identify/verify that the specimen is the correct specimen. At NPL's discretion, we may accept the specimen after a verification form is completed and a disclaimer statement is added to the result. Where specimen recollection is an option, this is the recommended avenue to ensure accurate results. Additional information is available in the Northern Plains Laboratory Test Catalog at www.northernplainslab.com.

SUPPLIES

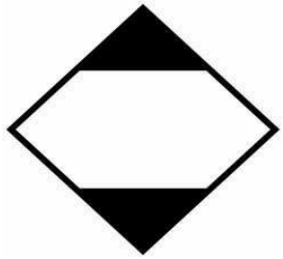
For the outreach clients utilizing the NPL Connect (HVR) system, supplies can be ordered electronically by going to the 'Main menu' and clicking on the 'Supply Orders' icon. Complete directions for ordering supplies through the NPL Connect (HVR) are available via hardcopy titled "HVR User's Manual". Please place orders no more than one time per week.

A manual supply order form is available to clients without the NPL Connect system. Supply orders may be faxed to 701-222-4537. Supplies ordered will be delivered as soon as possible, but there is no guaranteed time frame for delivery.

The following types of supplies are available from Northern Plains Laboratory:

- Specimen collection containers, tubes, microbiology collection supplies
- Shipping supplies including Styrofoam containers, specimen bags containing absorbent pads, and cardboard boxes. A double box system is available for clients shipping larger volumes of specimens.
- Manual Request forms
- Please note that some supplies have expiration dates. Supplies nearing expiration may be returned to NPL for replacement. This needs to happen at least 30 days before the supplies would expire.
- Please do not keep any more than 30 days of supplies on hand at one time.
- Supplies ordered from NPL can ONLY be used for testing being sent back to NPL.

When our mailroom ships your lab supplies, the DOT guidelines as printed in the 49 CFR will be followed. 10% formalin (4% formaldehyde) is not a regulated hazard for transport, therefore no additional markings or regulations apply. When we send the following cytology preservative supplies: 1) ThinPrep PreserveCyt (Flammable liquid, n.o.s) UN1993 or 2) ThinPrep CytoLyt Solution (Flammable liquid, toxic, n.o.s) UN1992, the address side of the package will be labeled with a “Limited quantities” label as shown below. When shipping as a limited quantity the primary container must contain < 5 L (1.3 gal) and the package (box & contents) must weigh less than 66 lbs. (Reference CFR, sections 172.315 & 173.150).



TEST REQUESTING

INSTRUCTIONS FOR CLIENTS USING MANUAL REQUEST FORMS

Manual test request forms are available at NPL. Please call 701-530-5700 if needed.

Complete a separate manual test request form for each patient with the following information:

a. Patient name, gender, birth date, chart number, collection date and time.
b. Billing information if tests are to be billed to patient or Medicare.
c. Type of specimen. (For cultures include the source and body site of each culture sent on both the test request form and each specimen.)
d. Patient’s fasting state.
e. Collection time and volume for urine specimens.
f. Provider/physician
g. Check appropriate boxes indicating test(s) requested.
h. Include an ICD10 diagnosis code for each test marked on the request form if NPL will be billing the patient’s insurance company directly.
i. Label the specimen with two positive identifiers such as the patient’s complete name and birthdate or medical record number.
j. Keep the back copy of the requisition form for your records.

INSTRUCTIONS FOR CLIENTS USING THE NPL CONNECT (HVR) SYSTEM

Complete directions for ordering test through the NPL Connect (HVR) are available via hardcopy titled “HVR User’s Manual”.

DOT and IATA REGULATIONS FOR PACKAGING:

There are 9 hazard classes defined by the DOT for packaging and shipping. Most laboratory specimens fall into class 6 Toxic and Infectious Substances or class 9 Miscellaneous Dangerous Goods, if dry ice is used. When preparing a specimen for shipping, you must know the hazard class to complete the packaging and documentation correctly.

