Q² Solutions[®]



Q² Solutions How Do I...? Guides for Site Coordinators

How Do I Ship Samples? (Europe)

Version 2.0 14 Mar 2022



Global Holiday Schedule

- Q² Solutions will provide your site with details of courier "no-delivery" days and Q² Solutions 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 Q² Solutions 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 Q² Solutions 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.



Import and Export Requirements (Europe)

Import Requirements

All non-European Union (EU) countries must hold import permits to allow the supply of laboratory kits to be imported into the country. In some circumstances, it may be required for sites in EU countries to hold an import permit – in these cases, your Q² Solutions Project Management team will provide further information. 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. Q² Solutions does provide assistance in the form of a template proforma invoice detailing all the lab kit contents for the full duration of the study.

Export Requirements

EU Countries

- Investigator sites within the EU require an EORI (Economic Operator Registration and Identification Number) number for trading with organisations outside of the EU an EORI number is therefore required for EU sites to ship samples to the Q² Solutions laboratory in Edinburgh, UK. It is likely that many investigator sites, or the institutions in which they are based, already hold this number, but we encourage you to request or confirm that this is the case for your site prior to study launch. If sites do not hold an EORI number, we recommend that sites initiate the process to obtain one.
- Spain requires an export license to ship samples to the UK. Please ensure relevant export licenses (and import if samples are to ship back to Spain) are applied for in advance of study start.

Non- EU Countries

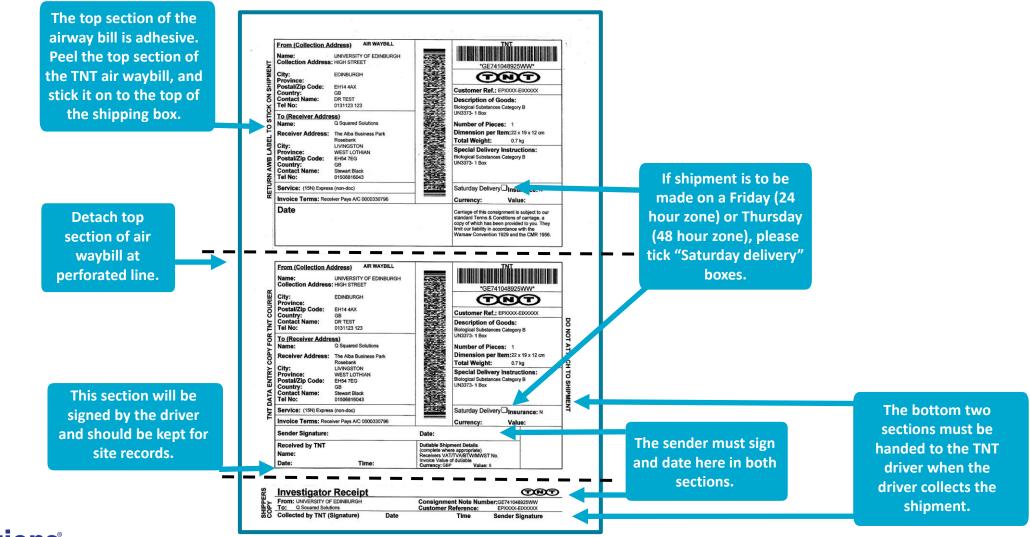
- The export of diagnostic samples out of any non-EU country to Q² Solutions will require an export permit. This can be in one of two formats:
 - 1. The permit can be for the country allowing exports from any point of export as long as the country regulations allow this.
 - 2. The permit can be a named city allowing exports from the designated city if the country regulations allow it.

For example: In Russia, to allow ambient samples to be shipped from Moscow and St Petersburg, the permit must be from either Moscow or St Petersburg. If each city has active sites enrolled in the study, the permit can also state both cities.



