HALT-C Trial Q x Q

Serum Fibrosis Marker AS Aliquot Form

Form # 102 Version A: 06/15/2000 (Revised 05/11/2006)

Purpose of Form #102: The Serum Fibrosis AS Aliquot form is used to record the specimens collected for the Serum Fibrosis Marker Ancillary Study that will be sent to the Central Repository (BBI).

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 entered as being collected on this form 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 #102: Form #102 should be completed in addition to the aliquot form specific for the regular study visit. Form #102 will be completed and data entered for patients participating in the Serum Fibrosis Marker Ancillary Study at the following clinical sites. Lead-In patients are eligible for this Ancillary Study. Express patients are not eligible for this Ancillary Study.

- Site 11 (University of Massachusetts / University of Connecticut).
- Site 13 (Massachusetts General Hospital).
- Site 19 (Virginia Commonwealth University).

Form #102 should not be completed for specimens collected at Site 18 (University of Michigan) because specimens will not be shipped to the Repository.

Form #102 should not be completed for patients who had a liver transplant.

Form #102 should be completed at the following study visits:

- Lead-in phase: Baseline (W00) and Week 24 (W24).
- Responder phase: Week 48 (W48) and Week 72 (W72).
- Breakthrough/Relapsers: Randomization (R00) visit.
- Randomization phase: Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).

SECTION A: GENERAL INFORMATION

A1. Affix a patient ID label in the space provided at the top of each page. If a label is not available, record the ID number legibly in ink.

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

A3. Record the visit number for this visit.

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

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

SECTION B: SAMPLE ID

At each visit, select the next available label packet supplied by the DCC or BBI. There are label packets for Screen 1, Screen 2, and each of Lead-In Phase, Randomized and Week 20 responder study visits.

B1. Record the sample ID for this patient and this visit in the space provided. An extra aliquot label from the label packet used for this patient may be placed on the form. If the label is not available, record the sample ID number legibly.

BBI and the DCC rely on the Sample ID as a link between the patient ID, the study visit, and location of collected specimens. It is very important that Sample ID is recorded and data entered accurately.

B2. Record the collection date in the MM/DD/YYYY format for the specimens to be aliquotted for shipment to BBI.

SECTION C: SPECIMEN INFORMATION

C1. Indicate if there were any problems or delays in specimen processing in C1.

Circle "No" for C1 if serum was separated within 2-4 hours of collection.
- Questions C2a and C2b must be completed for each aliquotted specimen.
- Questions C2c and C2d do not need to be completed.

Circle "Yes" for C1 if there was a problem with specimen processing.
- Questions C2a, C2b, C2c, and C2d must be completed for each aliquotted specimen.
- Question C2c should be completed with one of the codes for specimen processing listed in the code box at the end of the form (below).

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