

National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

HPV Serum

Laboratory

Survey Years:
2003 to 2004

SAS Transport File:
L52SER_C.XPT



December 2008

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 52 Human Papillomavirus -6, 11, 16 and 18 (HPV-6, 11, 16, 18) Antibody Test in serum (L52SER_C)

First Published: December 2008

Last Revised: N/A

Component Description

Human papillomavirus (HPV) infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. No national surveillance system exists to measure the full burden of HPV infection, and no reliable national population estimate of HPV exists. NHANES offers a unique opportunity to assess the prevalence of HPV infection in the general population.

Reducing the prevalence of HPV infection is a Developmental Healthy People 2010 objective: “Reducing the number of new HPV cases can help minimize the overall number of cases of high risk subtypes associated with cervical cancer in females ...” An HPV vaccine has been licensed, and knowledge of the national prevalence of HPV infection is critical for planning vaccination strategies and monitoring the impact of vaccination in the United States.

Eligible Sample

All participants aged 14 to 59 years.

Description of Laboratory Methodology

Multiplex Luminex Assay of Antibodies to Neutralizing Epitopes on HPV 6, 11, 16 and 18 L1-Virus-Like Particles (VLPs)

This method uses the Luminex platform to simultaneously assay antibodies to HPV 6, 11, 16 and 18. Type-specific antibodies of any Ig class are detected by displacement of fluorescently tagged neutralizing monoclonal antibody from VLP-coated microspheres

Data Processing and Editing

Blood specimens were processed, stored and shipped to Atlanta, Ga. for analysis. 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 the Laboratory Methodology** section. The Multiplex Luminex assay was conducted at Merck Research Laboratories using their protocol established for vaccine clinical trials.

Analytic Notes

The analysis of NHANES 2003–2004 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2003–2004 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.

Serology Assay.

Competitive Luminex Assay for HPV 6, 11, 16, 18: Merck established the serostatus cut-off values for a positive result for each HPV type in the assay.

References

Dias D, Van Doren J, Schlottmann S, Kelly S, Puchalski D, Ruiz W, Boerckel P, Kessler J, Antonello J, Green T, Brown M, Smith J, Chirmule N, Barr E, Jansen KU, Esser MT. Optimization and Validation of a multiplexed Luminex assay to quantify antibodies to neutralizing epitopes on human papillomaviruses 6, 11, 16, and 18. *Clin Diag Lab Immunol* 12:959-969, 2005.

Opalka D, Lachman CE, MacMullen SA, Jansen KU, Smith JF, Chirmule N, Esser MT. Simultaneous quantitation of antibodies to neutralizing epitopes on virus-like particles for human papillomavirus types 6, 11, 16, and 18 by a multiplexed luminex assay. *Clin Diagn Lab Immunol* 10:108-115, 2003.

Locator Fields

Title: Human papillomavirus (HPV)

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: December 2008

Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Human papillomavirus (HPV)

Record Source: NHANES 2003–2004

Survey Methodology: NHANES 2003–2004 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 (2003-2004)**

**HPV Serum (L52SER_C)
Person Level Data**

December 2008



SEQN	Target
	B(18 Yrs. to 59 Yrs.)
Hard Edits	SAS Label
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

LBXS06MK	Target
	B(18 Yrs. to 59 Yrs.)
Hard Edits	SAS Label
	HPV 06 (Merck competitive Luminex assay)
English Text: HPV 06 (Merck competitive Luminex assay)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	417	417	
2	Negative	2875	3292	
.	Missing	261	3553	

LBXS11MK	Target			
	B(18 Yrs. to 59 Yrs.)			
Hard Edits	SAS Label			
	HPV 11 (Merck competitive Luminex assay)			
English Text: HPV 11 (Merck competitive Luminex assay)				
English Instructions:				
Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	151	151	
2	Negative	3141	3292	
.	Missing	261	3553	

LBXS16MK	Target			
	B(18 Yrs. to 59 Yrs.)			
Hard Edits	SAS Label			
	HPV 16 (Merck competitive Luminex assay)			
English Text: HPV 16 (Merck competitive Luminex assay)				
English Instructions:				
Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	338	338	
2	Negative	2954	3292	
.	Missing	261	3553	

LBXS18MK	Target			
	B(18 Yrs. to 59 Yrs.)			
Hard Edits	SAS Label			
	HPV 18 (Merck competitive Luminex assay)			
English Text: HPV 18 (Merck competitive Luminex assay)				
English Instructions:				
Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	145	145	
2	Negative	3147	3292	
.	Missing	261	3553	