

HALT-C Trial Q x Q

Histopathology – Iron & HFE Gene Mutation AS

Form #181 Version A: 06/15/2000 (Rev. 11/11/2003)

Purpose of Form #181: This form documents central determination of iron in hepatocytes, iron in Kupffer cells, and portal triads with stainable iron for the Iron and HFE Gene Mutation Ancillary Study.

When to complete Form #181: This form should be completed at the Screening (S00), Month 24 (M24) and Month 48 (M48) visit on biopsies from all patients participating in the HALT-C Trial. Form #181 is completed by HALT-C study pathologists. Form #181 is data entered at the DCC.

SECTION A: GENERAL INFORMATION

- A1. FOR NERI ONLY. After data entering the dummy ID for this form, record the patient ID number legibly in black or blue pen.
- A2. Record the Dummy ID found on the slide.
- A3. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A5. Record the date the form was completed using MM/DD/YYYY format.
- A6. Enter the initials of the person who is completing the form.

SECTION B: HISTOPATHOLOGY SUMMARY – STAINABLE IRON

- B1. Record the date the biopsy was read in MM/DD/YYYY format.
- B2. Record the initials of the first pathologist reading the biopsy.
- B3. If a second pathologist also read the biopsy, circle 1 for YES and continue to question B4. If only one pathologist read the biopsy, circle 2 for NO and skip to question B5.
- B4. Record the initials of the second pathologist reading the biopsy.
- B5. If the specimen is adequate to perform histopathology, circle 1 for YES and continue to question B6. If the specimen is inadequate to perform histopathology, circle 2 for NO. The form is complete.
- B6. Record location of iron in hepatocytes. Circle 1 for ABSENT. Circle 2 for PRESENT IN <50% OF CELLS. Circle 3 for PRESENT IN >50% OF CELLS.
- B7. Record location of iron in reticuloendothelial cells. Circle 1 for ABSENT. Circle 2 for PRESENT IN <50% OF CELLS. Circle 3 for PRESENT IN >50% OF CELLS.
- B8. Record the total number of Portal Triads.

- B9. Record the number of Portal Triads with stainable iron. If the answer is 0, the form is complete. If the answer is >0, continue to question B10.
- B10. Record whether there were endothelial cells with stainable iron. Circle 1 for YES, 2 for NO, and 3 for NOT SPECIFIED.
- B11. Record whether there were Kupffer and stromal cells with stainable iron. Circle 1 for YES, 2 for NO, and 3 for NOT SPECIFIED. The form is complete.

WHEN THE FORM IS COMPLETED PLEASE MAIL OR FAX TO THE DCC: 617-926-0144.