HALT-C Trial Q x Q

Quantitative Liver Function Test Results – QLFT AS

Form # 191 Version A: 06/15/2000 (Rev. 11/13/2001)

Purpose of Form #191: This form is used to record the results of the Quantitative Liver Function Tests done for the QLFT Ancillary Study at the University of Colorado Health Sciences Center QLFT Laboratory.

When to complete Form #191: 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 QLFT laboratory should complete and data enter form #191 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).

How to access Form #191: Data entry of this form will take place only at the University of Colorado Health Sciences Center QLFT Laboratory. In order to data enter Form #191, NERI must set up a special data entry account for your user name.

In order to access Form #191, log on to the HALT-C Production Data Management System (DMS). From the main menu, select "Central Lab D E". Then select "Enter Form 191". 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 #191 will appear.

→ The patient ID will begin with 14 (UCHSC), 15 (UCI), or 19 (VCU).
→ Valid visit numbers are W00, R00, 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, 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. 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: TEST RESULTS

B1. Enter the date the assay was done in MM/DD/YYYY format.
- Indicate the results of the cholate kinetic studies using the following units:
  B1a. K elimination in min-1
  B1b. V distribution in L/kg
  B1c. IV clearance in ml/min
  B1d. PO clearance in ml/min
  B1e. Shunt fraction in %

B2. Enter the date the assay was done in MM/DD/YYYY format.
- Indicate the results of the antipyrine clearance studies using the following units:
  B2a. K elimination in hr-1
  B2b. V distribution in L/kg
  B2c. Clearance in ml/min

B3. Enter the date the assay was done in MM/DD/YYYY format.
- B3a. Indicate the result of the caffeine clearance study in hr-1.

B4. Enter the date the assay was done in MM/DD/YYYY format.
- B4a. Indicate the result of the galactose clearance study in mg/min.kg.

B5. Enter the date the assay was done in MM/DD/YYYY format.
- Indicate the results of the Lidocaine/MEGX study using the following units:
  B5a. 15 Min – Base in ug/L.
  B5b. 30 Min – Base in ug/L.