HALT-C Trial Q x Q

Replication - Immunology/Virology AS

Form # 174 Version A: 06/15/2000

Purpose of Form #174: This form is used to record the Replication results of in situ detection and quantification of HCV RNAs as part of the Immunology/Virology Ancillary Study.

When to complete Form #174: This form is completed for patients participating in the Replication 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 #174 should be completed for participating 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 data enter Form #174: Data entry of this form will take place only at the University of Washington (Central Laboratory). In order to data enter Form #174, NERI must set up a special data entry account for your user name.

In order to access Form #174, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 174". 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 #174 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 competed 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 three-digit code corresponding to this visit.

A3. Record the date the form was completed in MM/DD/YYYY format.

A4. Enter the initials of the person completing the form.

SECTION B: BSI ID

B1. Record the BSI ID from the aliquot tube. The BSI ID begins with the letter “D”, followed by a second letter corresponding to the study site, followed by six numbers. The BSI ID is used by NERI and BBI to identify specimens by patient and study visit.

The BSI ID also appears on the shipping manifest received from the BBI Repository in the column named “bsi_id”. On the shipping manifest, the BSI ID is followed by a three-digit sequence number, which does not need to be recorded on the paper form.

SECTION C: In Situ Negative-Strand RNA Detection

C1. Record whether it was possible to perform in situ detection of HCV negative-strand RNA.
- If it was possible to perform the assay, circle "1" for YES and continue to question C2.
- If it was not possible to perform the assay, circle "2" for NO and skip to question C4.

C2. Record the date of HCV negative-strand assay in MM/DD/YYYY format.

C3. Record the Average IU negative-strand RNA per ml of liver tissue. Then skip to question D1.

- For the first field, enter a value between 1 and 9.
- For the second field, enter a value between 02 and 12.
- The upper limit is 1×10^{12}.

C4. Record a reason why it was not possible to perform the HCV negative-strand assay. If you circle "Other" or “99”, specify a reason in the space provided. 60 characters (including spaces and punctuation) are available. Continue to question D1.

SECTION D: Total HCV RNA in Liver Tissue

D1. Record if it was possible to measure the total HCV RNA by the Roche Monitor.
- If it was possible to measure the HCV RNA, circle "1" for YES and continue to question D2.
- If it was not possible to measure the HCV RNA, circle "2" for NO and skip to question D4.

D2. Enter the date the total HCV RNA was measured in MM/DD/YYYY format.

D3. Record the IU HCV RNA (positive & negative-strand) per ml of liver tissue. Then skip to question D1.

- For the first field, enter a value between 1 and 9.
- For the second field, enter a value between 02 and 12.
- The upper limit is 1×10^{12}.

D4. Record a reason why it was not possible to perform the HCV RNA assay. If you circle "Other" or “99”, specify a reason in the space provided. 60 characters (including spaces and punctuation) are available.

SECTION E: ADDITIONAL COMMENTS

Please use the space provided to record any additional comments or findings. 200 characters (including punctuation and spaces) are available. If there are no additional comments, then record "NA” or “Not Applicable” on the hard copy of the form and enter the special value “-1” in the DMS.