

IQVIA Laboratories "How To" Guide

Shipping Samples – SOUTH AFRICA

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 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.

SOUTH AFRICA - HOLIDAYS OBSERVED							
New Year's Day	Youth day						
Human Rights Day	National Women's Day						
Good Friday	Heritage Day						
Family Day	Day of Reconciliation						
Freedom Day	Christmas Day						
Workers Day	Day of Goodwill						

IMPORT AND EXPORT REQUIREMENTS - SOUTH AFRICA

Import Requirements (LTMS and QLIMS Studies)

If site is shipping to Cytespace Africa Laboratories (an IQVIA Laboratories partner): it is the responsibility of the IQVIA Laboratories responsibility to apply for the Import permits.

If site is shipping to another location: the responsibility for obtaining an import permit is with the sponsor or the third party working on the behalf of the sponsor.

The sponsor must provide IQVIA Laboratories with the Biological Sample Clearance Certificate. The general timeline to obtain this permit is 6 to 8 weeks, however it can take longer depending on whether all the documents are completed as required.

Export Requirements

The responsibility for obtaining an export permit is with IQVIA Laboratories. The general timeline to obtain this permit is 6 to 8 weeks, however it can take longer depending on whether all the documents are completed as required.

Commercial Invoice Requirements for Countries <u>Outside</u> of South African Border (Kits shipped from Cytespace)

The Cytespace Clinical Trial Materials (CTM) team provides a Proforma invoice once the kits are built. This is shared with Biocair. They send it to the Importer of Records (IOR). The IOR will contact the sites to confirm they have a valid Import License (IL). If sites do not have a valid IL kit will not be released to sites by the IOR teams.

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.

STANDARD AND PREMIUM COURIER SERVICES

Standard couriers are the most frequently 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.

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

Standard couriers

The standard courier used in South Africa is TNT/FedEx. Your IQVIA Laboratories Project Management team will provide courier information documents for the applicable courier via the Portal.

Ambient & Refrigerated Shipments: All materials required for ambient and refrigerated sample shipping via TNT/FedEx will be provided to you by IQVIA Laboratories. Please re-order these supplies from IQVIA Laboratories as required.

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.

Frozen Shipments: All materials and paperwork required for frozen sample shipping via TNT/FedEx.

Booking a collection with TNT/FedEx

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: Site must contact contact the Johannesburg TNT depot 24 hours prior to collection, using the TNT/FedEx Call-By Cut-Off (CBCO) document provided by the IQVIA Laboratories Project Management Team via the Portal.
 - Sites must contact TNT/FedEx before the call-by time detailed on this CBCO insert.
 - o The TNT/FedEx driver will deliver the dry ice to the site when required.
 - Please note, with this service, the TNT/FedEx driver only delivers the dry ice on the requested date and time.
- All shipment types: Please insert prepared biological samples into the box and seal the outer box. See <u>Shipping Guidance</u> for additional instructions.

Premium Courier Service (Marken)

If your site is set up to use Marken premium courier service, the IQVIA Laboratories Project Management Team will provide a Marken Welcome Pack, including a collection request form and transit/booking times, via the Portal. 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 with Marken (Premium)

Use the booking form included in your Welcome Pack to arrange the collection with your local Marken office. You can find the local contact details on the booking form.

Marken will confirm receipt of the booking request either via email or telephone and will process the booking within their system. A reference number will be generated and shared with the site for your reference.

On the day of collection

The Marken driver will go to the investigator site at the requested collection date and time to collect the samples.

The driver will have all packaging and dry ice, if required, with them at point of collection along with the Air Waybill document which will be applied to the site.

Please note: for same day collection requests, the driver may not always have the Air Waybill
with them and in this case this would be applied when the shipment arrives back at the local
Marken facility.

The shipping site should enclose a copy of the customs invoice within the shipment when packing the samples.

Marken will prepare the shipment for export to the receiving country within the required transit times.

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.

<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.

