

Screening Phlebotomy Form: Processing and Inventory Instructions
SPP Version B, 5/19/2003
QxQ Date: 4/4/2004

I. GENERAL INSTRUCTIONS

The Screening Phlebotomy Form: Processing and Inventory (SPP) is completed during the screening visit. It is used to document data during blood processing and inventorying.

If the specimen processing is done by a laboratory, they must be certified and familiar with and understand the Specimen Collection and Processing, Chapter 6, of FAVORIT Manual of Operations (MOP). The appropriate sections of the paper form must be completed by the phlebotomist/laboratory (processor) during specimen processing and then recorded in the data entry system by the Study Coordinator at the completion of the day's activities, and when shipping occurs, respectively. If processing is done by the Study Coordinator, s/he must be certified and familiar with and understand the MOP Chapter 6, Specimen Collection and Processing, and Chapter 14, Administration Procedure, prior to completing this form.

The header information ID, Contact Occasion, Sequence Number, Name and Initials are completed as described in the MOP. Data related to storage and shipping must be appropriately recorded by the Study Coordinator. If the laboratory is processing the specimen, then they should receive the form with **only the patient's ID Number**, Contact Occasion and Sequence Number. The Study Coordinator should complete the patient's Name after the laboratory has completed the processing

II. SPECIFIC INSTRUCTIONS

Label tubes with the provided aliquot labels. If a label is missing or unusable, prepare a hand-printed label using a Sharpee permanent marker on blank specimen label stock provided by the DCC.

During this visit one lavender and one marble tube are collected. It is very important the correct shipping date be recorded (i.e., the actual date the tubes are shipped to the lab) because this date is used by the DMS to create the Shipping Log sent with the tubes.

To avoid elevated plasma homocysteine values and to ensure optimal retrieval of the buffy coat, sample should be centrifuged and processed within 45 minutes from time of collection.

1. Time of Centrifugation:
 - a. Record the time of centrifugation (hour: minute), filling in the fields using leading zeroes where necessary.
 - b. Record the time of day of centrifugation indicating AM or PM.

2. Placement of Aliquots in the Freezer:
 - a. Record the time aliquots were placed in the freezer (hour: minute), filling in the field using leading zeroes where necessary.
 - b. Record the time of day aliquots were placed in the freezer, indicating AM or PM.
3. Record Date of Processing (month/day/year).
4. Record processor's three digit initials. If s/he has only two initials, record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

Items 5-11 require recording data related to collecting, evidence of hemolyzed specimen, and storing of information on aliquots.

Aliquotting Information:

Upon completion of aliquotting, all tubes should be tightly capped and frozen; remaining cells should be discarded per OSHA standards. All processing should be completed within 4 hours of specimen collection. SAMPLES must be placed IMMEDIATELY into the freezer.

The lavender top tube, EDTA Additive (LT) 5 mL, is used to create LT1, LT2, LT3 and LT4 vials. The marble top tube, Serum (MT) 5 mL, is used to create MT1, MT2 and MT3 vials.

5. LT1 (tHcy) from Lavender Top Vacutainer #1, is used to measure Total Homocysteine (tHcy). 1000 µL is required for the sample aliquot.
 - a. If sample aliquot was collected even if less than the required volume, record "Yes" and go to item 5b. Otherwise record "No" and go to item 6a.
 - b. If the specimen has been hemolyzed, record "Yes" and go to item 5c. Otherwise record "No" and go to item 5c.
 - c. Record the date (month/date/year) when the LT1 is shipped. The specimens will be shipped weekly (Mondays) to the Central Lab located at the USDA Human Nutrition Research Center on Aging at Tufts University.

The LT1 tube must be stored at -80°C, shielded from light, and in an upright position until time of shipping.

6. LT2 (Archive) from Lavender Top Vacutainer #1, is used to collect a Plasma Specimen for the Archive. 1000 µL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record "Yes" and go to item 6b. Otherwise record "No" and go to item 7a.

- b. If the specimen was hemolyzed, record “Yes” and go to item 6c. Otherwise record “No” and go to item 6c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT2. The LT2 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.
- 7. LT3 (Buffy Coat) from Lavender Top Vacutainer #1, contains a specimen of White Blood Cells (Buffy Coat). Approximately 500 µL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 7c. Otherwise record “No” and go to item 8a.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT3. The LT3 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.
- 8. LT4 (RBCs) from Lavender Top Vacutainer #1, contains a specimen of Red Blood Cells (RBCs) for the Archive.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 8c. Otherwise record “No” and go to item 9a. 1000 µL is required for the sample aliquot.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT4. The LT4 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.
- 9. MT1 (Creatinine) from Marble Top Vacutainer #1, contains a specimen for measuring Creatinine. 750 µL is required for the sample aliquot.
 - a. If the MT1 vial was collected even if less than the required volume, record “Yes” and go to item 9b. Otherwise record “No” and go to item 10a.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 9c. Otherwise record “No” and go to item 9c.
 - c. Record the date (month/date/year) when the MT1 is shipped. See item 5c for specific instructions. The MT1 must be stored temporarily at -80°C, shielded from light, and in an upright position until time of shipping.
- 10. MT2 (Glucose) from Marble Top Vacutainer #1, contains a specimen for measuring Glucose. 750 µL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 10b. Otherwise record “No” and go to item 11a.

