

HALT-C Trial Q x Q

CTL Liver Aliquot Form

Form #271 Version A: 06/15/2000

Purpose of Form #271: The CTL Liver Aliquot form documents the liver that is being sent to Dr. Margaret Koziel's or Dr. Alan Rothman's CTL laboratories for the Cytotoxic T Lymphocyte sub-study of the Immunology/Virology Ancillary Study.

When to complete Form #271: This form is completed following processing and aliquoting of Immunology/Virology Ancillary Study specimens at the following clinical sites. Lead-In patients are eligible for this Ancillary Study. Express patients are not eligible.

- Site 11 (University of Massachusetts / University of Connecticut).
- Site 12 (Saint Louis University).
- Site 16 (University of Texas Southwestern).
- Site 17 (University of Southern California).

Form #271 should be completed when fresh liver tissue is collected for the CTL sub-study at the Screening (S00), Month 24 (M24), and Month 48 (M48) study visits.

Form #271 is data entered at the clinical sites. Data entry of Form #271 must be done prior to shipment of fresh liver to the CTL laboratories. Data entry of this form allows the receiving laboratory and the DCC to track the shipment and receipt of the specimens.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the patient 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 specimen was collected and shipped in MM/DD/YYYY format.
- A5. Record the initials of the person completing the form.

SECTION B: COLLECTION DATE

- B1. Record the date of the liver biopsy in MM/DD/YYYY format. The fresh liver sample must be processed and shipped in media on the same date as the biopsy. Shipments must be sent via overnight Federal Express.

SECTION C: SPECIMEN INFORMATION

C1. If liver was collected for the CTL sub-study, the answer for C1a is “Yes”. Circle 1 and complete Column C1b. Enter the total length of the sample cm.

If liver was not collected for the CTL sub-study, the answer for C1a is “No”. Circle 2 and the Form is complete.

Shipping and Receiving Procedures: When you have data entered Form #271 and are ready to prepare the CTL fresh liver shipment; the specimens will appear in the LP/CTL Shipment Database as being available for shipment. The LP/CTL shipping database is similar to the Main Trail shipping database. Please refer to section C (Specimen Shipping and Tracking) in the Manual of Operations (MOO) for complete information on general use of the HALT-C shipping database. The liver must be batch overnight shipped in media at ambient temperature to the designated laboratory.

When the CTL shipment has been successfully finalized in the DMS, an automated email is sent to the receiving Laboratory and the DCC. The subject heading for this email will read: **Site 1X HALTC Automate Specimen Tracking batch#000 type: CTL Liver.**

The receiving laboratory **must Reply All** to the automated email informing NERI and shipping clinical site that the shipment has been received. The subject heading should be changed to read: **Batch #: 000: type; Liver; received MM/DD/YYYY; condition OK.**