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.
- 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)
- Air Waybill

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

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

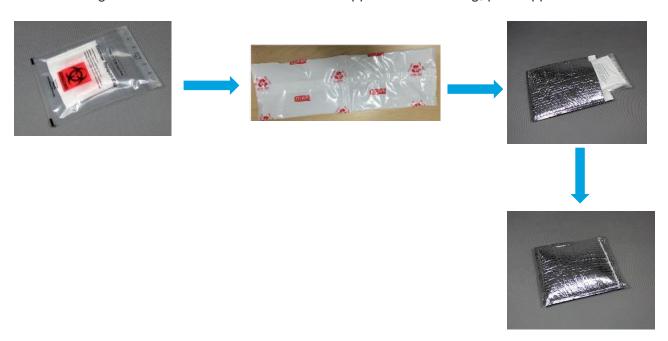


2) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.





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)
- 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).

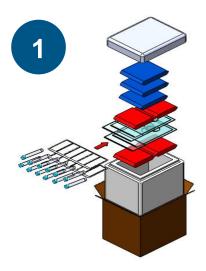


3) Place tube holder (and plastic bag with urine tube, if applicable) into the front pouch of the Specimen Shipping Bag (SSB) and place the corresponding requisition form into the back pouch. Seal bag.



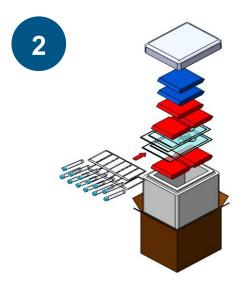


- 4) Place 1 refrigerated 675g Gel Pack into the cooler on top of the SSB, then:
 - a. **Summer packaging (see image 1 below)**: Place **3** frozen 500g Gel Packs on top of the refrigerated Gel Pack.
 - b. Winter packaging (see image 2 below): Place 1 refrigerated 500g Gel Pack on top of the first refrigerated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

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
 - used ambient year round.

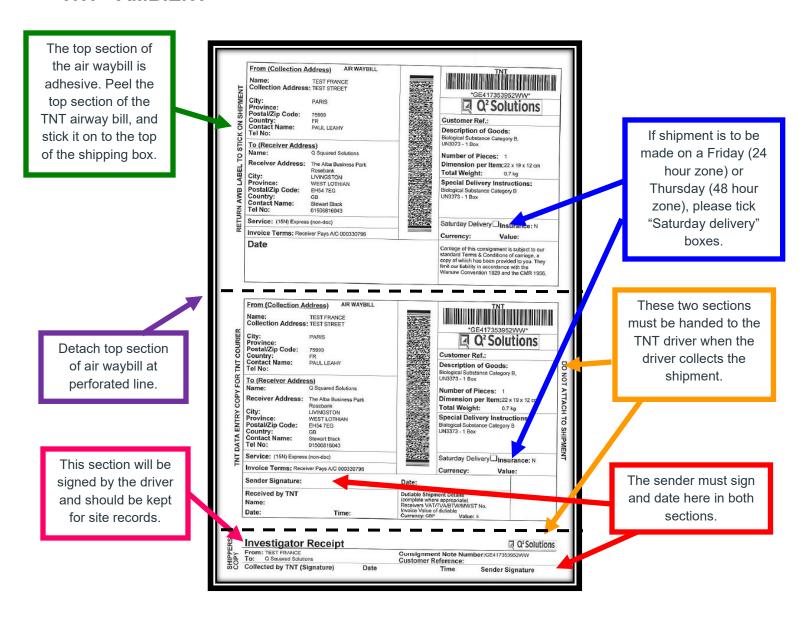
 o FROZEN: Place the sealed SSB with frozen samples in the bottom
 - FROZEN: Place the sealed SSB with frozen samples in the <u>bottom</u> section of the combination shipper and cover with enough dry ice to fill up the remainder of the box. Place foam lid over.
- 4) Place the IATA contents card on top 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)