Determine the type of specimen to be sent. Laboratory specimens are divided into three categories:

1) Exempt Human Specimens

   a) The exempt human specimens classification is used for clinical specimens (blood, secreta, excreta, tissue, tissue fluid) not known to contain or suspected to contain a pathogen; or a Biological Substances, Category B, specimen in which the pathogen has been neutralized or inactivated so it cannot cause a disease when exposure to it occurs. Specimens in 10% formalin, ThinPrep Preserve Cyt or ThinPrep CytoLyt fall into this class.

   b) Although the packaging for these specimens is not subject to the hazardous material regulations, packaging must include at the minimum 1) triple-packaging with leakproof primary and secondary containers enclosed in a rigid outer container 2) sufficient cushioning and absorbent materials surrounding the primary container and 3) appropriate markings on the outside of the package. If specimens are being shipped directly to Northern Plains Laboratory, it is suggested that the packaging instructions on the following page for “Biological Substance, Category B” packaging be followed.

2) Biological Substance, Category B **–** UN 3373

   a) Biological substance, Category B, are defined as an infectious substance not in a form capable of causing permanent disability or life-threating or fatal disease in otherwise healthy humans or animals when exposure occurs. This includes infectious substances transported for **diagnostic or investigational purposes**. Cultures can be shipped as category B if they are not intended for intentional generation of pathogens and cannot be found in Table 3.6 D of the International Air Transport Association (IATA) regulations.

   b) Examples include HIV, Hepatitis, West Nile, SARS and cultures for diagnostic purposes (urine, blood, CSF, stool, sputum or chlamydia swabs in transport medium).

3) Infectious Substance, Category A

a) A category A infectious substance is an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Any items found in Table 3.6 D of the International Air Transport Association (IATA) regulations must be sent as Infectious Substance, Category A. Only specimens meeting these qualifications must be shipped as infectious substances.

Examples include: Shigella dysenteriae, type 1 (culture only), Herpes B virus (culture only), Mycobacterium tuberculosis (culture only), Ebola virus, etc.

Triple packaging is required when shipping any Category A or when sending Category B specimens by commercial carrier. Triple packing involves three watertight layers to contain the specimen and prevent leakage during transport. The three layers are:

1) Primary Receptacle
2) Secondary Receptacle
3) Outer Container

Many of NPL outreach laboratories send specimens via the post office or private courier and need to follow the applicable USPS or DOT regulations. When sending mail within ND, all mail is transported via ground transportation only. For out of state clients using FedEx air or UPS air shipments, IATA regulations must be followed.

In addition to the 9 hazard classes, most hazardous substances are further assigned to a packing group. The 3 packing groups indicate the degree of hazard the substance presents. When shipping medical specimens you will not need to refer to a packing group, as neither 6.2 Infectious Substances or Biological Substance Category B are assigned to a packing group. Dry ice under Class 9, Miscellaneous, may require a packing group. Please check with your regulating agency's shipping instructions before transporting any type of acid, corrosive, or flammable material.

If sending a specimen directly to ARUP, MAYO or LabCorp Laboratories, the IATA guidelines for Biological Substance, Category B, would need to be followed. If the sample is an Infectious Substance, Category A specimen, please refer to the appropriate reference laboratory's website for proper mailing instructions.

POSTAL GUIDELINES:

A. USPS Biological Substances, Category B (Instructions also apply for ground & air carriers which follow the DOT & IATA guidelines.

Primary Receptacle – Place the specimen in a durable and securely sealed primary container. The primary receptacle is pressure certified to withstand, without leaking, an internal pressure of 95 kPa in the temperature range of –40 degrees F to 130 degrees F. The primary container cannot contain more than one liter of a liquid specimen.

Example- Screw top urine containers, Specimen collection tubes, Microbiology collection transport media.

