

Standard Operating Procedure

Sample Collection, Processing, Storage and Shipping at BSTOP Partner Sites

| DOCUMENT DETAILS | |
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| Originally Prepared by | David Baudry |
| Reviewed by | |
| Approved by (Signature and date) | Pr. Catherine Smith on 10/01/23 <i>catherine smith</i> |

| CHANGE HISTORY | | | |
|----------------|----------------|---|-------------|
| Date | Version Number | Change details | Approved by |
| 10/01/23 | 1.0 | Cancels and replaces previous SOP: BSTOP Sample Collection SOP v4.0 from Mar-2017 Cancels and replaces previous manual: Sample Processing and Storage Manual v1.0 from Jan-2017 New format, sample types collected updated and shipment methods updated | C. Smith |
| 19/04/23 | 1.1 | Change of site classification: BG, JC, KG, PO, WM no longer following up former PSORT-D patients | C. Smith |
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Purpose:

The aim of this document is to provide a standard operating procedure for sample collection, processing and storage for BSTOP Partner Sites, as well as transport of such samples to the BSTOP Central Co-ordinating Site, St Johns Institute of Dermatology, Guy's Hospital.

Important note: the appropriate study consent must be in place from patients prior to sample collection.

Contents:

1. Requirements
2. Sample labelling
3. Sample collection and storage
 - 3.1. Whole blood for DNA
 - 3.2. Whole blood for serum
4. Sample shipments
5. List of supplies provided by the Co-ordinating Centre
6. Study contact details

Related documents:

- BSTOP All Sites CAPTURE Training Manual
- BSTOP Former PSORT-D Sites CAPTURE Training Manual
- BSTOP Sample Request Form DNA-only
- BSTOP Sample Request Form PSORTD
- BSTOP Site Training

1. Requirements

Each site must have as a minimum:

- Venepuncture facilities
- Sample collection tubes (provided by Study Team)
- Royal Mail shipment boxes (provided by Study Team)
- Former PSORT-D sites (~~EG~~, GY, ~~JG~~, ~~KG~~, LD, LV, NE, ~~PG~~, SR, WL, ~~WM~~) don't need any Royal Mail boxes, but must have instead:
 - Centrifuge capable of centrifuging at 1000g
 - Microtubes and single use pipettes (provided by Study Team)
 - -20°C freezer or colder

2. Sample Labelling

- All tubes must be labelled with the following fields:
 - BSTOP Study ID (e.g. ZZBST0001 – where ZZ is your 2-letter site code)
 - Unique CAPTURE generated Sample ID (e.g. ZZ000001.1 – where ZZ is your 2-letter site code)
 - Patient initials
 - Sample collection date
- **Note:** If you see ZZ at any stage during data entry, it means you are on the Training Location. **Stop data entry immediately** and contact capture@gstt.nhs.uk to ask to be switched to your Site Location
- Use a fine tip, black Staedtler™ Lumocolor™ permanent marker to label the samples (provided by the Study Team upon request).
- Please note that the CAPTURE generated Sample ID and the BSTOP Study ID are separate identifications. Although the Sample IDs are generated automatically by CAPTURE using the next number available in the sequence, they should never be guessed.
- Partner Sites not using CAPTURE for data entry won't have access to the unique Sample ID – this can then be omitted.

3. Sample collection and storage

3.1. Whole Blood for DNA

- At baseline, collect a one-off 12mL of whole blood in 2x6mL K₃EDTA Vacuette™ tubes (pink top) – provided by the Study Team. Make sure tubes have not expired.
- Invert 3 times to mix blood with EDTA.
- Label the tubes as per labelling instructions detailed on page 3.
- If your current stock has expired or has been misplaced and you are waiting for a replacement, any EDTA bottles available locally can be used instead in the meantime.
- Complete the Sample Request Form (this form must be completed and sent along with all samples)