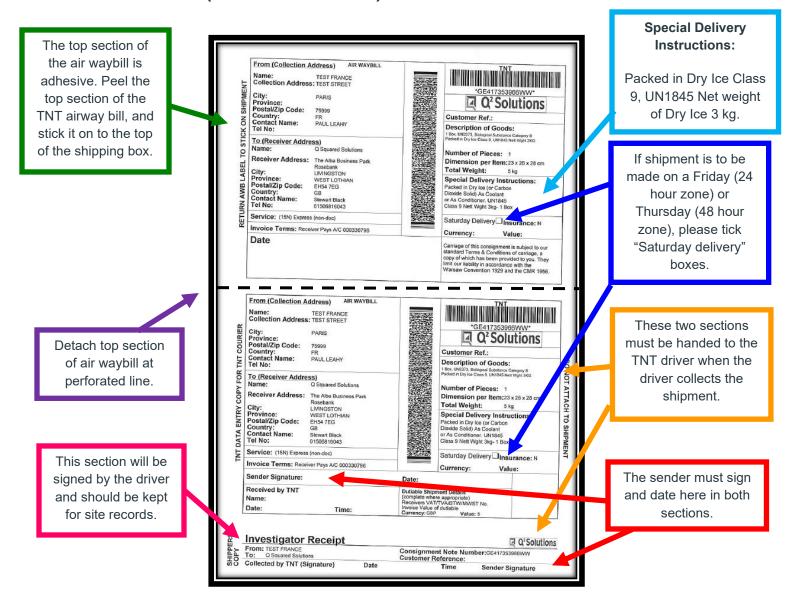
EXAMPLE AIR WAYBILLS & COMMERCIAL INVOICES

TNT - AMBIENT



On FRIDAYS, it is mandatory to insist on having the samples delivered to IQVIA Laboratories the next morning (SATURDAY). Please make sure that you write the words "SATURDAY DELIVERY" in the section "SPECIAL DELIVERY INSTRUCTIONS" on the air waybill before handing it to the TNT courier and attach a 'Weekend delivery' label to the shipper.

TNT - FROZEN (with combination)



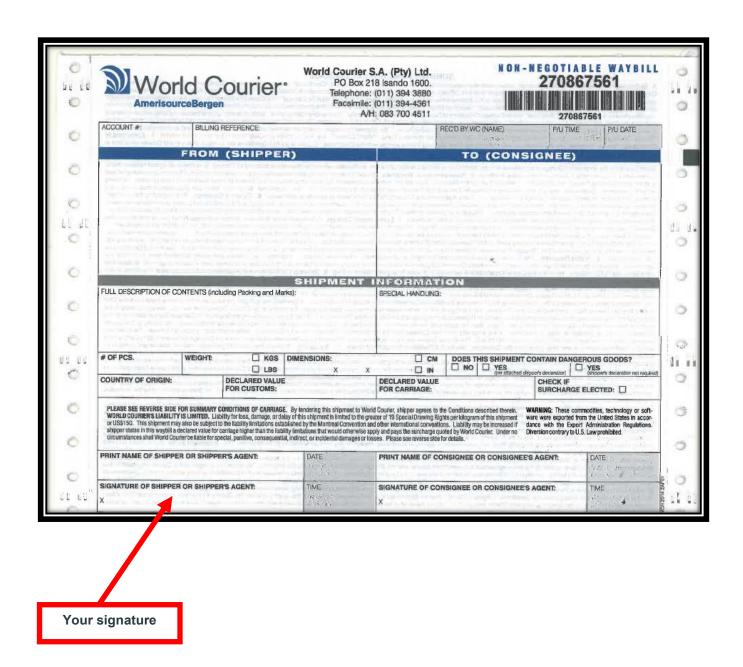
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If you are shipping samples on a Thursday (48 hours transit zone) or a Friday (24 hours transit zone) and they will be delivered on a Saturday, please ensure that you inform Marken that it is a Saturday delivery when booking the shipment. Failure to do so may result in your samples not being delivered to IQVIA Laboratories within stability.

WORLD COURIER



REVISION LOG

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