

IQVIA Laboratories "How To" Guide

How to Ship Samples (North America)

August 2025





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GLOBAL HOLIDAY SCHEDULE

IQVIA Laboratories will provide your site with details of courier "no-delivery" days and IQVIA Laboratories opening. The IQVIA Laboratories holiday letter will be shared on a quarterly basis.

Site personnel are recommended to review holiday letters and upcoming subject visit dates to properly plan visits requiring sample shipments.

What action should be taken if there are critical patient visit collections on a holiday?

- Review the holiday letter provided by IQVIA Laboratories (available on the Site Portal) to determine if all departments (sample receiving and testing facility) will be closed or if the departments will be operating on skeleton staff.
- Discuss with the CRA/Sponsor if the visit cannot be moved to a non-holiday date.
- Query with the assigned courier local office in time to determine if they will be able to collect and make deliveries on that day. It may also need to be established if customs will be open during that time.
- Discuss with CRA or IQVIA Laboratories assigned project manager on alternative pick up arrangements.

Please note that pickup arrangements are subject to holiday/premium surcharges by the courier that will be charged to the study.

Please contact your local courier office for confirmation that deliveries can be made prior to local or global holidays.

In addition, there may be site and/or country-specific "no-pick-up" days. Please check these days with your local courier office prior to collecting samples.

US Holidays Observed by IQVIA Laboratories

IQVIA Laboratories observes the following US statutory holidays:

- New Year's Day
- Martin Luther King Jr. Day
- President's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Day After Thanksgiving
- Christmas Eve
- Christmas

STANDARD AND PREMIUM COURIER SERVICES

Standard couriers are the most used couriers and handle the majority of sample shipments between investigator sites and IQVIA Laboratories facilities.

Depending on study needs, the sponsor may request that IQVIA Laboratories set up your site to use the Marken premium courier service. The booking and collection process for the premium courier service will differ from that of any standard courier you may also be working with.

Standard couriers

The standard courier used for US sites is **UPS**. Sites in Canada can use either **FedEx or UPS** (but encouraged to UPS).

Ambient and Refrigerated Shipments:

 FedEx and UPS: All materials required for ambient and refrigerated sample shipping will be provided to you by IQVIA Laboratories. Please re-order these supplies from IQVIA Laboratories as required.

Frozen and combination Shipments:

- **FedEx**: All materials required for frozen and combination sample shipping will be provided to you by IQVIA Laboratories. Please re-order these supplies from IQVIA Laboratories as required.
- UPS: All materials required for frozen and combination sample shipping via UPS can be provided to you either through IQVIA Laboratories or UPS.
 - If using UPS: the shipping material will be provided to you by the courier directly on day of collection. Ordering supplies and shipping samples are two separate UPS processes.
 Make sure the shipping supplies are available on site prior to booking the Airwaybill.
 - If using IQVIA Laboratories: Please re-order the shipping supplies from IQVIA Laboratories as required.

Airwaybills process:

When contacting the courier to book a collection, please ensure you have the pre-printed air waybill (AWB) number you will be using to ship available. The AWB number will be provided to you by the courier when using the portal to book the collection.

Premium Courier Service (Marken)

If your site is set up to use Marken premium courier service, Marken will provide a Welcome Pack, including a collection request form and transit/booking times. Note the responsible CRA for your site will likely also receive a copy of the Welcome Pack directly from Marken via email.

Marken will provide all packaging materials and paperwork (air waybills, commercial invoices, etc.) for shipping so there is no need to order these from IQVIA Laboratories. However, you can refer to the Shipping Guidance in this document for **general** packaging instructions.

Booking a collection of samples

To book a collection from either Standard or Premium courier, please refer to the Starter Pack provided to you by the courier.

It is important to be aware of the **expected transit time** for shipments from your site – this can be found in the courier information sheet.

EXPORT REQUIREMENTS FOR SAMPLE SHIPPING - CANADA

Commercial Invoice Requirements (Canada)

All sample shipments from Canada to US must contain the below two documents:

- Commercial Invoice: list of items within the shipment.
- CDC statement: declaration that shipment items are not known to be infectious.

The template of both documents can be obtained from the Site Portal or in Appendix 1 of this document.

