PATHOLOGY EVALUATION FORM (PE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	A liver biopsy or liver tissue/slides from a previous biopsy must be sent to the central pathologist as part of the screening process. If a liver biopsy is performed, 4 slides should be prepared and sent directly to the central pathologist. Remaining tissue should be submerged in RNALater and stored locally. Slides must be labeled with Virahep-C Patient ID, Date of Biopsy, and Specimen Number. Section I of the Pathology Evaluation (PE) form is to be completed by the clinical coordinator and Section II will be completed by the central pathologist. Biopsies will be read within 7 business days and results will be available via the MATRIX system. Copies of the completed PE form can be printed and filed in the patient folders.
PATIENT ID	Record the Patient ID.
SPECIMEN INFORMATION	**GENERAL INSTRUCTIONS:** This section of the form is to be completed by the Clinical Coordinator. The PE form must be sent to the central pathologist along with the slides but a copy of the form must be placed in the patient folder at the clinical center. **SPECIFIC INSTRUCTIONS:** Specimen Number: Record the specimen number assigned by the clinical center pathologist. Date of biopsy: Record the date (month/day/year) that the biopsy was performed. Source of specimen: Check “Needle biopsy” or “Wedge biopsy” to indicate the source of the specimen. Adequate: “Check “Yes” or “No” to indicate if the specimen is adequate.
HISTOLOGY	**GENERAL INSTRUCTIONS:** This section is to be completed by the central pathologist. **SPECIFIC INSTRUCTIONS:** Date of Reading: Record the date (month/day/year) that the biopsy was read. HAI Scoring: Record the score in the space provided.

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	Periportal inflammation: Range 0-10, possible values: 0 = None 1 = Mild piecemeal necrosis 3 = Moderate piecemeal necrosis 4 = Marked piecemeal necrosis 5 = Moderate piecemeal necrosis plus bridging necrosis 6 = Marked piecemeal necrosis plus bridging necrosis 10 = Multilobular necrosis Lobular inflammation: Range 0-4, possible values: 0 = None 1 = Mild 3 = Moderate 4 = Marked Portal inflammation: Range 0-4, possible values: 0 = No portal inflammation 1 = Mild 3 = Moderate 4 = Marked Fibrosis: Range 0-4, possible values: 0 = No fibrosis 1 = Fibrous portal expansion 3 = Bridging fibrosis 4 = Cirrhosis Ishak Fibrosis Scale: Range 0-6, possible values: 0 = No fibrosis 1 = Fibrous expansion of some portal areas, with or without short fibrous septa 2 = Fibrous expansion of most portal areas, with or without short fibrous septa 3 = Fibrous expansion of most portal areas with occasional portal to portal bridging 4 = Fibrous expansion of portal areas with marked bridging portal to portal as well as portal to central 5 = Marked bridging with occasional nodules (incomplete cirrhosis) 6 = Cirrhosis, probable or definite Iron scoring: Range 0-4, possible values: 0 = Granules absent or barely discernible x 400 1 = Barely discernible x 250 / Easily confirmed x 400 2 = Discrete granules resolved x 100 3 = Discrete granules resolved x 25 4 = Masses visible x 10, or naked eye

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	Fat score: Range 0-4, possible values: 0 = Less than 5% of hepatocytes show steatosis 1 = 5-25% steatosis 2 = 26-50% steatosis 3 = 51-75% steatosis 4 = 76-100% steatosis Total portal areas: Record the count (integer values only). Steatohepatitis: Check “Yes” or “No”. Dysplasia: Check “Yes” or “No”. Number of slides: Record the number of slides received from the clinical center. Original slides: Check “Yes” if the original slides were sent. If not, check “No”. Comments: Check whether there are comments regarding the treatment evaluation. If yes, write your comments in the area provided. When referring to a specific item on the form, record the section and question number with the comment.