Secondary Container - The secondary packaging must have a leak proof barrier capable of preventing the failure of the secondary package should there be leakage from the primary container. The secondary container must be marked with the international biohazard symbol. Samples from only one patient should be placed in each secondary package (biohazard bag). Place the test requisition in the outer pouch of the secondary packaging (biohazard bag).

Example – The biohazard Ziploc bag. The primary receptacle and absorbent pad are placed inside the Ziploc bag and the bag must be zipped shut.

Absorbent Material - Absorbent material must be configured to take up all the liquid content of the primary container in case of leakage.

Example- The absorbent pad NPL supplies in the specimen bag is capable of absorbing 25 ml of specimen. Utilize 1 absorbent pad per 25 ml of fluid.

Cushioning material – must surround the secondary container so it won't shift in the outer container.

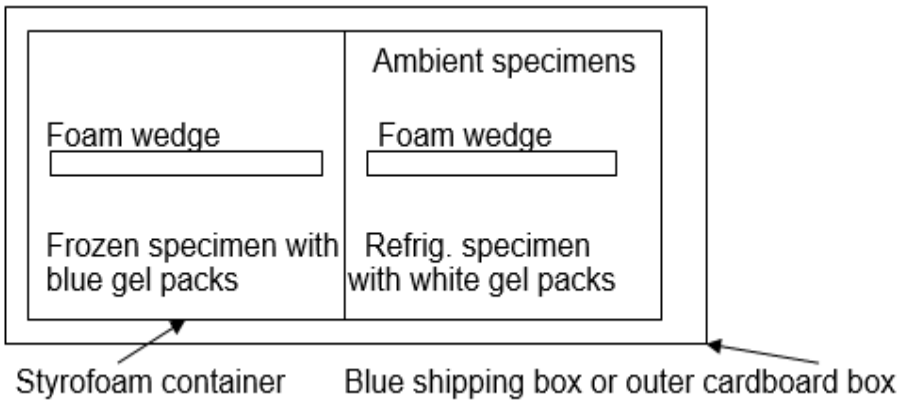
Example – In Styrofoam containers, bubble wrap, paper towels, peanuts, foam wrap should be placed around the group of biohazard Ziploc bags to cushion samples and keep specimens from moving around. The requisition is placed in the outer pocket of the biohazard Ziploc bag and also acts as a cushion. In the blue shipping containers the foam wedge should be pushed down to hold specimens firmly in place. Refrigerated specimens should be surrounded with cool packs. Any remaining empty space in the container should be filled with packing material.

Outer Packaging - The outer package must be a sturdy container "capable" of passing the drop test. At least one surface of the outer packaging must have a minimum dimension of 100 mm X 100 mm (3.9 inches) for biological substance,

category B packaging. The secondary package is enclosed in the outer packaging. (The outer packaging must not contain more than 4 liters if sample is going by air).

Example – box or cooler. DOT, IATA & USPS regulation says “capable” of passing drop test, the package does not have to specify it passed the test. The drop test is a 5-way test where the package is dropped from 4 feet, five different ways. No leakage of liquid or cushioning material is permitted and the package must remain undamaged. You do not need to ship Category B, Biological substances in a UN-certified box.

For substances shipped refrigerated or frozen with ice packs, the refrigerant must be placed outside the secondary packaging (plastic bag).



Gel packs may thaw more quickly in warm weather or freeze in cold weather. To maintain specimen integrity, always place a barrier of paper towels or other packing material between the specimen and the cool-pack. Take outside temperatures into account when packing specimens.

Packing Slip- Prior to sealing the container place a packing slip, the itemized listing of contents, between the secondary packaging and the outer packaging.

Marking - The address side of the mail piece must be clearly marked “Biological substance, Category B” along with “UN 3373”. A complete return address and delivery address must be used. The name and telephone number of a person who is knowledgeable about the material being shipped must also be noted on the box.

Refer to Diagram 1 for sending packages by air or ground courier.

