Protocol Number 175151

UK COURIER MANUAL:

Effective Date: 28.07.2026

Randox Courier Service

Prepared by: **Name:**	**Title:**	**Signature & Date:**
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Janis Best-Lane	International Trial Manager	Digitally signed by Janis Best-Lane Date: 2026.07.31 13:56:46 +01'00'

This document explains how to utilise the Randox courier service. This document will guide you through the steps from start to finish. Please read this manual carefully before using the courier service for the first time, and as a reference thereafter as needed.

ABBREVIATIONS

IL-6	Interleukin 6
sTNFR1	soluble Tumour Necrosis Factor Receptor 1

TABLE OF CONTENTS

1 CONTACT DETAILS

Nexus Technical Assistance
Contact the PANTHER Study Team, telephone: 07526 568215; 07714 051680 or email: pantheruk@imperial.ac.uk

Courier Assistance
Contact Randox Medical Accounts, telephone: 0151 665 0301

Out of Hours

The courier service runs till 5pm daily. If you require a courier after this time please contact 07526 568215; 07714 051680

2 OVERALL PROCESS

The process of utilizing the Randox courier services involves the following steps:-

a) Select a suitable patient
b) Book a courier via the Randox courier service - RandoxHealthCourierRequestSubmission
c) Collect the patient sample
d) Order the test via the Randox 'Nexus' order system, labels are produced.
e) Label the sample
f) Wait for the courier.

This manual will cover each of these steps in more detail.

3 PATIENT IDENTIFICATION & ELIGBIITY

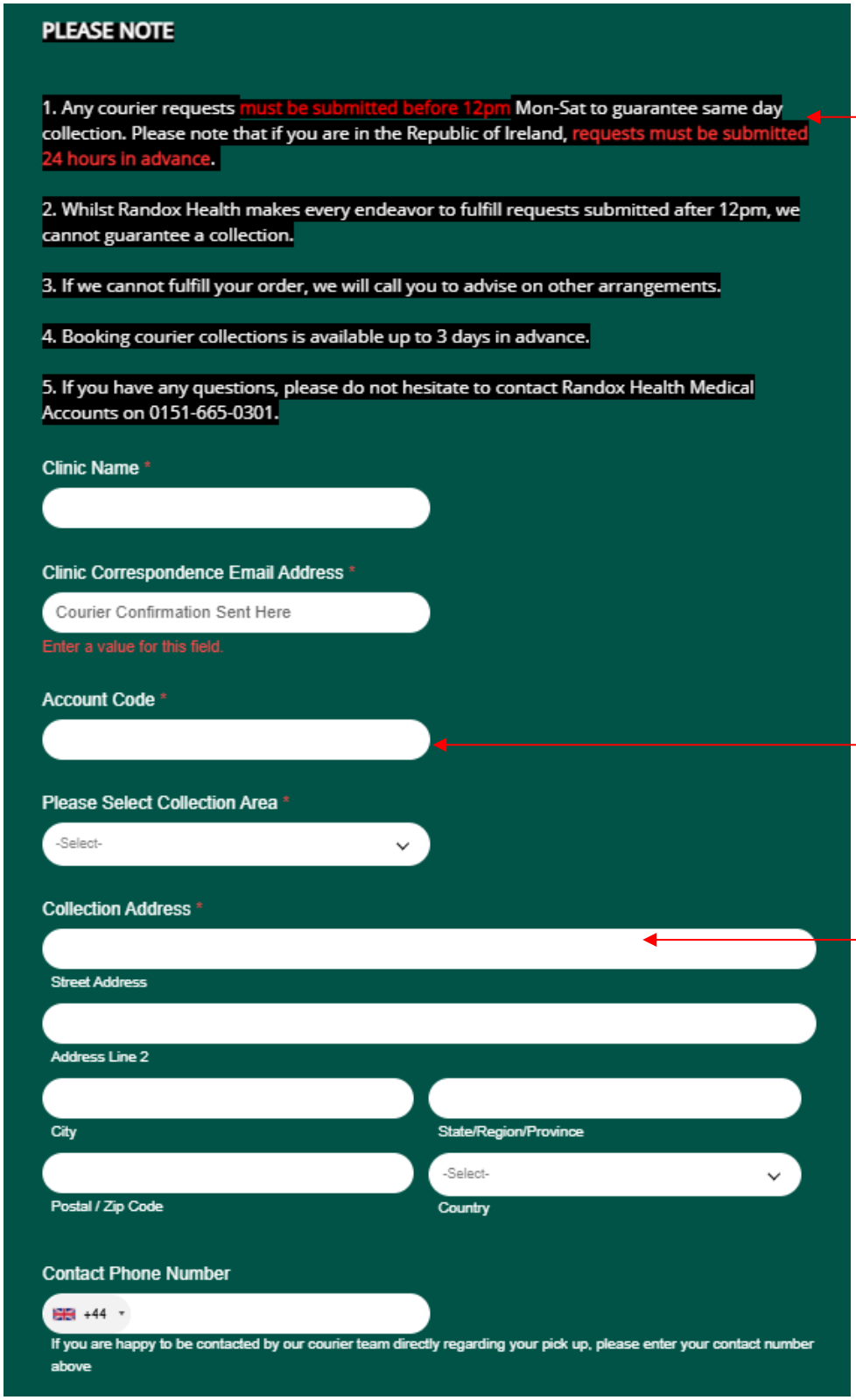
Once a patient has been and identified and confirmed as eligible, please obtain consent and request for a Randox courier. Please also begin data entry on the database. Complete all forms in the pre-randomisation event apart from the phenotyping which should be completed when you have received the result.

4 BOOKING THE RANDOX COURIER

A Randox courier can booked on the following link:
RandoxHealthCourierRequestSubmission

Please book the courier prior to collecting the blood sample.

Enter all fields on the form.

