National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Hepatitis B: Core antibody, Surface antigen, and Hepatitis D antibody (HEPBD_I)

Data File: HEPBD_I.xpt

First Published: September 2017

Last Revised: NA

Component Description

Hepatitis viruses constitute a major public health problem because of the morbidity and mortality associated with the acute and chronic consequences of these infections. Co-infection with hepatitis D virus (HDV) in persons with acute or chronic hepatitis B virus (HBV) infection can lead to fulminant hepatitis. New immunization strategies have been developed to eliminate the spread of 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 Sample

Examined participants aged 6 years or older were eligible.

Description of Laboratory Methodology

Hepatitis B core antibody (anti-HBc)

The VITROS Anti-HBc assay is performed using the VITROS Anti-HBc Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc Calibrator on the VITROS ECi/ECiQ or VITROS 3600 Immunodiagnostic System.

A competitive immunoassay technique is used. This involves the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg) coated wells. Unbound sample is removed by washing. Horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the concentration of anti HBc present.

Hepatitis B surface antigen (HBsAg)

The VITROS HBsAg test is performed using the VITROS HBsAg Reagent Pack and VITROS Immunodiagnostic Products HBsAg Calibrator on the VITROS ECi/ECiQ Immunodiagnostic Systems and the VITROS 3600 Immunodiagnostic System. An immunometric immunoassay technique is used, which involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal anti-HBs antibody coated onto the wells and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs antibody in the conjugate. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample.

Hepatitis D antibody (anti-HDV)

The method for qualitative anti-HD determination is a simultaneous competitive assay. Anti-HD present in the sample and labeled anti-HD antibodies complete for a fixed quantity of HDAg bound to the solid phase. The quantity of enzyme tracer bound to the solid phase and consequently the enzyme activity are inversely proportional to the anti-HD concentration present in samples or controls.

Enzyme activity is measured by adding a colorless chromogen/substrate solution. The enzyme action on the chromogen/substrate produces a color which is measured with a photometer.

Refer to the Laboratory Method Files section for a detailed description of the laboratory methods used.

There were no changes to the lab method, lab equipment, or lab site for this component in the NHANES 2015-2016 cycle.

Laboratory Method Files

Hepatitis D Antibody (September 2017)

Hepatitis B Surface Antigen (HBsAg) (September 2017)

Hepatitis B Core Antibody (September 2017)

Laboratory Quality Assurance and Monitoring

Serum specimens were processed, stored, and shipped to the Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA for analysis.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Vials are stored under appropriate frozen (–30°C) conditions until they are shipped to Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention for testing.

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed QA/QC instructions are discussed in the NHANES LPM.

Mobile Examination Centers (MECs)
Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured competency assessment evaluation during visits to evaluate both the quality of the laboratory work and the quality-control procedures. Each laboratory staff member is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff member. Formal retraining

sessions are conducted annually to ensure that required skill levels were maintained.

Analytical Laboratories
NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing blind split samples collected on “dry run” sessions. In addition, contract laboratories randomly perform repeat testing on 2% of all specimens.

Data Processing and Editing

The data were reviewed. Incomplete data or improbable values were sent to the performing laboratory for confirmation.

Analytic Notes

Refer to the 2015-2016 Laboratory Data Overview for general information on NHANES laboratory data.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2015-2016 Demographics File contains demographic data, health indicators, and other related information collected during household interviews as well as the sample design variables. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

This laboratory data file can be linked to the other NHANES data files using the unique survey participant identifier (i.e., SEQN).

The age range and constraints for Hepatitis B and D testing are as follows:

Hepatitis B

The hepatitis B core antibody test is performed on all examined participants aged 6 years and older while the hepatitis B surface antibody test is performed on all examined participants aged 2 years old and older. The Hepatitis B surface antigen is tested only when the Hepatitis B 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.

Hepatitis D

The Hepatitis Delta Virus (HDV) is a RNA defective virus; and an 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 all examined participants 6 years and older who test positive for anti-HBc and HBsAg. The denominator for anti-HDV includes all anti-HBc negative samples, the anti-HBc positive samples that were subsequently found to be HBsAg negative, and the samples that were anti-HBc positive and HBsAg positive that were subsequently found to be anti-HDV negative.

Detection Limits

This data is qualitative. The use of lower limits of detection (LLODs) is not applicable.

Exam sample weights should be used for analyses. Please refer to the NHANES Analytic Guidelines and the on-line NHANES Tutorial for further details on the use of sample weights and other analytic issues.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name:	SEQN
SAS Label:	Respondent sequence number
English Text:	Respondent sequence number
Target:	Both males and females 6 YEARS - 150 YEARS

LBXHBC - Hepatitis B core antibody

binary

Variable Name: LBXHBC

SAS Label: Hepatitis B core antibody

English Text: Hepatitis B core antibody

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	448	448	
2	Negative	6676	7124	
3	Indeterminate	0	7124	
.	Missing	897	8021	

LBDHBG - Hepatitis B surface antigen

Variable Name: LBDHBG

SAS Label: Hepatitis B surface antigen

English Text: Hepatitis B surface antigen

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	33	33	
2	Negative	415	448	
3	Indeterminate	0	448	
.	Missing	7573	8021	

LBDHD - Hepatitis D (anti-HDV)

Variable Name: LBDHD

SAS Label: Hepatitis D (anti-HDV)

English Text: Hepatitis D (anti-HDV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	19	19	
2	Negative	429	448	
3	Indeterminate	0	448	
.	Missing	7573	8021	