

URINE COLLECTION

Background and Rationale

The Mr. OS Sleep study involves the collection of a urine specimen from each participant. Since the study depends on the voluntary return of participants over an extended period of time, every effort must be made to make the entire procedure as easy and painless as possible both for the participants and for the clinical center personnel. A standard informed consent has been prepared for this study.

Equipment and Supplies

Sample ID Labels

You will be supplied with sheets of sample ID barcode labels to use for labeling forms, draw tubes, cryovials and the shipping grid sheet. A sample sheet of barcode labels can be found in Appendix 1. All labels on each sheet have the same 6-digit sample ID number (the first two characters identify the clinic: BI = Birmingham, MN = Minneapolis, PA = Palo Alto, PI = Pittsburgh, PO = Portland, SD = San Diego). Each label contains a barcode with the ID and sample type embedded in the bar code.

There are 22 labels per participant, containing the ID number and specimen information. The labels identify the draw tubes (3), urine collection container (1), specimen collection Teleform (1), blood blotters (2), each of the cryovials (7) and the location on the shipping grid sheet (8).

Safety Issues and Exclusions

Participant Refusal to Provide Urine Sample

Rarely, a participant will refuse to provide a urine sample. Please mark on the Urine Collection & Processing Form to identify any of these participants.

Subject Preparation

Preparation of Participants for Urine Collection

Urine will be collected on all participants whenever possible. Collection is considered a 1st morning void urine collection. When scheduling the in-home polysomnography study, inform all participants that we will be collecting a urine specimen and we'd like to get the first void and participant will be given urine collection container, ZipLoc plastic bag, and instruction. Give participant a cooler if participant is not comfortable putting urine sample in the refrigerator. The participant should collect 1st void the morning after the in-home polysomnography study. After collection, participant should keep it refrigerated until the PSG equipment being picked up by clinic staff. When the specimen arrives at the clinic, it should be dealt with as quickly as possible so that it gets frozen within as close to the allotted time frame as possible.

If participants refuse or are uncertain about the polysomnography study, collect the urine samples while at the clinic and record which void the specimen is on the Urine Collection & Processing Form.

Participants may urinate directly into a specimen collection container. Containers for routine specimens should be chemically clean, should hold about 3 oz in volume, and must have a tight-fitting lid to prevent leakage during transportation to the lab.

Instructions for Participants:

The participant's privacy should be assured. He should perform the following steps:

1. Have all equipment ready.
2. Void directly into the collection container until half full.
3. Carefully seal the cap of the container so that it is tight and leak proof.

Detailed Procedures

Form

The purpose of the forms is to facilitate the collection of urine samples. The collection must be done in a rapid and efficient manner, with maximum protection for the participant. In addition, the process must facilitate all quality assurance parameters. All forms must be completed in ink. Please refer to the 'Scannable Forms Guidelines' protocol for more information.

Quality Assurance

Training Requirements

Clinical experience with phlebotomy is mandatory. Additional training should include:

- Read and study manual
- Attend Mr. OS Sleep training session on techniques (or observe procedure by experienced examiner)
- Discuss problems and questions with local expert or QC officer

Certification Requirements

- Complete training requirements

Quality Assurance Checklist

Preparation:

Proper instructions given for urine collection

Urine Collection & Processing Form properly filled out:

Date and time of urine collection recorded

Date and time of lab processing recorded
ID from barcode entered

LAB PROCESSING GUIDELINES

Equipment and Supplies

A complete supply list with ordering information can be found in Appendix 6. Necessary supplies include:

- -20° Freezer space is required
- Dry Ice
- Pipets and tips: 1.0 mL volumes
- Lab coat and gloves
- Biohazardous waste disposal container
- Lab mat
- 10% bleach solution
- Freezer boxes with 9 x 9 cell grid (for 1.8 mL and 4 mL serum and urine cryovials)
- Rubber bands

Sample ID Labels

Each cryovial label also has a 1-digit vial # (#1 to #7) that serves as a unique identifier for each cryovial with MrOS ID #. The labels for cryovials have bar codes to help track the repository. See Appendix 4 for proper orientation of the barcode label.

Beneath the ID number, cryovial labels also have lines of text: vial #, cap color, and type of specimen (serum or urine). This line of text is intended to increase accuracy in the labeling and filling of the cryovials.

There are a total of 22 labels for each participant. There is one label for the urine specimen cup.

Laboratory Room Preparation

All items that are required for sample processing should be on hand before processing starts.

Aliquot racks will be set up to correspond to each urine collection. Rack setup is completed the previous day. All tubes and vials are labeled with sample ID bar codes (see Label Orientation diagram in Appendix 4) and arranged in appropriate working order.

Detailed Procedures

Aliquots per Sample Type

The following is a summary of the processing. Detailed instructions follow (volume indicates sample size, not cryovial size). Please see Appendix 2 for a flow chart that illustrates this graphically.

Urine: The urine is aliquoted into two 4 mL samples, which are contained in 4.5 mL cryovials, numbered cryovial #6 and # 7.

