

**National Health and Nutrition
Examination Survey 2005–2006**

**Documentation, Codebook,
and Frequencies**

Hepatitis C Antibody

Laboratory

**Survey Years:
2005 to 2006**

**SAS Transport File:
HEPC_D.XPT**



**First Published: February 2008
Last Revised: May 2009**

NHANES 2005–2006 Data Documentation

Laboratory Assessment: Hepatitis C: confirmed antibody (HEPC_D), Hepatitis C RNA (HCV-RNA), and Hepatitis HCV genotype

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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. 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

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

Description of Laboratory Methodology

Hepatitis C Antibody

Qualitative determination of the human antibody directed against hepatitis C virus (anti-HCV) in human serum or plasma is measured using direct solid-phase enzyme immunoassay with the anti-HCV screening ELISA. Positive specimens are repeated in duplicate according to the same procedure. Repeatedly positive specimens are tested supplementally using the Chiron RIBA Processor System (Chiron Corporation, Inc.).

The Chiron RIBA HCV 3.0 Strip (confirmation test)

The Chiron RIBA 3.0 Strip Immunoblot Assay (SIA; Chiron Corporation,

Inc.) 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 specific immunogens (i.e. antigenic polyproteins) encoded by the HCV genome are immobilized onto a membrane support. Visualization of anti-HCV reactivity in specimens to the individual HCV-encoded proteins is accomplished with anti-human IgG enzyme-conjugates in conjunction with a colorimetric enzyme substrate. Samples where the RIBA result was positive are reported as confirmed positive for antibody to HCV. Samples where the RIBA result was negative are reported as negative for antibody to HCV and indeterminate results are reported as indeterminate.

Hepatitis C RNA (HCV-RNA)

The COBAS AMPLICOR HCV MONITOR Test, version 2.0 (v2.0) is an in vitro nucleic acid amplification test for the quantitation of Hepatitis C Virus RNA in human serum or plasma on the COBAS AMPLICOR Analyzer.

Hepatitis HCV genotype

The VERSANT® HCV Genotype 2.0 Assay (LiPA) is a line probe assay designed to identify Hepatitis C virus (HCV) genotypes 1 to 6 in human serum or EDTA plasma samples. Subtype information is available in the majority of cases.

A detailed description of the laboratory method used can be found on the NHANES website.

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 Description of Laboratory Methodology section above. 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 C-The screening hepatitis C antibody test is performed on all examinees 6 years old and older. Samples testing positive for anti-HCV by the screening EIA test were tested in the confirmatory RIBA assay for antibody to hepatitis C virus. Samples where the RIBA result was positive are reported as confirmed positive for antibody to HCV. Samples where the RIBA result was negative are reported as negative for antibody to HCV. Samples where the RIBA result is indeterminate are reported out as such and subsequently tested for HCV RNA to attempt to confirm the infection status of the patient. Samples that tested negative by the screening EIA test were not tested by RIBA. These samples were reported as negative for antibody to HCV. Samples that tested positive or indeterminate by the HCV RNA were subsequently tested for HCV genotyping.

References

N/A

Locator Fields

Title: Hepatitis C Antibody (Confirmed), Hepatitis C RNA (HCV-RNA), and Hepatitis HCV genotype

Contact Number: 1-866-441-NCHS

Years of Content: 2005–2006

First Published: February 2008

Last Revised: May 2009

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Hepatitis C Antibody (Confirmed), Hepatitis C RNA (HCV-RNA), and Hepatitis HCV genotype

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 C antibody (HEPC_D)
Person Level Data**

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

LBDHCV	Target
	B(6 Yrs. to 150 Yrs.)
Hard Edits	SAS Label
	Hepatitis C antibody (confirmed)
English Text: Hepatitis C antibody (confirmed)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	78	78	
2	Negative	7278	7356	
5	Indeterminate	37	7393	
.	Missing	693	8086	

LBXHCR	Target			
	B(6 Yrs. to 150 Yrs.)			
Hard Edits	SAS Label			
	Hepatitis C RNA (HCV-RNA)			
English Text: Hepatitis C RNA (HCV-RNA)				
English Instructions:				
Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	54	54	
2	Negative	58	112	
.	Missing	7974	8086	

LBXHCG	Target			
	B(6 Yrs. to 150 Yrs.)			
Hard Edits	SAS Label			
	Hepatitis HCV genotype			
English Text: Hepatitis HCV genotype				
English Instructions:				
Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	39	39	
2	Negative	13	52	
3	Undetermined	1	53	
.	Missing	8033	8086	