

I. Introduction

Welcome to the Shipping Infectious Substances, Category A (BIO202) Course Material. This course covers classification of materials, procedures for packaging, marking and labelling; permits and documentation required to ship Infectious Substances, Category A as per regulations. Any UAB employee handling, offering transport, or shipping Infectious Substances, Category A must complete training every two years (or if federal regulations change)



Failure to properly pack and ship materials is a violation of the law and is punishable with fines or imprisonment.

Note: If you anticipate the need to use dry ice for your infectious substance shipment, we advise taking the Shipping with Dry Ice course (BIO200) before proceeding with this course.

Objectives:

At the conclusion, participants should be able to:

1. Identify and adequately classify Infectious Substances, Category A.
2. Pack samples with the appropriate primary and secondary containment.
3. Mark and label shipping packages correctly.
4. Complete the appropriate shipping documents or permits accurately.
5. Follow the necessary safety guidelines avoiding any accidents, injuries, or spills.

II. Regulatory Agencies

When shipping Infectious Substances, Category A, you are bound by regulations established by national and international regulatory agencies. These regulatory bodies ensure infectious substances or materials are transported as safely as possible (specifically by air).

Regarding the shipping and receiving of Infectious Substances, Category A, the University of Alabama at Birmingham (UAB) follows:

- [International Air Transportation Association Dangerous Goods Regulations](#)

Major organization that regulates the transport of dangerous goods by air is the International Air Transport Association (IATA). IATA is a member-driven, industry organization which helps regulate all shipments on air crafts or by air carriers.

- [United States Department of Transportation Hazardous Materials Title 49 Code of Federal Regulations Parts 171-180](#)

In the United States, the Pipeline and Hazardous Materials Safety Administration (PHMSA), a branch of the U.S. Department of Transportation (DOT), publishes regulations for the transport of hazardous materials.

III. Classifications

Classification of an item to be shipped is used to identify the actual hazard and not the substance itself. Classification is necessary to follow both International and National regulations.

1. Infectious Substances, Category A

Infectious Substances, Category A, are capable of posing a risk to health and safety, causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. To help correctly classify your sample, you can use the terms in the [Shipping Glossary](#), [Examples of Infectious Substances in Category A](#), and the [Classification Flowchart](#). Keep in mind, professional judgement must be used to classify the biological material being shipped. This means classification is based on endemic conditions, detailed knowledge of the sample, and/or known medical history or symptoms of the animal the material was collected from. If there is any doubt on how to classify a particular pathogen it must be shipped as a Infectious Substance, Category A.

2. Genetically Modified Organisms (GMOs/GMMOs)

If your sample is considered a genetically modified organism (GMO) or genetically modified micro-organism (GMMO) and meets the classification of an Infectious Substance, Category A, then it must be classified and shipped as an Infectious Substances, Category A. The BIO201 course covers shipping training for Biological substance, Category B, Exempt Human or Animal Specimens, and Genetically-modified Organisms. Check with your carrier if you are unsure or have questions.

IV. Identification and Packaging System

1. United Nations (UN) Number

The UN Number is taken from the [List of Dangerous Goods](#), and used in identifying a substance or group of substances. This UN Number always precedes the Proper Shipping Name (PSN):

- UN 2814 Infectious Substances, affecting humans
- UN 2900 Infectious Substances, affecting animals only

2. Proper Shipping Name (PSN)

The IATA, ICAO, 9 CFR assign the Proper Shipping Name (PSN) and is the name used on shipping documents to describe substances.



The words diagnostic specimen and clinical specimen are no longer allowed as Proper Shipping Names (PSN).

- The PSN, **Infectious Substances, affecting animals** (along with the preceding UN 2900 number), refers to infectious substances affecting animals and is only allowed if the Infectious Substance is an animal pathogen and can in no way pose a threat to humans.
- The PSN, **Infectious Substances, affecting humans** (along with the preceding UN 2814 number), is used if the infectious substance can pose a threat to humans as well as animals.

