

HALT-C Trial Q x Q

Local AFP

Form # 34 Version B: 08/20/2001

Purpose of Form #34: The Local AFP form is used to record the AFP result. This form should be completed by the coordinators or other designated staff at the clinical centers.

When to complete Form #34: Upon receiving the AFP result from your local lab, the Local AFP Form #34 should be completed and data entered. An AFP result should be entered on Form #34 at the following study visits:

- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00) and Week 20 (W20).
- **Express patients:** Baseline (R00) visit.
- **Randomization phase:** every clinic visit from Month 9 (M09) through Month 54 (M54).
- **Responder phase:** Week 36 (W36), Week 48 (W48), Week 60 (W60), and Week 72 (W72).

The Visit Control Sheet lists the lab tests required at each visit. All results should be reviewed to see if they are within the reference range specified. A value outside the reference range may indicate that further evaluation is required.

SECTION A: GENERAL INFORMATION

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

SECTION B: AFP RESULT

- B1. Record the date drawn in MM/DD/YYYY format.
- B2. Record the AFP result in ng/ml. Range is 0.10 to 300.00.
- B2a. Record the laboratory's reported upper limit of normal for the AFP test in ng/ml. Range is 0.10 to 100.00.