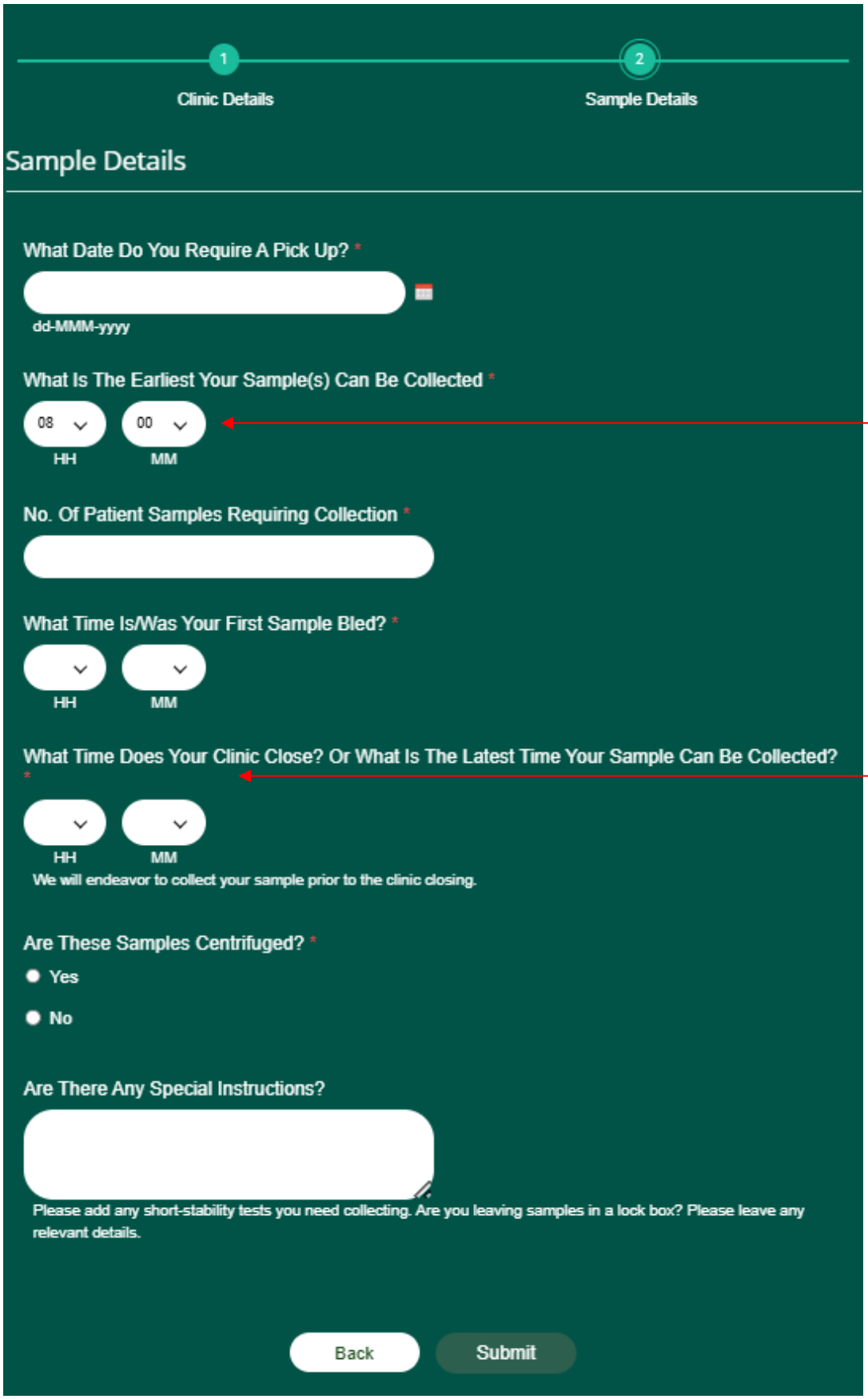


Please note that this does not apply to PANTHER, but please do check the opening hours of your clinic.

The account code will have been provided to you during your onboarding training. It will start with 'PANT'

Please ensure a 'Pick up location' is added in the collection address which is clear for the courier. Please be as specific as possible i.e. include department/building/floor level.

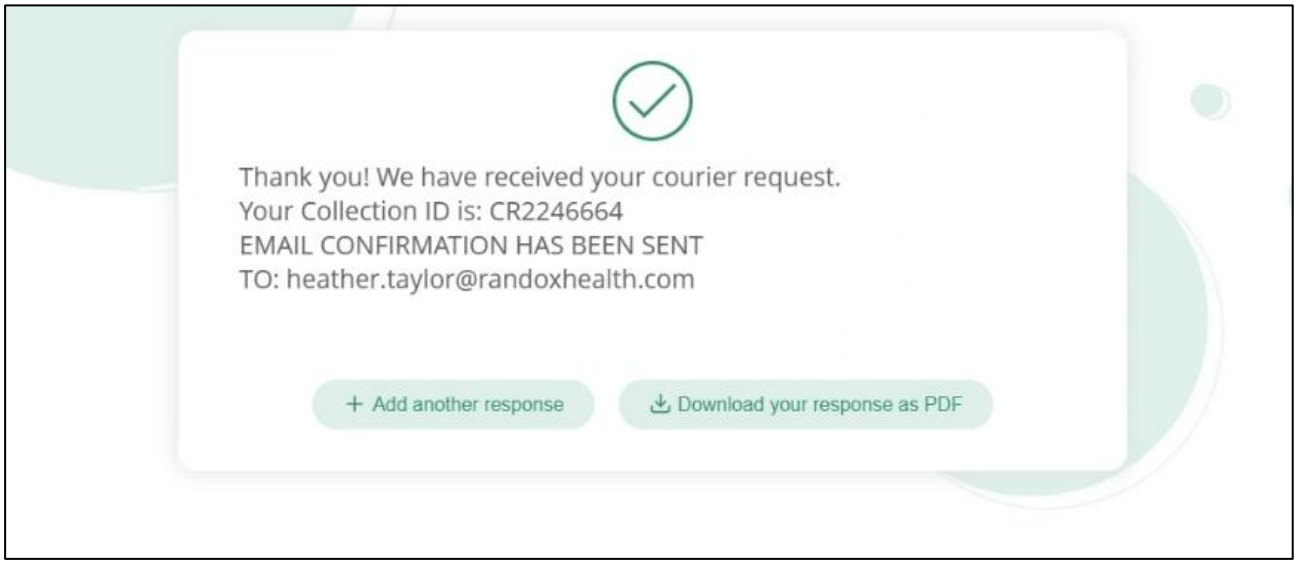
Once completed you will then need to enter the fields below.



Please always enter the time you are currently filling in the form.

Please always enter **30minutes** from the time you plan on collecting the sample. For example, if you are collecting the sample now at 12:00, then for the latest time the sample could be collected enter 12:30 as it is best for the sample to be collected as soon as possible to enable swift subphenotyping.

After selecting submit the notification below should appear:



You should also receive an email like the one shown below. In the email there is a hyperlink which if selected would allow you to cancel the courier if necessary.

5 COLLECTING THE SAMPLE FROM THE PATIENT

Personnel must follow 'Universal Precautions' when handling blood products as well as site-specific requirements for handling each type of specimen. Processing of blood specimens should be initiated as soon as possible (~ 30 minutes) following collection with all plasma and serum samples ideally processed within one hour.

5.1 EQUIPMENT PREPARATION

Before the sample is collected, ensure you have the following equipment available and ready:-

- 1 x 4ml Lithium Heparin Tube
- Ice for temporary storage
- 1 x centrifuge
- 1 x Pasteur pipette
- 1 x 1ml cryovial tube
- 1 x Randox labelling paper
- 1 x Plastic wallet

5.2 COLLECTING THE SAMPLE FOR THE SUBPHENOTYPE DETERMINATION

Before the patient is randomised we need to determine the subphenotype, this sample will determine if the patient is hyper or hypo inflammatory.

- Collect 4ml of whole blood from the patient in a lithium heparin tube, invert the tube several times, ready for the centrifuge

<u>4ml Lithium Heparin Tube</u>

- Centrifuge the blood at 2000g for 10 minutes.
- Pipette the plasma into the 1ml cryovial tube.
- The cryovial and lithium heparin tubes should be labelled, where possible, (once labels are printed from Nexus) and placed into the shipment bag.
- Keep the sample refrigerated until the courier is ready to collect the sample.