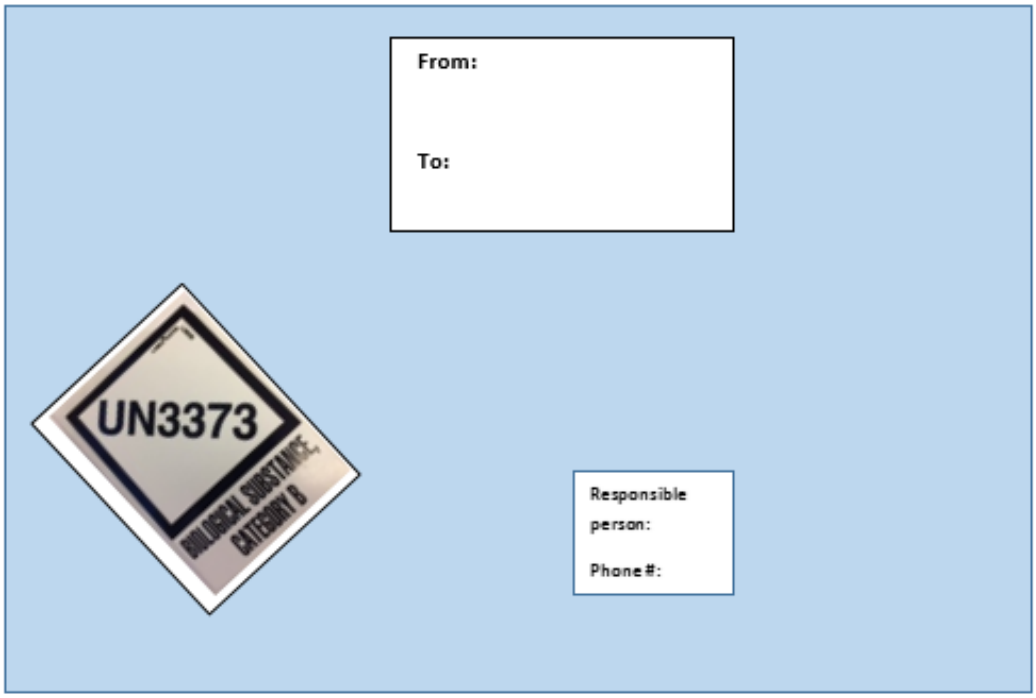
Refer to Diagram 2 for sending packages by USPS (Mail).

USPS packages must be sent via Express Mail, Priority Mail, or First-Class Mail.
Note: The NPL address label states it is first class mail.

Diagram 1

Labeling of Boxes for Air & Ground Courier

Blue boxes, cardboard boxes and Styrofoam coolers should be labeled as shown below when sending blood, cultures, body fluids or tissues / fluid in CytoLyt solution or 10% formalin:

