

MONOGRAPH

National Academy of Clinical Biochemistry Standards of Laboratory Practice: Laboratory Guidelines for Screening, Diagnosis and Monitoring of Hepatic Injury

D. Robert Dufour¹, John A. Lott², Frederick S. Nolte³, David R. Gretch⁴, Raymond S. Koff⁵, Leonard B. Seeff⁶

¹Chief, Pathology and Laboratory Medicine Service, VA Medical Center, Washington, DC; Professor of Pathology, George Washington University School of Medicine.

²Professor of Pathology, The Ohio State University College of Medicine

³Associate Professor of Pathology and Laboratory Medicine, Emory University School of Medicine

⁴Associate Professor of Laboratory Medicine, University of Washington School of Medicine

⁵Professor of Medicine, University of Massachusetts Medical Center

⁶Senior Scientist, Hepatitis C Programs, National Institute of Diabetes, Digestive, and Kidney Diseases, National Institute of Health; Professor of Medicine, Georgetown University School of Medicine

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The portion of this monograph dealing with laboratory test performance requirements guidelines was jointly developed with the American Association for the Study of Liver Diseases through their Practice Guidelines Committee

Introduction

Hepatocyte injury is commonly encountered in the practice of medicine. The incidence of acute viral hepatitis has markedly decreased in the past decade due to the introduction of vaccines for hepatitis A and B and testing of the blood supply for hepatitis C. Other forms of acute hepatic injury have not changed appreciably in incidence, and

recognition of chronic hepatic injury has increased. In the United States, an estimated 1 million individuals are chronically infected with hepatitis B and 2.1-2.8 million are chronically infected with hepatitis C. (1) Cirrhosis is currently the 9th leading cause of death in the United States (2); deaths from cirrhosis are predicted to increase 223% by 2008 and 360% by 2028 due to cases developing from chronic hepatitis C infection. (3) Hepatocellular carcinoma incidence has doubled in the past 20 years (4), and is expected to rise another 68% over the next decade from cancers developing in hepatitis C infected individuals (3).

Liver disease is often clinically silent until late in its course. For this reason, laboratory tests are usually needed for recognition and characterization of the type of liver injury present. The most common cause of liver injury world-wide is infection with viruses that primarily infect the liver, often termed hepatitis viruses. Serologic and nucleic acid-based tests are required to document exposure to and presence of these viruses, and are also used to monitor treatment of infected individuals. A number of other diseases may also cause liver injury, particularly autoimmune disorders and congenital or acquired disorders of metabolism. Laboratory tests are critical for recognition of these other diseases, particularly in patients who lack evidence of viral infection. Finally, exposure to ethanol and other drugs can cause hepatic injury; clinical information is the most reliable means to recognize these potential causes of liver damage.

Specific recommendations in this Monograph are based on relevant published information. The strength of scientific data supporting each recommendation is characterized using the scoring criteria adopted by the Practice Guidelines Committee of the American Association for the Study of Liver Diseases, as summarized in Table 1. For each recommendation, the roman numerals I through IV describe the quality of evidence upon which recommendations are based, and the upper case letters A through E describe the significance of the recommendation. Because of the nature of these guidelines, only categories B and E are used in the recommendations.

I	Evidence from multiple well-designed randomized controlled clinical trials each involving a number of patients to be of sufficient statistical power
II	Evidence from at least one large well-designed clinical trial with or without randomization, from cohort or case-controlled analytical studies, or well-designed meta-analysis
III	Evidence based on clinical experience, descriptive studies, or reports of expert committees
IV	Not rated
A	Survival benefit
B	Improved diagnosis
C	Improvement in quality of life
D	Relevant pathophysiologic parameters improved
E	Impacts cost of health care