

IQVIA Laboratories "How To" Guide

How To Ship Samples – CENTRAL & LATIN

AMERICA

August 2025

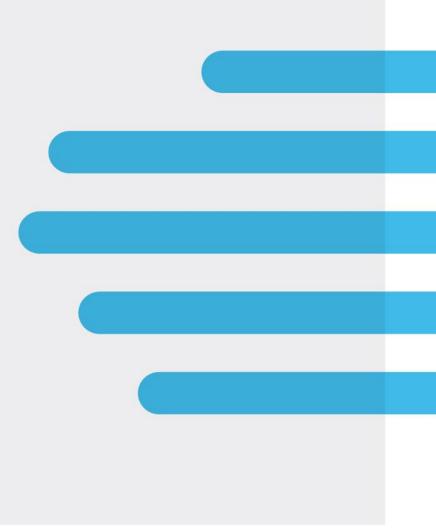




TABLE OF CONTENTS

Global holiday schedule	2
What action should be taken if there are critical patient visit collections on a holiday?	2
Shipping Samples from Latin America to IQVIA Laboratories in North America	3
Import Requirements	3
Export Requirements	3
Standard and Premium Courier Services	4
Standard couriers	4
Shipping Guidance	5
IATA Requirements	5
Commercial Invoice Requirements	5
Ambient and Refrigerated Samples	5
Frozen samples	10
Example Air Waybills & Commercial Invoices	12
MARKEN	12
OCASA	14
Revision Log	15

GLOBAL HOLIDAY SCHEDULE

IQVIA Laboratories will provide your site with details of courier "no-delivery" days and IQVIA Laboratories opening hours in advance of each national holiday.

Site personnel are recommended to review holiday letters and subject visit dates to come up with contingency plans with regards to subject 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 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.

SHIPPING SAMPLES FROM LATIN AMERICA TO IQVIA LABORATORIES IN NORTH AMERICA

Import Requirements

Many countries must hold import permits to allow the supply of laboratory kits to be imported into the country.

The responsibility for obtaining an import permit is with the sponsor or the third party working on the behalf of the sponsor. The person/company applying for the permit must be located in the country where the permit is required. The general timeline to obtain this permit is 4 to 8 weeks. IQVIA Laboratories provides assistance in the form of a template proforma invoice detailing all the lab kit contents for the full duration of the study.

Export Requirements

Argentina and Brazil: The exportation process is led by Marken team, and all the information and forms are provided in the starter pack. Marken team provides specific instruction for each international destination. Please contact Marken team for assistance in case any doubt arises, they have a specialized team to support on the process.

Chile: The exportation process is led by OCASA team, and all the information and forms are provided in the starter pack. OCASA team provides specific instruction for each international destination. Please contact OCASA team for assistance in case any doubt arises, they have a specialized team to support on the process.

STANDARD AND PREMIUM COURIER SERVICES

Standard couriers are the most commonly 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 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.

Your IQVIA Laboratories Project Management team will provide courier information documents for the applicable courier via the Portal.

Standard couriers

The standard courier used by your site will depend on the country:

Your IQVIA Laboratories Project Management team will provide courier information documents for the applicable courier via the Portal.

Ambient, Refrigerated and Frozen Shipments: All materials required for ambient and refrigerated sample shipping via **standard couriers** will be provided to you by **IQVIA Laboratories**. Please re-order these supplies from IQVIA Laboratories as required.

Exceptions:

o Brazil: Shippers are provided by the courier directly on the day of collection.

When contacting the courier to book an ambient or refrigerated collection, please ensure you have the pre-printed air waybill (AWB) number you will be using to ship available.

Booking a collection with standard couriers

To book a collection, please refer to the courier booking information pack or sheet provided to you by the IQVIA Laboratories project management team.

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

On the day of collection

- Frozen shipments only: The courier will deliver the box containing dry ice. If your shipping box
 is received inside a brown overpack box, please discard the overpack box. Please only use the
 validated packaging provided by the driver. The driver will automatically return to pick up the
 prepared shipment later on the same day.
- *All shipment types:* Please insert prepared biological samples into the box and seal the outer box. See <u>Shipping Guidance</u> for additional instructions.

