HALT-C Trial Q x Q

Pre-treatment Express Blood Work

Form # 38 Version A: 06/15/2000

Purpose of Form #38: This form is used to record the results of pre-treatment blood work (within a month before the commencement of the patient's current treatment) for the Express patients coming into the Screening Phase of the HALT-C Trial. The blood work includes: complete blood count, serum chemistries, liver chemistries, and prothrombin time. The values for the pre-treatment blood work can be used as entry criteria if the blood work collected on Form # 30 during the Screening process is not within the range specified by the protocol.

A copy of the local lab report(s) should be filed in the patient chart.

When to complete Form #38: This form can be completed as part of the Screening process for the Express patients.

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.

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

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 <u>never</u> 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 <u>may</u> 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 # 30 (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: COMPLETE BLOOD COUNT

The following are needed from the Complete Blood Count (CBC) report:
- white blood cell count (WBC)
- neutrophils (ANC)
- hematocrit (Hct)
- hemoglobin (Hgb)
- platelets

B1.   Record white blood cell count as $x10^3/mm^3$. Range is 2.0 to 14.0.

B1a.   Record the date of the WBC blood draw in MM/DD/YYYY format.

B2.   Record neutrophils as $x10^3/mm^3$. Range is 0.800 to 10.000.

B2a.   Record the date of the ANC blood draw in MM/DD/YYYY format.

B3.   Record hematocrit in %. Range is 30.0 to 55.0.

B3a.   Record the date of the Hct blood draw in MM/DD/YYYY format.

B4.   Record hemoglobin in g/dL. Range is 10.0 to 18.0.

B4a.   Record the date of the Hgb blood draw in MM/DD/YYYY format.

B5.   Record platelets as $x10^3/mm^3$. Range is 35 to 500.

B5a.   Record the date of the platelet blood draw in MM/DD/YYYY format.

SECTION C: SERUM CHEMISTRIES

The following are needed from the serum chemistry report:
- blood urea nitrogen (BUN)
- creatinine
- glucose
- triglycerides

C1.   Record BUN in mg/dL. Range is 0 to 40.

C1a.   Record the date of the BUN blood draw in MM/DD/YYYY format.

C2.   Record creatinine in mg/dL. Range is 0.0 to 2.0.

C2a.   Record the date of the creatinine blood draw in MM/DD/YYYY format.

C3.   Record fasting glucose in mg/dL. Range is 50 to 300.

C3a.   Record the date of the glucose blood draw in MM/DD/YYYY format.

C4.   Record triglycerides in mg/dL. Range is 30 to 600.

C4a. Record the date of the triglycerides blood draw in MM/DD/YYYY format.

SECTION D: 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

D1. Record AST (SGOT) in U/L. Range is 0 to 500.

D1a. Record the AST upper limit of normal documented on the lab report. Range is 0 to 100.

D1b. Record the date of the AST blood draw in MM/DD/YYYY format.

D2. Record ALT (SGPT) in U/L. Range is 0 to 500.

D2a. Record the ALT upper limit of normal documented on the lab report. Range is 0 to 100.

D2b. Record the date of the ALT blood draw in MM/DD/YYYY format.

D3. Record alkaline phosphatase in U/L. Range is 0 to 350.

D3a. Record the alkaline phosphatase upper limit of normal documented on the lab report. Range is 0 to 200.

D3b. Record the date of the alkaline phosphatase blood draw in MM/DD/YYYY format.

D4. Record total bilirubin in mg/dL. Range is 0.0 to 6.0.

D4a. Record the date of the bilirubin blood draw in MM/DD/YYYY format.

D5. Record albumin in g/dL. Range is 2.5 to 6.0.

D5a. Record the date of the albumin blood draw in MM/DD/YYYY format.

D6. 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.

D6a. Record the date of the globulin blood draw in MM/DD/YYYY format.

SECTION E: PROTHROMBIN TIME

E1. Record Prothrombin Time in INR (International Normalized Ratios). Range is 0.5 to 2.0.

E1a. Record the date of the PT-INR blood draw in MM/DD/YYYY format.