Note - please see Sample Manual for details on the other tiers

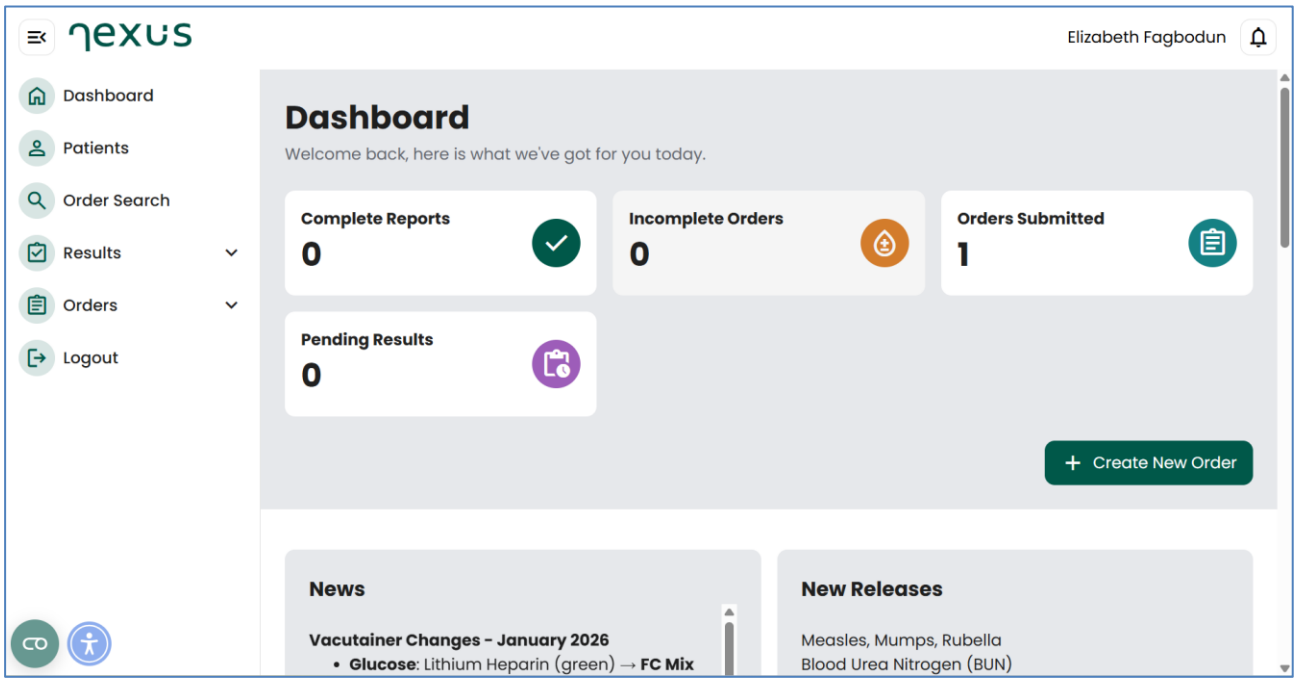
6 ONBOARDING TO THE NEXUS SYSTEM

6.1 NEXUS

When your site is ready to Go Live, you will receive a training session on Nexus from Randox Health/Sponsor Team. Nexus is the system that will be used to notify the Randox Lab that a sample is ready for subphenotyping.

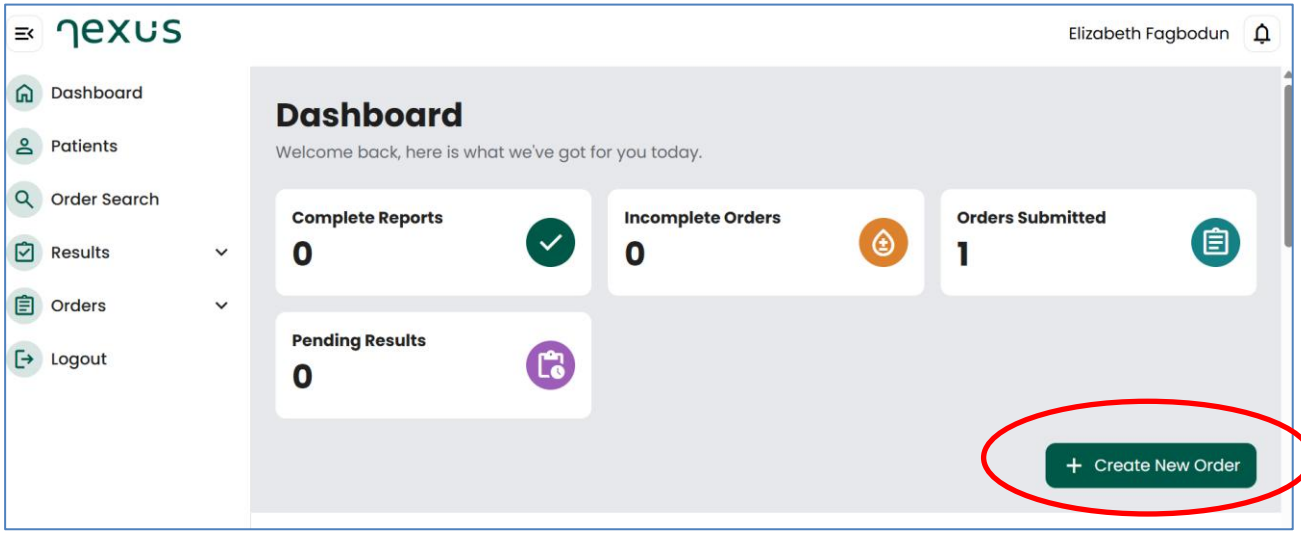
6.2 LOGGING INTO NEXUS

After your training session you will receive an email asking you to set your password for the system. Selecting the link in this email will direct you to the login page where you will need to enter your email address and **select 'Forgot Password'**. You will then be prompted to create a new password. Once you have created your password you will be able to login into the system and the dashboard, as shown below, should appear.

