HALT-C Trial Q x Q

Sustained Virologic Responder Follow-up Ancillary Study:

Laboratory Results

Form #730 Version A: 05/01/2008

Purpose of Form #730: The Laboratory Results form is used to record the results of complete blood count, serum chemistries, liver chemistries, prothrombin time, AFP, and HCV RNA assays from the local lab report. A copy of the lab reports should be filed in the patient chart.

When to complete Form #730: Upon receiving the results from the laboratory, Form #730 should be completed once for all patients who consented to the Sustained Virologic Responder Follow-up Ancillary Study.

If a patient is unable to come into the HALT-C clinical center, lab tests can be recorded that were done at an outside laboratory. Use the most recent lab test results when recording data from an outside laboratory onto Form #730. Lab tests done within the last 6 months are preferred.

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. The visit number, SVR, is pre-printed on the form and does not need to be data entered.

A4. Record the date that this form was completed in MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: LABORATORY INFORMATION

B1. Were the lab tests performed at HALT-C Clinical Center or at another location?

- Circle 1 if all the lab test results recorded on the form were performed at a HALT-C Clinical Center visit.
- Circle 2 if all the lab test results recorded on the form were performed at a non-HALT-C location.
- Circle 3 for "Other". For example, if some of the lab test results were performed at the HALT-C Clinical Center and some results were from a different laboratory, circle 3.

General Instructions for completing and data entering Sections C through H:

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 #730, then this out-of-range value may be overridden. Type a brief explanation in the "Reason" box (e.g., "Confirmed with lab source documentation"). Enter your initials and click the "Set Override" button.

If a particular lab test was not done or the results will never be available write "not done", or "not available" on Form #730 with a brief reason in the margin. When data entering Form #730 in the DMS, enter the value "-9". A data entry validation 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 is determined to be unobtainable and an override "Reason" provided.

There may be occasions when a repeated lab value must be entered on a Form #730 (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 #730. 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 C: COMPLETE BLOOD COUNT

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

C1. Record in MM/DD/YYYY format the date of the CBC blood draw. If the CBC was not done enter 01/01/0101 and skip to Section D.

C2. Record white blood cell count as $x10^3/mm^3$. Range is 2.0 to 14.0.

C3. Record hematocrit in %. Range is 30.0 to 55.0.

C4. Record hemoglobin in g/dL. Range is 10.0 to 18.0.

C5. Record platelets as $x10^3/mm^3$. Range is 35 to 500.

SECTION D: SERUM CHEMISTRIES

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

D1. Record in MM/DD/YYYY format the date of the serum chemistry blood draw. If serum chemistry tests were not done enter 01/01/0101 and skip to Section E.

D2. Record BUN in mg/dL. Range is 0 to 40.

D3. Record creatinine in mg/dL. Range is 0.0 to 2.0.

D4. Record fasting glucose in mg/dL. Range is 50 to 300.

D5. Record triglycerides in mg/dL. Range is 30 to 600.

SECTION E: 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 in MM/DD/YYYY format the date of the liver chemistry blood draw. If serum chemistry tests were not done enter 01/01/0101 and skip to Section F.

D2. Record AST (SGOT) in U/L. Range is 0 to 500.

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

D3. Record ALT (SGPT) in U/L. Range is 0 to 500.

D3a. Record the ALT upper limit of normal documented on the lab report. Range is 0 to 100.

D4. Record alkaline phosphatase in U/L. Range is 0 to 350.

D4a. Record the alkaline phosphatase upper limit of normal documented on the lab report. Range is 0 to 200.

D5. Record total bilirubin in mg/dL. Range is 0.0 to 6.0.

D6. Record albumin in g/dL. Range is 2.5 to 6.0.

D7. 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 F: PROTHROMBIN TIME

F1. Record in MM/DD/YYYY format the date of the prothrombin time blood draw. If prothrombin time was not done enter 01/01/0101 and skip to Section G.

