

PATHOLOGY EVALUATION FORM (PE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	<p>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.</p> <p>Slides must be labeled with Virahep-C Patient ID, Date of Biopsy, and Specimen Number.</p> <p>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.</p> <p>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.</p>
PATIENT ID	Record the Patient ID.
SPECIMEN INFORMATION	<p>GENERAL INSTRUCTIONS:</p> <p>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.</p> <p>SPECIFIC INSTRUCTIONS:</p> <p><u>Specimen Number:</u> Record the specimen number assigned by the clinical center pathologist.</p> <p><u>Date of biopsy:</u> Record the date (month/day/year) that the biopsy was performed.</p> <p><u>Source of specimen:</u> Check “Needle biopsy” or “Wedge biopsy” to indicate the source of the specimen.</p> <p><u>Adequate:</u> “Check “Yes” or “No” to indicate if the specimen is adequate.</p>
HISTOLOGY	<p>GENERAL INSTRUCTIONS:</p> <p>This section is to be completed by the central pathologist.</p> <p>SPECIFIC INSTRUCTIONS:</p> <p><u>Date of Reading:</u> Record the date (month/day/year) that the biopsy was read.</p> <p><u>HAI Scoring:</u> Record the score in the space provided.</p>

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	<p><u>Periportal inflammation:</u> Range 0-10, possible values:</p> <ul style="list-style-type: none"> 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 <p><u>Lobular inflammation:</u> Range 0-4, possible values:</p> <ul style="list-style-type: none"> 0 = None 1 = Mild 3 = Moderate 4 = Marked <p><u>Portal inflammation:</u> Range 0-4, possible values:</p> <ul style="list-style-type: none"> 0 = No portal inflammation 1 = Mild 3 = Moderate 4 = Marked <p><u>Fibrosis:</u> Range 0-4, possible values:</p> <ul style="list-style-type: none"> 0 = No fibrosis 1 = Fibrous portal expansion 3 = Bridging fibrosis 4 = Cirrhosis <p><u>Ishak Fibrosis Scale:</u> Range 0-6, possible values:</p> <ul style="list-style-type: none"> 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 <p><u>Iron scoring:</u> Range 0-4, possible values:</p> <ul style="list-style-type: none"> 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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	<p><u>Fat score</u>: Range 0-4, possible values:</p> <p>0 = Less than 5% of hepatocytes show steatosis 1 = 5-25% steatosis 2 = 26-50% steatosis 3 = 51-75% steatosis 4 = 76-100% steatosis</p> <p><u>Total portal areas</u>: Record the count (integer values only).</p> <p><u>Steatohepatitis</u>: Check "Yes" or "No".</p> <p><u>Dysplasia</u>: Check "Yes" or "No".</p> <p><u>Number of slides</u>: Record the number of slides received from the clinical center.</p> <p><u>Original slides</u>: Check "Yes" if the original slides were sent. If not, check "No".</p> <p><u>Comments</u>: 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.</p>