



ConcizuTrace™ Sample Collection

SUPPORT GUIDE

REMINDER: No real patients or blood samples will be used in this market research project. This market research is intended to simulate and evaluate process only.

You will be provided additional directions specific to this market research test.

This diagnostic is not approved in the US and the associated draft materials are being shown in this market research solely to gauge your reactions.

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WELCOME

Every patient receiving Product X should have their plasma concentration measured at week 4 to allow for a personalised dose optimisation.

Randox Laboratories are providing an integrated service solution ConcizuTrace™ to healthcare professionals to allow to perform the Product X plasma concentration measurement.



The Randox ConcizuTrace™ service solution comprises:

- Randox ConcizuTrace™ Sample Collection Kit, a kit to provide physicians and healthcare staff with all needed materials for compliant blood sample collection and plasma preparation.
- Randox ConcizuTrace™ ELISA Kit, an IVD kit for laboratories to perform the laboratory analysis.
- Randox ConcizuTrace™ Portal to access patient test results.
- Logistical support to transport blood samples to the analytical laboratory.

This brochure is a guide for healthcare professionals using the Randox ConcizuTrace™ Sample Collection Kit.



Product X



ConcizuTrace™
Sample Collection Kit



ConcizuTrace™ ELISA Kit

INTRODUCTION TO RANDOX CONCIZUTRACE™ SAMPLE COLLECTION KIT

YOUR STEP-BY-STEP GUIDE

Patient blood sample collection, plasma preparation & registration of samples on the Randox ConcizuTrace™ Portal

The Randox ConcizuTrace™ Sample Collection Kit is intended for use in the collection and transport of a blood sample, taken by a trained professional. The samples will be transported to a professional laboratory for testing using the Randox ConcizuTrace™ ELISA.



RANDOX CONCIZUTRACE™ SAMPLE COLLECTION CONTENTS

- Instructions for use
- 1x disposable quick release tourniquet
- Winged butterfly needle with 30cm tubing. For adults use the 21 gauge needle; for adolescents use the 23 gauge needle.*
- 1x 70% alcohol wipe
- One-use tube holder
- Cotton or Rayon balls
- Vacuette 3ml No Additive blood collection tube (pre-labelled discard tube)
- 1x spot waterproof or fabric plaster
- Vacuette 2ml sodium citrate tube (3.2% concentration pre-labelled blood collection tube)
- 1x 1ml transfer pipette
- 2x pre-labelled cryotubes
- 1x pre-labelled cryobox with grid for aliquoted samples in cryotubes
- 2x pre-labelled pathoseal bag with absorbent liner
- 2x circular stickers to secure box lid during transportation

Please ensure that expiration dates are checked on the kit before samples are collected. Please do not collect samples in expired containers. If you have expired tubes, please order additional ConcizuTrace™ Sample Collection Kits through the Randox ConcizuTrace™ web portal. If the user has access to sample collection kit management, they will be able to do this by selecting 'Order New Kit' button from either the dashboard or the navigation menu. If the user does not have access to this area, they should contact their Super User. *Please be advised that needles are not supplied within catalogue number CZM10597. Please consult the Instructions For Use provided within the kit for the recommended supply of appropriate

STEP 1 - BLOOD SAMPLE COLLECTION PROTOCOL

Ideally, venepuncture should be performed in a designated, non-carpeted, clinical room, with facilities for hand washing, sharps and clinical waste disposal.

Collect all the equipment necessary for the procedure and place it within safe and easy reach on a tray or trolley, ensuring that all the items are clearly visible. The blood is collected using a winged blood collection set (butterfly needle with attached tubing).

1. Choose an appropriate gauge (G) of needle, provided in the kit (for an adult use the 21G needle; for an adolescent use the 23G needle).
2. Apply the disposable quick release tourniquet.
3. Insert butterfly needle.
4. Using the discard tube, collect some blood to ensure all the air in the line has been removed. **Note the discard tube does not have to be filled completely.**
5. Attach the 2ml sodium citrate (3.2% concentration) blood collection tube to the winged butterfly needle and fill completely.
6. Once full, remove tube, and mix the tube immediately by gently inverting the tube at least 8 to 10 times.
7. Discard the used blood sampling device into a puncture resistant sharps container and treat the puncture site astringed. Dispose the discard tube into appropriate biohazard container (not provided).
8. Prior to centrifugation, gently invert the tube back and forth while examining the sample for visible clots. If visible clot seen, recollect the sample.

Please be advised that processing (centrifugation, plasma separation, aliquoting freezing) of the sample should be completed within four hours maximum of blood draw.

STEP 2 - PLASMA PREPERATION

1. Promptly centrifuge the sample no more than 4 hours after collection at 1500 to 2000 x g for 15 minutes. RCF ($g = 1.12 \times \text{radius (mm)} \times \text{RPM}/1000$)². The cells and plasma should be separated.
2. Using the disposable 1ml transfer pipette (included), remove the plasma (from the top) without disturbing the cells to promptly aliquot equal portions of the plasma into the appropriately pre-labelled cryotubes. Do NOT touch or pipette the interface (hazy layer between the cells and plasma).
3. Ensure the lids are closed tightly on the cryotubes.
4. Dispose of the 2ml sodium citrate (3.2% concentration) blood collection tube in appropriate biohazard waste.
5. Freeze both tubes immediately at -20°C or lower is acceptable, in an upright position, in the cryobox until frozen.
6. Ship the pre-labelled cryotube with pre-fix -1 (frozen on dry ice) to the selected laboratory at your earliest convenience, ideally the same day that the sample is collected, via the selected courier company. Tube should be placed inside the cryobox, add circular stickers (one either side of lid) to adhere lid to base of cryobox and the cryobox should be sealed airtight in the pathoseal bag for shipment. Please ensure that the pathoseal bag is placed in the dry ice box provided by the selected courier.
7. Retain the second pre-labelled cryotube with pre-fix -2 as a backup sample maintained within a -20°C freezer or lower is acceptable. If required, and you need to return backup sample, please use additional packing materials supplied. Please ensure you retain labelled pathoseal bag with absorbent liner for this process.
8. If backup sample is not requested/ needed within 2 weeks of collection, we recommend that you dispose of it. Please ensure to observe appropriate biohazard protection.