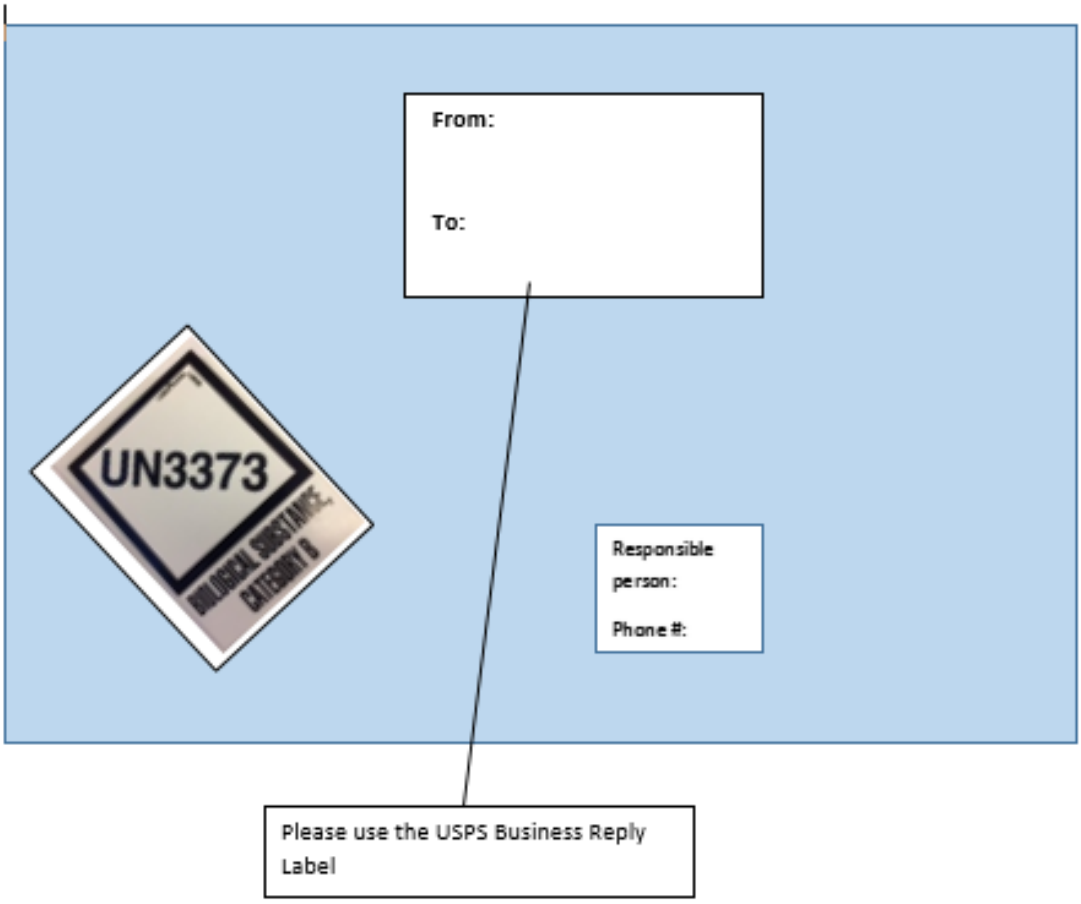


- Large blue box is labeled as above on top side of box
- Small blue box is labeled as above on front side of box
- Location label is often marked on both ends of box for storing purposes
- Courier's label is put on both ends of box
- NPL's location barcode is put on one end of box
- Orientation arrows are optional but could be placed on side of box.

Diagram 2

Labeling of Boxes for Mail / USPS

Blue boxes, cardboard boxes and Styrofoam coolers should be labeled as shown below when sending blood, cultures, body fluids or tissues / fluid in CytoLyt solution or 10% formalin:



- Large blue box, cardboard box or Styrofoam cooler is labeled as above on top side of package
- Small blue box is labeled as above on front side of box
- Orientation arrows are optional, but could be placed on side of box

B. USPS INFECTIOUS SUBSTANCES, CLASS A

No Class A infectious substances can be sent via the U.S. postal service. These specimens must be packaged by a properly trained person and sent via a properly trained hazardous goods carrier, such as FedEx. Refer to the following IATA Infectious Substance, Class A, guidelines or refer to package instructions 620 in the 49 CFR or IATA guidelines.

C. USPS - DRY ICE

Generally frozen blue ice packs are used to send frozen specimens rather than dry ice. However, dry ice is permitted to be sent in domestic mail when it is used as a refrigerant to cool the contents of a mailable hazardous or nonhazardous material, provided that all applicable requirements are met.
Packaging – Packing Instruction 954. Dry ice must be packed in containers, such as Styrofoam coolers, that permit the release of carbon dioxide gas.

If shipping diagnostic specimens, place the dry ice outside the biohazard Ziploc bag in the Styrofoam coolers. Dry ice must never be placed in a sealed primary or secondary container because pressure can build up and cause the container to explode. Place cushioning material inside the container to prevent the secondary containers from moving if the dry ice dissipates.