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 to 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.

<u>IMPORTANT</u>: 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.

Commercial Invoice Requirements

For shipments where a commercial invoice is required, please verify and sign the pre-printed customs invoice provided. Place a copy of the invoice into the document pouch provided and affix it to the box. Provide a copy to the driver and retain a copy at site. **Do not label over any existing print on the box.**

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

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)
- Foil bag
- Gel packs 1 x 16oz (refer to above instructions for conditioning)
- IATA contents card
- Shipper (box)
- Air Waybill
- Commercial Invoice

To package ambient samples for shipment:

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

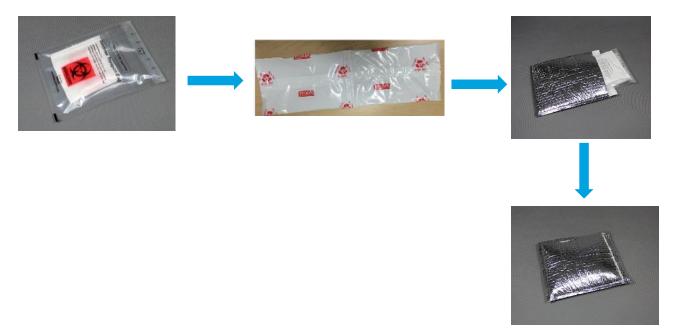


2) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.





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)
- Foil bag
- Gel Packs 2 x 675g, 3 x 500g (refer to above instructions for conditioning)
- IATA contents card
- Cooler (internal packaging)
- Shipper (external box)
- Air Waybill
- Commercial Invoice

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).

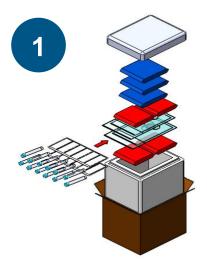


3) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.



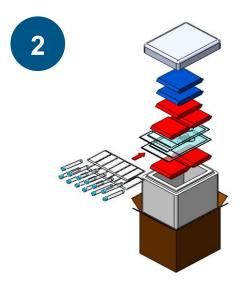


- 4) Place 1 refrigerated 675g Gel Pack into the cooler on top of the SSB, then:
 - a. Summer packaging (see image 1 below): Place 3 frozen 500g Gel Packs on top of the refrigerated Gel Pack.
 - b. Winter packaging (see image 2 below): Place 1 refrigerated 500g Gel Pack on top of the first refrigerated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

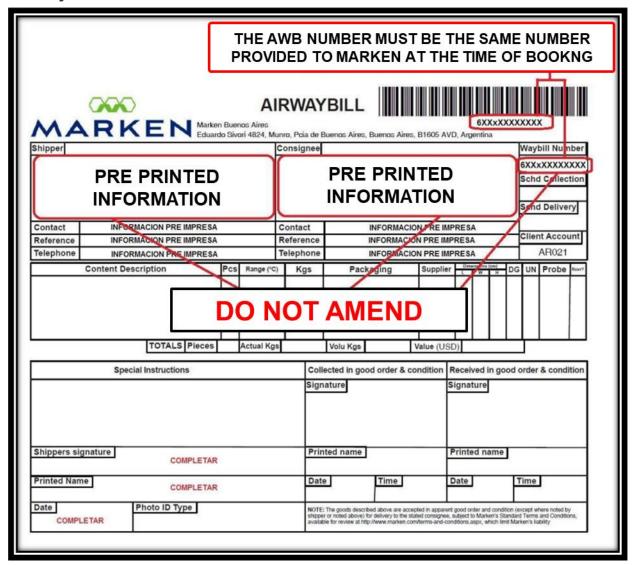


Example outer box (appearance may vary)