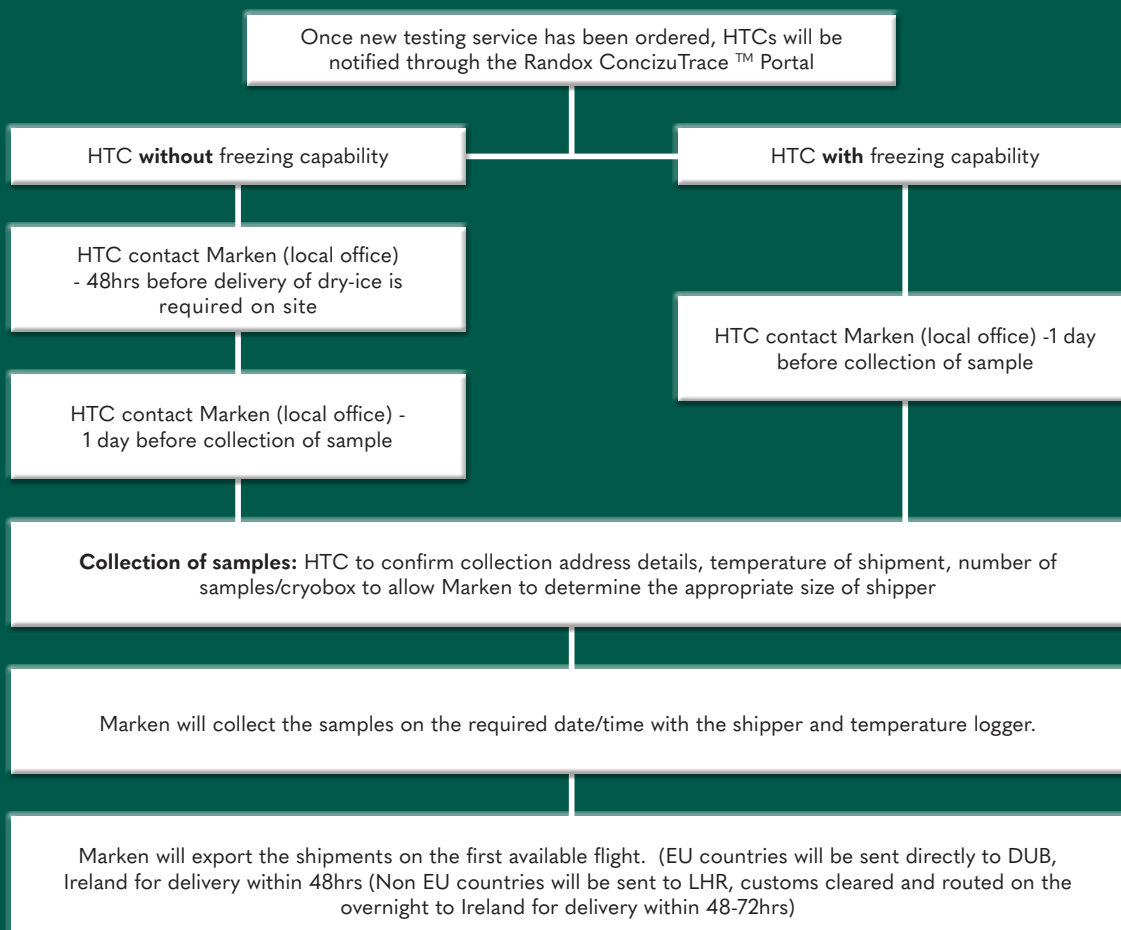
STEP 3 - RETURNING THE SAMPLE TO THE LABORATORY NETWORK

The selected courier company for this transportation is Marken.

Please be advised that Marken should be contacted at least 24 hours prior to ensure the required appointment slot.. **Please see appendix 1 - additional support to find your local Marken courier contact details.**

If you do not have freezing capabilities within your site, then courier shall be contacted at least 48 hours before the sample pick-up date, to ensure that dry ice can be delivered to your site to store the samples on prior to pick-up by the courier.

Courier will deliver the samples on dry ice to the Lab in charge of performing the test (based on the HTC location), within the contractual timelines (variable by country).



* Please be advised that freezing is acceptable at -20°C or lower

After the blood sample has been collected, the Randox ConcizuTrace™ Portal will be updated with the shipment information.

STEP 4 - PACKING SAMPLE TO RETURN TO THE LAB

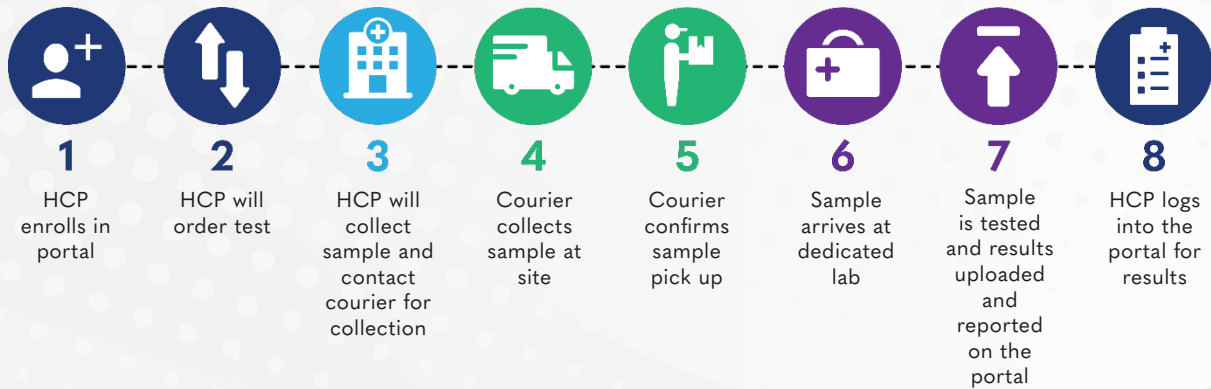
Marken will add a thin layer of dry ice to the bottom of the Biosystem shipper. A bag with the remaining dry ice will be placed inside the biosystem shipper along with the temperature logger which will have been started by Marken.

Upon collection the driver will arrive at site with the Biosystem shipper to complete the packing of samples / cryobox for return to the laboratory. **Please be advised that Marken is responsible for steps 1-7 below.**



THE RANDOX CONCIZUTRACE™ PORTAL

YOUR SIMPLE PROCESS OVERVIEW



 PHYSICIAN (LAB CORPORATE PORTAL)

 HTC/HOSPITAL

 COURIER

 LABORATORY

NAVIGATION - THE RANDOX CONCIZUTRACE™ PORTAL- SELF REGISTRATION



NEW: Super User Role Available

We have upgraded the platform to include a super user role.

You can now upgrade your account to have the Super User role in addition to your current role.

Super Users are responsible for managing the users within the HTC. Super Users can:

- ✓ View all users in HTC
- ✓ Update each user's details
- ✓ Add new users to the HTC
- ✓ Enable and disable users
- ✓ Approve new self-registration users to this HTC

Please be aware that you will be required to provide the "Super User Access Code" delivered to you

Should you no longer wish to be a Super User at any time, you may assign another user the Super User role before removing the Super User Role from your account.

Skip

Continue

Each HTC will have at least one dedicated Super User.

Super Users are provided with the permission to create and invite users to the Radox ConcizuTrace™ Portal.

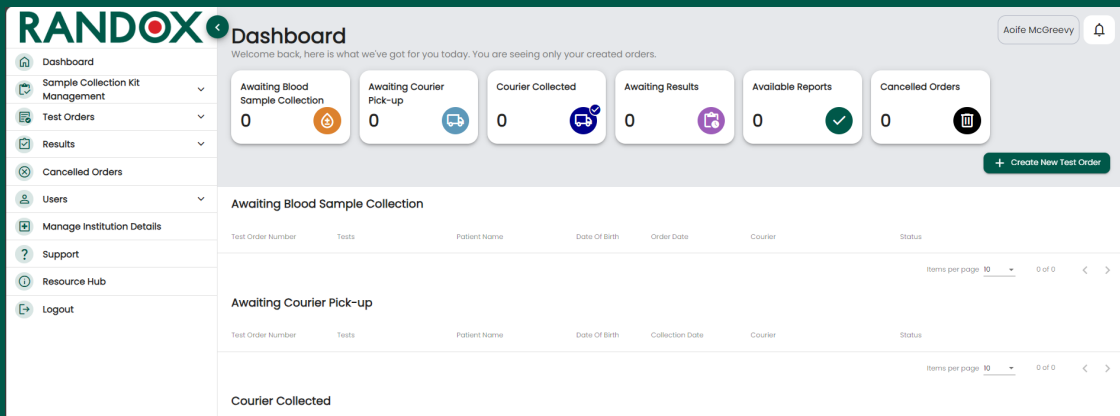
If invited by the Super User – you will receive a welcome email that will direct you to register for an account that will be pending until the Super User creates the account.