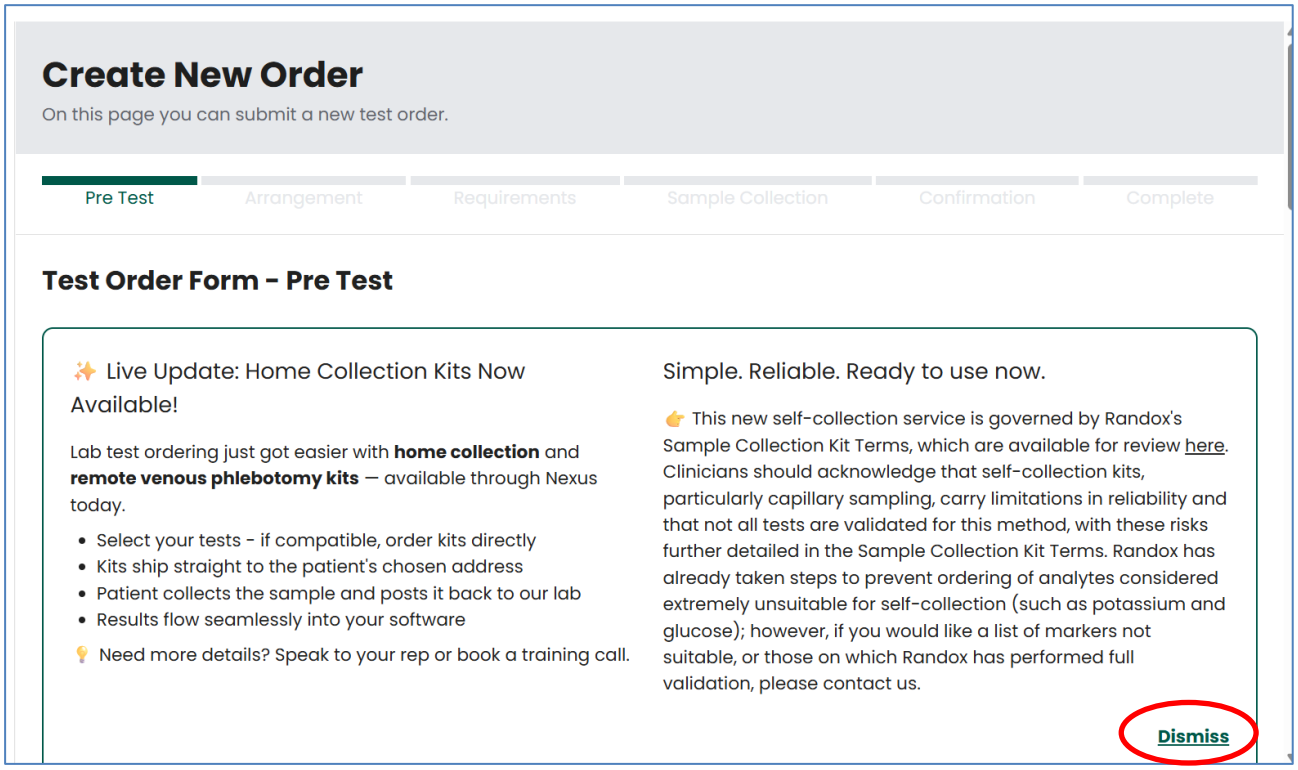


7 NOTIFYING THE LAB OF A SAMPLE

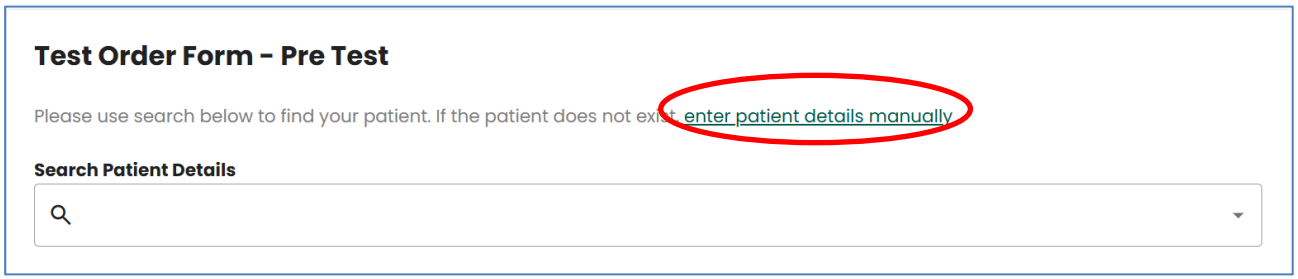
Log into the Nexus system. On the dashboard select ‘Create New Order’



You will then be taken to the create new order page. A notification may automatically appear here which will detail any system updates, you can select dismiss as shown by the red circle below.



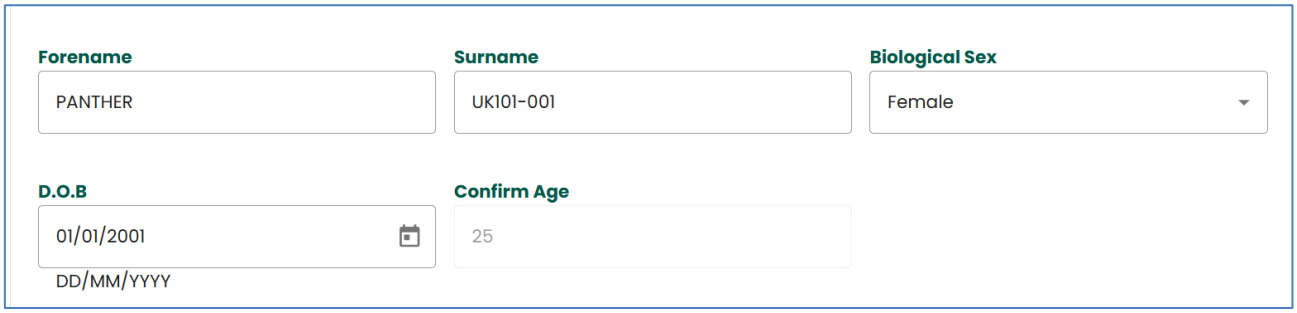
Then select 'enter patient details manually' the search option is for previous patients which does not apply to PANTHER.



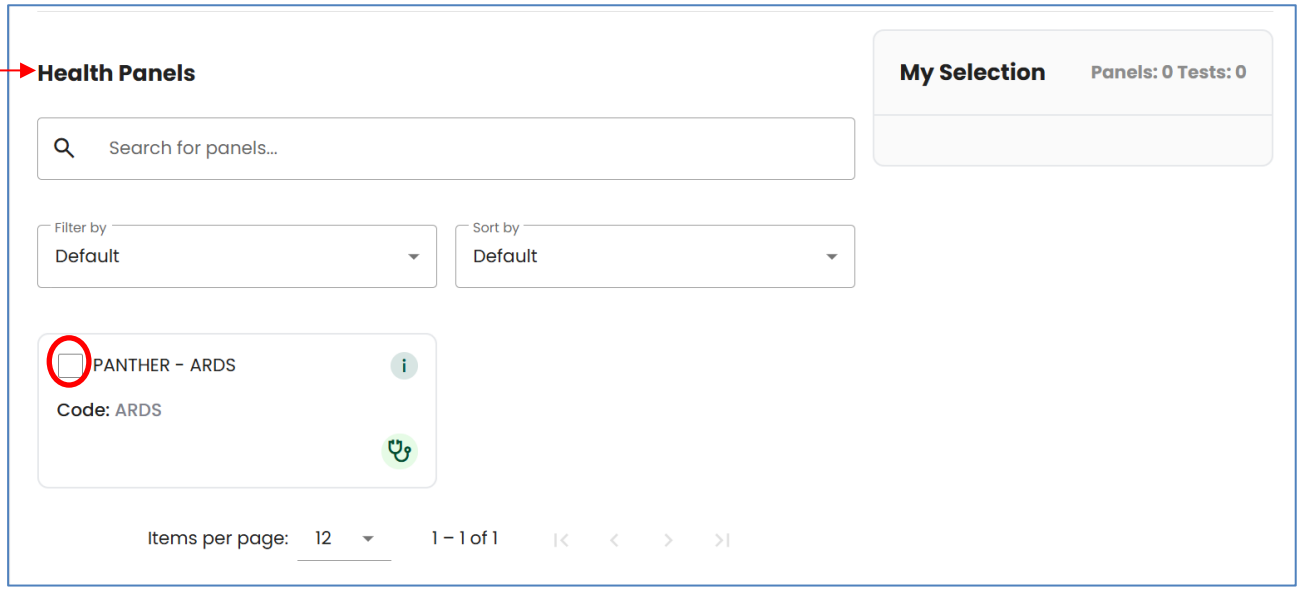
You will then be asked to enter the details as shown below. Enter the following information:-

- **Forename** – PANTHER
- **Surname** – Patient ID
- **Biological Sex** – patient biological sex
- **D.O.B** - always enter 01/01/2001.