3. Technical Name

The Technical Name is the substance's genus and species and required at the end of the Proper Shipping Name on the Shipper's Declaration when shipping Infectious Substances, Category A. It should be written or typed in parentheses. For example, an isolate of West Nile Virus cultured from a mouse can affect a human. Therefore, the Shipping Document for this sample would show **UN 2814 Infectious Substance, affecting humans (West Nile Virus)**. Remember, the Technical Name goes on the Shipper's Declaration – not the package!

Shipping Infectious Substances, Category A (BIO202) Course Material

4. Selecting the Proper Packaging

Packaging components for Infectious Substances, Category A must pass testing requirements as a system. Mixing and matching packaging components from different manufacturers is not permitted. When choosing the right packing materials, only use packaging in the tested and certified configuration. For example, you cannot ship Infectious Substances, Category A in an EXAKT-PAK™ secondary container and a SAF-T-PAK™ outer container (fiberboard box) since the containers have not been tested and certified together.



Disposable components of a packaging system must be replaced by components from the same vendor that have been tested and certified for that packaging system. Substituting alternative products is a violation of the law!

5. Outside Packaging

The recommended outside packaging must be sturdy, rigid, corrugated fiberboard, and be the appropriate size for the intended content. The box also serves as a surface for displaying clear marks, labels, and other important information. Only use boxes conforming to approved standards. Always look for the UN mark. The UN Mark indicates the box has been tested and meets standards. If you have questions about which boxes are approved, call EH&S at (205) 934-2487.



4G/CLASS 6.2/13
CAN?SAF-T-PAK 8-39

6. Inside Packaging

Kilopascal (kPa) is a unit of pressure measurement like Pounds per Square Inch (PSI). Either the primary or secondary container must be able to withstand an internal pressure of 95 kPa in a temperature of -40 °F to 130 °F (-40 °C to +55 °C).

Note: In case of damage or leakage, immediately notify a UAB EH&S at (205) 934-2487

V. Marks and Labels

General Information

Marks and labels provide information about the contents of the package, the nature of the hazard, and any special handling requirements. Any marks and labels should be durable, placed so that they are apparent, not obscured by any other labels or markings, and put all on the same face of the package (if possible).

Infectious Substances, Category A

Infectious Substances, Category A shipments require the following labels:

- Infectious Substance Black & White Diamond-On-Point Label.
- Proper Shipping Names and Number
 - UN 2814 Infectious Substances, affecting humans
 - UN 2900 Infectious Substances, affecting animals only



- Complete name and address of the Shipper and Consignee (Receiver)
- Name and telephone number of a reliable and responsible person that can answer the phone (no voicemail and no answering machines). They should be able to answer any questions about the content, shipper, recipient details, or permit inquiries.
- Orientation Marks or the words “this side up” on packages containing liquids. Two orientation marks or the words “this side up” should be on two opposite sides of the box. However, they must match. Both sides must be orientation marks or both sides must be marked “THIS SIDE UP.”

Shipping Infectious Substances, Category A (BIO202) Course Material

Appendix A at the end of this course contains picture showing the correct shipping label requirements for a package containing Infectious Substances, Category A.

If you have any questions about the appropriate required marks and labels, contact EH&S Biosafety representative at (205) 934-2487.

VI. Documentation

1. Centers for Disease Control (CDC) Import and Transport Permits

The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans, including pathogens and biological toxins. In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases, acquisition or subsequent distribution of an agent (e.g., viruses requiring BSL-3 or BSL-4 containment) is prohibited within the United States and requires CDC authorization and permits before transfer to another location within the United States.

Select Agent permits may only be obtained through UAB's Responsible Official, in coordination with the Federal Select Agent Program. A list of Select Agents and Toxins can be found [here](#). Domestic transport may or may not require a permit. To determine if your shipment requires a permit, see the [CDC Import Permit Program](#).

i) Agents Requiring a Permit for Subsequent Distribution

According to [CDC Import permit program](#), following infectious agents require additional approval before they can be transferred by the original permit holder to an additional recipient. All subsequent transfers of the following agents require the intended recipient to submit a new permit application for approval.

