

HALT-C Trial Q x Q

Lymphoproliferation - Immunology/Virology AS

Form # 173 Version D: 02/12/2004

Purpose of Form #173: This form is used to record the results of the Lymphoproliferation (LP) assay at the University of Washington (Central Laboratory).

When to complete Form #173: This form is completed for patients participating in the Lymphoproliferation 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).

Form #173 should be completed for participating patients at the following study visits:

- **Screening Phase:** Form not completed during this phase.
- **Lead-In Phase:** Baseline (W00) and Week 24 (W24) visits.
- **Responder Phase:** Form not completed during this phase.
- **Breakthrough/Relapser Patients:** Randomization (R00) visit.
- **Randomized Phase:** Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54) for Lead-In, Breakthrough, and Relapser patients.

How to access Form #173: Data entry of this form will take place only at the University of Washington (Central Laboratory). In order to data enter Form #173, NERI must set up a special data entry account for your user name.

In order to access Form #173, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 173". 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 #173 will appear.

- The patient ID will begin with 11 (UMASS/UCONN), 12 (SLU), 16 (UTSW), or 17 (USC).
- Valid visit numbers are W00, W24, R00, M12, M24, M36, M48, and M54.

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, the data collector should write a concise explanation including her/his initials and the date 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 the explanation in the "Reason" box. Enter the data collector's 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 filling out the form.

SECTION B: ASSAY LAB AND STATUS

- B1. If the LP assay was attempted within one day, circle "1" for YES and skip to question B2. If the LP assay was not attempted within one day, circle "2" for NO and continue to question B1a.
- B1a. Record the number of days between the blood draw and the assay setup (must be >1 day).
- B2. If it was possible to perform the LP assay, circle "1" for YES and skip to question B4. If it was not possible to perform the LP assay, circle "2" for NO and continue to question B3.
- B3. Record a reason why it was not possible to perform the LP assay. If you circle "Other" or "99", specify a reason in the space provided. 60 characters (including spaces and punctuation) are available. The form is complete.
- B4. Record the percent viability in the space provided. The range is 0-99%.
- B5. Record the total cell yield in the spaces provided. The range is 10 - 95 cells.
- B5a. Record the total cell yield exponent . The range is 4-9.

SECTION C: ASSAY RESULTS

C1a. Enter the date the assay was performed in MM/DD/YYYY format.

C1b. Enter the batch number of the assay. Batch numbers can range from 001 to 999.

C2 – C13. Record Mean cpm Incorporated in the spaces provided.

Note on Mean cpm Incorporated values: The DMS has been set up to expect a range of 100 – 999,999 for Mean cpm Incorporated. If the obtained value falls outside of this range, it should still be recorded on the paper form and data entered. Upon entering an out of range value in the DMS, a data entry validation error screen will appear. If the data entered value is the actual obtained value recorded on the paper form, then this out-of-range value may be overridden. Type a concise explanation in the "Reason" box (e.g., "Confirmed, correct value"). Enter your initials in the space provided and click the "Set Override" button.

SECTION D: ADDITIONAL COMMENTS

D1. 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 enter a code of "-1" in the Data Management System.