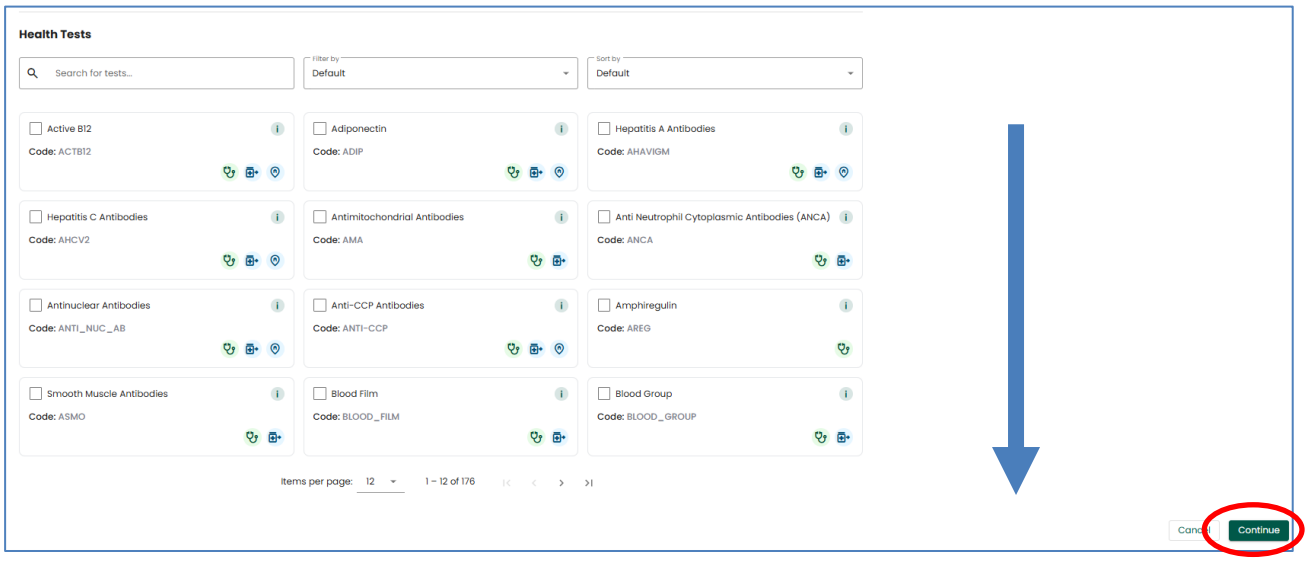
**Please note if the participants actual date of birth is 01/01/2001, please enter 12/12/2001*



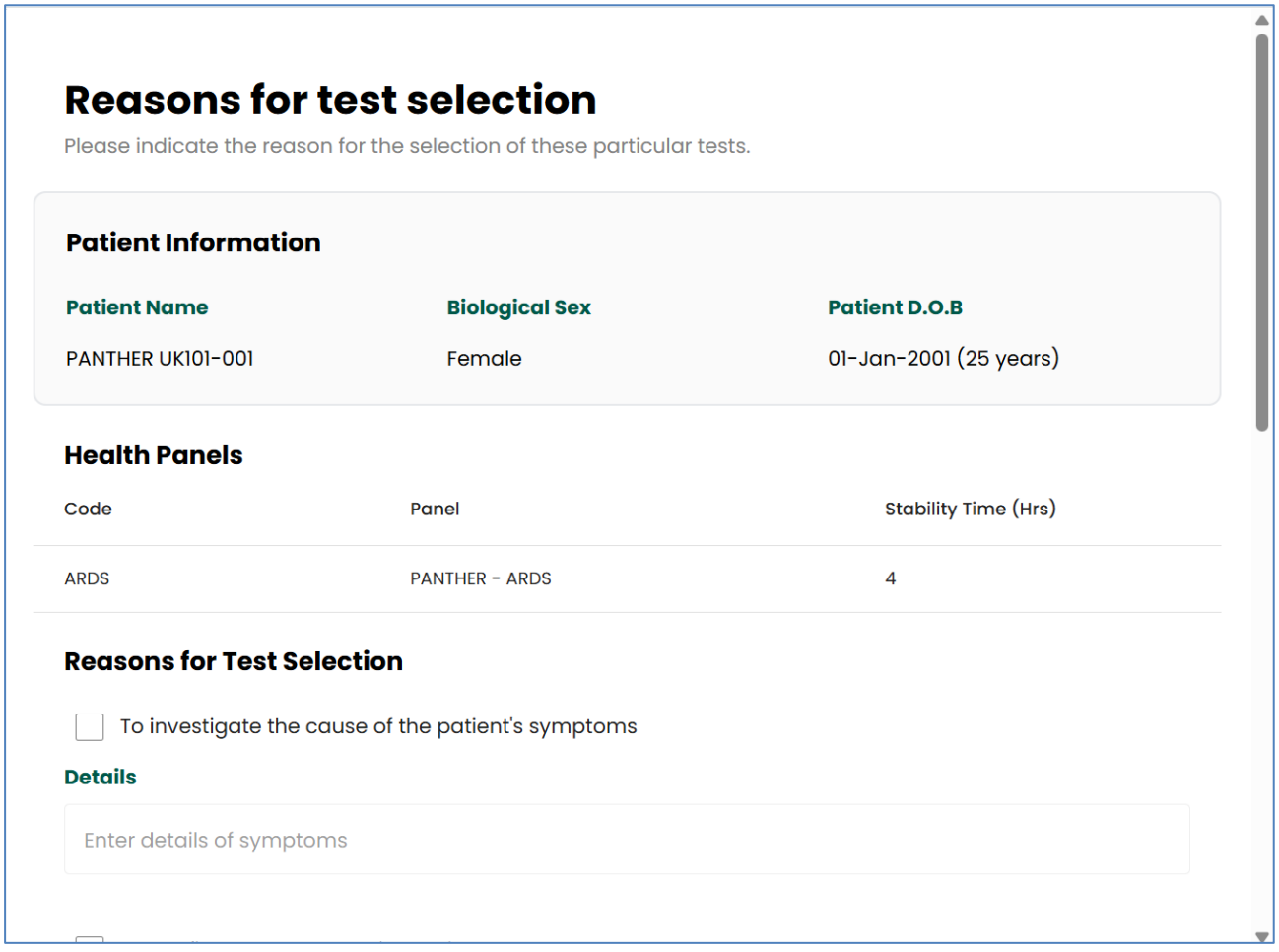
In the **Health Panels** section select '<u>PANTHER – ARDS</u>'

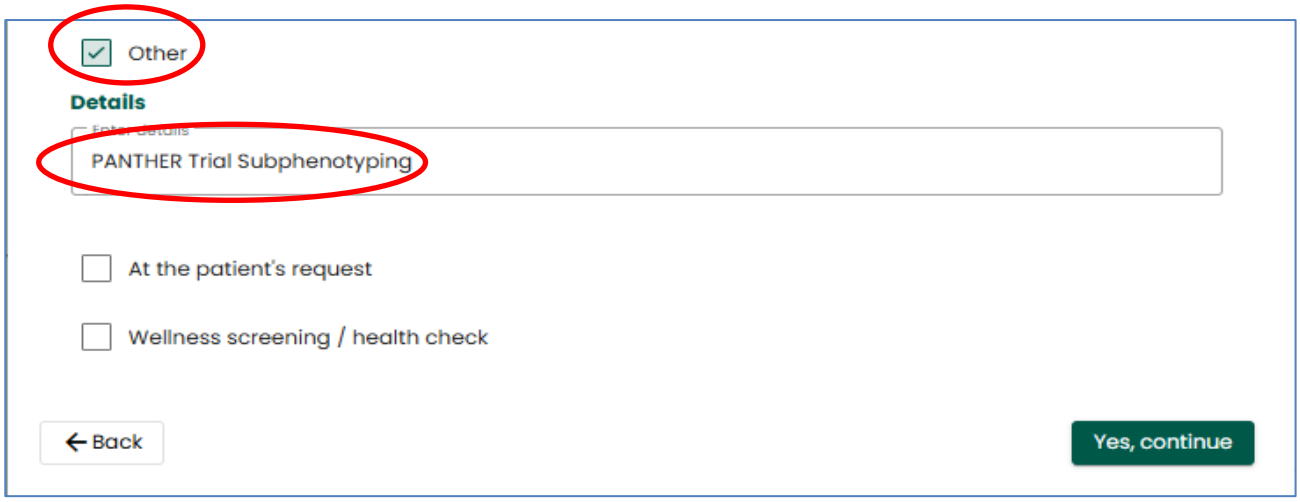


Scroll past **all** the health tests to the bottom of the page and select continue