- b. If the specimen has been hemolyzed, record “Yes” and go to item 10c. Otherwise record “No” and go to item 10c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT2 . The MT2 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.
11. MT3 (Archive) from Marble Top Vacutainer #1, contains a serum for the Archive. 1000 µL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 11b. Otherwise record “No”.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 11c. Otherwise record “No” and go item 11c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT3. The MT3 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.

Blind Replicate Matching (BRM) Instructions

Items 12 through 20 refer to Blind Replicate Matching (BRM) specimens used for quality control. These are specimens processed from extra tubes drawn from participants and labeled with a BRM ID assigned by the DCC. This extra tube must be the last tube drawn from the participant. Never perform a second stick to obtain a BRM; instead obtain the BRM tube from the next appropriate participant. The BRM specimens are stored and shipped along with regular specimens. See MOP chapter 11, for more information.

When it is time for a site to start a BRM collection for a screening clinic visit, the DCC will email a BRM notification and an BRM ID sheet which contains the BRM ID to be used as well as the contact occasion for which samples are required. When you have been notified to do a blind replicate, a complete set of duplicate vials must be created and labeled using the BRM ID. Only one extra tube of blood may be drawn from a participant, therefore multiple participants will need to donate an extra tube each to complete the blind replicate matching. Each of the participants will have the items 12 through 20 entered in their respective SPP forms; all will show the same BRM ID in item #13. For example, at the screening visit two participants will be used to complete the BRM, one will have data for the lavender top tube, and the other will have data for the marble top tube.

The following is an example of a BRM request and collection scenario:

- The clinic is sent an email containing a blind replicate matching notification request and a BRM ID sheet. The notification sheet and ID sheet contain the BRM ID (e.g.

- WU12343) that should be used for these BRM samples. The notification sheet indicates that screening visit BRM specimens are requested
- Screening ID labels are mailed to clinic for BRM WU12343
 - The coordinator sees on his/her schedule that Susan P., a screening participant is due in today
 - The coordinator takes one extra lavender tube of blood from Susan P. and puts the BRM label (WU12343) on the extra lavender top tube (note the extra tube should be the last tube drawn)
 - The coordinator processes the extra BRM lavender top tube along with the participant's study lavender tube (aliquots it into 4 vials)
 - Susan P.'s ID label (e.g., WU24680) is placed on the BRM ID sheet under lavender top tube #1 for the screening visit to keep track of which participant donated which specimen
 - The coordinator puts a check mark on the notification sheet under lavender top tube #1 for the screen contact
 - When Susan P.'s SPP is completed, the section on BRM (SPP items 12-20) is completed to reflect the processing of the BRM tube

NOTE: Susan P.'s screening specimens will be shipped to the FAVORIT laboratory following the standard schedule. Since the screening BRM is incomplete (marble top tube is not yet available), vial LT1 must be stored until a screening BRM MT1 vial is prepared. Once the screening BRM is complete, both LT1 and MT1 vials can be shipped to the central lab.

- The following week, Fred Z. comes in for his screening visit
 - The coordinator takes one extra marble top tube from Fred Z. (last tube drawn) and puts the same BRM ID (WU12343) label on the extra marble tube
 - The coordinator processes the extra BRM marble top tube along with the participant's study marble top tube.
 - Fred Z.'s ID label (e.g., WU13579) is placed on the BRM ID sheet under marble top tube for the screen visit
 - The coordinator puts a check mark on the notification sheet under marble top
 - When Fred Z.'s SPP is entered, the section on BRM (SPP items 12-20) is completed to reflect the processing of the BRM tube
- This completes one SCREENING Blind Replicate Matching.

SPP ITEMS 12-20 BRM

12. Record whether a BRM tube was collected and processed from the participant. If “No”, data entry for the form is complete.
13. Record the BRM ID used to label the tube and the set of BRM aliquot vials being prepared. This ID is assigned by the DCC and sent with the BRM notification sheet and ID sheet.

