

# RAN<sup>O</sup>X

## ConcizuTrace™ Sample Collection

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SUPPORT GUIDE



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## WELCOME

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Radox Laboratories are providing integrated ConcizuTrace™ service process to healthcare professionals to allow to perform concizumab-mtci plasma concentration measurement.



### The Radox ConcizuTrace™ service solution comprises:

- Radox ConcizuTrace™ Sample Collection Kit, a kit to provide physicians and healthcare staff with all needed materials for compliant blood sample collection and plasma preparation.
- Radox ConcizuTrace™ ELISA Kit, a kit for laboratories to perform the laboratory analysis.
- Radox 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 Radox ConcizuTrace™ Sample Collection Kit.**



Concizumab



ConcizuTrace™  
Sample Collection Kit



ConcizuTrace™ ELISA Kit

*An FDA-authorized test for the measurement of concizumab-mtci concentration in plasma is not currently available.*

# 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
- Winged butterfly needle with 30cm tubing. For adults use the 21 gauge needle; for adolescents use the 23 gauge needle.\*
- One-use tube holder
- Vacuette 3ml No Additive blood collection tube (pre-labelled discard tube)
- Vacuette 2ml sodium citrate tube (3.2% concentration pre-labelled blood collection tube)
- 2x 1.8 ml pre-labelled cryotubes
- 1x disposable quick release tourniquet
- 1x 70% alcohol wipe
- Cotton or Rayon balls
- 1x spot waterproof or fabric bandage
- 1x 1ml transfer pipette
- 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 needles required.

## STEP 1 - BLOOD SAMPLE COLLECTION PROTOCOL

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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

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1. Promptly centrifuge the sample no more than 4 hours after collection at 1500 to 2000 x g for 15 minutes. RCF ( $g = 1.12 \times \text{radius (mm)} \times \text{RPM}/1000$ )<sup>2</sup>. 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.

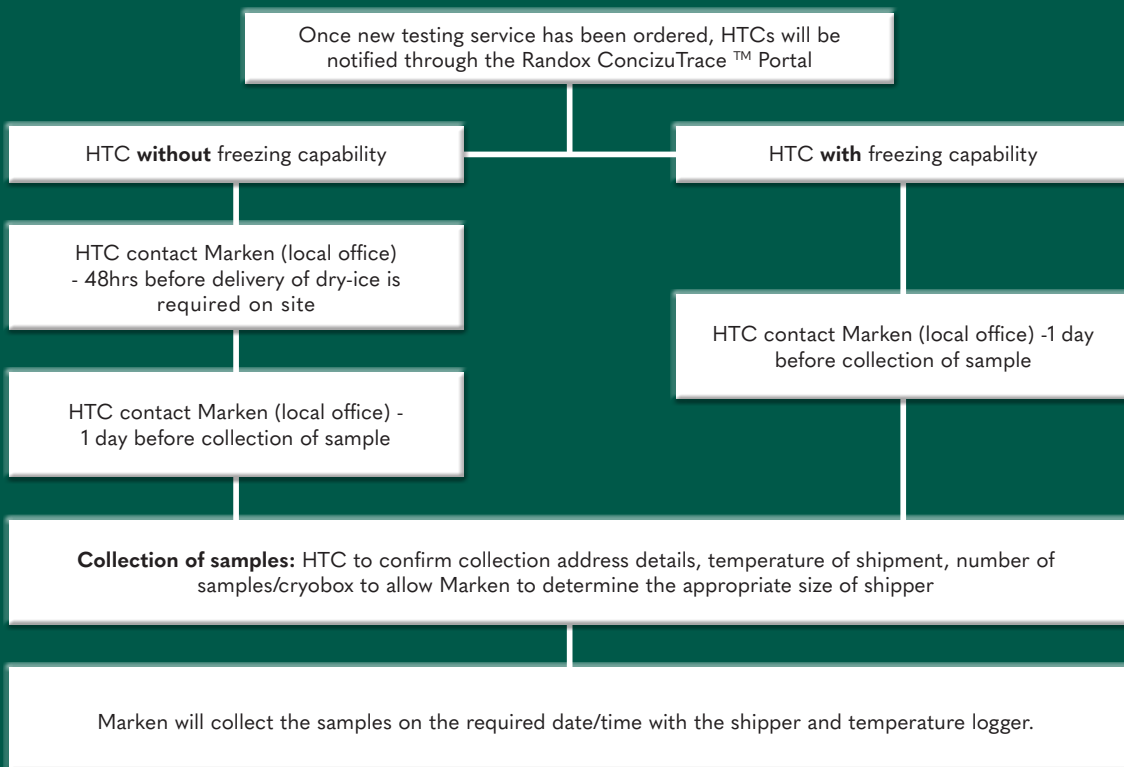
## STEP 3 - RETURNING THE SAMPLE TO THE LABORATORY NETWORK