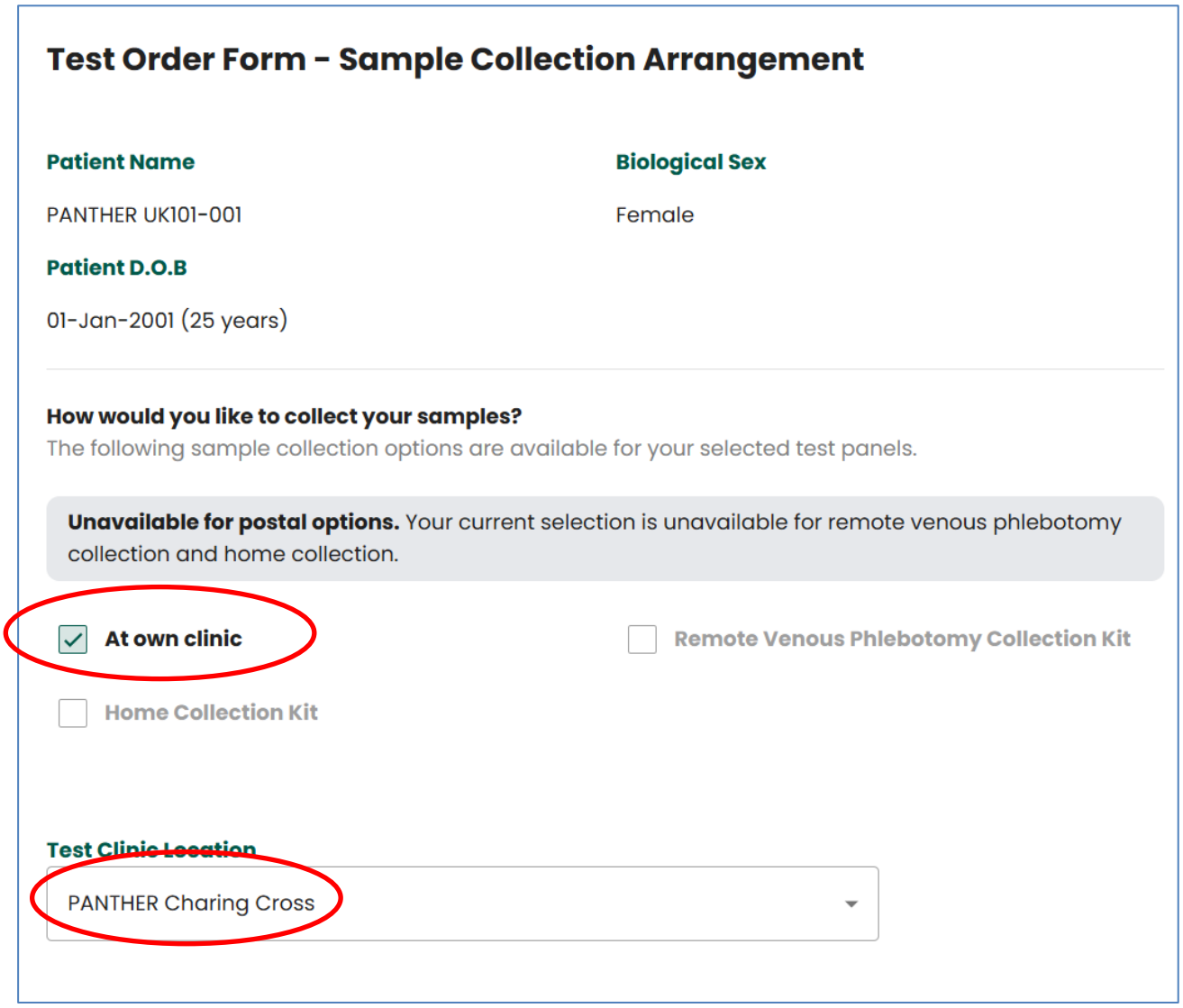


A pop box will appear asking for the Reasons for Test Selection (see below). Please scroll down the list and select 'other' in the details section please enter 'PANTHER Trial Subphenotyping' and then select continue.





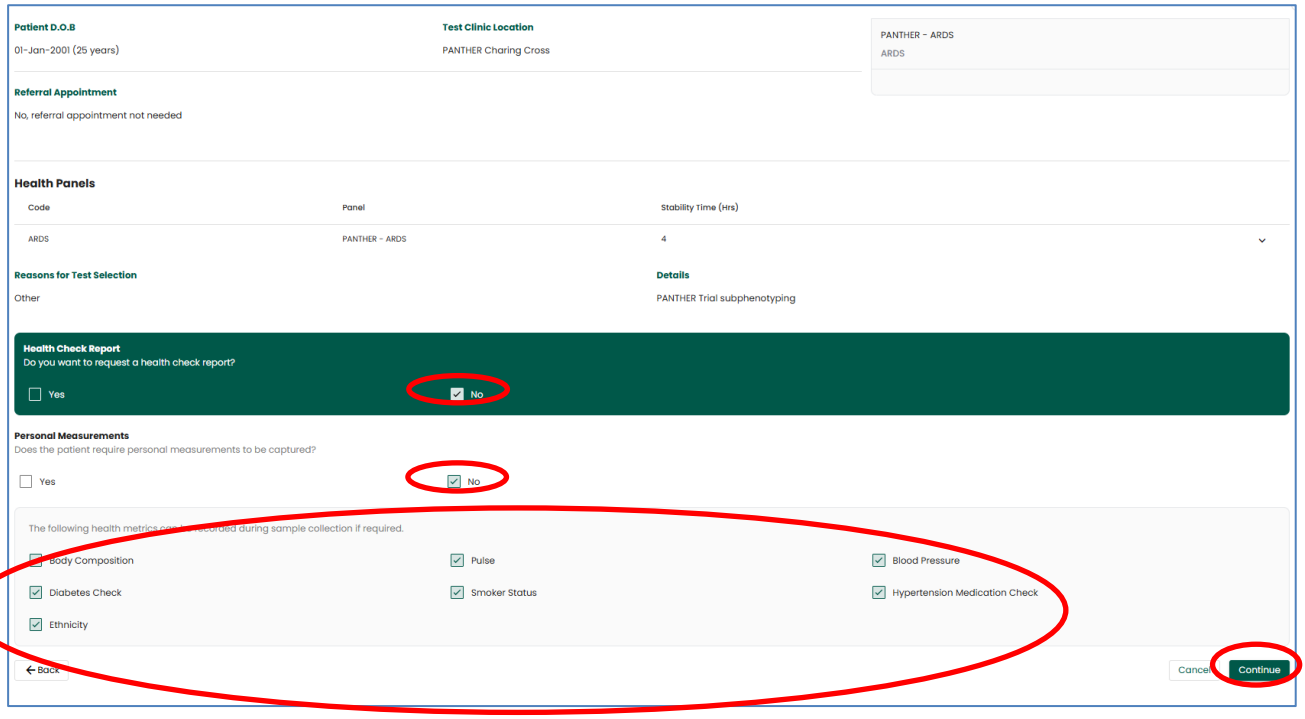
On the next page select '<u>At own clinic</u>' after selecting this your site name should automatically appear in the 'test clinic location' field. Once you have confirmed the details are correct select 'continue' at the bottom of the page.



