HALT-C Trial

Lead in Phase Aliquot Form

Form # 72 Q x Q Version B: 08/20/2001

Purpose of Form #72: The Lead in Phase Aliquot form should be used to record specimens collected for a Lead-In Phase visit that will be sent to the Central Repository (BBI). Specimens that will be tested at local labs are not recorded on this form.

Data entry of Form #72 adds specimens to the HALT-C shipping database. The DMS uses this database to track all specimens and compile future shipments from the clinical centers to the central repository and to track what specimens should be in the freezer at the clinical site.

When to complete Form #72: This form should be completed following processing and aliquotting of specimens for each Lead in phase visit: Baseline (W00) through Week 24 (W24).

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 code corresponding to this visit.

A4. Record the date the form was completed in 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. Labels contain the patient ID, visit number, sample ID, and sequence number.

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 patients 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 date when the blood sample was collected using MM/DD/YYYY format.

SECTION C: SPECIMEN INFORMATION

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

Circle "No" for C1 if there were no problems with specimen processing.
- Questions C2a-b must be completed for each aliquotted specimen.
- Questions C2c-d do not need to be completed.

Circle "Yes" for C1 if there was a problem with specimen processing.
- Questions C2a-d 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 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

General Instructions on using spare sequence numbers:

Extra frozen serum collected.
If extra frozen serum was collected, use the spare ID sequence numbers 123 and/or 124.