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.

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.**

01

Marken will be required to open the box and remove the bag of dry ice, transport bag and U shaped fibreboard pad.

(Please ensure special gloves are used for protection against -80C temperatures)



02

Once step 1 has been completed, Marken will place the sample/ cryobox into transport bag and seal as per the printed instructions on the bag.



03

The transport bag containing the samples/cryobox and temperature logger is then placed on top of the thin layer of dry ice within the shipper by Marken.



04

Marken place the U shaped fibreboard pad on top of the transport bag to secure in the original position.



05

Marken will then fill the Biosystem shipper with dry ice to the top of the box.

(Please ensure special gloves are used for protection against -80C temperatures)



06

Marken will then place the lid on to the cooler and enclose your itemised list of contents between lid and outer fibreboard box.



07

Marken close the outer box and secure with locking tape and security seal sticker. Do not tape over any labels or markings on the external surface.



### IMPORTANT NOTE:

Please leave the temperature logger within the dry ice biosystem shipper.

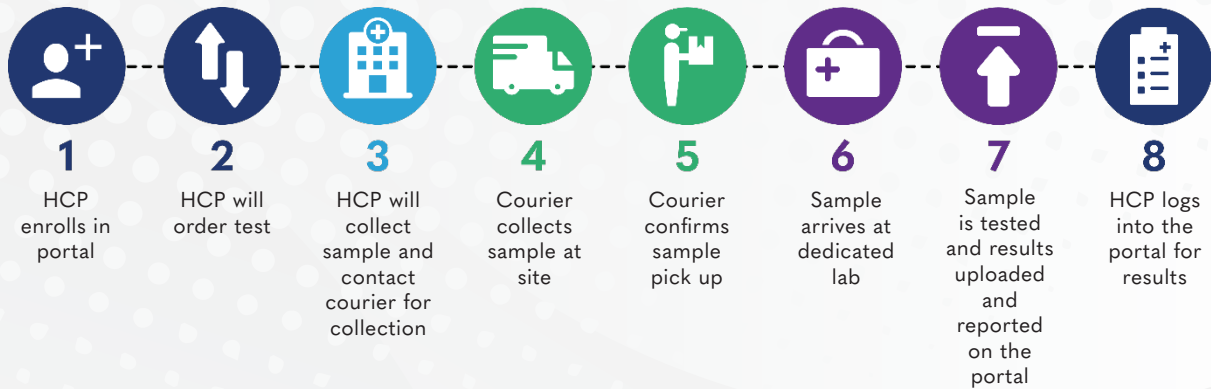
**DO NOT REMOVE THE LOGGER FROM THE SHIPPER.**



# THE RANDOX CONCIZUTRACE™ PORTAL

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## YOUR SIMPLE PROCESS OVERVIEW



 PHYSICIAN (LAB CORPORATE PORTAL)

 HTC/HOSPITAL

 COURIER

 LABORATORY

## NAVIGATION - THE RANDOX CONCIZUTRACE™ PORTAL- SELF REGISTRATION

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### 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 Randex ConcizuTrace™ Portal.