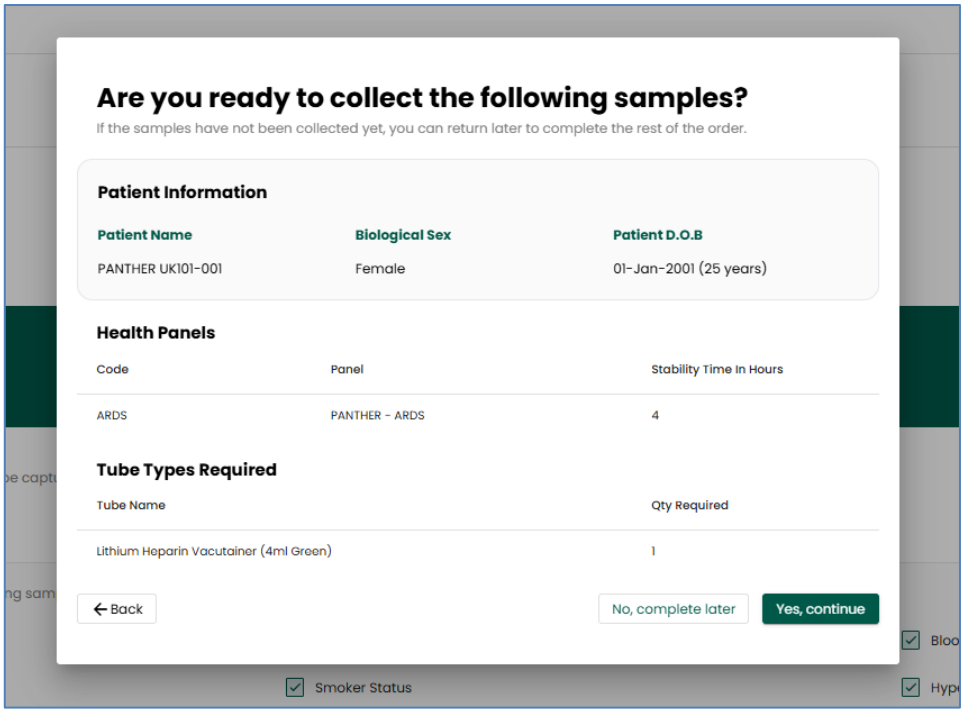
On the next page the following boxes will be pre-selected:

- **Health Check report** – No
- **Personal Measurements** - No

Please do not amend this and select continue at the bottom of the page.



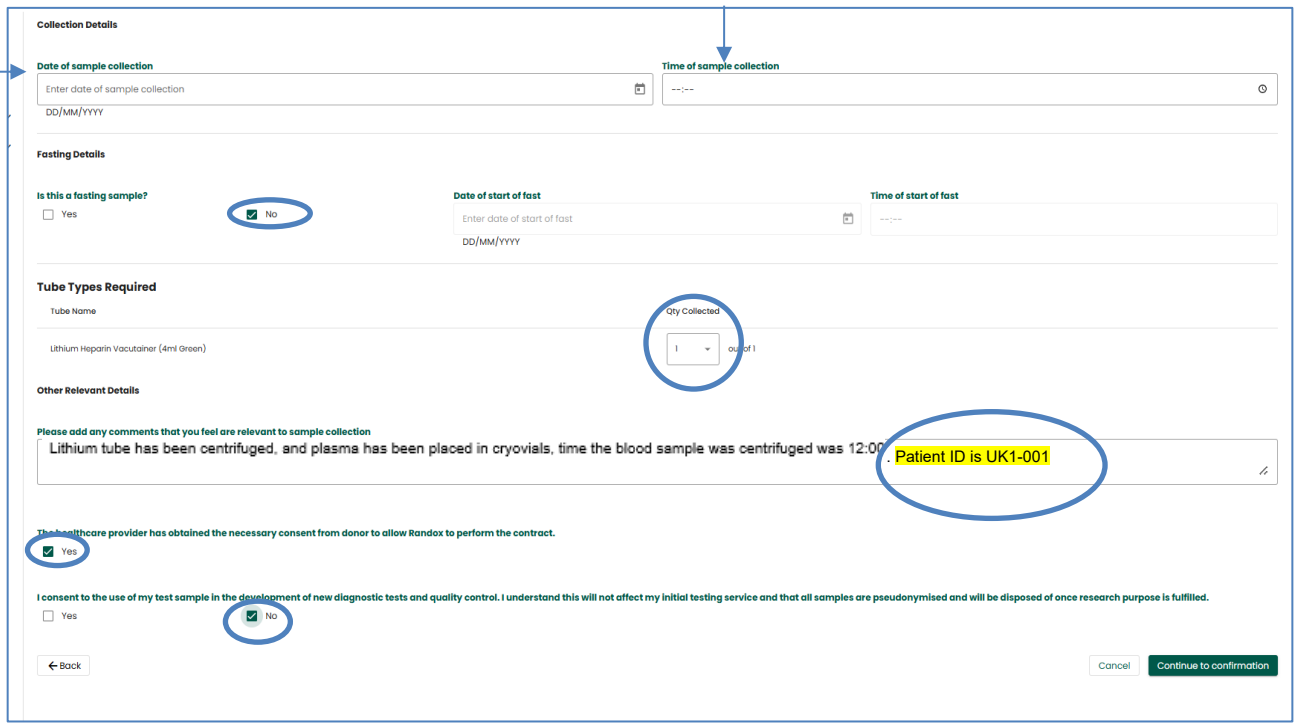
The following pop-up will appear. If the sample has been drawn, please select 'yes, continue'



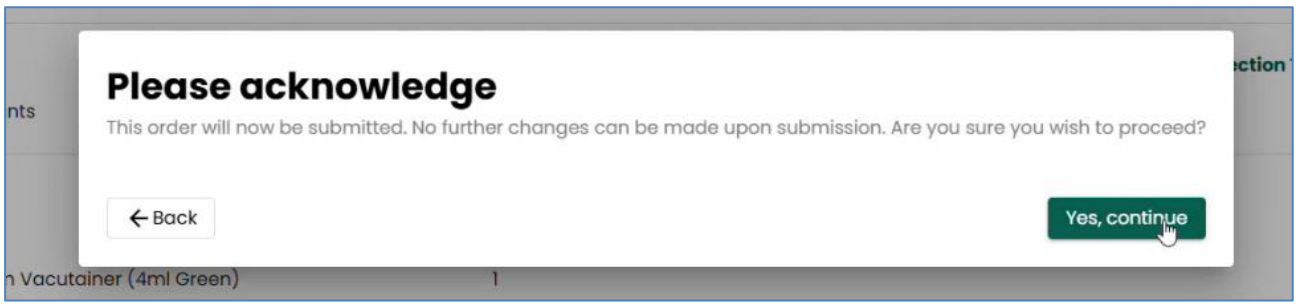
You will then need to enter the date and time the sample was collected. Please ensure the following are selected:-

