HALT-C Trial QxQ

HCV Quasispecies: HTA Immunology/Virology AS

Form # 172 Version A: 06/15/2000

Purpose of Form #172: This form is used to record the results of the HCV Quasispecies Heteroduplex Tracking Analysis at the University of Washington (Central Laboratory).

When to complete Form #172: This form is completed for all patients participating in the Quasispecies 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 Quasispecies laboratory should complete form #172 for patients at the following study visits:

- **Screening Phase:** Form not completed during this phase.
- **Lead-In Phase:** Week 24 (W24) visit.
- **Responder Phase**: Form not completed during this phase.
- **Breakthrough/Relapser Patients**: Randomization (R00) visit.
- **Randomized Phase:** Month12 (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 #172: Data entry of this form will take place only at the University of Washington (Central Laboratory). In order to data enter Form #172, NERI must set up a special data entry account for your user name.

In order to access Form #172, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 172". 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 #172 will appear.

→ The patient ID will begin with 11 (UMASS/UCONN), 12 (SLU), 16 (UTSW), or 17 (USC).
→ Valid visit numbers are 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 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 filling out 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: ASSAY STATUS

C1. Record whether it was possible to perform the HCV Quasispecies Heteroduplex Tracking Analysis. If it was possible to perform the assay, circle “1” for YES and skip to question D1. If it was not possible to perform the assay, circle “2” for NO and continue to question C2.

C2. Record why it was not possible to perform the HCV quasispecies 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 D: RESULTS OF HCV QUASISPECIES HTA TESTING

D1. Enter the date the assay was done in MM/DD/YYYY format.

D2. Enter the Heteroduplex Mobility Ratio (HMR) as per HTA in the space provided.

SECTION E: 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 enter a code of "-1" in the Data Management System.