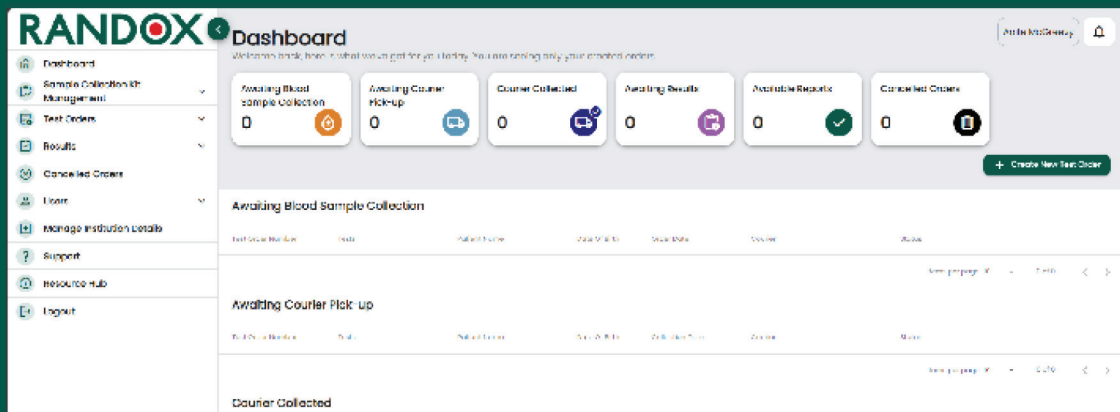
If invited by the Super User – you will receive a welcome email that will direct you to register for an account that will be pending until the Super User creates the account.

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

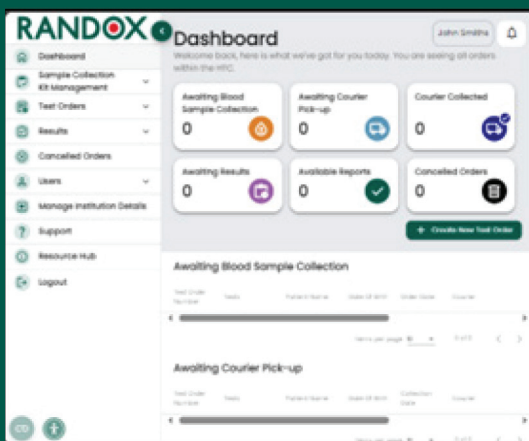
Upon successful login, you will enter the main dashboard of the Randox ConcizuTrace™ Portal.

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.



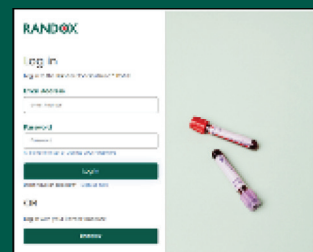
The Navigation Menu can be found on the left side of the screen.

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

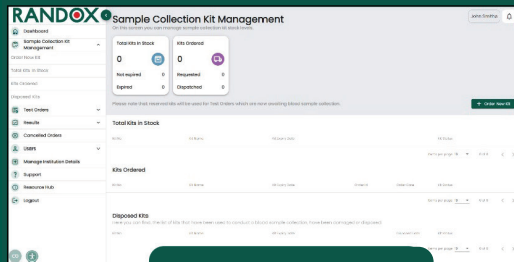


Selecting the Resource Hub will open a new tab where you can access additional training materials.

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



# NAVIGATION- THE RANDOX CONCIZUTRACE™ PORTAL ORDERING SAMPLE COLLECTION KITS



In the kit stock management area, users 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.

+ Order New Kit

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”.

<b>Kits Ordered</b>	
2	
Requested	2
Dispatched	0

**Kit Stock Update**

This is a system generated notification email.

John Smiths

Kit Stock Order 22

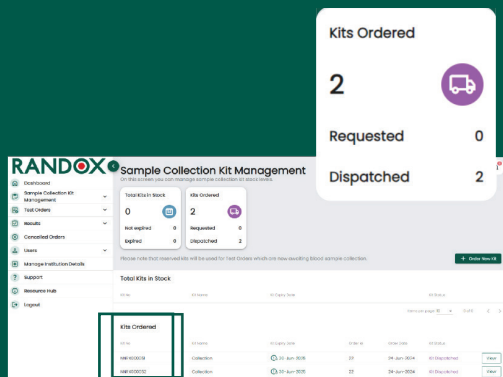
Message: New sample collection kit order has been placed. Total Kits: 2

