

Baseline Collection

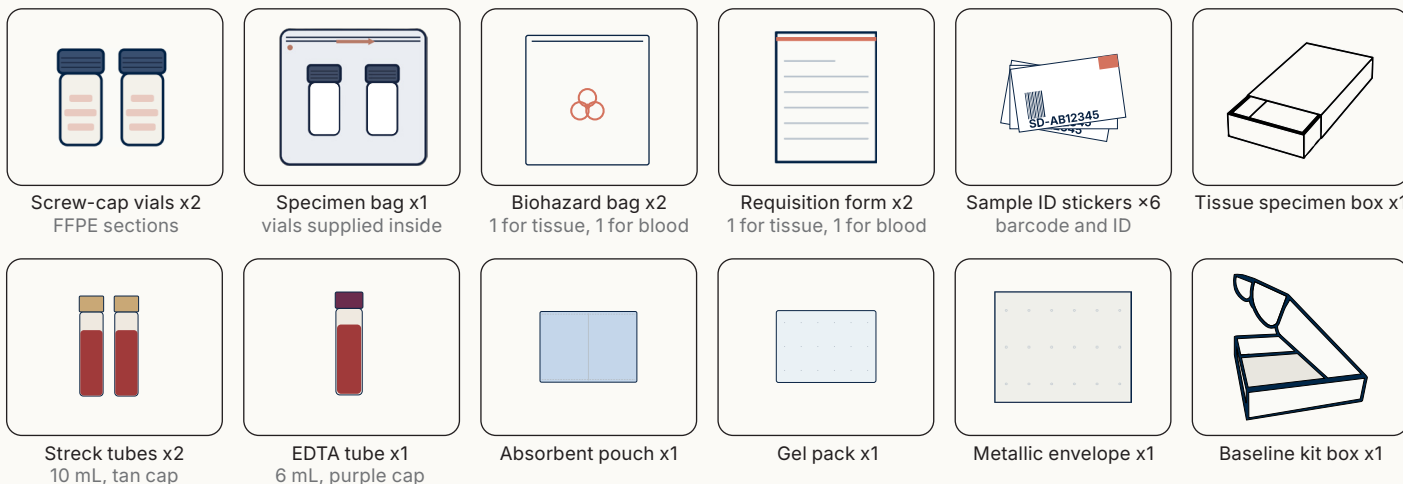
Instructions for Use

Simsen® Personal Baseline Kit



Use this kit at the first (baseline) timepoint: formalin-fixed paraffin-embedded (FFPE) tumour tissue for tumour profiling and a venous blood sample for tumour-informed ctDNA analysis. The baseline blood draw includes the matched normal control. Follow the steps in order.

KIT CONTENTS



STORAGE

18 to 30 °C

Unopened kit
Store 18 to 30 °C.
Do not exceed this range.

6 to 37 °C

Drawn blood
Keep 6 to 37 °C.
Do not freeze.

Room temp

FFPE tissue
Room temperature.
Do not freeze.

1

CONFIRM PATIENT IDENTITY

Positive identification at the point of collection is essential before any sample is drawn. Match the patient to the requisition form, then apply a sample ID sticker to each tube and vial.



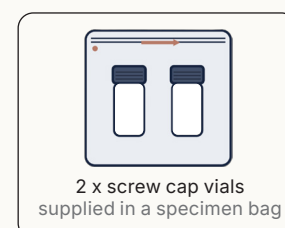
PART A - TUMOUR TISSUE

2

PREPARE THE TUMOUR TISSUE SAMPLE

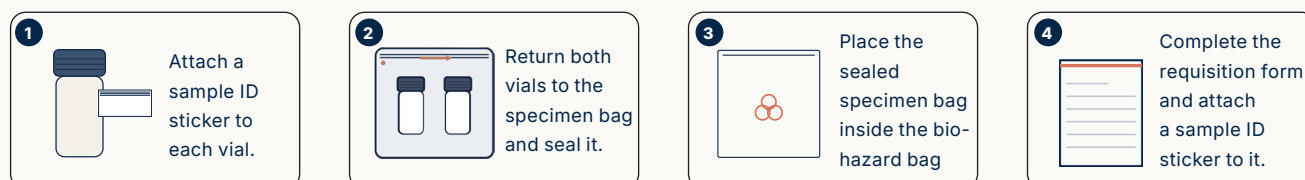
Use FFPE tissue fixed in 10 percent neutral-buffered formalin. Send the most recent FFPE section that corresponds to the current clinical presentation.

1. Place 5 fresh sections from the FFPE block into each vial: 10 sections in total, 10 to 20 µm each.
2. Tumour content should be greater than 30 percent (assessed by the customer).
3. Avoid heavily necrotic, poorly fixed, or overly fixed tissue.



3

PREPARE THE TISSUE FOR SHIPMENT



4

SHIP THE TISSUE



5

COLLECT THE BLOOD SAMPLES

1. Draw two 10 mL Streck tubes (tan cap); at baseline, also one 6 mL
2. EDTA tube (purple cap) as the matched normal control.
3. Fill each tube to capacity; if insufficient, draw another.
4. Allow 60 to 90 seconds per tube.
5. Use a 21-gauge straight needle for venepuncture.
6. If a vein collapses, use a fresh tube for a second attempt.

IMPORTANT – Order of draw

If the Streck (cfDNA) tubes and the EDTA (germline) tube are drawn during the same venepuncture, **draw the EDTA tube first.**



2 × 10 mL Streck
1 × 6 mL EDTA

6

ROTATE THE STRECK TUBES GENTLY

Immediately after drawing, gently rotate each Streck tube at least ten times to mix the blood with the reagent. Invert the EDTA tube gently ten times as well.

- **Do not** shake the samples.
- **Do not** seal the tubes with parafilm.



X10 GENTLE ROTATIONS

7

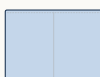
PREPARE THE BLOOD FOR SHIPMENT

1



Label each tube with the patient ID and collection date or timepoint.

2



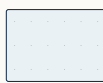
Place the tubes inside the absorbent pouch.

3



Insert the absorbent pouch into the biohazard bag.

4



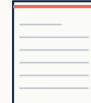
Place the biohazard bag inside the gel pack for cushioning.

5



Put the gel pack and biohazard bag into the metallic envelope.

6

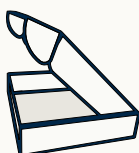


Complete the requisition form and attach a sample ID sticker.

8

SHIP THE BLOOD

1



Place the sealed metallic envelope and the completed requisition form into the Baseline kit box.

2



Attach the return label and seal the package. If preferred, use a secondary envelope and apply the label there.

SHIPPING

SHIP WITHIN 24 HOURS

Ship all blood samples to the Simsen laboratory within 24 hours of collection. The baseline blood draw already includes the matched normal control (6 mL EDTA tube), so no separate blood kit is needed at baseline. For later timepoints, use the Simsen Personal Follow-up Kit (ordered separately).

WASTE MANAGEMENT

Dispose of all collection materials in line with your site's biomedical/clinical waste procedures and applicable local, regional, or national regulations.