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# Laboratory Component:

Hepatitis B core antibody and surface antigen & Hepatitis D antibody(HEPBD\_D)

Survey Years: 2005 to 2006

SAS Export File: HEPBD\_D.XPT



First Published: February 2008 Last Revised: N/A

### NHANES 2005–2006 Data Documentation

### Laboratory Assessment: Hepatitis B core antibody, Hepatitis B surface antigen, and Hepatitis D antibody (HEPBD\_D)

First Published: February 2008

Last Revised: N/A

Component Hepatitis viruses constitute a major public health problem because of Description the morbidity and mortality associated with the acute and chronic consequences of these infections. New immunization strategies have been developed to eliminate the spread of hepatitis B virus (HBV) and hepatitis A virus (HAV) in the United States. Recommendations have also been developed for the prevention and control of hepatitis C virus (HCV) infection. Because of the high rate of asymptomatic infection with these viruses, information about the prevalence of these diseases is needed to monitor prevention efforts. By testing a nationally representative sample of the U.S. population, NHANES will provide the most reliable estimates of age-specific prevalence needed to evaluate the effectiveness of the strategies to prevent these infections. In addition, NHANES provides the means to better define the epidemiology of other hepatitis viruses. NHANES testing for markers of infection with 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

Eligible All participants aged 6 years and older are eligible to be tested. Sample

### Description of Laboratory Hepatitis B core antibody Methodology

The Ortho HBc ELISA Test System is a qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of total antibody to anti-HBc in human serum or plasma. Anti-HBc appears in virtually all individuals infected with HBV and is an accurate serological marker of current and past infection.

ELISA procedures provide a means for routinely detecting antibodies to specific antigens. This FDA-licensed method is commercially obtained in kit form. The literature and instructions with each kit constitute the standard operating procedure (SOP) for the method.

### Hepatitis B surface antigen

The AUSZYME Monoclonal test is a solid-phase "sandwich" enzyme immunoassay used to detect the presence of HBsAg, which indicates current infection with HBV. Specimens that test nonreactive by the AUSZYME Monoclonal tests (Abbott Diagnostics) are considered negative for HBsAg and are not tested further. All specimens considered reactive initially are repeat-tested in duplicate using the same procedure as that used in the initial test. If neither of the repeat tests is reactive, the specimen is considered negative for HBsAg. If the specimen is reactive in either of the repeat tests, the sample is considered repeatedly reactive.

### Hepatitis D antibody

The International Immunodiagnostics HDV Ab assay is a competitive enzyme immunoassay (ELISA) for the determination of antibodies to Hepatitis D Virus or HDV in human plasma and sera with a 'two step" methodology. Anti-HDV antibodies, if present in the sample, compete with a virus specific polyclonal IgG, labeled with peroxidase (HRP), for a fixed amount of rec-HDV coated on the Microplate, in"two step" incubation. The concentration of the bound enzyme on the solid phase is inversely proportional to the amount of anti-HDV antibodies in the sample and its activity is detected by adding the chromagen/substrate in the second incubation. The concentration of HDV-specific antibodies in the sample is determined by means of a cut-off value that allows for the semi-quantitative detection of anti-HDV antibodies.

### Laboratory Quality Control and Monitoring

The NHANES quality assurance and quality control (QA/QC) protocols 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. A detailed description of the quality assurance and quality control procedures can be found on the NHANES website

### 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 LPM. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Analytic Notes for Data Users section below. Detailed instructions on specimen collection and processing can be found on the NHANES website.

### Analytic Notes

The analysis of NHANES laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables and sample weights for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

The age range and constraints for hepatitis testing are as follows:

- Hep B- The hepatitis B core antibody test is performed on all examinees 6 years old and older while the hepatitis B surface antibody test is performed on all examinees 2 years old and older. The surface antigen is tested only when the core antibody test is positive. Participant results are coded positive for surface antigen if the surface antigen test is positive; they are coded negative for surface antigen if the test for surface antigen is negative or if the test for hepatitis B core antibody is negative.
- Hep D-The Hepatitis Delta Virus (HDV) is a RNA defective virus and infection with HDV only occurs in the presence of acute or chronic HBV infection. In NHANES, the test for antibody to HDV is performed on participants 6 years of age or older who test positive for hepatitis B core antibody and hepatitis B surface antigen. Participant results are coded positive for anti-HDV if the anti-HDV test is positive; they are coded negative if the anti-HDV test is negative, or if they are negative for hepatitis B surface

antigen, or if they are negative for hepatitis B core antibody.

References N/A

### **Locator Fields**

Title: Hepatitis B core antibody, Hepatitis B surface antigen, and Hepatitis D antibody

Contact Number: 1-866-441-NCHS

Years of Content: 2005–2006

First Published: February 2008

Last Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Hepatitis B core antibody, Hepatitis B surface antigen, and Hepatitis D antibody

Record Source: NHANES 2005–2006

Survey Methodology: NHANES 2005–2006 is a stratified multistage probability sample of the civilian

non-institutionalized population of the U.S.

Medium: NHANES Web site; SAS transport files

## National Health and Nutrition Examination Survey Codebook for Data Production (2005-2006)

# Hepatitis B core antibody and surface antigen and Hepatitis D antibody (HEPBD\_D) Person Level Data

February 2008



SEQN	Target			
	B(6 Yrs. to 150 Yrs.)			
Hard Edits	SAS Label			
	Respondent sequence number			
English Text: Respondent sequence number.				
English Instructions:				

LBXHBC		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Hepatitis B core antibody				
English Text: Hepatitis B core antibody						
English Instructions:						
Code or Value	I	Description	Count	Cumulative	Skip to Item	
1		Positive	327	327		
2		Negative	7066	7393		
		Missing	693	8086		

LBDHBG		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Hepatitis B surface antigen				
English Text: Hepatitis B surface antigen						
English Instructions:						
Code or Value	I	Description	Count	Cumulative	Skip to Item	
1		Positive	22	22		
2		Negative	7371	7393		
· .		Missing	693	8086		

LBDHD		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Hepatitis D (anti-HDV)				
English Text: Hepatitis D	(anti-HDV)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
1	Positive	0	0			
2	Negative	7393	7393			
	Missing	693	8086			