

Lab samples



Blood samples

- Blood samples should be obtained as per Laboratory Manual.
- NHS samples:
 - Results should be reviewed by a doctor on the Delegation Log in a timely manner.
 - A copy of the results signed and dated by a delegated doctor must be filed in the participant's medical notes.
- Research samples:
 - Processed as per Laboratory Manual
 - Stored at site and transferred to core labs, University of Dundee, twice, during trial and at end of trial.

Pregnancy Test

Visit 1

- Blood should be sent to local NHS lab for a serum pregnancy test.

All other visits

- Urine pregnancy test should be carried out
- A copy of the results signed and dated by a delegated doctor should be filed in the participant's medical notes.

Sputum samples

- Sputum samples should be obtained as per Laboratory Manual.

Visit 1

- *P. aeruginosa* in sputum, bronchoalveolar lavage or another airway sample at least once in the **24 months prior to screening.**

and

A sputum sample that is culture or PCR positive for *P. aeruginosa* sent at the screening visit and **within 35 days of randomization.** Sputum sample should be sent to your local lab for culture.

OR

- A participant who does not have a positive sample for *P. aeruginosa* in the previous 24 months may submit two samples, **at least 21 days apart, during the 35-day screening period.** If these samples are **both** positive for *P. aeruginosa* then inclusion criteria will be deemed met and the patient may be enrolled.
- Results should be reviewed by a doctor on the delegation log and a signed and dated copy filed in the participant's medical notes.

Research Sputum Samples

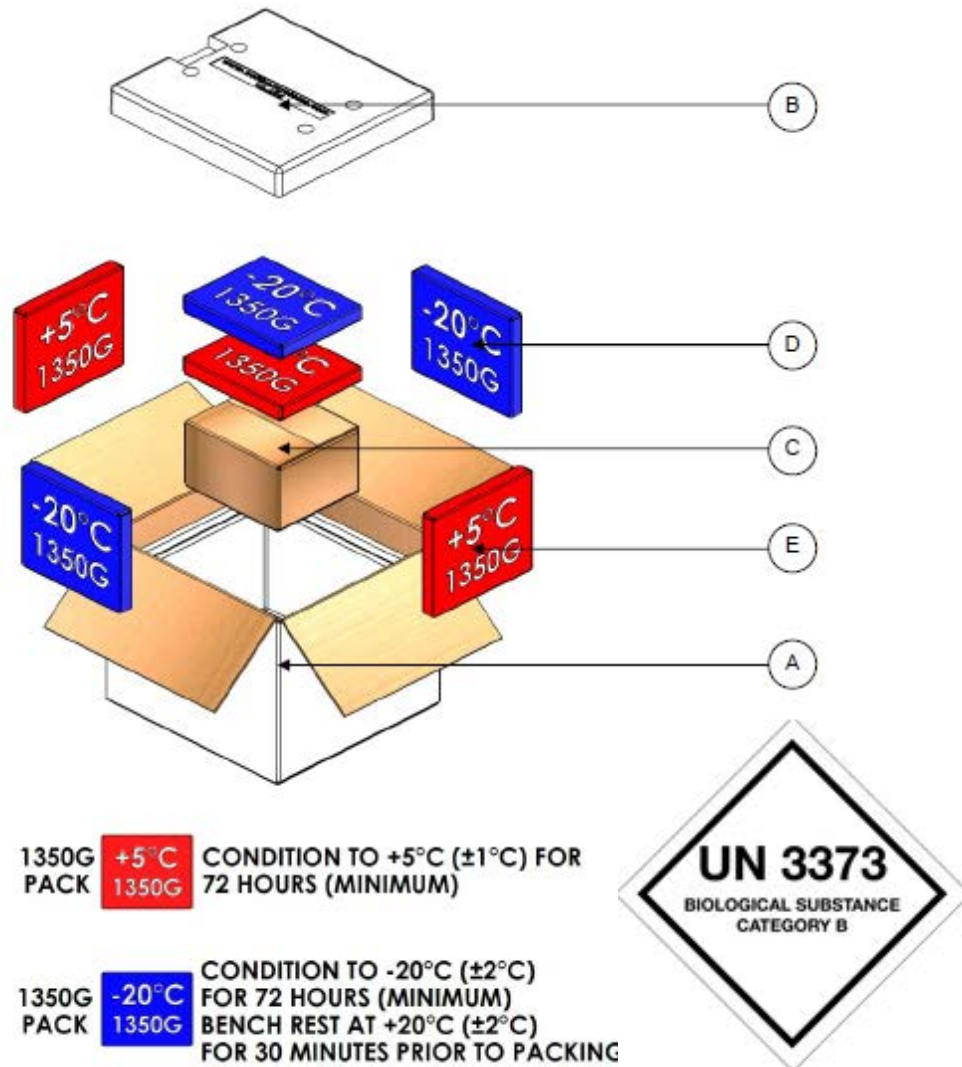
- All Transferred to core lab, Queens University Belfast, **on day of collection.**
- All visits and sputum sample shipments should take place **Monday – Thursday**
- Samples will be shipped next day delivery using DHL medical express
- Steps for arranging a courier are detailed in GREAT-2 Sputum Sample Shipment Process document