| BSTOP ID <input type="text"/> <input type="text"/> B <input type="text"/> S <input type="text"/> T <input type="text"/> O <input type="text"/> <input type="text"/> | | DNA Only | |
|---|---|--|---|
| Patient Initials <input type="text"/> <input type="text"/> <input type="text"/> | Date of Birth <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Gender M <input type="checkbox"/> F <input type="checkbox"/> | |
| Samples taken | Blood drawn | Blood Posted | Sample IDs (CAPTURE generated) Please write these on blood tubes |
| | Date and Time | Date and Time | |
| Pink top EDTA <input type="text" value="1"/> DNA <input type="text" value="2"/> | | | <hr/> <hr/> |
| PLEASE NOTE: If this sample was exposed to any event that could potentially compromise its integrity, or otherwise deviates from standard protocol, please detail on the rear of this sheet. (Such as - unplanned thaw, mislabelling, left out overnight, etc) | | | |

V6 - 30/11/2022

- Post blood to the Co-ordinating Centre using the Royal Mail boxes provided (up to 4 patients per box). Does not apply to former PSORT-D sites (~~BE~~, GY, ~~JE~~, ~~KG~~, LD, LV, NE, ~~PO~~, SR, WL, ~~WM~~). Instead, store the whole blood at -20°C or colder until transported to the Co-ordinating Centre via dry-ice courier.
- Do not forget to update CAPTURE

3.2. Whole blood for Serum

- **IMPORTANT:** Only applies to former PSORT-D sites (BG, GY, JC, KG, LD, LV, NE, PO, SR, WL, WM)
- Serum is collected from former PSORT-D patients at each BADBIR visit (every 6 months).
- Collect 10mL of whole blood in 2x5mL serum separating clotting factor Vacuette™ tube (yellow top). Make sure tubes have not expired.
- Invert 3 times to mix blood with clotting factor and rest for at least 30 minutes.
- Centrifuge samples at 1000g for 15 minutes at ambient temperature, ideally within 2 hours of (but a maximum of 4 hours) after collection.
- Immediately following spin, use a pipette to transfer the separated serum into a 2mL microtube.
- Use a fresh pipette for each serum tube.
- Use only one microtube if all the serum can fit into one tube.
- Leave some space at the top of each microtube tube as the serum will expand in the tube once frozen. Fill to the 1.5mL graduation line (approximately ¾ full).
- Label the microtubes as per labelling instructions detailed on page 3.
- Complete the Sample Request Form (this form must be completed and sent along with all samples)