[Click here to go to Web Portal](#)

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

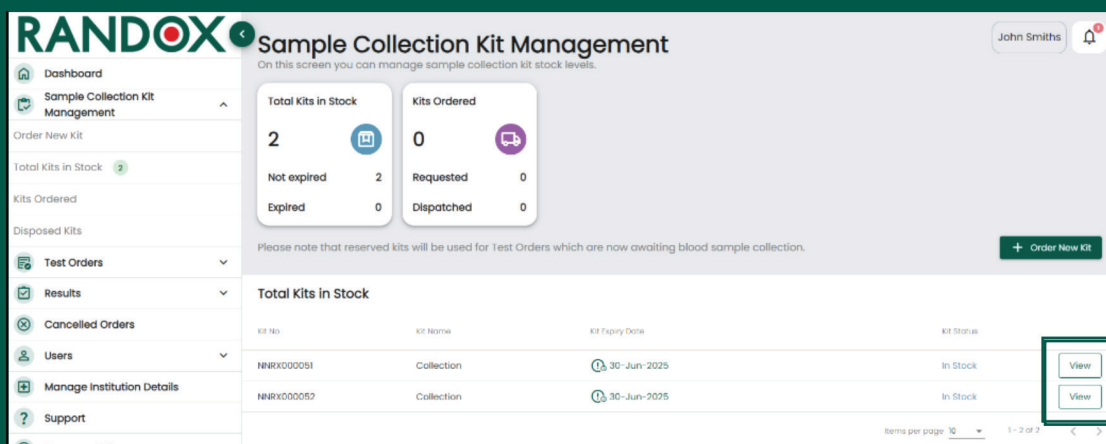
You will also receive an email notification alerting you of the order being placed successfully.

# 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”.

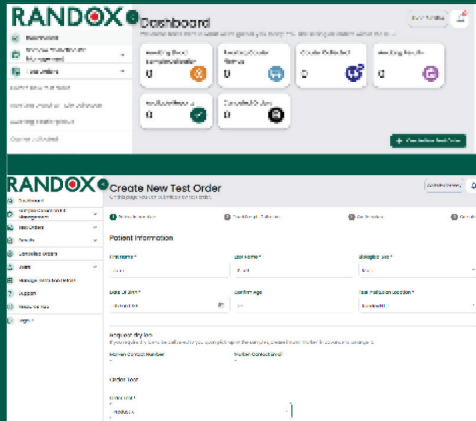


Once the user has confirmed delivery, this will reflect under “Total Kits in Stock”.

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](mailto:concizutrace.support@randox.com).

# NAVIGATION – THE RANDOX CONCIZUTRACE™ PORTAL CREATING A TEST ORDER



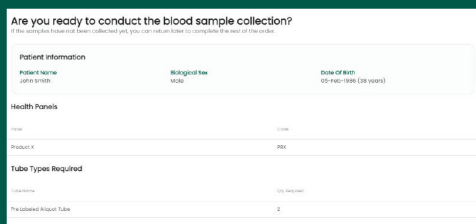
To begin creating a new test order, you can select the “Create New Test Order” button from either the Dashboard or under the “Test Orders” section in the navigation menu.

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 concizumab.

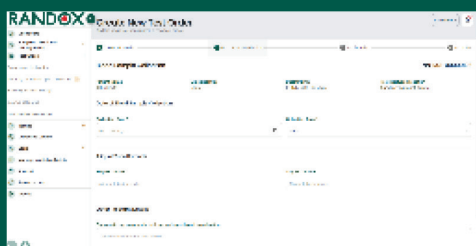
Prior to conducting blood sample collection if you do not have -20 degree storage, contact Marken to arrange a dry ice shipment.



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.

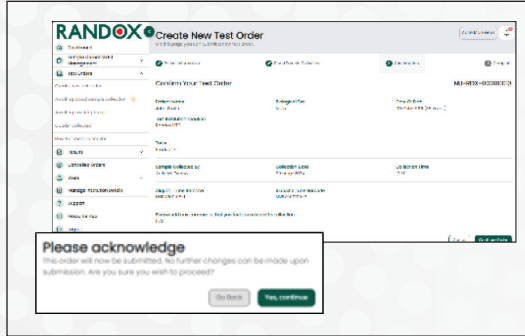
Details including the Collection Date and Collection Time and the Aliquot Tube Barcodes are mandatory fields.