- *Mycobacterium tuberculosis*
- Coronaviruses (SARS-CoV-2, MERS-CoV)
- Influenza viruses (H2N2, H6N1, low pathogenic avian H7N9)
- Viral hemorrhagic fevers (e.g., Tick-borne encephalitis viruses – Central European subtypes, Old World hantaviruses that cause hemorrhagic fever with renal syndrome (HFRS))
- Mpox (clade II) (formerly known as: Monkeypox – West African clade)
- Poliovirus (serotypes 1, 2, 3)

2. USDA/APHIS Import and Transport Permits

The USDA/APHIS (Animal and Plant Health Inspection Service) regulates the transporting of materials that potentially harm U.S. agricultural products, including livestock, poultry, and crops. APHIS requires permits for the import, export, and interstate transport of animal or plant pathogens, pathogen vectors, animals, animal products, plants, plant products, and the introduction of genetically modified organisms into the environment. For more information, see [Import and Export](#).

The intended receiver of the material must obtain USDA/APHIS Import and Transport permits before preparing a shipment. These permits are good for one year, amendable, and renewable.

The application for foreign import or interstate transfer is found [here](#). This application requires 6 to 8 weeks for processing.

i) Animal-Related: USDA/APHIS requires permits for imports and exports and interstate transport of:

- Animal or plant pathogens including challenge material from the USDA
- Specimens reasonable believed to contain animal or plant pathogens¹
- Vectors of animal or plant disease¹
- Potentially hazardous animal or plant products

ii) Plant Related: USDA/APHIS Regulation 7 CFR Part 330 Federal Plant Pest Regulations covers the transport of plant pests.

For more information refer links below:

[USDA APHIS | Import and Export: Animal and Animal Products](#)

[USDA APHIS | Plants and Plant Products Permits](#)

¹ USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

Shipping Infectious Substances, Category A (BIO202) Course Material

Genetically Modified Organisms (GMOs): To determine if a permit is needed to import or transport a GMO, contact the APHIS Biotechnology permit branch via a letter of notification.

3. Permits

Additional documentation (i.e., permits or certificates) may be required when shipping any biological substances, particularly those designated Infectious Substances, Category A. Federal permits are required to import and export disease-causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Chemically inactivated agents are exempt from dangerous goods regulations but may still require permits for receipt or transfer. Permits may also be needed for domestic transport of some agents. The recipient of the material must obtain any required permits. If you are the shipper, request a copy of any applicable permits from the recipient and include a copy of the permit with the shipping documents. The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver assures that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and IATA Regulations. The importer must send the proper shipping labels and a copy of their import permit to the shipper. Complying with import regulations should prevent packages from being held at customs or denied entry.

4. Department of Commerce Export Licenses:

Exports of designated biological agents and toxins having the potential to pose a threat to human, animal, or plant life require a license from the U.S. Department of Commerce Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than “select agents,” and researchers must consult with the University’s Export Controls Officer at exportcontrol@uab.edu, or (205) 996-2735 to conduct a separate review to determine if a BIS export license is required.

Shipping Infectious Substances, Category A (BIO202) Course Material

[Export Control at UAB](#) is mediated through the **Director of Export Control & International Compliance**, located within the **Office of Research Regulatory Oversight**. BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonoses, and toxins
- Genetically Modified Microorganisms or genetic elements containing nucleic acid sequences associated with the pathogenicity of a controlled organism or that code for a controlled toxin
- Genetic material and products used for the culture of large amounts of agents.

For further guidance on whether or not the agents you are shipping or receiving require permits, contact UAB's Department of Environmental Health and Safety (EH&S) (205) 934-2487.