Alternatively, the Super User can create an account directly – you will then receive a welcome email inviting you to set up your password for the account.

NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL

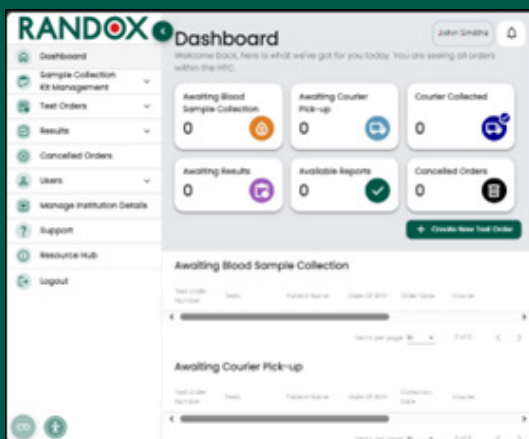
Upon successful login, you will enter the main dashboard of the Randox ConcizuTrace™ Portal.

Along the top of the dashboard, you will observe a summary of all test orders at each stage of the process – these also provide access to stage-specific screens.



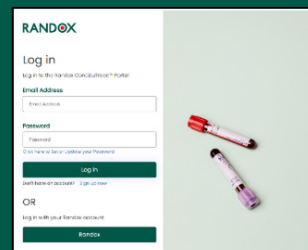
The Navigation Menu can be found on the left side of the screen.

This provides a simple menu system focused around the status of test orders.

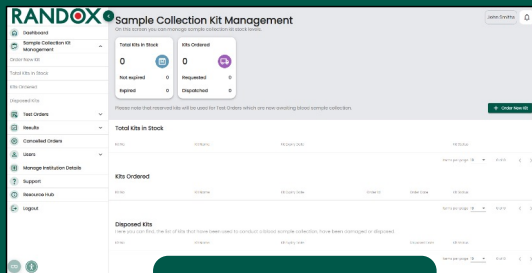


Selecting the Resource Hub will open a new tab where you can access additional training materials.

Selecting the logout button will return you to the login screen.



NAVIGATION- THE RANDOX CONCIZUTRACE™ PORTAL ORDERING SAMPLE COLLECTION KITS



+ Order New Kit

Order New Kit
Complete the form below to order new collection kits.

Sample collection kit quantity
The minimum kit order for this account has been set to 2 sample collection kits.

Kit Quantity *
2

Stock delivery address

Institution Name
Radox Treatment Centre

Address line 1 *
30 Randalstown Road

Address line 2
Enter address line 2

Address line 3
Enter address line 3

Town or City *
Antrim

Postal or Zip Code *
BT61 4FL

Country *
UK

Contact Name *
Enter contact name

Contact Telephone Number *
Enter contact telephone number
Contact telephone number is required


Contact Mobile Number
Enter contact mobile number

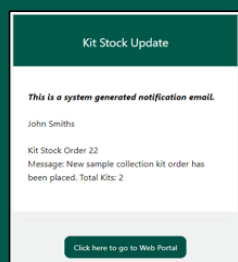
Stock special delivery instructions
Please include any special instructions, such as building code or which door to use here.

Special Delivery instructions
Enter special delivery instructions

Cancel **Order Now**

Kits Ordered

2	
Requested	2
Dispatched	0



If the user has access to the kit stock management area, available within the navigation menu on the portal they can view the number of sample collection kits they have in stock, how many have expired, how many have been requested and how many have been dispatched. If you do not have access to this area, contact your Super User.

You can also select the “Order New Kit” button from the dashboard or the navigation menu to order new kits.

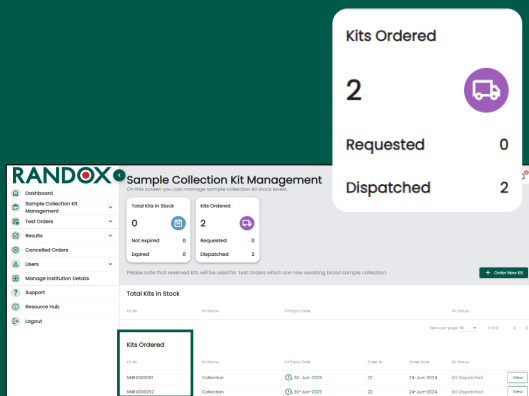
Selecting “Order New Kit” will open the pop-up window requesting the number of kits required, delivery details and any delivery instructions that are required.

Once all mandatory fields have been completed, select “Order Now”.

Once the order has been placed, it will update the number of kits that have been requested.

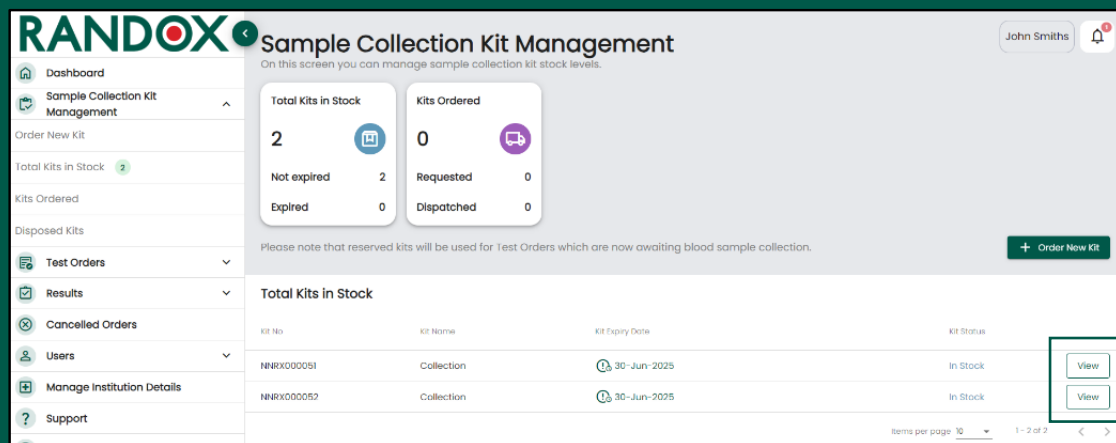
You will also receive an email notification alerting you of the order being placed successfully.

NAVIGATION- THE RANDOX CONCIZUTRACE™ PORTAL ORDERING SAMPLE COLLECTION KITS



Once the order has been dispatched, the portal will update to reflect this.

Within the portal the user will be able to see the kit numbers, their expiry date, Order ID, order date and the kit status, including order placed, kit dispatched, and in stock. Once the kits are received, the user should navigate to the kit number of interest, select “view”, followed by “Confirmed delivered”.

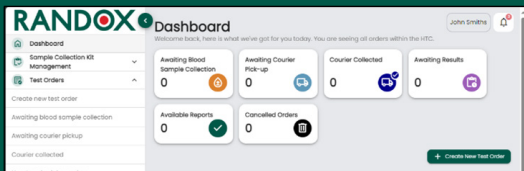


Once the user has confirmed delivery, this will reflect under “Total Kits in Stock”.