- **Is this a fasting sample** – No
- **Date and time of fast** – leave blank
- **Tube Types Required** – Lithium Heparin Vacutainer (4ml Green)
- **Qty Collected** – 1
- **Other Relevant Details**
- **Please add any relevant comments that you feel are relevant to the sample collection**:- enter 'Lithium tube has been centrifuged, and plasma has been placed in cryovials, time the blood sample was centrifuged was – HH:MM.
- In this box please also enter the patient ID from OpenClinica, as this will then be printed on the order form to facilitate traceability.
- **The healthcare provider has obtained the necessary consent from donor to allow Randox to perform the contract** - yes
- **Consenting to be part of quality control** should always be marked as no.

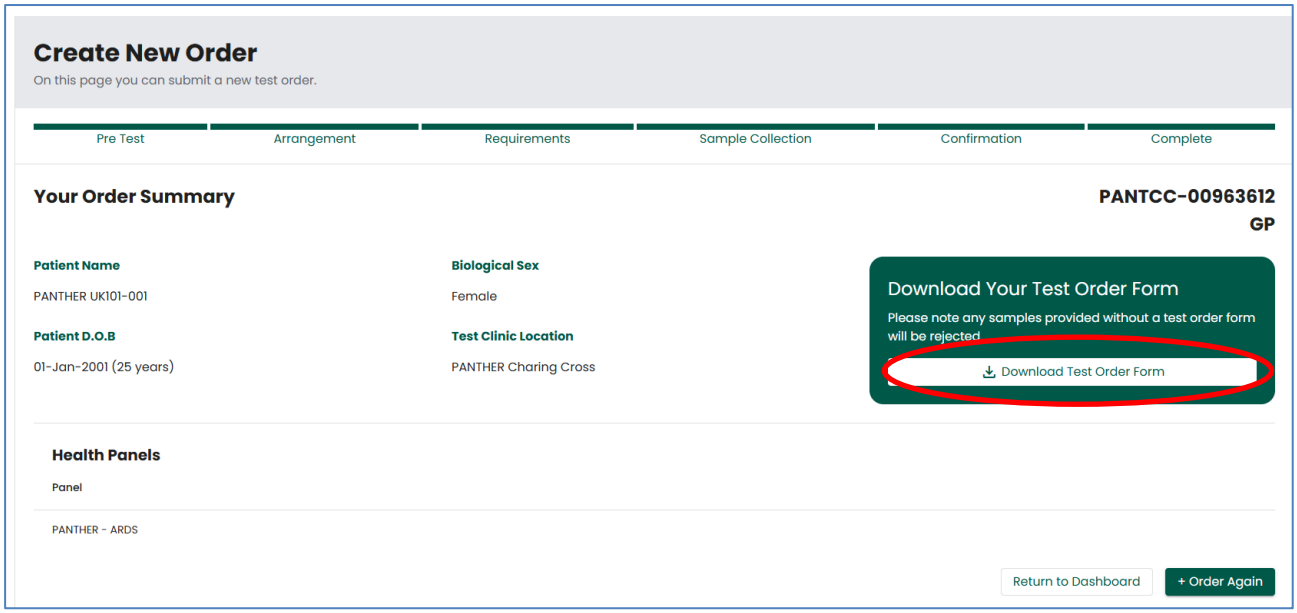
Once complete, select 'continue to confirmation' at the bottom of the page.



A pop-up will appear asking you if you wish to proceed. If you are happy with the information that has been entered, please select 'Yes, continue'.



Your order is now complete and a summary page will appear. Select ‘Download Test Order form’



Open the form which should look like the image below and complete the following steps:-

1. Save a copy of the form and email this to the PANTHER study team:- pantheruk@imperial.ac.uk
2. Save a copy of the form in the site eISF
3. Print the form and labels using the paper Randox have provided. Label the lithium heparin tube and cryovial and place these with the test order form in a plastic bag provided by Randox.

RANDOX HEALTH

Randox GP Test Order Form
Page 1 of 1
18-Feb-2026 10:18

Order Details

Order Number:	PANTCC-00963612
Order Date:	17-Feb-2026 16:19
Date Of Birth:	01-Jan-2001
Sex:	Female
Health Check Panel Report:	No
R & D Consent Given:	No

PANTCC-00963612

Sample Collection

Collection Location:	PANTHER Charing Cross	**Fasting Required:**	No
Collection Date/Time:	17-Feb-2026 14:19	**Fasting Start Date/Time:**	N/A

Panel/Test Details

RDX_DEFAULT RANDOX_HEALTH_DEFAULT

Tube Details

Lithium Heparin Vacutainer (4ml Green) 1 of 1

centrifuged at 12:00

PANTCC-00963612
DOB: 01-Jan-2001
SEX: Female

(repeated 9 times)

Your sample is now ready for collection.

8 THE SUBPHENOTYPING RESULT

The subphenotyping result will be sent to the email that created the order on Nexus. It will also appear in the results section in the tab on the left-hand side of the Nexus system. Please note it may take up to 6 hours for your site to receive the result.

Concentration values for IL-6 (pg/mL) and sTNFR1 (ng/mL) will be provided. Make a note of these to enter in the eCRF to allow the patient to be randomised. Please also ensure that the result is printed and filed in the eISF.

Example results

Analyte	Concentration	Units
IL-6	253.09	pg/mL
sTNFR1	7.18	ng/mL

8.1 ENTERING ON THE DATABASE

Once the MultiSTAT has provided the required concentration values (IL-6 and sTNFR1) these can now be entered into the CRF and the patient can be randomised.

UA0-003: Phenotyping

Device type?
- (•) Randox
- ( ) Ella
- ( ) Other

Date the subphenotyping was completed	Time the subphenotyping was completed format (hh:mm [0-23] hrs [0-59] min)
2025-08-06	13:00

The lowest/worst bicarbonate in past 24h: 25

sTNFr1 Collected	sTNFr1 Value (ng/ml)
(•) Yes ( ) No	125

IL-6 Collected	IL-6 Value (pg/ml)
(•) Yes ( ) No	96

9 ON SITE EQUIPMENT

All sites will be required to process the initial blood sample for centrifugation to separate plasma.

All participating centres must be equipped with the following minimum equipment:

- Centrifuge with 2000g force capability

10 TROUBLESHOOTING

- Printer is not working – if the hospital printer is not working information can be written on the tubes. Please ensure the following information is included on the tube:-
    - Order ID (provided by Nexus)
    - Patient ID
    - Biological Sex
- Will the courier come to our office?

  Yes, as long as you provide instructions such as '10th Floor room 1064' or 'please call this number when you arrive' the courier will meet you and collect from there.
- What is the latest time I can arrange a courier?

  This will be confirmed during your test run.

11 REVISION HISTORY

Version	Date	Summary of changes
1.0	06 MAR 2026	First version
2.0	29 May 2026	Minor updates regarding out of hours and printing results.
3.0	28 Jul 2026	Update to text entered in comments section on nexus.