Foreign imports of the following materials required a permit to import and transport agents or vectors of human disease:

- Etiologic agent
- Arthropod or other animal host or vector of human disease
- Exotic living arthropod or another animal capable of being a host or vector of human disease
- Non-human primate material (e.g., blood, plasma, tissue, urine, and feces) requires an import permit unless it has been specifically treated and rendered non-infectious.



Before shipping anything internationally, please submit the UAB International Shipment Export Control Review Form.

Link to Form: <https://www.uab.edu/exportcontrol/exportcontrol/international-shipping>

A review will be performed in consideration of the item being shipped; its destination; its recipient; and its use abroad.

5. Before You Ship Anything Internationally

Although UAB does not have an overall centralized shipping process for international or domestic shipments, there remain export control regulatory requirements for international shipping. All physical items, equipment, materials, commodities (including food and medicines), software and biologics (collectively “things”)

Shipping Infectious Substances, Category A (BIO202) Course Material

are subject to export control regulations and require some form of shipping documentation prior to shipping abroad. It is important to understand that everything that crosses the border is an export, even if the item is abroad only temporarily, or if it will be used for research.

6. Security

ICAO and IATA require any company or institution handling or transporting dangerous goods provide associated security training for any staff who come in contact with the dangerous goods. This training should encompass the nature of the risks, recognition of risks, practices used to reduce risks, and procedures for a security breach. The following security guidelines apply to Category A shipments at UAB:



If you suspect a package has been tampered with, notify EH&S immediately at (205) 934-2487.

- Making arrangements with the courier receiving the package directly. Do not leave dangerous goods packages in non-secure areas for pickup. Before handing the package over to the carrier for shipment, it is the shipper's responsibility to ensure that all federal and international regulations are met. International shipments may require additional permits.
- Ensuring package tracking is available through the courier.
- Restricting dangerous goods access to appropriately trained and qualified staff. After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. By restricting access, this reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature, and signifies 49 CFR/IATA Regulations prepared the package.
- Inventorying dangerous good stocks to track theft or loss
- Reporting all suspicious activity or persons to the UAB Police at (205) 934-3535
- Exposure and Incident Response Plans are in place to define procedures in the event of a release or exposure.
- Select Agents transfer requires additional CDC and APHIS approval through coordination with UAB's Responsible Official

7. Shipper's Declaration

A shipper's declaration for dangerous goods is a **REQUIRED** legal document for each shipment of Infectious Substances, Category A. To keep your shipper's declaration from being rejected, here are some things that you must do:

1. Prepare three copies (one for the shipper and two for the carrier). However, some carriers may require more. Check with your courier before submitting.
2. Keep your copies for two years in case there are questions later.
3. If you have made prior arrangements with the courier, submit your Shipper's Declaration information electronically.
4. Fill out each line or space correctly.

Appendix B at the end of this course, has examples of Waybill information for shipping Infectious Substances, Category A.

VII. RESPONSIBILITIES

1. Operator (or Carrier) Responsibilities

Not all couriers or carriers transport Infectious Substances, Category A, and not all foreign countries or states within the U.S. will accept Infectious Substances, Category A. Where there are variations (restrictions) by state, country, courier, and carrier, they may be more restrictive than the IATA DGR or ICAO TI, but never less restrictive.

The airline industry is very strict about transporting infectious materials. You cannot carry these materials or samples onto a passenger plane no matter how it is packaged. You must use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations, depending on the samples being shipped, and on the courier's method of transport. For more information, please check with EH&S and your courier.

Quantity Limits: If the package contains ≤ 50 milliliters or ≤ 50 grams Cat A substance per package, then it can be shipped in the cargo hold of a passenger airplane. Ship packages exceeding 50 milliliters/grams Cat A material, or ≥ 200 kilograms Dry Ice by cargo aircraft. Packages exceeding 4 L/Kg of Cat A material must be shipped by ground transportation or divided to remain under the limit. Mark the quantities for all UN numbers on the outside of the package.