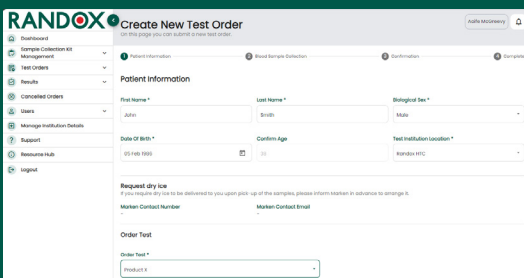
Selecting to “view” a specific kit, the user will be able to select “dispose of kit”. This should be performed if the kit has expired or if there are any issues with the kit preventing its usage.

Any issues with sample collection kits should be reported to Randox Technical Support at concizutrace.support@randox.com.

NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL CREATING A TEST ORDER



To begin creating a new test order, you can select the “Create New Test Order” button from either the Dashboard or under the “Test Orders” section in the navigation menu.

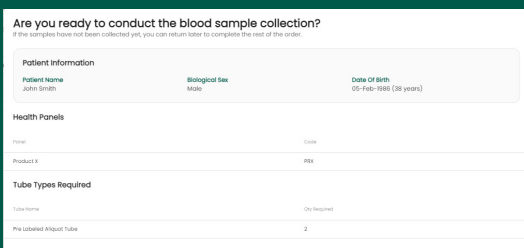


All mandatory fields marked with an * must be completed.

Upon entering the date of birth, the age of the patient should automatically populate.

The Order Test field will automatically populate with the Product X.

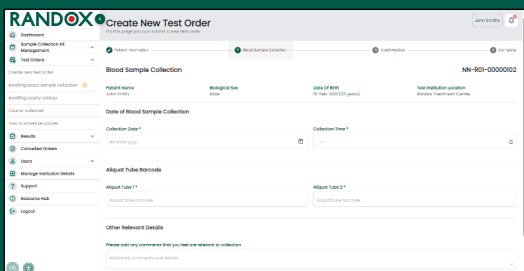
Prior to conducting blood sample collection if you do not have -20 degree storage, contact Marken to arrange a dry ice shipment.



Once all mandatory fields are completed, click the “Continue” button to progress. If “Continue” is selected a pop up will appear asking if the user is ready to conduct the blood sample collection.

If “No, complete later” is selected, the order will be saved, the Order Number assigned and will be placed in the “Awaiting Blood Sample Collection” Section.

If “Yes, continue” is selected, the order will be saved, the Order Number assigned and the user interface will progress to the next step, “Blood Sample Collection”.



All mandatory fields marked with an * must be completed.

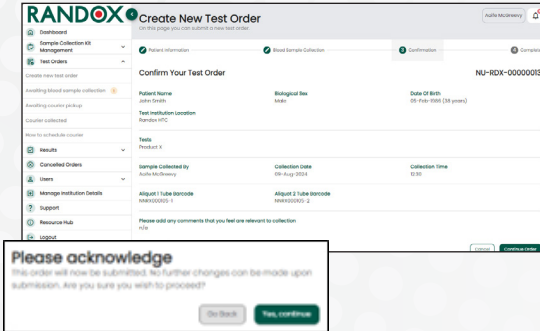
Details including the Collection Date and Collection Time and the Aliquot Tube Barcodes are mandatory fields.

Samples must have been collected on the same day or within the previous three days.

The same barcode cannot be entered for both tubes.

Barcode needs to be in the correct format of NNRXxxxxxx-1/2

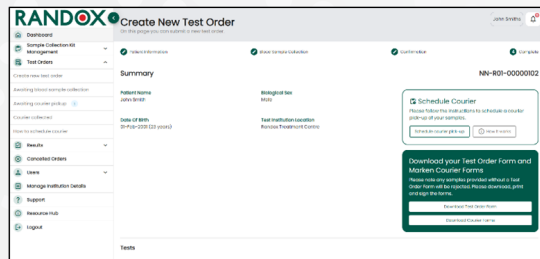
NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL CREATING A TEST ORDER



The user interface should contain all entered patient information, collection information and sample tube information.

If “Continue Order” is selected, the user will be prompted with the final confirmation acknowledgement.

If “Yes, continue” is selected, the user interface will progress.

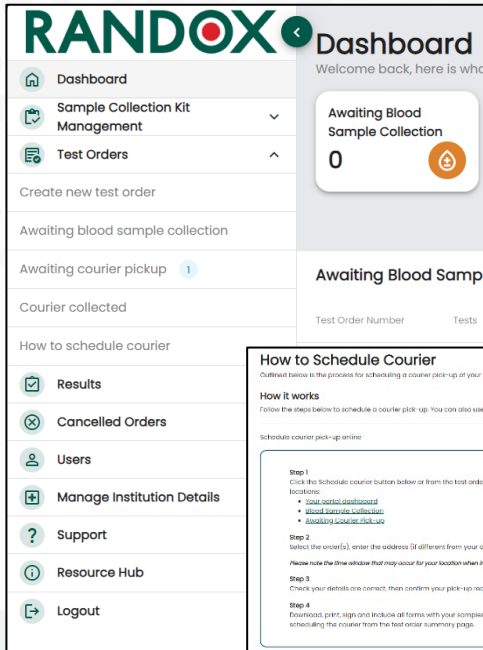


The user interface will display a test order summary containing the entered information.

The user will be prompted to download the test order form for printing – This is an essential requirement and needs to be included in the shipper box when sending the sample to the lab and therefore should be downloaded and printed.

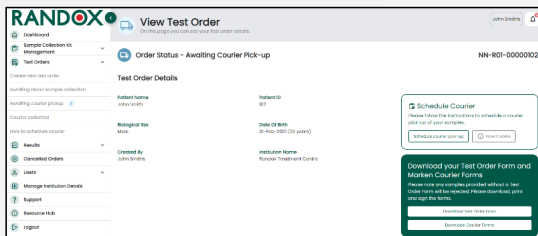
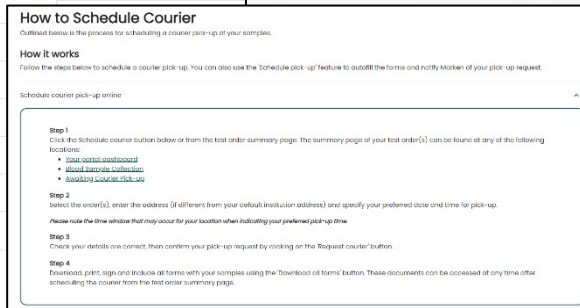
You can select the “How it works” section for further guidance on how to schedule the courier via the portal or manually.

NAVIGATION - THE RANDOX CONCIZUTRACE™ PORTAL SCHEDULING THE COURIER TO RETURN YOUR SAMPLES TO THE LABORATORY NETWORK - VIA THE PORTAL

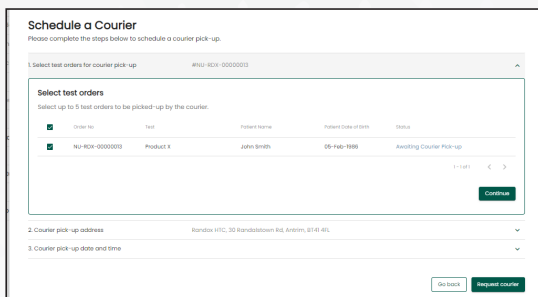


Selecting “How to schedule courier” from the navigation menu will appear below the pop-up.

From here, it instructs the user on how to schedule the sample pick-up online via the portal and manually by downloading the relevant forms.



To begin to schedule the courier, click the scheduled courier button from the test order summary page of interest.



Select the test order(s) of interest from your list of orders that are awaiting courier pick-up.

Once the correct samples are selected, click continue to proceed to the pick-up address.

