

## HALT-C Trial Q x Q

### Cytotoxic T Lymphocyte Assay - Immunology/Virology AS

Form # 170 Version A: 06/15/2000

**Purpose of Form #170:** This form is used to record the results of the Cytotoxic T Lymphocyte (CTL) assay tested at the University of Massachusetts laboratory of Dr. Alan Rothman and the Beth Israel Deaconess Medical Center Boston laboratory of Dr. Margaret Koziel.

**When to complete Form #170:** This form is completed for all patients participating in the Cytotoxic T Lymphocyte sub-study of the Immunology/Virology Ancillary Study at the following clinical sites. Lead-In patients are eligible for this Ancillary Study. Express patients are not eligible for the Immunology/Virology Ancillary Study.

- 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).

The CTL laboratories should complete form #170 for patients at the following study visits:

- **Screening Phase:** Screening (S00) visit for Lead-In patients.
- **Lead-In Phase:** Form not completed during this phase.
- **Responder Phase:** Form not completed during this phase.
- **Randomized Phase:** Month 24 (M24) and Month 48 (M48) visit for Lead-In, Breakthrough, and Relapser patients.

**How to access Form #170:** Data entry of this form will take place at the CTL laboratories. In order to data enter Form #170, NERI must set up a special data entry account for your user name.

In order to access Form #170, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 170". Enter the HALT-C patient ID number and the visit number in the appropriate boxes. Click the "Submit" button. A data entry screen for Form #170 will appear.

- The patient ID will begin with 11 (UMASS/UCONN), 12 (SLU), 16 (UTSW), or 17 (USC).
- Valid visit numbers are S00, M24, and M48.

After you have data entered the entire form, it will be saved in the system. You may perform edits to the form by following the same directions above for the given patient.

**Note on form completion and data entry:**

- Forms must be completed in black ink. Pencil is not acceptable. Blue ink does not photocopy well.
- Corrections are made by drawing a single line through the errant data and writing in the correct data. You must initial and write the date you make any change.
- When a result will not completely fill the blank spaces, use a "0" to fill the space.
  - If a result of 592 has space for 4 digits, write in: 0 5 9 2
  - If a result of 3.647 has space for 5 digits, write in: 3 . 6 4 7 0

- If data was not collected or not analyzed, write in “ND” or “not done” on the hard copy of the form. When data entering the form, enter the special value “-9” in the DMS. An error message will now appear on your screen.
  - If the value will never be obtained in the future, type a concise explanation in the "Reason" box. Enter your initials in the space provided and click on the “Set Override” button.
  - If the value may be obtained in the future, click on the “Ignore Value” button. An edit report will be generated after the rest of the form is entered. The form will have a “Pending Edits” status until the value is completed and data entered, or determines to be unobtainable and an override "Reason" provided.

**SECTION A: GENERAL INFORMATION**

- A1. Record the ID number legibly.
- A2. Enter the patient's initials exactly.
- A3. Enter the three-digit 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: ASSAY LAB AND STATUS**

- B1. Record the laboratory that is performing this CTL assay. Enter “1” for Dr. Margaret Koziel’s lab and “2” for Dr. Alan Rothman’s lab.
- B2. Record whether it was possible to perform the CTL assay. If it was possible to perform the assay, circle “1” and skip to question C1. If it was not possible to perform the CTL assay, circle “2” and continue to question B3.
- B3. Record why it was not possible to perform the CTL assay. If the two reasons provided do not adequately explain why the assay could not be performed, then circle “99” and specify the reason in the space provided. 60 characters (including spaces and punctuation) are available. The form is complete.

**SECTION C: ASSAY RESULTS**

- C1. Enter the date the assay was done in MM/DD/YYYY format.
- C2. Target 1: vvLacZ.
- C2a. Record if Target 1: vvLacZ was included in the CTL assay. If “yes”, then answer questions C2b, C2c, C2d, and C2e. If “no”, then skip to question C3a.
- C3. Target 2: 9A(CE-1).
- C3a. Record if Target 2: 9A(CE-1) was included in the CTL assay. If “yes”, then answer questions C3b, C3c, C3d, and C3e. If “no”, then skip to question C4a.
- C4. Target 3: vsc11(c-NS2).
- C4a. Record if Target 3: vsc11(c-NS2) was included in the CTL assay. If “yes”, then answer questions C4b, C4c, C4d, and C4e. If “no”, then skip to question C5a.
- C5. Target 4: 1H(E2-NS2).
- C5a. Record if Target 1: 1H(E2-NS2) was included in the CTL assay. If “yes”, then answer questions C5b, C5c, C5d, and C5e. If “no”, then skip to question C6a.
- C6. Target 5: vsc-59(E2-NS3).
- C6a. Record if Target 5: vsc-59(E2-NS3) was included in the CTL assay. If “yes”, then answer questions C6b, C6c, C6d, and C6e. If “no”, then skip to question C7a.
- C7. Target 6: vv-827-3011.
- C7a. Record if Target 6: vv-827-3011 was included in the CTL assay. If “yes”, then answer questions C7b, C7c, C7d, and C7e. If “no”, then skip to question D1.

**SECTION D: ADDITIONAL COMMENTS**

Please use the space provided to record any additional comments or findings. 200 characters (including punctuation and spaces) are available. Please be sure to write legibly and provide as much detail as possible. If there are no additional comments, record “not applicable” on the paper form and data enter a code of “-1” in the DMS.