Making Urine Aliquots

- Pipet 4.0 mL of urine into each of the two 4.5 mL capped cryovials and place on ice. (Yellow cap, cryovials # 6 and #7)
- Discard the remaining urine.

Freezing

Upon completion of the processing steps, urine aliquots must be frozen at -20° or on dry ice within 30 minutes.

After aliquoting is complete, the rack containing the cryovials should be removed from the ice bath and placed upright in the freezer at -20° C (or on dry ice or colder) for at least half an hour (preferably until the end of the day). Make sure the aliquots are not wet when placed in the freezer. If a freezer is not immediately available, place the rack of samples on dry ice.

End of the Day Procedures

- Frozen cryovials in racks are packaged into freezer boxes by numeric order of cryovials per participant. The cryovials will be placed into the boxes with the 9 x 9 grid. Do not leave empty spaces in the boxes. Do not put empty tubes in the boxes. Samples from one participant may overlap into two boxes, and each box will have samples from more than one participant. Complete the shipping grid sheet (see Appendix 8) for each box as the boxes are filled with specimens.

Separate the 4 mL serum and urine cryovials and 1 mL serum cryovials into different storage boxes. Use 3 inch tall storage boxes for 4 mL cryovials and 2 inch tall storage boxes for 1 mL cryovials.

- Wipe down all work areas with 10% Clorox solution.

Shipping the Blood and Urine Samples

General

Frozen blood and urine samples are shipped *bimonthly* to BRI by Federal Express overnight delivery. Do not ship on Thursdays or Fridays to avoid delivery of shipments during a weekend.

Shipments to BRI are charged to your local Federal Express account number.

This shipping protocol follows the procedures mandated by the International Air Transport Association's Dangerous Goods Regulations-Packaging Instructions 650 and 904.

Methods for shipping frozen samples

The frozen blood cryovials are already packaged in prelabeled freezer boxes and stored in the -20° C freezer by consecutive box number.

A grid sheet detailing the contents of the shipment will be completed as the samples are stored in the box. The grid will use bar code labels for each square.

Do not leave empty spaces in the boxes. Each box for shipment will contain samples from more than one participant. Additionally, a participant's samples may be shipped in two separate boxes. Separate the 4 mL cryovial and 1 mL cryovial into different storage boxes. Use 3 inch tall storage boxes for 4 mL cryovials and 2 inch tall storage boxes for 1 mL cryovials (see Appendix 5 for shipping grid sample).

Samples should be prepared for shipping as follows:

- Wrap each freezer box in absorbent strips to absorb possible leakage. Put a rubber band around the strip-wrapped box. Using two rubber bands, put a rubber band in each direction (horizontally and vertically), forming a cross with the rubber bands.
- Put the individual freezer boxes containing the samples into inner leakproof poly bag and then the outer envelop.
- Place approximately one third of the dry ice on the bottom of the mailer.
- Carefully place the freezer boxes into the styrofoam mailer. Place no more than a total of 4 L of sample into the styrofoam shipping container. Use two or more styrofoam mailers for the BRI shipment when necessary. (In this case, label the mailers "1 of 2" and "2 of 2").
- Place the remaining dry ice (approximately 7 - 14 lbs. total) on top and around the samples to fill the styrofoam container.
- Enclose the styrofoam container in the outer cardboard sleeve.
- Enclose the completed grid sheet with cryovial information and copies of the Blood Collection & Processing and Urine Collection Processing Forms. Carefully fold the completed grid to ensure that no bar codes are damaged by the fold. Folding between the labels is preferable.

The BRI mailing address is:

Chris Kennell
Biomedical Research Institute
12264 Wilkins Avenue
Rockville, MD 20852

FAX the following information to BRI at (301) 770-9811 when a shipment is sent:

Date of shipment
Expected arrival date
Number of styrofoam mailers shipped
FedEx airbill number

Quality Assurance

Training Requirements

- Read and study manual
- Attend Mr. OS Sleep training session on techniques (or observe processing by experienced examiner)
- Discuss problems and questions with local expert or QC officer

Certification Requirements

- Complete training requirements
- Recite shipping schedule.
- Process samples from volunteer or participant while being observed by QC officer using QC checklist.

Quality Assurance Checklist

Preparation

Aliquot racks correctly set up
Cryovials correctly labeled
Non-permeable lab coats, gloves, and face shields used

Processing urine

Urine correctly aliquoted

Freezing

Rack placed upright in -20° C freezer or samples placed on dry ice

End of day procedure

Frozen aliquots removed from rack and placed in appropriate freezer boxes
Freezer boxes correctly labeled

Shipment procedures -- dry ice

Freezer boxes correctly wrapped -- absorbent material, rubber band, and secondary pressure vessel system
Styrofoam mailers correctly packed -- absorbent material, dry ice, top sealed with tape
Grid and forms included in package

Styrofoam mailer sealed in cardboard sleeve
FedEx airbill correctly filled out
Labels correctly affixed