NAVIGATION - THE RANDOX CONCIZUTRACE™ PORTAL SCHEDULING THE COURIER TO RETURN YOUR SAMPLES TO THE LABORATORY NETWORK- VIA THE PORTAL

The pick-up address will be pre-populated based on the address of the HTC. These details can be altered as necessary.

Any special instructions can also be stipulated at the bottom of this page as necessary. Once completed, select continue to move to the pickup time.

Finally, request the preferred sample pick-up date and pick-up time.

Please note that your pick-up time may occur up to 2 hours before or after your selected preferred time.

Upon completion, you will be prompted to download all the associated forms for inclusion with the sample shipment.



These forms are the Sample Shipping Booking Form, the Proforma Invoice and the Packing List. This is a requirement for customs clearance and traceability and therefore all three forms must be downloaded.

The specific test order form(s) must also be included with the sample shipment.

Upon completion, Marken will confirm the exact date and time of collection which will be reflected in the test order summary as highlighted.

From here you will also have the options of rescheduling the courier or cancelling the collection if necessary.

NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL SAMPLE BOOKING FORM

SAMPLE SHIPPING BOOKING FORM

PROJECT DETAILS

MARKEN ACCOUNT NUMBER: UK736

SPONSOR: Radox Laboratories Ltd.

BOOKING PROCESS

- Please fill out section 1 of this form and contact your local Marken office by email, 24 hours prior to sample pick-up date to schedule the collection. (For urgent collections please telephone directly.)
- Marken contact information (email and phone number) is available on the Radox ConcizuTrace™ Portal and in the Radox ConcizuTrace™ Sample Collection Guide.
- Await arrival on site of the Marken Representative at the agreed collection time.

Section 1: HTC COLLECTION DETAILS

FACILITY NAME:	COLLECTION DATE REQUESTED:
STREET NAME (LINE 1):	COLLECTION TIME REQUESTED:
STREET NAME (LINE 2):	COLLECTION DEPT / FLOOR:
TOWN / ZIP CODE:	CONTACT NAME FOR COLLECTION:
COUNTRY:	CONTACT TEL. FOR COLLECTION:
BOOKING REQUESTED BY:	

Section 2: TYPE OF SAMPLES

Frozen Samples

Section 3: PACKAGING PROVISION

Marken to provide the following:

Frozen Packaging

Dry Ice

Temperature Logger

Section 4: DELIVERY ADDRESS

<p>RANDOX CLINICAL LABORATORY SERVICES (RCLS) – Lab E FAO REBECCA MOLLOY 30 RANDALSTOWN RD, ANTRIM, BT41 4LF, NORTHERN IRELAND</p>	<p>THIS SHIPMENT IS SET-UP TO BE SENT TO RANDOX CLINICAL LABORATORY SERVICES (RCLS) WHICH IS THE SELECTED LABORATORY SERVICE FOR THE RANDOX CONCIZUTRACE™ ELISA MEASUREMENT. IF YOU THINK THAT THE SAMPLE SHOULDN'T BE SHIPPED TO THIS LOCATION, PLEASE NOTIFY MARKEN IMMEDIATELY.</p>
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The Sample Shipping Booking form, Proforma Invoice and Packing List, are easy-to-complete PDF documents that are required by Marken for scheduling the pick-up and shipping the sample.

Many of the details will be autopopulated once downloaded

Complete the Sample Shipping Booking form, print and sign.



PROFORMA INVOICE
FACTURE PROFORMA

SHIPPER: (Name and address of health institution sending samples)
Expéditeur: (Nom et adresse de l'établissement de santé qui envoie les échantillons)

RECEIVER: (Name and address)
Récepteur: (Nom et adresse)

Radox Clinical Laboratory Services (RCLS) - Lab E
FAO Rebecca Molloy, Radox Science Park,
30 Randalstown Road, Co. Antrim
BT41 4FL United Kingdom +4402894422413 radox.import@radox.com

DATE:

INCOTERM: FCA

DELIVERED BY: MARKEN

DOCUMENT REFERENCE NUMBER (Unique Sample Number)
DOCUMENT REFERENCE NUMBER (Numéro d'échantillon unique)

The unique sample number can be found on the aliquot tube.
Le numéro unique de l'échantillon se trouve sur le tube aliquot.

THE UNDERMENTIONED GOODS ARE:
LES BIENS MENTIONNÉS SONT DESTINÉS À:

NON FLAMMABLE NON INFLAMMABLE
NON HAZARDOUS NON DANGEREUX
NON TOXIC NON TOXIQUE
NOT FOR HUMAN CONSUMPTION NON DESTINÉ À LA CONSOMMATION HUMAINE

QUANTITY	DESCRIPTION	*UNIT PRICE	TOTAL AMOUNT
QUANTITE		PREX UNITAIRE	TOTAL QUANTITE (GROS)
	Human Blood Sample UN 3373 Biological Substance Category B* <small>Échantillon de sang humain UN 3373 CATEGORIE DE SUBSTANCE BIOLOGIQUE B*</small>	€15.00	

TARIFF HEADING: 3002 9010 00
DESIGNATION TARIFAIRE

PURPOSE OF USE: Diagnostic Testing
DESTINATION D'EMPLOI

COUNTRY OF ORIGIN:
PAYS D'ORIGINE

TRANSPORT @ -20°C CREDO S20M 12168L (NESTED)
TRANSPORT @ -20°C EN CREDOS S20M 12168L (NIDÉ)

UN 3373 BIOLOGICAL SUBSTANCE CATEGORY B
UN 3373 CATEGORIE DE SUBSTANCE BIOLOGIQUE B

I DECLARE THAT ALL OF THE INFORMATION CONTAINED IN THIS DOCUMENT IS TRUE AND CORRECT
JE DÉCLARE QUE TOUTES LES INFORMATIONS CONTENUES DANS CE DOCUMENT SONT VRAIES ET CORRECTES

Signed by:
Signé par:

FREIGHT, PACKING AND ALL IMPORT DUTIES WILL BE PAID BY
NET AMPLIABLE ET TOUTES IMPORTATION DUES DÉPENS SÉPAREMENT PAIÉS PAR

RANDOX LABORATORIES LTD.
30 Diamond Road, Crumlin,
Co. Antrim, BT29 4QY
United Kingdom
EORI XI 151 6827 08 000

Complete the Proforma Invoice form, print and sign.

The document reference number refers to the specific test order number specific to your sample that was generated when creating the order.

Failure to include within the shipment could prevent successful sample delivery.

NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL PACKING LIST

RANDOX
PACKING LIST
LISTE DE COLIAGE

SHIPPER: (Name and address of health institution sending samples)
RECEVEUR: (Nom et adresse de l'établissement de santé qui envoie les échantillons)

DATE: _____

INCOTERM: FCA

DELIVERED BY: MARKEN

RECEIVER:
RECEVEUR:

Radox Clinical Laboratory Services (RCLS) - Lab E
FAD Rebecca Molloy, Radox Science Park,
39 Ransdowntown Road, Co. Antrim
BT41 4FL +4402894422413
United Kingdom radox.import@radox.com

DOCUMENT REFERENCE NUMBER: (Unique Sample Number)
DOCUMENT RÉFÉRENCE N°: (Numéro d'échantillon unique)

The unique sample number can be found on the aliquot tube.
Le numéro unique de l'échantillon se trouve sur le tube aliquot.

