

Instructions for taking biological samples in RECOVERY

From January 2022, two kinds of biological samples will be collected in RECOVERY; serum samples and viral swabs. These will help us identify which, if any, patients respond to the trial treatments, and provide additional information on what effects these drugs have.

The samples are initially being taken only from participants in the sotrovimab and molnupiravir comparisons, **including those allocated usual care in these comparisons**. Future treatments may also require sampling, and requirements for sampling may change as the trial progresses, so please refer to the trial website (www.recoverytrial.net/for-site-staff/site-teams) for current information.

Sampling scheme

All samples should be taken using the serum sampling or viral swab kits provided. A stock of these will be held by the local research team, which will be replenished by the central co-ordinating team when running low. If additional supplies are required e-mail recoverytrial@ndph.ox.ac.uk.

Both samples are taken at baseline (day 1), after consent has been taken but before randomisation. Viral swabs are also taken on day 3 and day 5. Sites should make local arrangements for taking these at the weekend. If research staff are unavailable, consider arranging for a ward nurse to take swabs. No training is required to follow the swabbing & postage instructions in each kit. If it's not possible to do this, please take swabs as close as possible to the sampling time (Friday afternoon for swabs due on Saturday, or Monday morning for swabs due on Sunday).

	Serum sample	Nose swab
Baseline (Day 1) Take <u>after</u> consent, and <u>before</u> randomisation	✓	✓
Day 3	✗	✓
Day 5	✗	✓

If a 'day 3' sample has not been taken by the end of day 3, take this soon as possible the following day. If a 'day 3' sample has not taken by the end of day 4, ignore this sample and just take the day 5 sample. If a 'day 5' sample has not been taken by the end of day 5, take this as soon as possible afterwards. Samples do not need labelling with 'd1/d3/d5', but please ensure collection dates & times are accurately written on each sample box.

Procedure for taking SERUM SAMPLES

The serum sample kit contains material for postage of serum samples, but **does not** contain a blood tube (vacutainer) or any equipment for phlebotomy. These must be obtained from the ward. The kit contains:

- A plastic screw top container which is used to transport the blood tube
- A cardboard box, which is used to transport the screw top container
- A plastic envelope with pre-printed return label, which the box is posted in

Taking serum samples

- 1) Ensure you are wearing appropriate PPE, have a serum sample kit, and have equipment for phlebotomy.
- 2) Confirm patient's identity, if not done already, and explain the procedure
- 3) Take blood into a 5-6ml serum tube (yellow top SST or red-top serum tube like those shown here, or local equivalent).



Procedure for taking VIRAL SWABS

The viral swab kit contains everything you need to take the viral swabs:

- One swab
- A collection tube containing 2ml of viral transport medium
- A larger screw top container which is used to transport the collection tube
- A cardboard box, which is used to transport the screw top container
- A plastic envelope with pre-printed return label, which the box is posted in

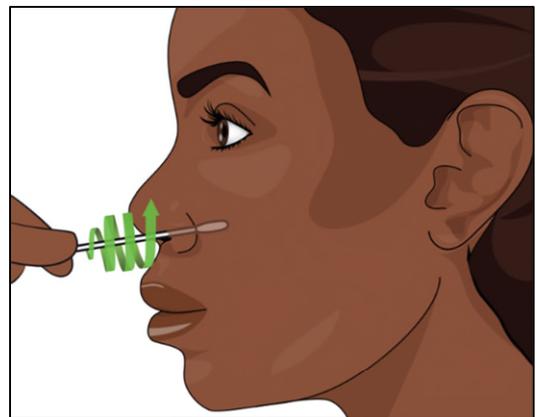
It is important that swabbing is done as consistently as possible for each patient (ideally by the same person, but this is not mandatory), so that changes in viral carriage can be detected. Nose swabs here are mid-turbinate swabs, *not* swabs of the anterior nostril as often used in self-swabbing. Note, although some training materials for the antivirals mentioned throat (oropharyngeal) swabbing, it is only a nose swab that should be collected.

Preparation

- 1) Ensure you are wearing appropriate PPE and have a viral swab kit to hand
- 2) Confirm the identity of the patient, if not done already, and explain the procedure

Swabbing (both nostrils)

- 3) Take the swab out of its packet.
- 4) Ask the patient to tilt their head back slightly.
- 5) If the patient is on nasal oxygen, pull the cannula slightly away from the side being swabbed for a few seconds whilst the swab is taken.
- 6) While gently rotating the swab, insert about 2 cm into one nostril pointing directly backwards (not upwards) until resistance is met. Do not use force.
- 7) Rotate the swab five times against nasal wall.
- 8) Repeat in the other nostril using the same swab.
- 9) Place the swab tip first into the collection tube, break off plastic end, and replace lid.



Labelling and returning SERUM SAMPLES and VIRAL SWABS

- 1) Participants should be randomised as soon as possible after sample collection, at which point a participant ID will be generated. If this is not done straight after sample collection, keep a temporary identifier with the sample & collection kit so they do not get mixed up with others prior to labelling (e.g. by writing patient details on a piece of paper kept along with the sample in the box). Please do not write anything on the serum/swab tube or box at this stage.
- 2) As soon as the participant ID is generated, label the blood/swab tube just with the 7-digit participant ID. Do not add any other identifiers.
- 3) Place the blood/swab tube inside the larger screw top tube and close the lid tightly.
- 4) Place the larger tube inside the box and write participant ID and collection date & time on the front of the box in the spaces provided. Discard any temporary identifiers.
- 5) Place the box in the plastic pre-addressed envelope. Do not mix up the envelopes for serum samples and viral swabs, which are sent to different laboratories (viral swab envelopes are marked with a lilac sticker).
- 6) Put the envelope in the internal hospital post, **do not** send it to a local clinical laboratory. At some sites other arrangements may be made for sample postage, which will be explained to those collecting samples. Samples can remain at room temperature if collection is delayed (e.g. over the weekend if there are no Royal Mail collections), but if it is convenient to keep these samples at 4°C whilst awaiting collection this is preferable.