Courier Information for TNT

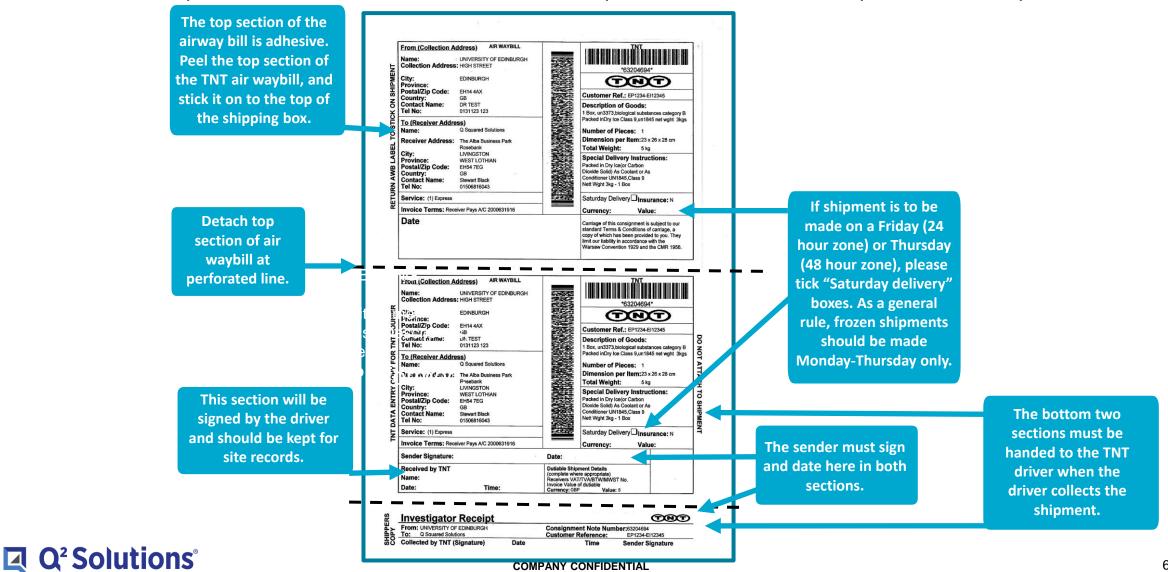
- Air Waybills (Ambient and Refrigerated) will be provided to site by Q² Solutions.
- To contact TNT, please refer to the courier information sheet provided in the initial kit shipment or via the portal.



Q Solutions

Courier Information for TNT

- Air Waybill (Frozen) will be provided to site by the Courier.
- To contact TNT, please refer to the courier information sheet provided in the initial kit shipment or via the portal.



Courier Information for TNT

Frozen Sample Shipping

- To book a frozen shipment collection, please call TNT using the country specific number provided in courier information sheet.
- TNT have now implemented the Med Pak Ice service and this should be used instead of ordering frozen shippers and Air Waybills directly from Q² Solutions via our resupply ordering process.
- On the day of you booked collection, you will receive a Med Pak frozen shipper, pre-printed returning Airway bill & customs documentation (where required for export from Non EU locations).
- Dry ice for the transportation of specimens back to the central laboratory will already be included within the frozen shipper. The Med Pak Ice service will be obtained via a 1-step process, ordering with TNT directly, while booking the courier pick-up, thus eliminating the need for multiple orders to be placed.
- · Detailed below are the contact details for making a booking.
- Packing instructions & TNT booking information sheet will be included in the Laboratory Manual where applicable.

TNT contact Details for Russia

Email: clinical.express.RU@tnt.com
Phone: 8800 700 3094 (Toll Free)

Fax: +7495 797 2701

TNT contact details for Bulgaria Email: clinical.express.BG@tnt.com

Phone: +359 29339 199
Fax: +359 29339 182

TNT contact details for UK/Ireland/Belgium and all other countries

Email: clinical.express.BE@tnt.com

Phone: +32 2 754 2540 **Fax**:+32 2 754 4965

- Please note that most sites are located within a 24-hours delivery zone. However some might be located in a 48-hours delivery zone; the transit time for your site can be found in the courier information sheet inserted in your flowchart.
- To ensure compliance with IATA (International Air Transport Association) Dangerous Goods Regulations, please note that as you are the shipper, you are responsible to pack, mark, label the shipment and declare on the TNT Air Waybill all in accordance to IATA Dangerous Goods regulations requirement. TNT couriers/contractor will inspect your completed shipment/shipping paperwork in your presence and if there are mistakes made, will guide you through making the necessary corrections.



Frozen Sample Shipping with TNT (Includes Combination shipping with dry ice)

Medpak Frozen Packing Instructions





Frozen Sample Shipping with Marken-UPS (Includes Combination shipping with dry ice)

To book a frozen shipment collection, please call Marken-UPS using the country specific number provided in courier information sheet.

Please provide the following information at the time of booking:

- Sample temperature: Frozen
- Study protocol and site number
- Confirm address details, including specific location details (e.g. floor and room number)
- Contact person and contact phone number for the collection
- Confirm earliest and latest possible pickup times
- Remember to have the samples ready for collection before the latest collection time
- Package weight: 10 kg Frozen
- Destination laboratory: Q Squared Solutions in Livingston, UK

BOX PREPARATION:

UPS driver will deliver the box containing dry ice. If your shipping box is received inside a brown overpack box, please discard the overpack box.

Please insert prepared biological samples into the box and seal the outer box.

UPS driver will automatically return to pick up the prepared shipment later on the same day. Please only use the validated packaging provided by the driver.

The UPS pre-printed label, and other stickers, will be affixed to the box provided by the driver.