BRM Aliquotting

Follow the same aliquotting procedures for items 14 – 20 on this form as was done for items 5 – 11. If a replicate lavender tube was collected from this participant, complete sections 14 through 20, answering ‘NO’ to questions on processing of the marble tube (questions 18-20). Likewise, if the replicate marble tube was collected from this participant, complete section 14 through 20, answering ‘NO’ to the questions on the processing of the lavender tube (questions 14-17).

14. LT1 (tHcy) from Lavender Top Vacutainer #1, is used to measure Total Homocysteine (tHcy). 1000 µL is required for the sample aliquot.
 - a. If sample aliquot was collected even if less than the required volume, record “Yes” and go to item 14b. Otherwise record “No” and go to item 15a.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 14c. Otherwise record “No” and go to item 14c.
 - c. Record the date (month/date/year) when the LT1 is shipped. The specimens will be shipped along with regular specimens weekly (Mondays) to the Central Lab located at the USDA Human Nutrition Research Center on Aging at Tufts University.

The LT1 tube must be stored at -80°C, shielded from light, and in an upright position until time of shipping.

15. LT2 (Archive) from Lavender Top Vacutainer #1, is used to collect a Plasma Specimen for the Archive. 1000 µL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 15b. Otherwise record “No” and go to item 16a.
 - b. If the specimen was hemolyzed, record “Yes” and go to item 15c. Otherwise record “No” and go to item 15c.

- c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT2. The LT2 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position. BRM specimens are stored along with participant study specimens of the same vial type.
16. LT3 (Buffy Coat) from Lavender Top Vacutainer #1, contains a specimen of White Blood Cells (Buffy Coat). Approximately 500 μL is required for the sample aliquot.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 16c. Otherwise record “No” and go to item 17a.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT3. The LT3 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position. BRM specimens are stored along with participant study specimens of the same vial type.
17. LT4 (RBCs) from Lavender Top Vacutainer #1, contains a specimen of Red Blood Cells (RBCs) for the Archive.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 17c. Otherwise record “No” and go to item 18a. 1000 μL is required for the sample aliquot.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT4. The LT4 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position. BRM specimens are stored along with participant study specimens of the same vial type.
18. MT1 (Creatinine) from Marble Top Vacutainer #1, contains a specimen for measuring Creatinine. 750 μL is required for the sample aliquot.
- a. If the MT1 vial was collected even if less than the required volume, record “Yes” and go to item 18b. Otherwise record “No” and go to item 19a.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 18c. Otherwise record “No” and go to item 18c.
 - c. Record the date (month/date/year) when the MT1 is shipped. See item 14c for specific instructions. The MT1 must be stored temporarily at -80°C , shielded from light, and in an upright position until time of shipping.
19. MT2 (Glucose) from Marble Top Vacutainer #1, contains a specimen for measuring Glucose. 750 μL is required for the sample aliquot.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 19b. Otherwise record “No” and go to item 20a.

- b. If the specimen has been hemolyzed, record “Yes” and go to item 19c. Otherwise record “No” and go to item 19c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT2 . The MT2 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position. BRM specimens are stored along with participant study specimens of the same vial type.
20. MT3 (Archive) from Marble Top Vacutainer #1, contains a serum for the Archive. 1000 µL is required for the sample aliquot.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 20b. Otherwise record “No” and stop; this is the end of data collection for the form.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 11c. Otherwise record “No” and go item 20c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT3. The MT3 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position. BRM specimens are stored along with participant study specimens of the same vial type.

Screening Phlebotomy Form: Processing and Inventory Instructions
SPP Version A, 11/05/01
QxQ Date: 06/10/2002

I. GENERAL INSTRUCTIONS

The Screening Phlebotomy Form: Processing and Inventory (SPP) is completed during the Screening Visit. It is used to document data during the blood processing and inventorying process.

If the specimen processing is being done by a Laboratory, they must be familiar with and understand the Specimen Collection and Processing, Chapter 6, of FAVORIT Manual of Operations (MOP). The appropriate sections of the paper form must be completed by the Phlebotomist/Laboratory (processor) during specimen processing and then recorded in the data entry system by the Study Coordinator at the completion of the day's activities, and when shipping occurs respectively. If processing is being done by the Study Coordinator, s/he must be certified and familiar with and understand the Specimen Collection and Processing Chapter 6, and the Administration Procedure, Chapter 14, in the Manual of Operations, prior to completing this form.

The header information ID, Contact Occasion, Sequence Number, Name and Initials are completed as described in the MOP. Data related to storage and shipping must be appropriately recorded by the Study Coordinator. If the Laboratory is processing the specimen, then they should receive the form with only the patient's ID Number, Contact Occasion and Sequence Number. The Study Coordinator should complete the patient's Name and ID after the laboratory has completed the processing

II. SPECIFIC INSTRUCTIONS

Label tubes with the provided aliquot labels. If a label is missing or unusable, prepare a hand-printed label using a Sharpee Permanent Marker on the blank specimen label stock provided by the DCC.

