

HALT-C Trial Q x Q

Neutralizing Antibody Test Results – Immunology/Virology AS

Form # 171 Version A: 06/15/2000 (Rev. 05/23/2001)

Purpose of Form #171: This form is used to record the results of the Neutralizing Antibody (NA) assay at the Saint Louis University laboratory of Dr. Ranjit Ray.

When to complete Form #171: This form is completed for all patients participating in the Neutralizing Antibody 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 NA laboratory should complete form #171 for patients at the following study visits:

- **Screening Phase:** Form not completed during this phase.
- **Lead-In Phase:** Baseline (W00) visit.
- **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), and Month 48 (M48) for Lead-In, Breakthrough, and Relapser patients.

Data entry of Form #171: Data entry of Form # 171 will take place at the DCC. Retain the original of the completed form and a photocopy of each form to:

HALT-C Trial
New England Research Institutes Inc.
9 Galen Street
Watertown, MA 02472

Note on form completion:

- 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.

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 Neutralizing Antibody assay. If it was possible to perform the assay, circle "1" and continue to question D1. If it was not possible to perform the assay, circle "2" and the form is complete.

SECTION D: NEUTRALIZING ANTIBODY TITER (reciprocal serum dilution)

- D1. Enter the date the E1 assay was performed in MM/DD/YYYY format.
- D2. If the E1 titer was at or above set detectable limits [1:20], circle "1" for YES and continue to question D3. If the E1 titer was not at or above set detectable limits [1:20], circle "2" for NO and skip to question D4.
- D3. Record the titer of E1.
- D4. Enter the date the E2 assay was performed in MM/DD/YYYY format.
- D5. If the E2 titer was at or above set detectable limits [1:20], circle "1" for YES and continue to question D6. If the E2 titer was not at or above set detectable limits [1:20], circle "2" for NO and skip to Section E.
- D6. Record the titer of E2.

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 write "Not applicable" and the DCC will record a "-1" in the DMS.