If you are shipping from a non-EU country, please verify and sign the pre-printed customs invoice provided. Place **3 copies** of the invoice into the document pouch provided and affix it to the box. Do not label over any existing print on the box.





Courier Information Marken-UPS

- Air Waybills (Ambient and Refrigerated) will be provided to site by Q² Solutions.
- To contact Marken-UPS, please refer to the courier information sheet provided in the initial kit shipment or via the portal.







Courier Information Marken-UPS

- Air Waybill (Frozen) will be provided to site by the Courier.
- This should be used also for Combination Shipping with Dry Ice.
- To contact Marken-UPS, please refer to the courier information sheet provided in the initial kit shipment or via the portal.



Please refer to instructions for frozen sample shipping on the following page.



Courier Information Marken-UPS

Frozen Sample Shipping

- To book a frozen shipment collection, please call Marken-UPS using the country specific number provided in courier information sheet.
- Please note that most sites are located within a 24-hours delivery zone. However some might be located in a 48-hours delivery zone; the transit time for your site can be found in the courier information sheet.
- Please provide the following information at the time of booking:
 - Sample temperature: Frozen
 - Study protocol and site number
 - Confirm address details, including specific location details (e.g. floor and room number)
 - Contact person and contact phone number for the collection
 - Confirm earliest and latest possible pickup times
 - Remember to have the samples ready for collection before the latest collection time
 - Package weight: 10 kg Frozen
 - Destination laboratory: Q² Solutions in Livingston, UK
- UPS driver will deliver the box containing dry ice. If your shipping box is received inside a brown overpack box, please discard the overpack box.
- · Please insert prepared biological samples into the box and seal the outer box.
- UPS driver will automatically return to pick up the prepared shipment later on the same day. Please only use the validated packaging provided by the driver.
- The UPS pre-printed label, and other stickers, will be affixed to the box provided by the driver.
- If you are shipping from a non-EU country, please verify and sign the pre-printed customs invoice provided. Place 3 copies of the invoice into the document pouch provided and affix it to the box.

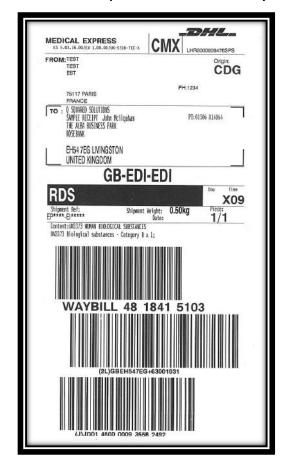
 Do not label over any existing print on the box.
- To ensure compliance with IATA (International Air Transport Association) Dangerous Goods Regulations, please note that as you are the shipper, you are responsible to pack, mark, label the shipment and declare on the Air Waybill all in accordance to IATA Dangerous Goods regulations requirement. UPS Marken couriers/contractor will inspect your completed shipment/shipping paperwork in your presence and if there are mistakes made, will guide you through making the necessary corrections.
- For any queries about specimen shipments at any time, please contact Marken-UPS using the details provided on your courier information sheet, or call +44 131 333 4012, or e-mail QLE@marken.com

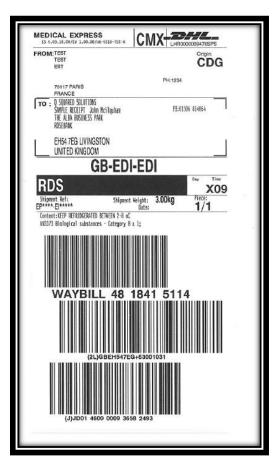


Courier Information DHL

AIR WAYBILL AMBIENT & REFRIGERATED

These will be provided to site by Q² Solutions







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Courier Information DHL

Frozen Sample Shipping

- To book a frozen shipment collection, please call DHL on the country specific number provided in courier information sheet.
- Please note that most sites are located within a 24-hours delivery zone. However some might be located in a 48-hours delivery zone; the transit time for your site can be found in the courier information sheet inserted in your flowchart.
- Upon booking your frozen shipment collection with DHL the following will be required:
 - How much dry ice is required?
 - Collection address
 - Contact person & contact number
 - Date/Time of collection.
- To ensure compliance with IATA (International Air Transport Association) Dangerous Goods Regulations, please note that as you are the shipper, you are responsible to pack, mark, label the shipment and declare on the DHL air waybill all in accordance to IATA Dangerous Goods regulations requirement. DHL couriers/contractor will inspect your completed shipment/shipping paperwork in your presence and if there are mistakes made, will guide you through making the necessary corrections.
- When contacting DHL, you will be requested to provide the following information:
 - Investigator's name and study number, found at the bottom of your courier information sheet, for immediate verification.
 - For ambient shipments, have the pre-printed DHL air-way-bill (AWB) number you will be using to ship available.
 - The DHL Call Center Agent will confirm the details they have in relation to the collection address, contact person & contact number and will provide an estimated collection time.
- For ambient shipment, please ensure that you use the correct DHL air-way-bill (AWB) with the following declaration