EXAMPLE AIR WAYBILLS & COMMERCIAL INVOICES

MARKEN

Air Waybill

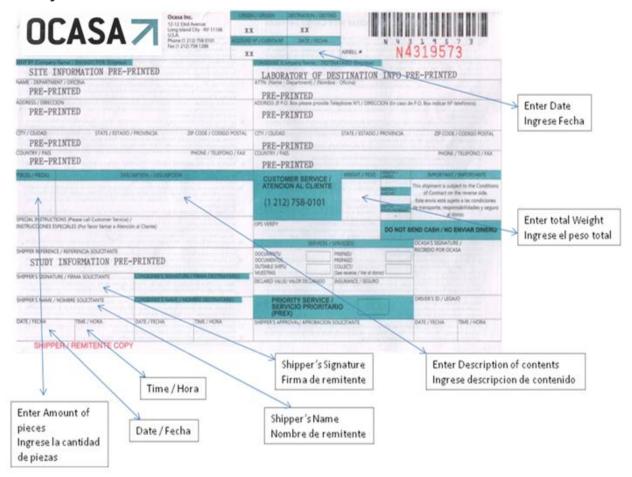


Commercial Invoice

INVO	INVOICE NUMBER: N/A MARKEN BOOKING CONFIRMATIION#:							
	DATE:		PO OR SALES ORDER#: N/A					
SHIPE	SHIPPER/EXPORTER:		DELIVERY TO :					
	COUNTRY OF EXPORT: AR COUNTRY OF ORIGIN: AR		IMPORTER OF RECORD IF DIFFERENCT FROM ULTIMATE CONSIGNEE:					
COUN	COUNTRY OF ULTIMATE DESTINATION: US		Consider					
NO (TYPE OF PKG	FULL DESCRIPTION OF GOODS	QTY	нтѕ	NET WEIGHT	UNIT VALUE	TOTAL Value
-		510			2222.00	PER BOX	(Currency)	(Currency)
		BIO	Biological Subs Cat B UN3373 Blood Plasma	ml	3002.90 150)5 Kg	USD \$5.00	USD \$5.00
			Urine					
			Other Body Fluids:					
			Temperature Condition:					
			Ambient(15-25°C)					
			Refrigerated (2-8°C)					
TOT								USD:\$5.00
PKO	GS.	I certify that the stated prices and descriptions of goods are true and correct						
Statements (only as applicable) NON INFECTIOUS HUMAN BLOOD (UN3373 BIOLOGICAL SUBSTANCE CATEGORY B) FOR CLINICAL RESEARCH ONLY CDC IMPORT PERMIT IS NOT REQUIRED FOR THIS SHIPMENT/CDC IMPORT STATEMENT (USPHS 42 CFR – PART 71) PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650 THE MATERIAL IS NOT KNOWN TO CONTAIN ANY ETIOLOGICAL AGENT, HOST OR VECTOR OF HUMAN DISEASE AND/OR SHOWS NO INDICATION THAT IT CONTAINS AN INFECTIOUS AGENT.								
USDA PERMIT IS NOT REQUIRED, EXEMPTED UNDER USDA IMPORT GUIDLINE# 1101: HUMAN MATERIAL CONTAINING NO ANIMAL MATERIAL AND NOT OF TISSUE CULTURE ORIGIN. HUMAN MATERIAL THAT WAS NEITHER EXPOSED TO OR INOCULATED WITH ANY EXOTIC LIVESTOCK OR AVIAN DISEASE AGENTS. NOT ORIGINATING AT ANY FACILITY THAT WORKS WITH ANY EXOTIC LIVESTOCK OR AVIAN DISEASE AGENTS. NOT EXPOSED TO INFECTIOUS AGENTS OF INFECTIOUS AGENTS OF AGRICULTURE CONCERNS, INCLUDING ZOONOTIC AGENTS.								
OBTAIN	OBTAINED DIRECTLY FROM HUMANS, NOT RECOMBINANT NOT CULTURED.							
EXPORTED FOR SPECIFIC ANALYSIS IN ACCORDANCE WITH CLINICAL STUDIES REQUIRED BY CENTRAL LABORATORIES. PERISHIBLE PROTECT FROM EXTREME TEMPERATURES								
SIGNATURE OF SHIPPER/EXPORTER DATE								

OCASA

Air Waybill



REVISION LOG

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