

# HALT-C Trial

## Repeat AFP Aliquot

Form # 75 Q x Q Version A: 6/15/00

**Purpose of this form:** This aliquot form should be used to document the repeat AFP specimens that will be sent to the Central Repository. The results for the repeat AFP are entered into Form # 36 at NERI. The centers should also receive the results via email from the Repository. The centers can also print out the AFP report from the DMS to use as a source document. The following outlines when AFP's can be repeated at the study visits. For more clarification, refer to section C.2 (HCC Screening) of the Protocol Appendix.

<b>SCREENING</b>	If initial AFP results are out of range, then the AFP can be repeated a second time. If AFP > 200, then the patient must be excluded from the study.
<b>LEAD-IN</b>	If abnormal findings are detected, then refer to the HCC Screening guidelines.
<b>RANDOMIZATION</b>	If abnormal findings are detected, then refer to the HCC Screening guidelines.

**When to complete this form:** This form should be completed following processing and aliquotting of the repeat AFP specimen. Data entry of Form # 75 is the first step of the shipping and tracking procedures. When this form has been data entered, the specimen will be recorded as collected and will go into a database of specimens available for shipment to the Repository for your clinical center. Entry of this form also allows NERI to link up the HALT-C Trial ID's and study visits with the Sample ID assigned by the Repository.

**Shipping Procedures:** When you are ready to prepare a frozen shipment, specimens included on data entered Form # 75 will appear in the shipping database as being available for shipment. Please refer to section C (Specimen Shipping and Tracking) in the Manual of Operations (MOO) for complete information on use of the shipping database. If the shipment has been successfully finalized, an automated email is sent to the Repository and NERI, alerting them that the AFP specimen is on route. For more clarifications on shipping to the Repository, refer to section E (Specimen Collection, Processing & Shipping) and section C (Data management) in the MOO.

### **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 of this visit.
  - When entering this date, use the MM/DD/YYYY format.
  - Enter the 2 digit number for the month in the first 2 spaces provided (i.e., January = "01", February = "02", etc.), the 2 digit number for the day of the month in the second 2 spaces provided, and the 4 digit number for the year in the final 4 spaces provided.
- A5. Enter the initials of the person completing the form.
  - Enter the first initial in the first space provided, middle initial in the second space provided and the last initial in the third space provided.
  - If the person does not have a middle name, enter the first initial in the first space provided, leave the second space blank, and enter the last initial in the third space provided.

- If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the last space.

### **SECTION B: SAMPLE ID**

- B1. For every repeat AFP at a given visit, you should select one aliquot label/sample ID label from the sheet of repeat AFP labels supplied by the Repository.

Please record the sample ID specific for this patient and this visit in the space provided. Please note that once a specimen is shipped to the Repository, NERI will rely on the information entered for this question to link up all data and information on location of this specimen with the HALT-C Trial ID and study visit. It is very important that this information be recorded and data entered accurately.

- B2. Please record the collection date for the specimen to be aliquotted for shipment to the Repository.

### **SECTION C: SPECIMEN INFORMATION**

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

- If serum was separated within 2-4 hours of collection please circle No for C1.
- If No is circled, please indicate in questions a and write in the volume aliquotted in question b.

If there was a problem with specimen processing, please circle Yes for C1.

- Questions a, b, c + d must be completed.
- Question c should be completed with one of the codes for specimen processing listed in the code box at the end of the form.

Serum collected for this visit can be frozen at  $-20^{\circ}\text{C}$  or  $-70^{\circ}\text{C}$  prior to batch shipment to THE REPOSITORY.

The AFP specimen collected at the various study visits is listed in C2.

- The sequence number for this specimen is 129.