Sputum packaging requirements:

- Chilled packaging for sputum samples will be provided
- +5°C and -20°C cool packs must be chilled at least 72 hours prior to the shipment
- Human sputum samples are considered category B dangerous goods
- Each sputum shipment **must be labelled with the category B sticker provided**
- Government regulations for packaging category B samples are in: GREAT-2 Sputum Shipment Requirements document



- System Comprises :
- A. 1 x Outer Corrugated Carton
 - B. 1 x 58mm Insulation System
 - C. 1 x Product Carton
 - D. 3 x Frozen-Conditioned Pharmacool 1350 P.
 - E. 3 x Chilled Pharmacool 1350 Packs



Sputum Sample Shipments

Each shipment must contain:

- 1 sputum sample placed in the inner packaging box
- Ensure sputum sample is secured by packing with an absorbent material (e.g. paper towel) to prevent movement
- Surround inner box with cool packs (as shown in diagram)
- Ensure category B label is placed on the outer packaging
- Box must contain a printed sputum sample log & completed sputum shipment document
- Must also email the sample log & shipment document to:
Trial Manager: great-2-tm@dundee.ac.uk
Belfast lab: Chloe.McLaughlin@qub.ac.uk

For more details refer to: GREAT-2 Lab Manual

Sputum samples

All other visits

- Participants will be asked to produce a spontaneous sputum sample at each visit.
- A hierarchical approach to obtaining sputum samples will be used:
 1. spontaneous sputum sample produced at the visit
 2. spontaneous early morning sputum brought from home on the day
 3. spontaneous early morning sputum brought in within 48 hours of the scheduled visit.
 4. Induced sputum in sites able to perform induced sputum according to local protocols.
- Sputum colour will be assessed using the Murray Sputum Colour Chart, see eCRF.

● 46.2 Result of sputum colour assessment

- Clear
- Clear to yellow
- Yellowish-green
- Brownish-dark
- Green with traces of blood
- No sputum produced
- Other

- Samples transferred to core lab, Queens University Belfast, **on day of collection.**

Research Blood Samples

See the lab manual for the blood samples & volumes to be collected at each visit and the sample processing required.

PK blood samples




















PK samples (SST tubes) should be collected from the opposite arm to the infusion.

The pre-dose samples should be taken within 1 hour of the start of infusion.

Post infusion samples should be taken between 10 minutes and 1 hour after the end of infusion.

All times of sample collection and start/end of infusion should be recorded.

Sample Processing

TUBES	INVERT TUBE	ALLOW TO STAND	CENTRIFUGE	TRANSFER	LABEL	FREEZE
 PAXgene	 8-10 times	 Stand upright min 2 hours				 Store upright Transfer to -20°C freezer within 2-72 hours from collection
 SST	 5 times	 Stand upright 30 mins	 1100 to 1300 xg for 15 mins	 Transfer 0.5 ml serum	 As many cryovials as required for available serum	 Store upright Transfer to -80°C freezer within 1 hour from collection
 EDTA	 8-10 times					 Store upright Transfer to -80°C freezer within 1 hour from collection
 Sputum						 Refrigerate 2-8°C Arrange shipment to Queens University Belfast on day of collection

Tayside team only:

Invert the tubes the required time (as stated in lab manual)
Transfer samples at room temperature to lab team within 1 hour of collection.
Tayside site are also collecting additional blood samples.

Sample Labelling

- All study samples should be labelled with labels provided
- Each sample label must be completed with the sample ID and date of collection
- Sample ID is made up of:
 - site number – participant number – visit number – sample number
 - e.g. sample ID 01-01-02-01 would be site 01 – participant 01- visit 02- sample number 01
- Samples should be stored in separate boxes according to sample type.
- Storage boxes should be labelled with trial title, site number, sample type and box number.
- Sample type, date of collection and storage location should be recorded on the GREAT-2 Sample Log.

GREAT-2 Whole Blood

Sample ID: ___-___-___-___

Date: ___-___-___