THE UNDERMENTIONED GOODS ARE:
LES BIENS MENTIONNÉS SONT CLASSÉS:

NON FLAMMABLE NON INFLAMMABLE
NON HAZARDOUS NON DANGEREUX
NON TOXIC NON TOXIQUE
NOT FOR HUMAN CONSUMPTION NON DESTINÉ À LA CONSOMMATION HUMAINE

QUANTITY	DESCRIPTION	NET WEIGHT	GROSS WEIGHT
QUANTITÉ	DESCRIPTION	POIDS NET	POIDS BRUT
1	Human Blood Sample Échantillon de sang humain UN 3373 Biological Substance Category B*	0.5kg	10.5kg

PACKAGE DIMENSIONS: (L) 39.5cm x (H) 34.4cm x (W) 36.3cm
DIMENSIONS DE L'EMBALLAGE

TARIFF HEADING: 3002 9010 00
NOMENCLATURE TARIFAIRE

PURPOSE OF USE: Diagnostic Testing
*SAMPLER FOR EVALUATION PURPOSES
*ÉCHANTILLONS À DES FINS D'ÉVALUATION

COUNTRY OF ORIGIN: _____

TRANSPORT @ 20°C CREDO S20M 12168L (NESTED)
MODE DE TRANSPORT

UN 3373 BIOLOGICAL SUBSTANCE CATEGORY B
CLASSIFICATION DES BIENS

I DECLARE THAT ALL OF THE INFORMATION CONTAINED IN THIS DOCUMENT IS TRUE AND CORRECT
JE DÉCLARE QUE TOUS LES RENSEIGNEMENTS CONTENUS DANS CE DOCUMENT SONT VRAIS ET CORRECTS

Signed by: _____
Signé par

FREIGHT, PACKING AND ALL IMPORT DUTIES WILL BE PAID BY:
FRAIS D'EMBALLAGE ET TOUS LES DROITS D'IMPORTATION SONT DÉCOUVERTS PAR LES

RANXOX LABORATORIES LTD.
35 Diamond Road, Curriton,
Co. Antrim, BT29 4CY
United Kingdom
EORI XI 151 6827 08 000

Complete the packing list form, print and sign

The document reference number refers to the specific test order number specific to your sample that was generated when creating the order.

Failure to include within the shipment could prevent successful delivery

09-Aug-2024 13:57

RANDOX

Radox ConcizuTrace™ Test Order Form

Order Number:	NU-RDX-00000005
Date Of Birth:	14-Feb-2001
Biological Sex:	Male
Test:	Product X
Sample Collection	
Site Location:	Radox HTC
Sample Collection Date:	02-Aug-2024
Sample Collection Time:	08:00
Sample Collection Tube Barcode:	NNRX000103-1

Aliquot 1 Barcode



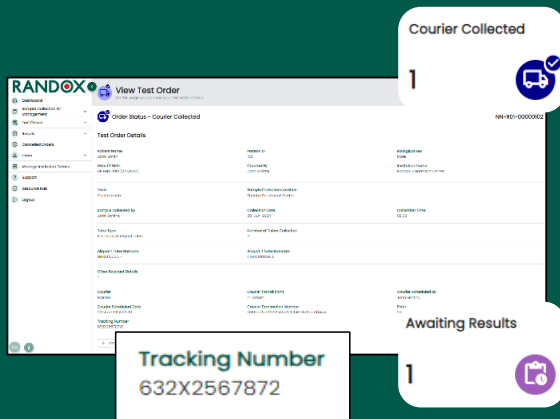
NNRX000103-1

The Test Order Form is generated when the order is created for each sample in the portal.

This can be downloaded as a PDF document from the 'Create New Test Order' section of the portal, once the order has been created.

This should be printed and included in the clear pouch on the front of the Marken Shipper Box.

NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL SAMPLE SHIPPING BOOKING FORM

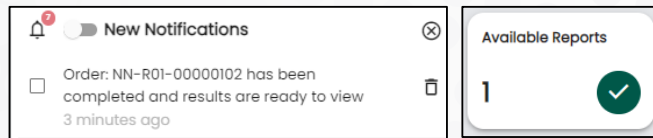
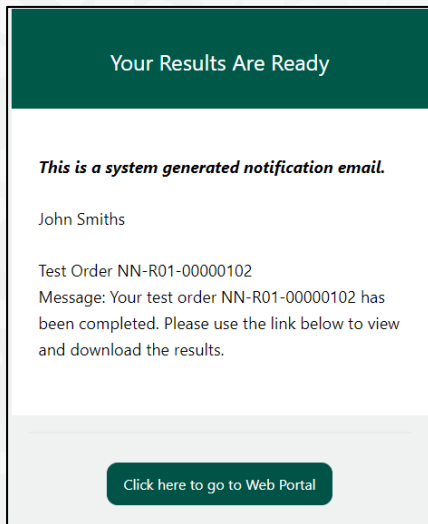


Once the courier has collected the sample(s), it will be moved along within the portal to the “Courier Collected” status.

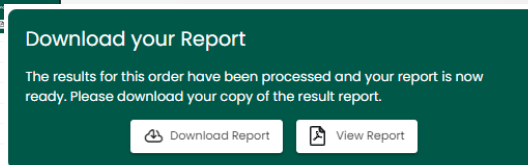
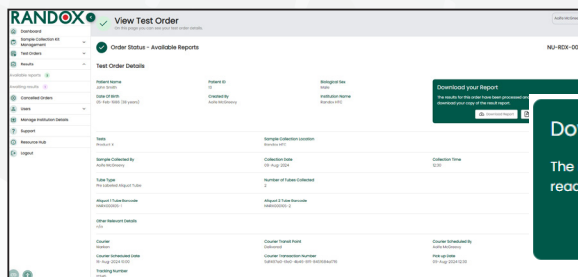
Once received by the lab, the sample will move to the “Awaiting Results” status.

Navigating to view the test order will allow the user to locate the specific Marken tracking number.

NAVIGATION - THE RANDOX CONCIZUTRACE™ PORTAL COLLECTING RESULTS



When the result has been uploaded by the laboratory – the user who created the test order will be notified both via email and through the notifications within the portal that the result report is now available for download.



To download a completed report proceed to “Available Reports” under the “Results” tab. Select the sample of interest and proceed to download or view the report.

The original order and related non patient information will be retained indefinitely however patient PII (Personally Identifiable Information) and PHI (Protected Health Information) will be removed 30 days after order date where a results report has been downloaded or after 60 days regardless of results report download.

RANDOX SUPPORT NETWORK

How to reach out?

All support queries in regards to sample collection, kit ordering and the Randox portal are to be directed to **concizutrace.support@randox.com** where a member of our global team will assist. Please see below process flow and response times for all internal queries.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

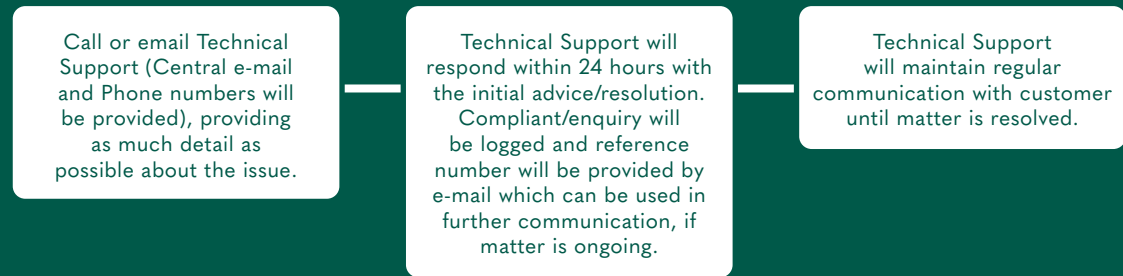
To speak directly with Randox Technical support, please directly contact Randox HQ by phone on [redacted]. If you wish to speak with a local representative in your country please see appendix 2 - additional support for local Randox Technical support contact details and operating times.

