

HALT-C Trial Q x Q

Serum TGF-B1 – Serum Fibrosis Markers AS

Form # 100 Version B: 12/03/2003

Purpose of Form #100: The Serum TGF-B1 Form #100 records the results of the serum fibrosis marker TGF-B1 assay as part of the Serum Fibrosis Marker Ancillary Study.

When to complete Form #100: Form #100 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 #100 should be completed at the following study visits:

- Lead-in phase: Baseline (W00) and Week 24 (W24).
- Randomization phase: Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).
- Responder phase: Week 48 (W48) and Week 72 (W72).
- Breakthrough/Relapser patients: Randomization (R00) visit.

The serum TGF-B1 assay will be performed at Site 18. Form #100 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 serum collection.
- A4. Record the date of the serum collection in MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: RESULTS OF SERUM FIBROSIS MARKER TGF-B1 TEST

B1. Record the date of testing in MM/DD/YYYY format.

B2. Plasma TGF-B1 is tested only at Site 18.

Record the results of Plasma TGF-B1 protein levels in ng/ml. The field allows three numbers before the decimal point. Two numbers **must** be entered after the decimal point.

The normal range is 1.00 to 100.00 ng/ml. If the result falls outside of this range, please verify the result against the source documentation. If the abnormal result is correct, select the override button. Specify that the data was verified and is correct.