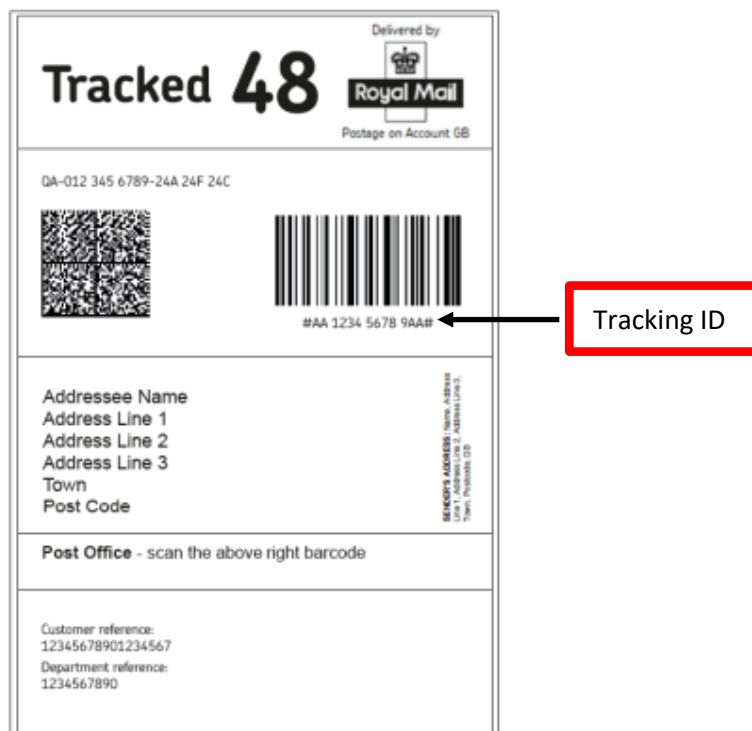
| BSTOP ID | | | <input type="text"/> <input type="text"/> <input type="text"/> B <input type="text"/> S <input type="text"/> T <input type="text"/> O <input type="text"/> <input type="text"/> <input type="text"/> | Former PSORTD | | | | |
|--|----------------------|----------------------|--|----------------------|--|--------------|---|----------------------------|
| Patient Initials | | <input type="text"/> | Date of Birth | | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Gender | M <input type="checkbox"/> | F <input type="checkbox"/> |
| Samples taken | | | Blood drawn | Blood spun | | Blood frozen | Sample IDs (CAPTURE generated) <small>Write these on blood tubes</small> | |
| | | | Date and Time | | Date and Time | | | |
| Pink top EDTA - DNA | <input type="text"/> | <input type="text"/> | | | | | | |
| Yellow top - Serum | <input type="text"/> | <input type="text"/> | | | | | | |
| Was blood for serum refrigerated between draw and spin? | | | Yes <input type="checkbox"/> | temp | <input type="text"/> | °C | No <input type="checkbox"/> | |
| Was the serum refrigerated between spin and freeze? | | | Yes <input type="checkbox"/> | temp | <input type="text"/> | °C | No <input type="checkbox"/> | |
| PLEASE NOTE: If this sample was exposed to any event that could potentially compromise its integrity, or otherwise deviates from standard protocol, please detail on the rear of this sheet. (Such as - unplanned thaw, mislabelling, left out overnight, etc.) | | | | | | | | |

V6 - 30/11/2022

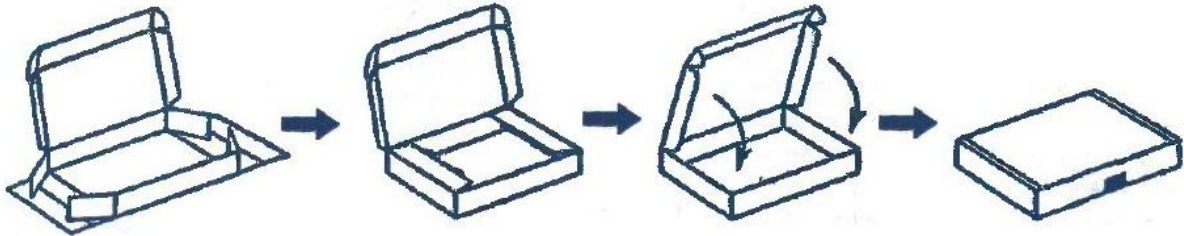
- Store at -20°C or colder until transported to the Co-ordinating Centre via dry-ice courier
- Do not forget to update CAPTURE