2. Shipper's Responsibilities

When shipping packages containing Infectious Substances, Category A, from UAB, your responsibilities are:

- Classifying the substance or material
- Identifying the substance or material
- Selecting the appropriate packaging system
- Packing, marking, and labeling the substance or material
- Completing documentation
- Making arrangements with your chosen courier and receiver (i.e., including obtaining any required documentation). For example, both the USDA and CDC have permit requirements.

Shipping Infectious Substances, Category A (BIO202) Course Material

3. Receiver (or Consignee) Responsibilities

If you are expecting to receive packages containing Infectious Substances, Category A at UAB, your responsibilities are:

- Obtaining the appropriate permits and sending a copy to the shipper
- Obtaining IBC approval before receiving Infectious Substance, Category A material
- Inspecting documents and packages
- Reporting any damages immediately to the shipper and UAB Biosafety at (205) 934-2487
- Notifying the sender of package arrival
- Keeping all shipping documents for a minimum of two years

Checklist: Use this "[Shipping Checklist](#)" to ensure that package is properly packed and provided with appropriate documents, marks and labels.

VIII. Conclusion

This section concludes the Shipping Infectious Substances, Category A (BIO202) Course Material. You should take the assessment now. The passing score is 90% or higher. By successfully completing this course, you have gained the essential knowledge and skills to navigate the safe and compliant transportation of the Category A materials. You must now complete the Reality Check.