- Randox has a global and experienced Technical Support Team of over 40 Technical Support Staff, providing best in class customer support.
- Specialists are located at Randox HQ in N. Ireland, France, Portugal, Italy, Poland, China, India, Puerto Rico, USA, Brazil, Australia & Japan.

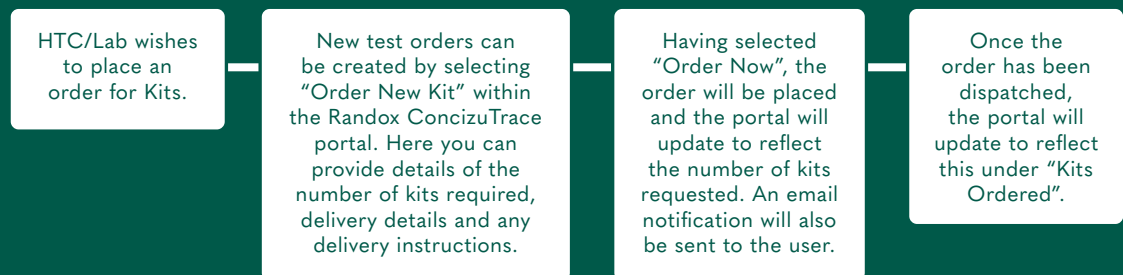


HTC TECHNICAL SUPPORT

SAMPLE COLLECTION KIT, RETURN OF SAMPLE & TRACKING SAMPLE



KIT ORDERING



RANDOX PORTAL



FREQUENTLY ASKED QUESTIONS

Sample Collection & Plasma Preparation

What patient identifiers are used?

- Three specific identifiers will be used to register patient samples : a unique sample number (pre-barcoded sampling and transfer tubes), patient date of birth and patient biological sex.

What is the maximum processing time allowed for the blood sample taken?

- Processing (centrifugation, plasma separation, aliquoting freezing) of the sample should be completed within four hours maximum of blood draw.

Who is responsible for packaging upon sample collection?

- It is expected that the HCP in charge of blood collection will package the samples, as directed per the sample collection kit instructions for use (IFU). The aliquot packed in its dedicated, pre-labelled pathoseal bag will be kept at - 20°C or lower temperature prior to collection by Marken. Marken will then complete the packaging of the sample for return to the laboratory.

What laboratory steps (e.g. centrifugation) are needed after blood withdrawal?

- In short: after blood sample collection, the sample must be centrifuged at 1500 to 2000 x G for 15 minutes to achieve plasma separation. Aliquoted plasma samples must then be frozen and stored within a -20°C or lower temperature freezer, in an upright position, in the cryobox provided.

Scenarios for failure of some kit components

- Please use an additional kit if any of the kit components are opened, tampered with or if the kits contents have expired.

FREQUENTLY ASKED QUESTIONS

Returning Samples to Laboratory Network Group

Where do you need to send the blood samples taken to?

- Pre-organized sample logistics is arranged with the selected courier service provider (Marken), based on HTC location. Samples will be transported by Marken to pre-identified labs within the Randox Laboratory Network for laboratory analysis.

How do I arrange for samples to be collected?

- Navigate to the “How to Schedule Courier” section of the portal. From here you will be provided with instructions on how to schedule the sample pick-up online via the portal or manually by downloading the relevant forms.

What if I don't have freezing capabilities ?

- Logistics provider/courier (Marken) will provide dry ice for shipment. If needed dry ice can be requested for short term storage if there is no freezer capability. Dry ice will not be supplied for long-term (back-up) sample storage at HTC.

Who is responsible for the dry ice onsite and during shipment?

- Logistics provider (Marken) will provide dry ice for shipment, but not for sample storage at HTC.

FREQUENTLY ASKED QUESTIONS

Kit Ordering, Distribution & Inventory Management

How many kits will I be expected to receive?

- You will receive 2 kits within a delivery.

How will I be able to monitor stock levels?

- Within the portal, users with access to the “Sample Collection Kit Management” section of the portal, will be able to see the kit numbers, their expiry date, order ID, order date and kit status. As a kit approaches expiry, a notification will be sent to the user. Once a kit has been used for sample collection, it will automatically be moved to the kit disposed area. This can also be performed manually.

Who replenishes stock?

- Radox will replenish stocks based on orders received from the HTC.

FREQUENTLY ASKED QUESTIONS

Radox Portal

How do I register a sample on the Radox Portal?

- Users with the Full Access role will be able to register a sample via a “Create New Test Order” option. This allows the user to enter the necessary data in a simple step by step process. Data will include basic patient information alongside sample collection information.

How do I access results on the Radox Portal?

- Users will be provided with a unique URL for the portal according to their location. Logging into the portal will be via the user’s registered email address, password and an additional 2FA (2 factor authentication) code emailed to their registered email address. The user will be able to view all their orders including the testing laboratory’s result PDF document for completed orders.

How long is data retained on the Radox Portal?

- The original order and related non patient information will be retained indefinitely however patient PII (Personally Identifiable Information) and PHI (Protected Health Information) will be removed 30 days after order date where a results report has been downloaded or after 60 days regardless of results report download.

Will I get a reminder that results are available on the Radox Portal?

- Yes when the testing laboratory uploads a result PDF document onto the sample order the system will send a notification via the portal and also an email to the user’s registered email address.

Can patient results be exported from the Radox Portal?

- Yes the result PDF document, uploaded by the testing laboratory, can be exported / downloaded by a user with the Full Access role to their local / clinic folder. From there this file can be imported to an appropriate patient system.

What is the turnaround time from blood sample collection by courier until the results are available?

- Guaranteed turn-around time is 10 working days, regardless of geographical location.

Is the data on the Radox portal within this process validated legally in relation to GDPR?

- Test access solution will be compliant with relevant local data privacy requirements (GDPR etc.).

APPENDIX I

ADDITIONAL SUPPORT - MARKEN COURIER CONTACT DETAILS

COUNTRY	EMAIL	TELEPHONE
Algeria	Marken.ME@aramex.com par.cs@marken.com	+213783630344
Argentina	marken.bue.cs@marken.com	0800 555 MARKEN (6275)
Australia	Marken.AUS.CS@marken.com	(+61) 02 9318 1777
Austria	marken.austria@marken.com	+43 166160 11
Belgium	BRU.CS@marken.com	+32 2 718 08 30
Brazil	ExpoBrasil@marken.com	+55 (11) 5033-4900 – option 2
Bulgaria	SofBiopharm@aramex.com par.cs@marken.com	+ 359 0700 1 86 86
Canada	mkn.canada@geoexpressinternational.com NYCCS@marken.com	+1-905-564-5555
Chile	markenCSCL@marken.com	800 914614
Colombia	markencsbog@marken.com	800 5185204
Croatia	mario@zor-mar.com vanja@zor-mar.com marken.austria@marken.com	+385 1 3770577
Cyprus	info@starex.gr biopharma.cs@starex.gr Marken.CustomerService@marken.com	+302109624003
Czech Republic	marken@rgw-express.cz marken.cz@rgw-express.cz marken.germany@marken.com	+420 224 310 537, +420 602 762 713
Denmark	marken.cph@marken.com pharma.cph@isanordic.com	+45 3246 5862
Estonia	Marken@logistika.ee joel@logistika.ee par.cs@marken.com	00372 6056184
Finland	marken@chs.fi Marken.STO@marken.com	+358 20 1669 514
France	par.cs@marken.com par.ops@marken.com	+33 01 71 04 57 57
Germany	marken.germany@marken.com	+49 6142 30182 0, +49 6107-7798900