During this visit one lavender and one marble tube will be collected. It is very important that the correct shipping date be recorded (i.e., the actual date the tubes are shipped to the lab) because this date is used by the DMS to create the Shipping Log that will accompany the tubes.

In order to avoid elevated plasma homocysteine values and to ensure optimal retrieval of the buffy coat, sample should be centrifuged and processed within 45 minutes from time of collection.

1. Time of Centrifugation:
 - a. Record the time of centrifugation (hour: minute), filling in the fields using leading zeroes where necessary.
 - b. Record the time of day of centrifugation indicating AM or PM.
2. Placement of Aliquots in the Freezer:
 - a. Record the time aliquots were placed in the freezer (hour: minute), filling in the field using leading zeroes where necessary.
 - b. Record the time of day that aliquots were placed in the freezer, indicating AM or PM.
3. Record Date of Processing (month/day/year).
4. Record processor's three digit initials. If he/she has only two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

Items 5-11 require recording data related to collecting, evidence of hemolyzed specimen, and storing of information on aliquots.

Aliquotting Information:

Upon completion of aliquotting, all tubes should be tightly capped and frozen; remaining cells should be discarded following OSHA standards. All processing should be completed within 4 hours of specimen collection. SAMPLES must be placed IMMEDIATELY into the freezer.

The lavender top tube, EDTA Additive (LT) 5 mL, is used to create LT1, LT2, LT3 and LT4 vials. The marble top tube, Serum (MT) 5 mL, is used to create MT1, MT2 and MT3 vials.

5. LT1 (tHcy) from Lavender Top Vacutainer #1, is used to measure Total Homocysteine (tHcy). 1000 µL is required for the sample aliquot.
 - a. If sample aliquot was collected even if less than the required volume, record "Yes" and go to item 5b. Otherwise record "No" and go to item 6a.
 - b. If the specimen has been hemolyzed, record "Yes" and go to item 5c. Otherwise record "No" and go to item 5c.

- c. Record the date (month/date/year) when the LT1 is shipped. The specimens will be shipped weekly (Mondays) to the Central Lab located at the USDA Human Nutrition Research Center on Aging at Tufts University.

The LT1 tube must be stored at -80°C , shielded from light, and in an upright position until time of shipping.

- 6. LT2 (Archive) from Lavender Top Vacutainer #1, is used to collect a Plasma Specimen for the Archive. 1000 μL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 6b. Otherwise record “No” and go to item 7a.
 - b. If the specimen was hemolyzed, record “Yes” and go to item 6c. Otherwise record “No” and go to item 6c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT2. The LT2 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position.
- 7. LT3 (Buffy Coat) from Lavender Top Vacutainer #1, contains a specimen of White Blood Cells (Buffy Coat). Approximately 500 μL is required for the sample aliquot.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 7c. Otherwise record “No” and go to item 8a.
 - b. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT3. The LT3 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position.
- 8. LT4 (RBCs) from Lavender Top Vacutainer #1, contains a specimen of Red Blood Cells (RBCs) for the Archive.
 - a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 8c. Otherwise record “No” and go to item 9a. 1000 μL is required for the sample aliquot.
 - b. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the LT4. The LT4 must be stored on site at -80°C , in the yellow storage boxes, with aliquots in an up-right position.
- 9. MT1 (Creatinine) from Marble Top Vacutainer #1, contains a specimen for measuring Creatinine. 750 μL is required for the sample aliquot.

- a. If the MT1 vial was collected even if less than the required volume, record “Yes” and go to item 9b. Otherwise record “No” and go to item 10a.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 9c. Otherwise record “No” and go to item 9c.
 - c. Record the date (month/date/year) when the MT1 is shipped. See item 5c for specific instructions. The MT1 must be stored temporarily at -80°C, shielded from light, and in an upright position until time of shipping.
10. MT2 (Glucose) from Marble Top Vacutainer #1, contains a specimen for measuring Glucose. 750 µL is required for the sample aliquot.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 10b. Otherwise record “No” and go to item 11a.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 10c. Otherwise record “No” and go to item 10c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT2 . The MT2 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.
11. MT3 (Archive) from Marble Top Vacutainer #1, contains a serum for the Archive. 1000 µL is required for the sample aliquot.
- a. If the specimen was collected even if less than the required volume, record “Yes” and go to item 11b. Otherwise record “No”.
 - b. If the specimen has been hemolyzed, record “Yes” and go to item 11c. Otherwise record “No” and go item 11c.
 - c. Using leading zeroes, record the three-digit number of the box that is used for long term storage of the MT3. The MT3 must be stored on site at -80°C, in the yellow storage boxes, with aliquots in an up-right position.