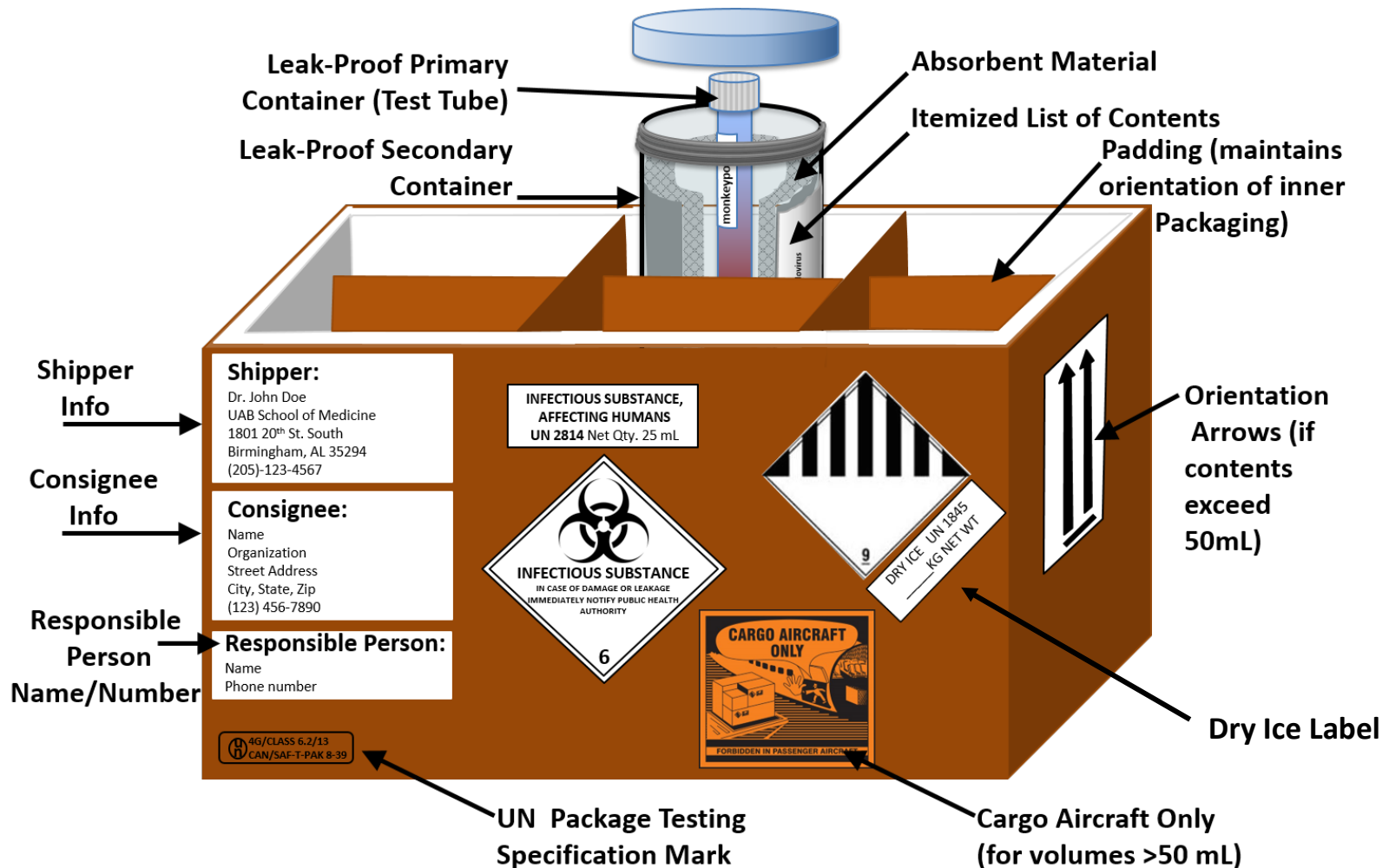
Other Trainings

- If you intend on shipping samples considered Biological Substances, Category B, Genetically Modified Organisms (GMOs), Exempt Human, or Animal Specimens, it is required to complete **Shipping Biological Substances, Category B (BIO201)**.
- If the sample you are shipping requires using Dry Ice as a refrigerant, it is required to complete **Shipping with Dry Ice (BIO200)**.
- UAB Campus Employees whose job duties put them at increased risk for exposure to bloodborne pathogens, it is required to complete **Bloodborne Pathogens Training (BIO500)**.

EH&S has many training courses available to all UAB active employees and students. A [decision tree](#) is available to assist you in choosing the right training courses to supplement the knowledge and skills you may need at work. If you have any questions or comments, contact EH&S at (205) 934-2487.

Appendix A: Shipping Label Requirements

Shipping Category A, Infectious Substances on Dry Ice
Follow Commercial System Instructions; IATA Packaging Instructions 620 & 954



Shipping Infectious Substances, Category A (BIO202) Course Material

Appendix B: Example Waybill Information

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Javier Doe University of Alabama at Birmingham 143 UAB Way Birmingham, AL 35294		Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number <i>(optional)</i>				
Consignee John Doe Mills Creek Laboratories 1234 Midway Lane Morgan, IN 55445		For optional use for Company logo name and address				
Two completed and signed copies of this Declaration must be handed to the operator.		WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.				
TRANSPORT DETAILS						
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure: BHM				
AIRCRAFT PASSENGER AND CARGO ONLY		Airport of Destination: MOR, Morgan Airport				
		Shipment type: <i>(delete non-applicable)</i> NON-HAZARDOUS				
NATURE AND QUANTITY OF DANGEROUS GOODS						
UN or ID No.	Proper Shipping Name	Class (or Division) (Subsidiary Risk)	Packing Group	Quantity and type of packing	Packing Inst.	Authorization
UN2814	Infectious Substance, Affecting Humans, (Monkeypox Virus)	6.2		1 x 5 ml tube	620	
UN1845	Dry Ice	9		5 kg All packed in one fiberboard box	954	
Additional Handling Information 24-hour Emergency contact (205) 111-2222 Person Responsible Javier Doe (205) 999-2345						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.					Name/Title of Signatory Javier Doe/Shipper Place and Date Birmingham, AL, 07-July-2017 Signature <i>(see warning above)</i>	

UN or ID No.	Proper Shipping Name	Class (or Division) (Subsidiary Risk)	Packing Group	Quantity and type of packing	Packing Inst.	Authorization
UN2814	Infectious Substance, Affecting Humans, (Monkeypox Virus)	6.2		1 x 5 ml tube	620	
UN1845	Dry Ice	9		5 kg All packed in one fiberboard box	954	