APPENDIX I

ADDITIONAL SUPPORT - MARKEN COURIER CONTACT DETAILS

COUNTRY	EMAIL	TELEPHONE
Greece	info@starex.gr biopharma.cs@starex.gr Marken.CustomerService@marken.com	+302109624003
Hungary	marken.hungary@marken.com	+36 96 884 144, +36 96 884 145, +36 96 884 059
Iceland	export@jonar.is Marken.STO@marken.com	+354 535-8000
India	bomcs@marken.com	Toll free :- 1800 22 2212
Ireland	marken.customerservice@marken.com	+44 20 8388 8555
Israel	orian-markenexport@orian.com marken.customerservice@marken.com	+972 39728897
Italy	marken.italy.cs@marken.com	+39 02 94 75 21 31
Japan	marken.tyo.cs@marken.com	+81 (0) 3 5640 3056
Korea	Marken.sel.booking@marken.com	+82 2 2634 6770
Kuwait	princegeorge@ups.com;vrindapaes@ups.com lbritto@ups.com; sunildsouza@ups.com Marken.CustomerService@marken.com	+9651840828 / +96596073265
Latvia	marken.latvia@marken.com;marken. customerservice@marken.com	+371 29721118 / +371 20014931
Lichtenstein	marken.zrh.cs@marken.com	+41 44 319 90 50
Lithuania	info.lt@a2cargo.com;marken. customerservice@marken.com	+370 5 2151352
Luxemburg	BRU.CS@marken.com	+32 2 718 08 30
Malaysia	marken.my@marken.com	+603-5650 8888
Malta	marken.italy.cs@marken.com	+39 02 94 75 21 31
Mexico	markenmexcs@marken.com	01 800 26 MKN MX
Netherlands	ams.cs@marken.com	+312 3799 6833
Norway	Marken.osl@marken.com pharma.no@isanordic.com	+47 6790 6666 / +47 45737406
Poland	marken.poland@ocs.com.pl marken.germany@marken.com	0048 22 644 20 70
Portugal	marken.lis@marken.com	+351 219 498 190

APPENDIX I

ADDITIONAL SUPPORT - MARKEN COURIER CONTACT DETAILS

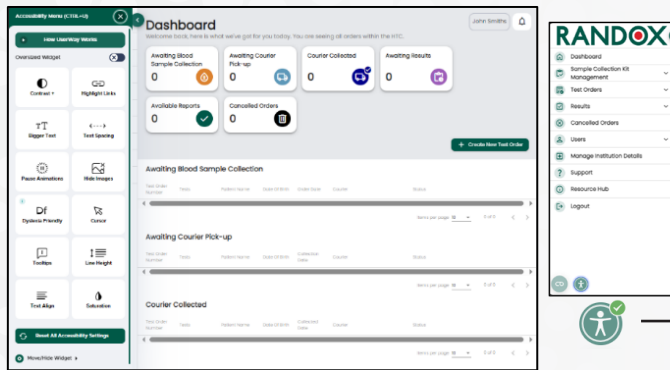
COUNTRY	EMAIL	TELEPHONE
Qatar	smajagaonkar@ups.com xfernandes@ups.com imohammed@ups.com gamit@ups.com Marken.CustomerService@marken.com	+97440119714 / +97433290551
Romania	marken@pegasus-scs.ro;par.cs@marken.com	+40 21 200 50 50
Saudi Arabia	marken.saudi@aj-ex.com firas.yahia@aj-ex.com Marken.CustomerService@marken.com	+966 11 253 2875 +966 596 680 680 966 55 0826 399
Slovakia	marken.austria@marken.com	+43 166160 11
Slovenia	marken.austria@marken.com	+43 166160 11
South Africa	marken.jnb@marken.com	+860 627 536
Spain	marken.spain@marken.com	+34 915199838
Sweden	Marken.STO@marken.com	+46 8594 41420
Switzerland	marken.zrh.cs@marken.com	+41 44 319 90 50
Taiwan	marken.tpe@marken.com	+886 2 7720 5068
Turkey	bio@transorient.com.tr;par.cs@marken.com	0090 549 211 00 48
UAE	Marken.ME@aramex.com Marken.CustomerService@marken.com	+213783630344
UK	Marken.CustomerService@marken.com	+44 (0)20 8388 8555
USA	WestCoast.Cs@marken.com	+1 310 641 8393
USA	marken.mia.cs@marken.com	+1 305 500-9288
USA	NYCCS@marken.com	+1 516-307-3287
USA	PHL-CS@marken.com	+1 484 754 7500

APPENDIX II

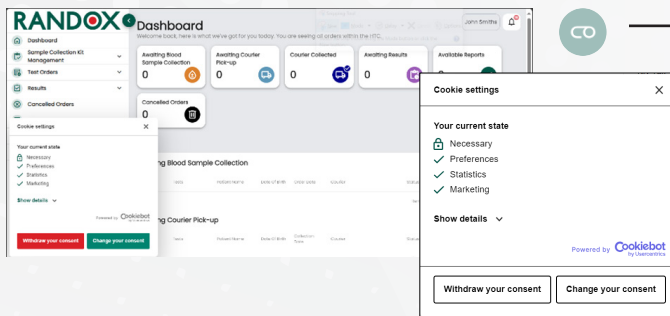
ADDITIONAL SUPPORT - RANDOX CUSTOMER SUPPORT CONTACT DETAILS

For email support please contact concizutrace.support@randox.com

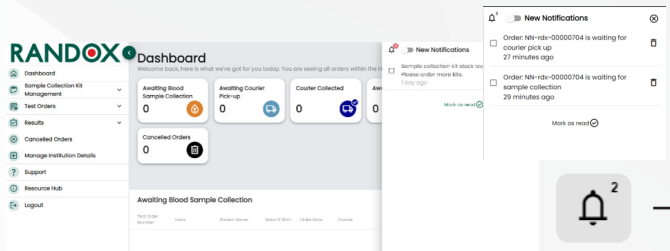
NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL



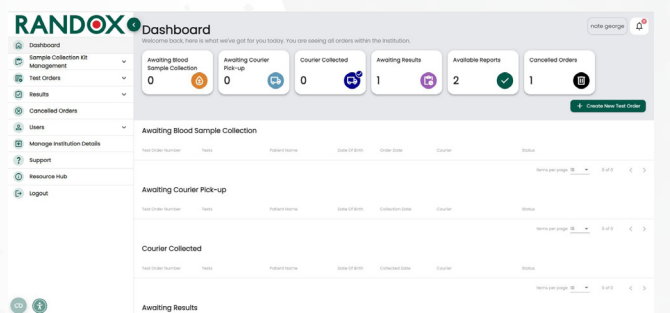
Select this icon to activate the accessibility menu



Select this icon to activate the cookie settings



Select this icon to access the notifications area



The portal display will also adjust to fit within the size of the window

Due to this, you should be able to adjust the browser window size and the user interface will adjust appropriately to your current screen size

You can also zoom in and out within the portal to adjust the size of the contents as required

RAN[●]OX

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