Note: If the sites are booking the shipment through the courier portal, the commercial invoice will be included with the Airwaybill. Therefore, only the CDC Statement will need to be attached to the shipment. If the site is using a Pre-Printed AWB, they will have to attach the Commercial Invoice alongside the CDC statement.

For any queries about specimen shipments at any time, please contact the courier using the details provided on your courier information sheet.

SHIPPING GUIDANCE

The IQVIA Laboratories Project Management Team will provide your site with booking and contact information for the applicable courier(s). This information can be found in the Document Center area of the Portal, along with <u>additional</u> documentation covering the **study-specific** sample collection, processing, and shipping information.

IATA Requirements

To ensure compliance with IATA (International Air Transport Association) Dangerous Goods Regulations, please note that, as the shipper, you are responsible to pack, mark, label the shipment and declare on the Air Waybill all in accordance with IATA Dangerous Goods regulations requirement. The courier will inspect your completed shipment/shipping paperwork in your presence and if there are mistakes made, will guide you through making the necessary corrections.

IMPORTANT: it is essential to ensure that the IATA labelling is not covered in any way. Take care when attaching Air Waybills and invoices to the packaging. If even a small portion of the IATA marking is covered, this may cause your shipment to be rejected.

Ambient and Refrigerated Samples

Gel Pack instructions

Note: should you require additional gel packs, these can be ordered via the Portal.

Gel Packs for Ambient Shipments

Gel packs should be shipped refrigerated **or** at room temperature, depending on the local, external temperature.

As temperatures and seasonal variances differ from country to country, please refer to the following guidelines for using your gel packs.

If External Temperature is ≥25°C (77°F)	If External Temperature is <25°C (77°F)
REFRIGERATE the gel wrap.	Store the gel pack at ROOM TEMPERATURE (Do not refrigerate).
NOTE: Refrigerate the gel wrap for a period of <u>24</u> hours prior to use.	

Gel packs for Refrigerated Shipments

A selection of gel packs should be stored in both the refrigerator and freezer, as both chilled and frozen gel packs are required for refrigerated sample shipments.

NOTE: It is not necessary to separate the gel from their sleeves.

Conditioning Frozen Gel Packs:

- Place the Gel Packs into a freezer set at -20°C.
- Let Gel Packs remain in the freezer for 72 hours before using. **Note**: any deviation from this could result in a different thermal performance.
- Let the Gel Packs remain at room temperature for a minimum of 30 minutes before using. Conditioning Refrigerated Gel Packs (shown in red):
- Place the Gel Packs into a refrigerator set at +5°C.
- Let Gel Packs remain in the refrigerator for 72 hours before using. **Note**: any deviation from this could result in a different thermal performance.

For an ambient sample shipment, you will be provided with:

- Absorbent tube holder
- Plastic bag (for urine tubes, if applicable)
- Specimen Shipping Bag (SSB)
- Gel packs 1 x 16oz (refer to above instructions for conditioning)
- IATA contents card
- Shipper (box)

To package <u>ambient</u> samples for shipment:

1) Place tubes in absorbent tube holder (urine tubes in plastic bag, if applicable).

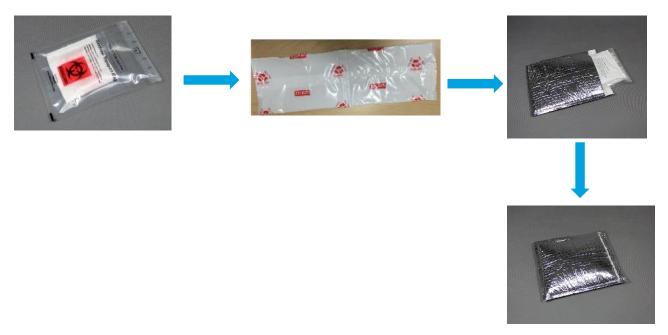


2) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.





3) Place sealed SSB between layers of gel pack (see below for gel pack guidance), then place into Foil Bag and seal. Note: two SSBs can be shipped in one foil bag, per shipper.



4) Place foil bag into shipper with IATA contents card.



5) Attach air waybill and, if applicable, a copy of the commercial invoice to outside of box.