4. Sample shipments

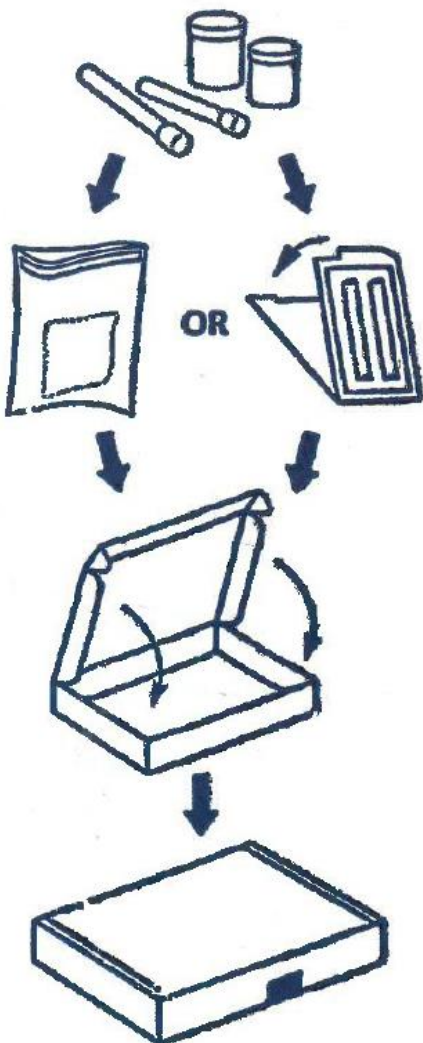
- All shipment manifests are handled electronically on CAPTURE.
- All samples are sent to the BSTOP Co-ordinating Centre on collection day, using the postal boxes provided.
- Follow the instructions at the back of the box for assembly and packaging, to insure compliance with UN3373 and P650 requirements and regulations.
- The amount of absorbent material provided is enough for shipping up to 50mL of blood – equivalent to 4 patients (8 tubes of 6mL each). Use more boxes as required if you need to post more samples.
- All samples coming to us, regardless of the study, can go in the same box (BSTOP, PLUM, A-STAR, BEACON, etc.), as long as the total amount is not more than 50mL.
- Make sure the box does not bulge once closed – this will ensure we are charged the correct price by Royal Mail.
- Boxes can be posted via your hospital post room, or dropped in any Royal Mail mailbox (the use of Post Office shops should be avoided as it will incur extra cost)
- Labels are provided – make a note of the Tracking ID before posting the samples. Labels should be applied at the back of the box (above assembly instructions) as to not cover the UN3373 markings.
- Make sure CAPTURE is updated to document the transfer (do not forget to report the Tracking ID)



Box Assembly



Sample Packing

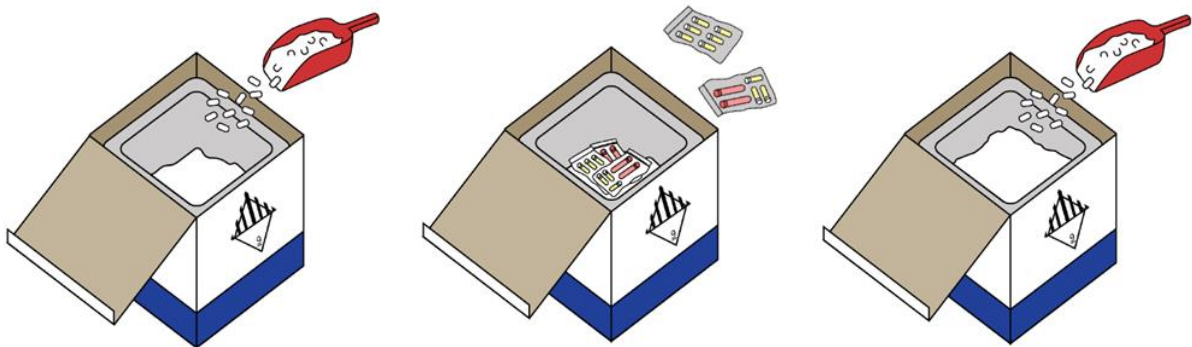


Place the samples in the 95kPa bag alongside the absorbent material. Follow the instructions on the bag to close it

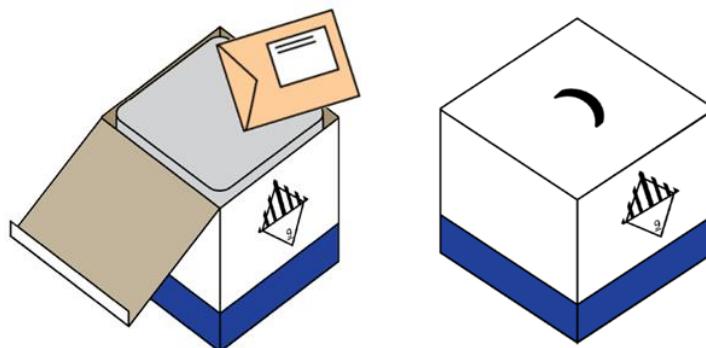
Close the box and apply the security seal

