HALT-C Trial Q x Q

QLFT AS Aliquot Form

Form # 193 Version A: 06/15/2000 (Rev. 06/30/2004)

Purpose of Form #193: The QLFT AS Aliquot form should be used to detail the specimens collected for the QFLT AS that will be sent to the Central Repository (BBI). This form should be completed in addition to the aliquot form specific for the regular study visit.

Data entry of this form for a patient visit is the first step of the shipping and tracking procedures for HALT-C. All of the specimens will go into a database of specimens available for shipment to the Central Repository for your clinical center. Entry of this form also allows NERI to link the HALT-C Trial ID's and study visits with the Sample ID assigned by the Central Repository.

When to complete Form #193: This form is completed for all patients participating in the QLFT Ancillary Study at the following clinical sites.

- Site 15 (University of California - Irvine).
- Site 19 (Virginia Commonwealth University).

The clinical centers should complete and data enter form #193 for patients at the following study visits:

- Lead-In Phase patients: Baseline visit (W00)
- Express patients: Randomization visit (R00)
- Randomized patients: Month 24 (M24) and Month 48 (M48).

Form #193 is not completed for specimens collected at the Site 14 (University of Colorado Health Sciences Center) because these specimens are not shipped to the BBI Repository.

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit.

A4. Record the date the form was completed using MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: BSI ID

B1. Record the BSI ID from the aliquot tube. The BSI ID begins with the letter "D", followed by a second letter corresponding to the study site, followed by six numbers. The BSI ID is used by NERI and BBI to identify specimens by patient and study visit.

The BSI ID also appears on the shipping manifest received from the BBI Repository in the column named "bsi_id". On the shipping manifest, the BSI ID is followed by a three-digit sequence number, which does not need to be recorded on the paper form.

B2. Record the date of the specimen collection using the MM/DD/YYYY format. This must be the same date that the specimen was aliquotted and frozen.

SECTION C: SPECIMEN INFORMATION

C1. Please indicate if there were any problems or delays in specimen processing in C1.
- If there was a delay of > 4 hours or problems with specimen processing, circle 1 for "Yes".
- If serum was separated within 2-4 hours of collection with no problems, circle 2 for "No".

C2. If the answer for C2a is "No", circle 2 and skip to the sequence number in the next row. If the answer for C2a is "Yes", circle 1 and follow the directions below.

If C1 = 1 (Yes) and C2a = 1 (Yes)
- Columns C2b, C2c, and C2d must be completed.
- Column C2b must list the total volume in ml of the sample in the cryovial.
- Column C2c must list one of the codes for specimen processing listed in the box below.
- Column C2d must list the data that processing of the sample was completed.

If C1 = 2 (No) and C2a = 1 (Yes)
- Only Column C2b must be completed. Enter the total volume in ml of the sample in the cryovial.

Codes for specimen processing

1. okay
2. hemolysis
3. delay in processing-processed within 4-6 hours of collection
4. delay in processing-processed within 6-8 hours of collection
5. delay in processing-processed within 8-12 hours of collection
6. delay in processing-processed within 12-18 hours of collection
7. delay in processing-processed within 18-24 hours of collection
8. delay in processing-processed within 24-48 hours of collection
9. delay in processing-processed 48+ hours after collection
10. delay in shipping
11. collected in incorrect tube-plasma collected instead of serum
12. delay in snap freezing liver tissue
13. Vacutainer tube stored in refrigerator
99. Other-please specify