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 NNRXxxxxx-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.

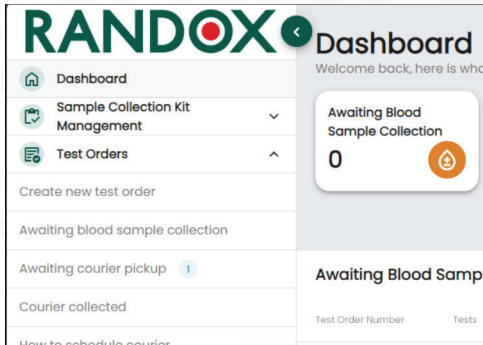


The user interface will display a test order summary containing the entered information.

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.

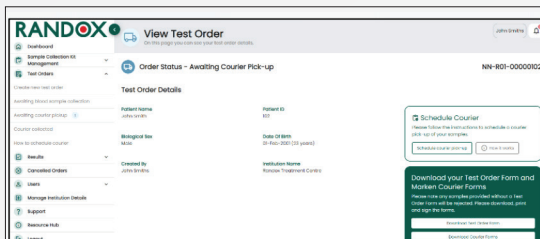
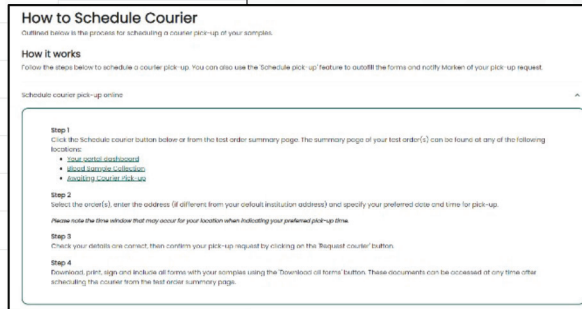
You can select the “How it works” section for further guidance on how to schedule the courier via the portal or manually.

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

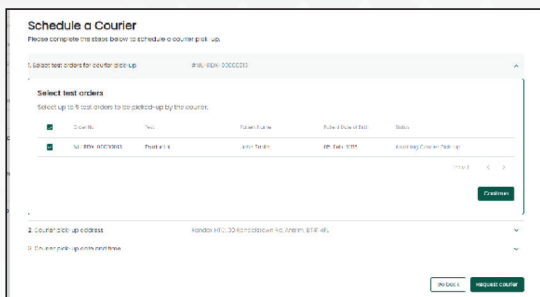


Selecting “How to schedule courier” from the navigation menu will appear below the pop-up.

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 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

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**PROJECT DETAILS**

**MARKEN ACCOUNT NUMBER:** UK736

**SPONSOR:** Radox Laboratories Ltd.

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**BOOKING PROCESS**

1. 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.)
- 1.1 Marken contact information (email and phone number) is available on the Radox Concizutrace™ Portal and in the Radox Concizutrace™ Sample Collection Guide.
2. Await arrival on site of the Marken Representative at the agreed collection time.

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**Section 1: HTC COLLECTION DETAILS**

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

---

**Section 2: TYPE OF SAMPLES**

**Section 3: PACKAGING PROVISION**

<input type="checkbox"/> Frozen Samples <input checked="" type="checkbox"/>	Marken to provide the following:
	<input checked="" type="checkbox"/> Frozen Packaging
	<input checked="" type="checkbox"/> Dry Ice
	<input checked="" type="checkbox"/> Temperature Logger

---

**Section 4: DELIVERY ADDRESS**

<b>RANDEX CLINICAL LABORATORY SERVICES (RCLS) - LAB E</b> FAO REBECCA MOLLOY 30 RANDALSTOWN RD, ANTRIM, BT41 4FL, NORTHERN IRELAND	THIS SHIPMENT IS SET-UP TO BE SENT TO RANDEX 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.
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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

