National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Hepatitis E: IgG & IgM Antibodies (HEPE_I)

Data File: HEPE_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. 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. Infection with hepatitis E virus (HEV) has been responsible for large water-borne epidemics of acute disease in developing countries and for acute sporadic disease in industrialized developed countries. In immunocompromised individuals, infection with HEV may also cause chronic infection, which may progress to fibrosis and cirrhosis. 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 E IgG Antibody (IgG Anti-HEV)

DS-EIA-ANTI-HEV-G is an enzyme immunoassay kit intended for the detection of IgG antibodies to hepatitis E virus in human serum or plasma. During an initial incubation, HEV antibody in the sample binds with HEV antigen coated onto wells of a polystyrene stripped plate. Unbound sample is removed by washing. During a second incubation, horseradish peroxidase-labeled antibody conjugate (monoclonal mouse antibodies against human IgG) binds to any human IgG from the sample that was captured on the well. Unbound conjugate is removed by washing and a substrate solution containing tetramethylbenzidine is added to produce color. The reaction is stopped by adding a sulphuric acid solution and the optical density (OD) of each well is read. The presence or absence of IgG antibodies to hepatitis E virus is determined by the ratio of the OD of each sample to the calculated cut-off value. A sample is considered negative if the sample OD value is < cut-off and is considered positive if the sample OD value is ≥ cut-off.

Hepatitis E IgM Antibody (IgM Anti-HEV)

DS-EIA-ANTI-HEV-M is an enzyme immunoassay kit intended for the detection of IgM antibodies to hepatitis E virus in human serum or plasma. During an initial incubation, HEV antibody in the sample binds with HEV antigen coated onto wells of a polystyrene stripped plate. Unbound sample is removed by washing. During a second incubation, horseradish peroxidase-labeled antibody conjugate (monoclonal mouse antibodies against human IgM) binds to any human IgM from the sample that was captured on the well. Unbound conjugate is removed by washing and a substrate solution containing tetramethylbenzidine is added to produce color. The reaction is stopped by adding a sulphuric acid solution and the OD of each well is read. The presence or absence of IgM antibodies to hepatitis E virus is determined by the ratio of the OD of each sample to the calculated cut-off value. A sample is considered negative if the sample OD value is < cut-off and is considered positive if the sample OD value is ≥ cut-off.

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

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

Laboratory Method Files

IgG Hepatitis E Antibody (September 2017)

IgM Hepatitis E 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.

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).

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

LBDHEG - Hepatitis E IgG (anti-HEV)

binary

Variable Name: LBDHEG

SAS Label: Hepatitis E IgG (anti-HEV)

English Text: Hepatitis E IgG (anti-HEV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	537	537	
2	Negative	6587	7124	
3	Indeterminate	0	7124	
.	Missing	897	8021	

LBDHEM - Hepatitis E IgM (anti-HEV)

Variable Name: LBDHEM

SAS Label: Hepatitis E IgM (anti-HEV)

English Text: Hepatitis E IgM (anti-HEV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	90	90	
2	Negative	7034	7124	
3	Indeterminate	0	7124	
.	Missing	897	8021	