UN3373 BIOLOGICAL SUBSTANCE CATEGORY B NO. OF PKG.__

• For frozen shipment with dry ice packing, ensure that you use the correct DHL air-way-bill (AWB) with the following declaration:

UN3373 BIOLOGICAL SUBSTANCE
CATEGORY B, PACKED IN UN1845, DRY ICE CLASS 9,
NO. OF PKG.__ AND NET QUANTITY PER PACKAGE __KG

• For any queries about specimen shipments at any time, please contact DHL European Key Accounts Desk (EKAS) on call +353 61 365551, fax +353 61 365596 or e-mail quintiles.ekas@dhl.com

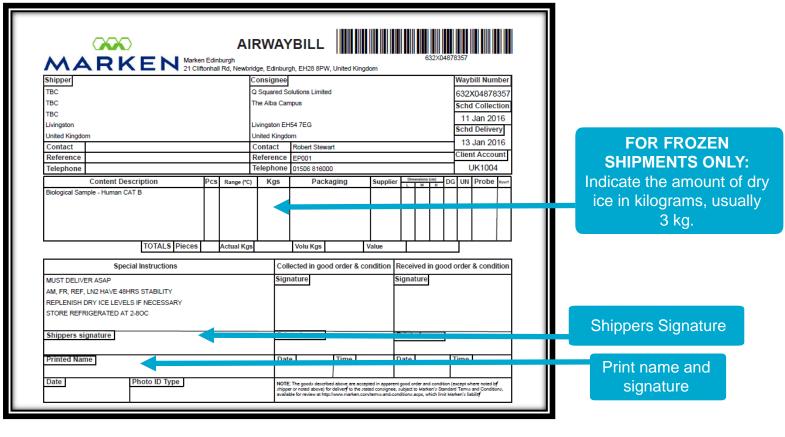


Courier Information Marken (Premium Service)

Air Waybill will be provided directly to site by the courier.

Marken will provide details instructions for completion of this form.

To contact Marken, please refer to the information provided in your booking pack.



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 Q² Solutions within stability.



How Do I Order Dry Ice?

Dry Ice no longer needs to be ordered separately for sites in the European Region, but will be provided by the courier directly on the day they pick up your frozen sample shipment.

- Please refer to the Courier Information section of this manual for full details regarding frozen sample shipping.
- Countries serviced by TNT: Austria, Belgium, Bulgaria, Czechia, Denmark, Estonia, Greece, Israel, Italy, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Portugal, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland and UK
- Countries serviced by Marken-UPS: Bosnia and Herzegovina, Croatia, Finland, France, Germany, Hungary, Iceland, Norway, Poland, Romania, Serbia, Turkey and Ukraine.
- Countries serviced by DHL: Cyprus, Kuwait, Monaco, North Macedonia and Qatar.
- Booking instructions and transit details will be provided to sites with the courier information sheet.
- Orders can be placed by phone, email or by using a self order form. Please refer to the Courier Information section of this manual for further details.
- For frozen shipments (including combination shipping with dry ice), the courier will provide dry ice on the morning of the collection, together with shipping supplies, a pre-printed returning Airway bill & customs documentation (where required for export from Non EU locations).
- The driver will then return to pick up the packaged samples.
- For a frozen shipment from a 24-hour delivery site, the booking must be completed at least 1 working day in advance and before 11:00 CET (Central European Time).
- For a 48-hours delivery Site, the booking must be completed at least 2 working days in advance and before 11:00 CET.



Ambient Shipments - Gel Wraps

Gel Wrap should be shipped <u>refrigerated</u> or at <u>room temperature</u>.

As external temperatures and seasonal variances differ from country to country, please refer to the following guidelines on using your gel packs:

External Temperature ≥25° C (77° F) **REFRIGERATE** the gel wrap.

NOTE: Refrigerate the gel wrap for a period of <u>24 hours</u> prior to use.

External Temperature < 25° C (77° F) - Store the gel wrap at **ROOM TEMPERATURE** — Do not refrigerate the gel wrap.

NOTE: Ambient / Frozen Combo Shipper – Gel Wrap should be used **ambient** year round.



Refrigerated Shipments – Gel Wraps

Gel Wrap should be shipped <u>frozen</u> or <u>refrigerated</u>.

As external temperatures and seasonal variances differ from country to country, please refer to study specific Laboratory Manual for instructions on using your gel packs.