For refrigerated samples, you will be provided with:

- Absorbent tube holder
- Plastic bag (for urine tubes, if applicable)
- Specimen Shipping Bag (SSB)
- Gel Packs 2 x 675g, 3 x 500g (refer to above instructions for conditioning)
- IATA contents card
- Cooler (internal packaging)
- Shipper (external box)

To package refrigerated samples for shipment:

- 1) Ensure Gel Packs have been removed from the cooler and have been conditioned per above instructions prior to use.
- 2) Place tubes in absorbent tube holder (urine tubes in plastic bag, if applicable).

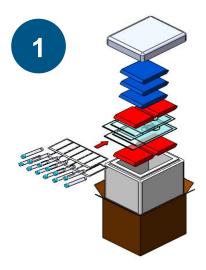


3) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.



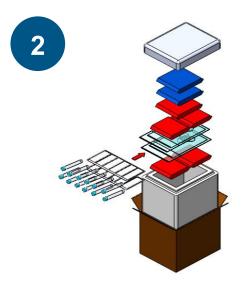


- 4) Place 1 refrigerated 675g Gel Pack into the cooler on top of the SSB, then:
 - a. **Summer packaging (see image 1 below)**: Place **3** frozen 500g Gel Packs on top of the refrigerated Gel Pack.
 - b. Winter packaging (see image 2 below): Place 1 refrigerated 500g Gel Pack on top of the first refrigerated Gel Pack.



SUMMER CONFIGURATION

When the shipper is exposed to temperatures greater than 15°C (59°F), at the point of origin



WINTER CONFIGURATION

When the shipper is exposed to temperatures less than 15°C (59°F), at the point of origin.

- 5) Place lid back on the cooler and place the IATA content card on top.
- 6) Close and seal the outer carton for shipment, with air waybill and, if applicable, a copy of the commercial invoice attached to the box.

Frozen & combination samples

NOTE: Dry ice and other packaging supplies will be delivered on the day of shipment and the driver will then return later in the day to pick up the samples. **It is the responsibility of site staff to pack the samples ready for collection.**

Instructions may vary depending on courier – please refer to your courier booking pack or information sheet.

To package frozen samples for shipment:

1) Place tubes in absorbent tube holder.



2) Place tube holder into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.





3) Place SSB and dry ice (20lb or 10kg) into bottom of shipper. For batch shipping, multiple SSBs or a cryobox may be placed in one frozen shipper.



4) Place the foam lid on the insulated container. Place the IATA contents card on top of the foam lid and secure shipper flaps.



- 5) Attach the air waybill to the outside of the box. Ensure to indicate the amount of dry ice and shipper information on the outside shipper label.
- 6) Do not cover any printed markings on the outside of the box!



Example outer box (appearance may vary)

Ensure that the amount of dry ice is clearly indicated on the outside of the box and matches the information on the air waybill.

To package samples for shipment in a combination shipper:

1) Place tubes in absorbent tube holder.



2) Place tube holder into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.





- 3) The combination shipper allows shipment of ambient and frozen samples in separate compartments (see image on right). NOTE: Combination shippers should only be used when shipping both ambient and frozen samples together. Please use the appropriate shipper (ambient OR frozen) if you are only shipping samples of one temperature.
 - AMBIENT: Place the sealed SSB with ambient specimens between the
 two layers of the gel wrap. Then, place the gel-wrapped SSB into the top
 section of the combination shipper and cover with lid.
 NOTE: when used with the combination shipper, the gel wrap should be

NOTE: when used with the combination shipper, the gel wrap should be used ambient year round.

 FROZEN: Place the sealed SSB with frozen samples in the <u>bottom</u> section of the combination shipper and cover with enough dry ice to fill up the remainder of the box. Place foam lid over.



- 4) Place the IATA contents card on top of the foam lid and secure shipper flaps.
- 5) Attach the air waybill to the outside of the box. Ensure to indicate the amount of dry ice and shipper information on the outside shipper label.
- 6) Do not cover any printed markings on the outside of the box!



