NHANES 2001-2002 Data Release
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Documentation for Laboratory Results

Laboratory 2 – Hepatitis C antibody, confirmed

(1) Documentation File Date – September, 2003

(2) Documentation File Name- Laboratory 2 – Hepatitis C antibody, confirmed

(3) Survey Years Included in this File Release – 2001-2002

(4) Component Description

Viruses that primarily infect the liver constitute a major public health problem because of the morbidity and mortality associated with the acute and chronic consequences of these infections. New immunization strategies have been developed to eliminate transmission of hepatitis B and hepatitis A viruses in the United States. Because of the high rate of asymptomatic infection with both viruses, NHANES will provide the best means for determining the age-specific effectiveness of immunization strategies to prevent these infections. In addition, NHANES provides the means to better define the epidemiology of hepatitis C and other hepatitis viruses such as HDV and HEV. In NHANES testing for markers of infection with the hepatitis viruses will be used to determine secular trends in infection rates across most age and racial/ethnic groups, and will provide a national picture of the epidemiologic determinants of these infections.

(5) Sample Description:

5.1 Eligible Sample
Participants aged 6 years and older are tested.

(6) Description of the Laboratory Methodology

a. Serum samples were tested for anti-HCV using a third generation enzyme immune assay (Ortho HCV Version 3.0 ELISA Test System). This is a solid-phase enzyme immunoassay which provides a qualitative determination of the human antibody directed against hepatitis C virus (anti-HCV). Repeatedly reactive samples by EIA were confirmed by supplemental testing.

b. The Chiron RIBA HCV 3.0 Strip Immunoblot Assay (SIA) which is used to confirm samples that test positive for anti-HCV by EIA is an in vitro qualitative enzyme immunoassay for the detection of antibody to hepatitis C virus (anti-HCV) in human serum or plasma. Detection of anti-HCV by SIA methodology is based upon traditional Western and dot blotting techniques, in which HCV-specific immunogens (i.e. antigenic polyproteins) are immobilized onto a membrane support. The presence of antibodies in tested sample sera which bind to the individual HCV-encoded proteins is visualized using anti-human IgG enzyme-conjugates in conjunction with a colorimetric enzyme substrate. (1).

(7) Laboratory Quality Control and Monitoring

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

(8) Data Processing and Editing

Blood specimens are processed, stored and shipped to the Division of Viral Hepatitis, National Center for Infectious Diseases, National Centers for Disease Control and Prevention. Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Analytic methodology section.

(9) Data Access:

All data are publicly available.

(10) Analytic Notes for Data Users:

Only samples that test positive for antibody to HCV (anti-HCV) by both the screening enzyme immunoassay (EIA) and the confirmatory test are reported out as positive. Samples that tested negative for anti-HCV by EIA or that tested positive by EIA but were negative or indeterminate in the confirmatory test are reported as negative.