Apply label provided and post, and update CAPTURE

- The shipment method described previously does not apply to former PSORT-D sites (BE, GY, JE, KG, LD, LV, NE, PE, SR, WL, WM). In this case, the Co-ordinating Centre will be in touch once a year to organise a dry ice shipment of all the samples collected within the past 12 months. Sites can also request shipments before being contacted, e.g. in case of freezer failure or staff change.
- Dry ice and packaging will be delivered to your site by the courier on the shipment (you may request a 2-hour window), the courier will then give you enough time to package the samples before taking the box away.
- When packing samples, make sure all samples are buried in dry ice. It is important that samples are contained in plastic sample bags to ensure no samples get lost within the dry ice. Most of the dry ice should be placed over the samples rather than underneath them. This ensures samples stay frozen for longer.



- Always include the completed Sample Request Form for each sample. It is best to keep these forms separately in either an A4 envelope or plastic wallet and place them down the side between the thermal container and the shipping box, or on top of the lid of the thermal container.



- Make sure CAPTURE is updated to document the transfer.

5. List of supplies provided by the Co-ordinating Centre

- Blood tubes



K3 Crossmatch EDTA Vacuette™ tubes, ref. 456052

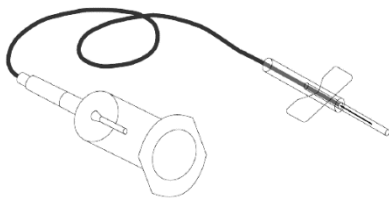
All sites



CAT serum gel Vacuette™ tubes, ref. 456018

Former PSORT-D sites only (~~BG~~, GY, ~~JE~~, ~~KE~~, LD, LV, NE, ~~PE~~, SR, WL, ~~WM~~)

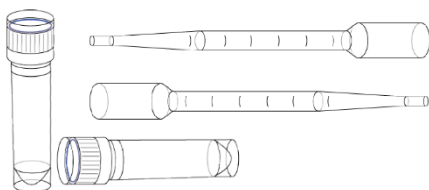
- Blood collection kits



Vacuette™ Safety Blood Collection Set 23Gx19cm or 21Gx19cm (ref. 450086 or 450085)

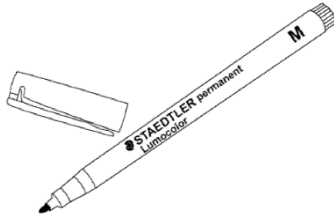
All sites

- Microtubes and pipettes



Former PSORT-D sites only (~~BG~~, GY, ~~JE~~, ~~KE~~, LD, LV, NE, ~~PE~~, SR, WL, ~~WM~~)

- Permanent fine tip marker



All sites

- Royal Mail shipment boxes



All sites except former PSORT-D sites

6. Study contact details

- Trial Management Team: Jade Pizzato
 - Jade.Pizzato@kcl.ac.uk
- Supplies & sample queries: David Baudry
 - David.Baudry@gstt.nhs.uk
 - David.Baudry@nhs.net – not monitored regularly, please notify of incoming emails to the GSTT email address above.
 - 0207 188 8203
- Data queries: Michael Duckworth
 - Michael.Duckworth@gstt.nhs.uk
- CAPTURE/database query: Tejus Dasandi
 - Tejus.Dasandi@gstt.nhs.uk
- Generic BSTOP email – for all queries or in case of out-of-office:
 - BSTOP@gstt.nhs.uk

Related documents:

- BSTOP DNA-only CAPTURE Training Manual
- BSTOP Former PSORT-D CAPTURE Training Manual
- BSTOP Sample Request Form DNA-only
- BSTOP Sample Request Form PSORTD
- BSTOP Site Training