Example outer box (appearance may vary)

APPENDIX 1 - EXPORT REQUIREMENTS FOR SAMPLE SHIPPING - CANADA

COMMERCIAL INVOICE

SHIPMENT AWB NUMBER	Packed in compliance with IATA Packing Instruction 650					
	0					
SHIP FROM (ADDRESS)	SHIP TO (ADDRESS)					
	Q ² SOLUTIONS					
	28454 LIVINGSTON AVE					
	VALENCIA, CA 91355 USA					
	TEL: 661-799-6480					
	EIN-47-418-1370					
SHIPPER EMAIL	CONSIGNEE EMAIL					
uslogisticsoperations@igvia.com						
CONTENTS						
HUMAN SPECIMENS, BIOLOGICAL SUBSTANCE CATE	GORY B (UN3373)					
TEMPERATURE (CIRCLE ONE)						
AMBIENT	REFRIGERATED FROZEN/COMBO Enter Dry Ice Amt Below					
DRY ICE QTY (N/A FOR NON-FROZEN SHIPMENT)						
KG (Please ensure UN1845 Class 9 labels with dry ice amount are attached to outer packaging)						
QTY UOM DESCRIPTION/HARMONIZED CODE	QTY UOM DESCRIPTION/HARMONIZED CODE					

QTY	UOM	DESCRIPTION/HARMONIZED CODE	
	ml	Human blood HTS: 3002.90.5210	
gm Human tissue			
	ml	Human urine HTS: 3001.20.00	
	ml	Human plasma	
	ml	Human serum hts: 3002.12.0020	

QTY	UOM	DESCRIPTION/HARMONIZED CODE			
	nbr	Prepared slides for human blood HTS: 3002.90.5210			
nbr Prepared slides for human tissue					
	nbr	Prepared paraffin blocks HTS: 27.12 / 3001.90.0150			
	nbr	Swabs of human blood HTS: 3002.90.5120			
	nbr	Swabs of human serum HTS: 3002.12.0020			

These specimens are for medical laboratory testing purposes and for research use only in conjunction with a pharmaceutical study. NO commercial value. The value for customs purposes only, is \$5.00.						
SIGNATURE (BLUE INK ONLY)	PRINT INVESTIGATOR'S NAME/TITLE OR APPLY OFFICIAL SEAL HERE					
DATE						

CDC STATEMENT

	HUMAN SPECIMENS, BIOLOGICAL SUBSTANCE CATEGORY B (UN3373)					
To v	vhom	it may concern:				
The	The enclosed package is intended for delivery to:					
Q ² SOLUTIONS 28454 LIVINGSTON AVE VALENCIA, CA 91355 USA TEL: 661-799-6480						
TEMPE	AMBIENT REFRIGERATED FROZEN/COMBO Enter Dry Ice Amt Below					
DRY IC	E QTY (N/	A FOR NON-FROZEN SHIPMENT) KG (Please ensure UN184	5 Cla	ass 9 I	labels	are attached to outer packaging)
QTY	UOM	DESCRIPTION/HARMONIZED CODE		QTY	UOM	DESCRIPTION/HARMONIZED CODE
	ml	Human blood hts: 3002.90.5210			nbr	Prepared slides for human blood
	gm	Human tissue HTS: 3001.90.0150			nbr	Prepared slides for human tissue
	ml	Human urine HTS: 3001.20.00			nbr	Prepared paraffin blocks HTS: 27.12 / 3001.90.0150
	ml	Human plasma HTS: 3002.12.0010			nbr	Swabs of human blood hts: 3002.90.5120
	ml	Human serum HTS: 3002.12.0020			nbr	Swabs of human serum
CDC import permit is not required for this shipment. The material is not known or suspected to contain an infectious biological agent. Specimen samples are collected as part of a clinical trial. All patient subjects are screened as a requirement to participate in the trial. (Human material that was neither inoculated with nor exposed to infectious agents of agricultural concern, including zoonotic agents; the material contains no animal or non-human primate material and is not of tissue						
culture origin.) These specimens are for medical laboratory testing purposes and for research use only in conjunction with a pharmaceutical clinical trial.						
Packed in compliance with IATA Packing Instruction 650.						
SIGNA	ΓURE (BLU	JE INK ONLY)		PRI	INT INVEST	'IGATOR'S NAME/TITLE OR APPLY OFFICIAL SEAL HERE
DATE						

REVISION LOG

Date/Version	Page(s)	Revision	Notes
V01/August 2025	N/A	N/A – first version	