

## HALT-C Trial Q x Q

### CTL Serum Aliquot Form

Form #270 Version A: 06/15/2000 (Revised 07/10/2003)

**Purpose of Form #270:** The CTL Serum Aliquot form documents the fresh serum 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 #270:** Form #270 should be completed for serum collected at the Screening (S00) study visit. This form is completed following processing and aliquoting of CTL serum 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 #270 is data entered at the clinical sites. Data entry of Form #270 must be done prior to shipment of fresh serum 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 (S00).
- 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 blood draw in MM/DD/YYYY format. The samples must be processed and shipped on the same date as the blood draw. Shipments must be sent via overnight Federal Express at room temperature.

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

- C1. Up to five 10 ml EDTA Vacutainer tubes can be prepared with fresh serum stored at room temperature. For each tube, fill out one row of the table.

If the answer for C1a is "Yes", circle 1 and complete Column C1b. Enter the total volume of the sample in the Vacutainer tube in ml. If the answer for C1a is "No", circle 2 and skip to the next row. If you are on the final row, the Form is complete.

**Shipping and Receiving Procedures:** When you have data entered Form #270 and are ready to prepare the CTL fresh serum 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 serum must be batch shipped 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 Serum.**

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; serum; received MM/DD/YYYY; condition OK.**