Markings – each mail piece must be marked on the address side with “Carbon Dioxide Solid“ or “Dry Ice” and “Surface Mail Only” along with the net weight of the dry ice. A DOT Class 9 warning label, although acceptable, is not required for dry ice being transported as surface mail. NPL does not provide the DOT Class 9 warning labels.

Documentation – For surface (ground) transportation a shipper’s declaration for dangerous goods is not required provided you are shipping diagnostic / non-infectious specimens.

D. ARUP, LABCORP AND MAYO SHIPMENTS FROM NPL

ARUP, LabCorp and Mayo laboratories have a contracted private courier that picks up specimens at NPL Monday-Saturday for same or next day delivery. This courier has been trained in packaging the specimens appropriately to comply with IATA guidelines. The courier places the specimens into approved shipping containers at the appropriate temperature and packages into site specific shipping boxes. The web based Internet is utilized to send orders to Mayo, LabCorp and ARUP.

E. DIRECT SENDS TO ARUP, LABCORP AND MAYO FROM CLIENT

On occasion due to a short specimen stability ($\leq$ 48 hrs.), a client may need to send a specimen directly to the reference lab rather than to NPL. The reference laboratory’s specimen collection and packaging instructions would need to be followed. Please refer

to their website for information, if needed. If the test order will be put into the NPL Connect (HVR), please contact a NPL client service representative at 701-530-5700 or 800-645-1003 on further instructions that need to occur to ensure that both the order and the specimen are received properly at the reference lab. It is best if the courier, such as FedEx, can be contacted the day before the pick up is needed. It is also recommended to avoid collecting or shipping these samples on Friday, Saturday or Sunday.

SPILL CLEAN-UP AND REPORTING

Couriers and commercial carriers are responsible for cleaning spill that occur in transit. Couriers are required to be trained in spill response and to carry spill kits for such situations.

Courier spill kits can vary but typically include gloves, scraper, scoop, chemical fixers, disinfectants, paper towels and disposal bags. A First Aid kit should also be available.

In the event of a spill:

- Wear appropriate protective equipment during clean up
- Prevent others from coming into contact with the spill
- Blot or absorb as much of the spill as possible with chemical fixers or paper towels.
- Disinfect area
- Place items and gloves in a Biohazard container and take to the lab for disposal
- Wash hands

Couriers and commercial carriers are required to secure leaking packages in a separate container and document the incident on the packing list or shipping form. Contact Northern Plains Laboratory at 701-530-5700 to report the spill or leak.

According to federal mandates, any spill or release of a Category A or B infectious substance, in any mode of transportation must be reported to the Department of Transportation. The responsibility for incident reporting rests with the originating location.

PACKING COURIER VEHICLES

Courier vehicles should be packed to avoid tipping of shipping containers. Couriers should monitor temperatures during extreme weather and be aware of the impact shipping delays can cause on specimen integrity.

DOT and IATA TRAINING REQUIREMENTS FOR SHIPPING INFECTIOUS SUBSTANCES

When preparing and shipping infectious substances it is essential that each specimen is packaged and shipped properly. Complying with the regulations set forth by the DOT and IATA will control or eliminate many health and financial liabilities, both criminal and civil.

Regulations require that anyone who packages and ships hazardous materials must have received training from a certified source. A record of this training must be maintained during the term of employment and one year following termination of employment.

Additional Information / Contacts:

Follow the IATA/ICAO regulations when shipping by air:
• Website: www.iata.org
• Email: information@iata.org
• Hotline: (514) 390-6770

Follow the US postal regulations when shipping by USPS:
• Website: https://pe.usps.com/text/pub52

Follow the DOT regulations in 49 CFR when shipping by ground:
• Website: www.dot.gov or www.phmsa.dot.gov/phmsa-regulations
• Email: dot.comments@dot.gov or infocntr@dot.gov
• Hotline: (800)467-4922

Pipeline and Hazardous Materials Safety Administration:
• Website www.phmsa.dot.gov

Northern Plains Laboratory Client Services
701-530-5700 or 1-800-645-1003