

HALT-C Trial Q x Q
Screening Visit 2 Local Lab
 Form # 35 Version B: 12/03/2001

Purpose of Form #35: The Screening Visit 2 Local Lab form is used to record lab results from the second Screening visit. This includes liver chemistries, TSH, and urine and pregnancy tests. A copy of the clinic note (with the results of the urine dipstick and pregnancy test) and local lab report (for all other labs) should be attached to this form. The Visit Control Sheet provides instructions for which lab is 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.

A copy of the clinic note (with results from the urine dipstick and pregnancy test) and local lab report (for all other labs) should be filed in the patient chart.

When to complete Form #35: This form should be completed only at Screening Visit 2 (S00). Upon receiving the results from your local lab, the Screening Visit 2 Lab Form #35 should be completed and data entered for all study patients.

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 in MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.
- A6. Record the date of the blood draw.
 - If blood was drawn on more than one day, record the date of the first blood draw. File a copy of each lab report in the patient chart.

General Instructions for completing and data entering Sections B through F:

The DMS has been set up to expect a certain range for most lab values. If an obtained value falls outside of this range, it should still be recorded on the paper form and data entered.

- Upon entering an out of range value in the DMS, a data entry validation error screen will appear. If the data entered value is the actual obtained value recorded on the Form #38, then this out-of-range value may be overridden. Type a brief explanation in the "Reason" box (e.g., "Confirmed, correct value"). Enter your initials in the space provided and click the "Set Override" button.

If a particular lab test was not done or the results will never be available write "ND", "not done", or "not available" on the hard copy of the form and the reason in the space provided for the lab result. When data entering Form #38 in the DMS, enter the value "-9". An error message will appear on the screen.

- If the value will never be obtained in the future, type a concise explanation in the "Reason" box. Enter your 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.

There may be occasions when a repeated lab value must be entered on a Form # 38 (i.e., if platelets clump). If a second test result is completed, cross out the previous value and write in the new value for the appropriate test on the paper Form #38. Write the new blood draw date next to the new lab value. Initial and date each edit. File relevant source documentation in the patient chart. Enter the new value in the DMS. Add a field level comment briefly explaining the change (e.g. Platelets clumped. Retested on 01/01/2004.)

SECTION B: LIVER CHEMISTRIES

The following are needed from the liver chemistry report:

- AST (SGOT) result and upper limit of normal
- ALT (SGPT) result and upper limit of normal
- alkaline phosphatase result and upper limit of normal
- total bilirubin result
- albumin result
- result for either globulin or total protein

B1. Record AST (SGOT) in U/L. Range is 0 to 500.

B1a. Record the AST upper limit of normal documented on the lab report. Range is 0 to 100.

B2. Record ALT (SGPT) in U/L. Range is 0 to 500.

B2a. Record the ALT upper limit of normal documented on the lab report. Range is 0 to 100.

B3. Record alkaline phosphatase in U/L. Range is 0 to 350.

B3a. Record the alkaline phosphatase upper limit of normal documented on the lab report. Range is 0 to 200.

B4. Record total bilirubin in mg/dL. Range is 0.0 to 6.0.

B5. Record albumin in g/dL. Range is 2.5 to 6.0.

B6. Record either globulin in g/dL (range is 1.2 to 5.0), or total protein in g/dL (range is 4.0 to 9.0).

- Data entry of globulin: Enter the globulin value. The DMS will skip automatically to the next section.
- Data entry of total protein: Enter a -1 for Globulin and the DMS will go to the total protein field. Then enter the Total Protein value.

SECTION C. SCREENING TSH

C1. Record Thyroid Stimulating Hormone (TSH) in mU/L. Range is 0.25 to 8.00.

SECTION D: URINALYSIS BY DIPSTICK

Document the results of the dipstick in the clinic note.

D1. Protein: circle one code that corresponds to the amount of protein found in the urine.

D2. Heme: circle one code that corresponds to the amount of heme found in the urine.

SECTION E: PREGNANCY TESTING

Complete this section for female patients. Do not complete this section for male patients.

E1. Pregnancy test:

- Circle "1" if the test was Positive. If positive, consult the DCC for instructions.
- Circle "2" if the test was Negative.
- If the female patient is not of childbearing potential, circle "-1" for Not Applicable.

SECTION F: PROTHROMBIN TIME

Prothrombin Time results are recorded at the Screening Visit 2 for Express patients only.

F1. Record Prothrombin Time in INR (International Normalized Ratios). Range is 0.5 to 2.0.