

## HALT-C Trial Q x Q

### TGF-B1 mRNA – Serum Fibrosis Markers AS

Form # 101 Version A: 06/15/2000

**Purpose of Form #101:** The TGF-B1 mRNA Form #101 records the results of hepatic TGF-B1 mRNA measured by quantitative RT-PCR as part of the Serum Fibrosis Marker Ancillary Study.

**When to complete Form #101:** Form #101 will be completed for patients participating in the Serum Fibrosis Marker Ancillary Study at Site 18 (University of Michigan). Lead-In patients are eligible for this Ancillary Study. Express patients are not eligible.

Form #101 should be completed at the following study visits:

- Screening (S00).
- Randomization phase: Month 24 (M24) and Month 48 (M48).

The TGF-B1 mRNA measurement will be performed at Site 18. Form #101 will be data entered at Site 18.

#### **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 the visit number at time of tissue collection.
- A4. Record the date the form was completed in the MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

#### **SECTION B: RESULTS OF TGF-B1 mRNA**

- B1. Record the date of TGF-B1 mRNA measurement in the MM/DD/YYYY format.
- B2. TGF-B1 mRNA is measured only at Site 18.

Record the results of TGF-B1 mRNA in copies/ ml housekeeper gene. The normal range is 100 to 100,000,000.