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**SHIPPER:** please use address of local Marken office

**RECEIVER:** please use address of Marken office

Radox Clinical Laboratory Services (RCLS) - Lab E  
 FAO Rebecca Molloy, Radox Science Park,  
 30 Randalstown Road, Co. Antrim  
 BT41 4FL, United Kingdom  
 +440294422413  
 radox.import@radox.com

**THE UNDERMENTIONED GOODS ARE:**  
 NOT HAZARDOUS  
 NON FLAMMABLE  
 NON HAZARDOUS  
 NON TOXIC  
 NOT FOR HUMAN CONSUMPTION

QUANTITY	DESCRIPTION	*UNIT PRICE	TOTAL AMOUNT
1	Human Blood Sample UN 3293 Biological Substance Category B*	£15.00	

**TARIFF HEADING:** 3002 9000 00  
**PURPOSE OF USE:** Diagnostic Testing  
**COUNTRY OF ORIGIN:**  
**TRANSPORT @ -20°C CREDO 320M 12168L (NBSTED)**

UN 3293 BIOLOGICAL SUBSTANCE CATEGORY B

I DECLARE THAT ALL OF THE INFORMATION CONTAINED IN THIS DOCUMENT IS TRUE AND CORRECT

Signed by \_\_\_\_\_

**DATE:** \_\_\_\_\_

**INCOTERM:** FCA

**DELIVERED BY:** MARKEN

**DOCUMENT REFERENCE NUMBER** (Unique Sample Number)

The unique sample number can be found on the signed label

**\*SAMPLES FOR EVALUATION PURPOSES**  
 \*NO COMMERCIAL VALUE  
 \*VALUE FOR CUSTOMS PURPOSES ONLY

**FREIGHT, PACKING AND ALL IMPORT DUTIES WILL BE PAID BY**  
 RANDEX LABORATORIES LTD.  
 55 Diamond Road, Crumlin,  
 Co. Antrim, BT29 4DY,  
 United Kingdom  
 EORI XT151 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 COLISAGE

**SHIPPER:** (Please send address of health institution sending samples)  
(S'il vous plaît adresse de l'établissement de santé qui envoie les échantillons)

**RECEIVER:**  
RECEVOIR:  
 Radox Clinical Laboratory Services (RCLS) - Lab E  
 FAD Rebecca Molloy, Radox Science Park,  
 30 Sandstone Road, Co. Antrim  
 BT41 4FL      +4402894422413  
 United Kingdom      radox.import@radox.com

**DATE:** \_\_\_\_\_  
**INCOTERM:** FCA  
**DELIVERED BY:** MARKEN

**DOCUMENT REFERENCE NUMBER**  
(Unique Sample Number)  
DOCUMENT REFERENCE NUMBER  
(numéro de référence unique)  
The unique sample number can be found on the aliquot tube.  
Le numéro de référence unique peut être trouvé sur le tube aliquot.

**THE UNDERMENTIONED GOODS ARE:**  
LES MARCHANDISES MENTIONNÉES CI-DESSOUS SONT:  
 NON FLAMMABLE    NON INFLAMMABLES  
 NON HAZARDOUS    NON DANGEREUSES  
 NON TOXIC    NON TOXIQUE  
 NOT FOR HUMAN CONSUMPTION    NON DESTINÉ À LA CONSOMMATION HUMAINE

QUANTITY	DESCRIPTION	NET WEIGHT <small>POIDS NET</small>	GROSS WEIGHT <small>POIDS BRUT</small>
	Human Blood Sample    UN 3373 Biological Substance Category B* <small>Échantillon de sang humain    UN 3373 Catégorie de substance biologique B*</small>	0.5kg	10.5kg

**PACKAGE DIMENSIONS**    (L) 39.5cm x (H) 34.4cm x (W) 26.3cm  
DIMENSIONS DE L'EMBALLAGE

**TARIFF HEADING: 3002 9010 00**  
NUMÉRO DE TARIF  
**PURPOSE OF USE: Diagnostic Testing**  
FIN DE DESTINATION  
**COUNTRY OF ORIGIN:** \_\_\_\_\_  
PAYS D'ORIGINE  
**TRANSPORT @ 30°C CREDITED IZOM 1216ML (NBATED)**  
TRANSPORT @ 30°C CREDITÉ IZOM 1216ML (NBATED)  
**UN 3373 BIOLOGICAL SUBSTANCE CATEGORY B**  
UN 3373 SUBSTANCE BIOLOGIQUE CATEGORIE B