F2. Record Prothrombin Time in INR (International Normalized Ratios). Range is 0.5 to 2.0.

SECTION G: AFP

G1. Record in MM/DD/YYYY format the date of the AFP blood draw. If AFP was not done enter 01/01/0101 and skip to Section H.

G2. Record the AFP result in ng/ml. Range is 0.10 to 300.00.

G2a. Record the laboratory's reported upper limit of normal for the AFP test in ng/ml. Range is 0.10 to 100.00.

SECTION H: HCV RNA ASSAY RESULTS

H1. Record whether there are results of an HCV RNA assay since the W72 HALT-C visit. If there were more than two HCV RNA testing results since the last HALT-C visit, please record ONLY the most recent test results.
- Circle 1 for YES if there are results available.
- Circle 2 for NO if there are no results available. The form is now complete.

H2. Record in MM/DD/YYYY format the date of the most recent blood draw for the HCV RNA testing.

H3. Record the HCV RNA assay performed for first test result. Choose the name of the assay from the HCV RNA Assay Code Box located to the right of the Specify field on the form.
- Record 1 in the small box for Monitor.
- Record 2 in the small box for Amplicor.
- Record 3 in the small box for TMA.
- Record 4 in the small box for bDNA.
- Record 5 in the small box for TAQman. Specify, if available, the type of PCR: i.e., Roche or the name of the lab performing the test, i.e., Quest, National Genetics Institute, etc. If the type or the laboratory is not available, record -8 in the Specify field.
- Record 6 in the small box for PCR. Specify, if available, the type of PCR: i.e., Superquant, or the name of the lab performing the test, i.e., Quest, National Genetics Institute, etc. If the type or the laboratory is not available, record -8 in the Specify field.
- Record 99 in the small box for other and write the name in the Specify field.
  - If the name of the test is not listed above, circle 99 and specify the name of the test.
  - If the name of the test is not specified, circle 99 and specify the laboratory where the test was performed, i.e., Quest, Labcorp, etc.

H4. Record the result of the HCV RNA Assay.

- Circle 1 if the result is Detected/Positive.
- Circle 2 if the result is Not detected/Negative. Skip to question H6.

If a qualitative assay was performed, the result will most likely be stated in clear cut terms of Detected/Positive or Not detected/Negative.

If a quantitative assay was performed, the result is usually expressed as a numeric value with a reference range indicating the sensitivity of the assay (e.g. 1,477,000 IU/mL; Reference range: < 50 IU/mL).

- o If the result is 8356 and the reference range is <50, then the result would be recorded as Detected/Positive.
- o If the result is <50 and the reference range is <50, then the result would be recorded as Not detected/Negative.
- o If the result is not clear, refer the lab test to the Principal Investigator for interpretation.

H5. Record the number and units of the assay result.

- Record the number of the assay result. Use the < symbol to stand for less than.
- Record the units indicated for the assay result.
  - o If there are different units used, **give priority to international units: IU/mL**.
  - o For example, a test result is given as < 50 **IU/ml** and <1.70 **Log IU/ml**. In this case, record <50 for the number and IU/ml for the units.
  - o For example, a test result is given as 65,000 **copies/ml** and 3100 **IU/ml**. In this case, record 3100 for the number and IU/ml for the units.
  - o If the units are not specified/not available, record a -8.

H6. Record the number and units of the reference range.

- Record the number of the reference range. The < symbol for less than is pre-printed on the form.
- Record the units indicated for the reference range.
  - o If there are different units used, **give priority to international units: IU/mL**.
  - o For example, a test result is given as < 50 **IU/ml** and <1.70 **Log IU/ml**. In this case, record <50 for the number and IU/ml for the units.
  - o For example, a test result is given as 65,000 **copies/ml** and 3100 **IU/ml**. In this case, record 3100 for the number and IU/ml for the units.
  - o If the units are not specified/not available, record a -8.