

HALT-C Trial Q x Q

QLFT AS – Methionine Breath Test Aliquot Form

Form # 195 Version A: 06/15/2000 (Rev. 06/30/2004)

Purpose of Form #195: This form should be used to record the specimens collected from the Methionine Breath Test for the QLFT AS that will be sent to the Central Repository (BBI).

Data entry of this form for a patient visit is the first step of the shipping and tracking procedures for HALT-C. All of the specimens will go into a database of specimens available for shipment to the Central Repository for your clinical center. Entry of this form also allows NERI to link the HALT-C Trial ID's and study visits with the Sample ID assigned by the Central Repository.

When to complete Form #195: This form is completed for all patients participating in the QLFT Ancillary Study at the following clinical sites.

- Site 14 (University of Colorado Health Sciences Center).
- Site 15 (University of California - Irvine).
- Site 19 (Virginia Commonwealth University).

The clinical centers should complete and data enter form #195 for patients at the following study visits:

- Lead-In Phase patients: Baseline visit (W00)
- Express patients: Randomization visit (R00)
- Randomized patients: Month 24 (M24) and Month 48 (M48).

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: SAMPLE 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.

- B2. Record the date of the breath specimen collection using the MM/DD/YYYY format.

SECTION C: SPECIMEN INFORMATION: BREATH

For each of the sequence numbers listed on the form (30 – 37), record if the specimen was collected.

- If “YES”, then circle 1.
- If “NO”, then circle 2.