**I DECLARE THAT ALL OF THE INFORMATION CONTAINED IN THIS DOCUMENT IS TRUE AND CORRECT.**  
J'ATTESTE QUE TOUS LES RENSEIGNEMENTS CONTENUS DANS CE DOCUMENT SONT VRAIS ET CORRECTS.

**Freight, Packing and All Import Duties will be paid by**  
Les frais d'emballage et toutes les dépenses des droits d'importation seront payés par  
 RANDOX LABORATORIES LTD,  
 55 Diamond Road, Crumlin,  
 Co. Antrim, BT29 4DT  
 United Kingdom  
 EORI XI 151 667 08 000

Signed by \_\_\_\_\_

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-2021

RANDOX

Radox ConcizuTrace™ Test Order Form

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

Aliquot 1 Barcode



NNRX000103-1

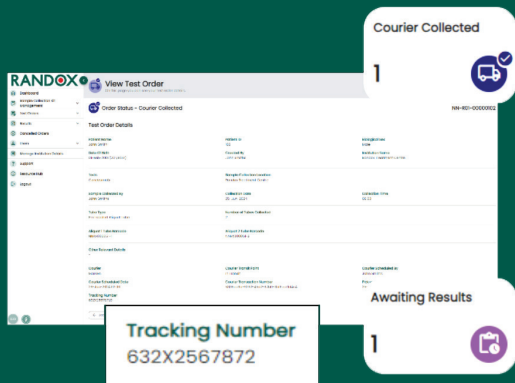
The Test Order Form is generated when the order is created for each sample in the portal.

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

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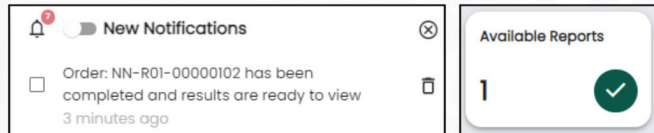
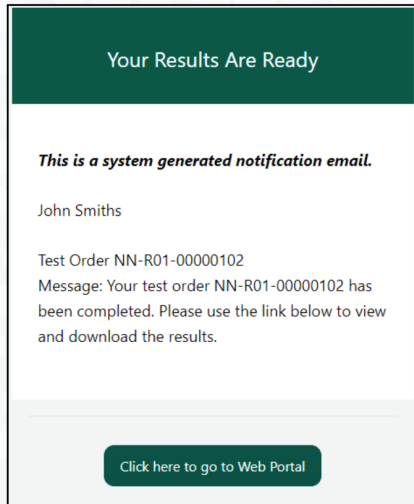


Once the courier has collected the sample(s), it will be moved along within the portal to the “Courier Collected” status.

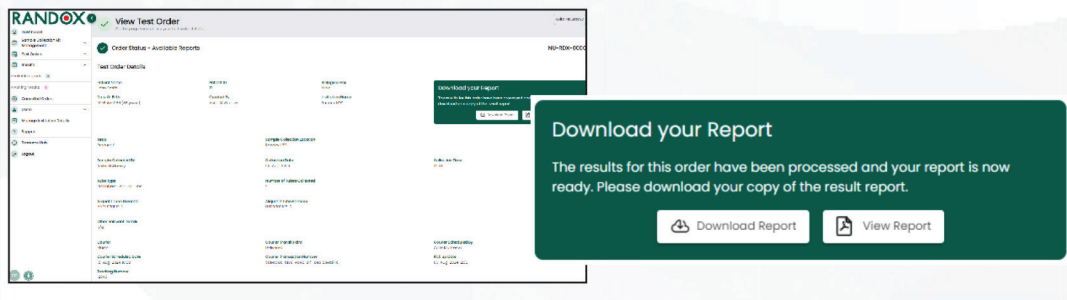
Once received by the lab, the sample will move to the “Awaiting Results” status.

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.



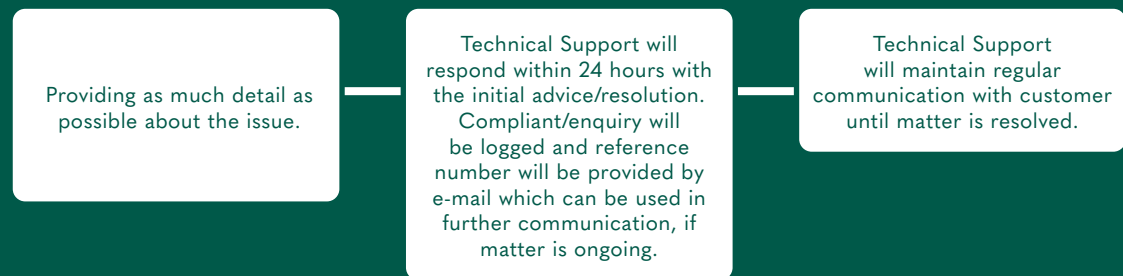
To download a completed report proceed to “Available Reports” under the “Results” tab. Select the sample of interest and proceed to download or view the report.

# HTC TECHNICAL SUPPORT

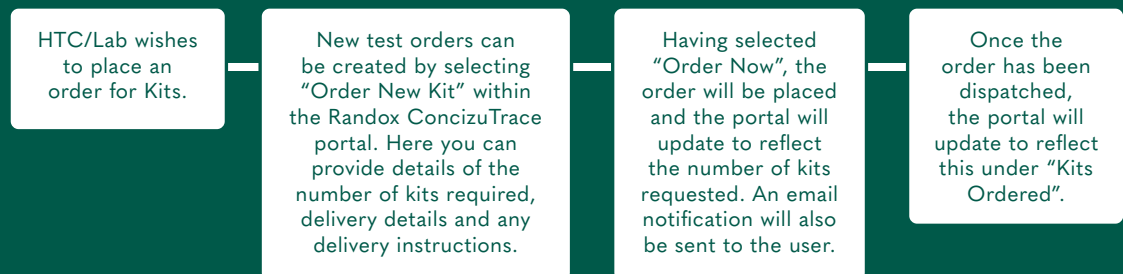
E: [concizutrace.support@randox.com](mailto:concizutrace.support@randox.com)

T: 213-533-9249

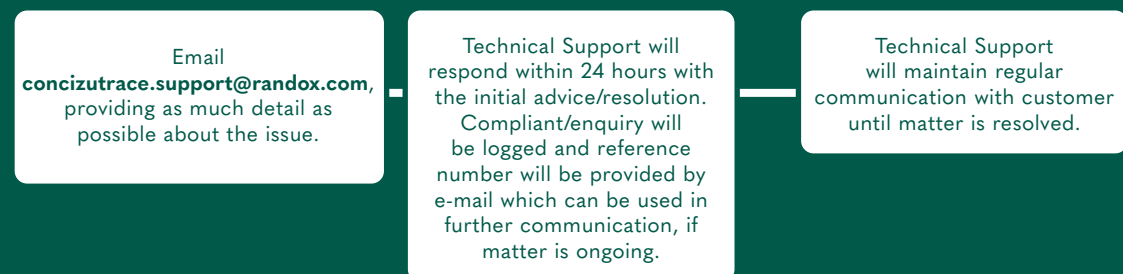
## SAMPLE COLLECTION KIT, RETURN OF SAMPLE & TRACKING SAMPLE



## KIT ORDERING



## RANDOX PORTAL



## FREQUENTLY ASKED QUESTIONS

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### 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

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### 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), who will transport the sample to the analytical laboratory.

#### 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

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### 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

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### Randox Portal

#### How do I register a sample on the Randox 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 Randox 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 Randox 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 Randox 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 Randox 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.

## RANDOX CUSTOMER SUPPORT CONTACT DETAILS

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For support please contact

- Email: [concizutrace.support@randox.com](mailto:concizutrace.support@randox.com)
- Call: 213-533-9249

# RANDOX

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