National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component: Human Papillomavirus (HPV) DNA Hybrid Capture, PCR, and Hybridization Results from Vaginal Swab Samples

Survey Years:
2003 to 2004

SAS Export File:
L37SWA_C.XPT

April 2006

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 37 Human Papillomavirus - HPV DNA Detection from Vaginal Swabs

Years of Coverage: 2003–2004 **First Published:** April 2006 **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. The "high-risk" types of HPV (e.g., HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) are associated with cervical cancer and the "low-risk" types (e.g., HPV 6, 11, 42, 43, 44) with genital warts. 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..." Detection and typing of HPV DNA in vaginal swabs (in conjunction with testing of NHANES sera for HPV 16 antibody) will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. HPV vaccine development is underway, and knowledge of the national prevalence of HPV infection will be critical for planning vaccination strategies in the United States.

Eligible Sample

Vaginal Swab - Females aged 14 to 59 years.

Description of Laboratory Methodology

Vaginal Swab

Digene hc2 HPV DNA Test

LBXH2RL (Hybrid Capture high risk result)

LBXH3RL (Hybrid Capture low risk result)

The Digene hc2 HPV DNA Test using Hybrid Capture 2 technology is a nucleic acid hybridization microplate assay with signal amplification. It uses chemiluminescence for the qualitative detection of eighteen types of human papillomavirus (HPV) DNA in cervical specimens. The hc2 HPV DNA Test can differentiate between two HPV DNA groups: low-risk HPV types (LR) 6, 11, 42, 43, 44; and high/intermediate-risk HPV types (HR)16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68. It cannot determine the specific HPV type present.

Specimens containing the target DNA hybridize with the HR or LR HPV RNA probe cocktail. The resultant RNA:DNA hybrids are captured onto the surface of a microplate well coated with antibodies specific for RNA:DNA hybrids. Immobilized hybrids are then reacted with alkaline phosphatase conjugated antibodies specific for the RNA:DNA hybrids, and detected with a chemiluminescent substrate. As the substrate is cleaved by the bound alkaline phosphatase, light is emitted which is measured as relative light units (RLUs) on a luminometer. The intensity of the light emitted denotes the presence or absence of target DNA in the specimen. An RLU measurement equal to or greater than the Cutoff Value indicates the presence of HPV DNA sequences in the specimen. An RLU measurement less than the Cutoff Value indicates the absence of the specific HPV DNA sequences tested or HPV DNA levels below the detection limit of the assay.

HPV PCR Assay

This assay uses HPV L1 consensus polymerase chain reaction (PCR) with biotinylated PGMY09/11 primer sets and β-globin as an internal control for sample amplification. The primer mix amplifies essentially all HPV types found in the genital tract. The amplicons are evaluated by gel electrophoresis for the presence of the 450 bp HPV amplicon. Positive samples are typed by hybridization to the Roche protype line probe typing strips followed by colorimetric detection. The strip is a linear array of probes specific for 37 HPV types (6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 42, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 64, 66, 67, 68, 69, 70, 71, 72, 73, 81, 82, 83, 84, IS39, and 89) and for the positive β-globin control as well. Types are read by comparing the reaction pattern to the typing template. Samples that do not hybridize to the typing strip are sequenced to determine the HPV type.

Laboratory Quality Control and Monitoring

While HC2 is approved for clinical testing, the self-collected vaginal sample does not meet clinical guidelines. The HPV PCR tests are research tests. The HPV laboratory followed strict research QC/QA but is not CLIA certified. 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.

Data Processing and Editing

Vaginal 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.

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.

Vaginal Swab

Digene hc2 HPV DNA Test

An RLU measurement equal to or greater than the Cutoff Value of 1.0 indicates the presence of HPV DNA sequences in the specimen. An RLU measurement less than the Cutoff Value indicates the absence of the specific HPV DNA sequences tested or HPV DNA levels below the detection limit of the assay.

HPV PCR Assay

HPV SUMMARY VARIABLE

The HPV PCR Summary variable (LBDHPCR) indicates if at least one type is positive (LBDHPCR=1), the sample is inadequate (LBDHPCR=3), the sample is negative (LBDHPCR=2), or the sample is missing (LBDPCR=.).

If there is no Beta globin present in the sample and no HPV type is detected either by hybridization or sequencing, the sample is coded as inadequate.

If any of the types on the strips (LBDH06-LBDHP1) are positive, or a type is identified by sequencing, the type is coded as positive. If all of the types on the strip are coded as negative or missing, and LBXNST is missing, the sample is coded as negative.

References

1. Hc2 HPV DNA Test Package Insert, Digene Corporation.

2. Gravitt PE, Peyton CL, Alessi TQ, Wheeler CM, Coutlee F, Hildesheim A, Schiffman MH, Scott DR, Apple RJ. Improved Amplification of Genital Human Papillomaviruses. J Clin Microbiol 2000; 38: 357-361

Locator Fields

Title: Human papillomavirus (HPV)

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: April 2006

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)

Human Papillomavirus (HPV) DNA Hybrid Capture, PCR, and Hybridization Results from Vaginal Swab Samples (L37SWA_C)
Person Level Data

April 2006

SEQN	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

LBXH2RL	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	Hybrid Capture high risk (RLU) result
English Text: Hybrid Capture high risk (RLU)result	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
0 to 1212	Range of Values	2025	2025	
.	Missing	362	2387	

LBXH3RL	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	Hybrid Capture low risk (RLU) result
English Text: Hybrid Capture low risk (RLU)result	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
0 to 999.9	Range of Values	2025	2025	
.	Missing	362	2387	

LBDHPCR	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV summary variable
English Text: HPV summary variable	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	572	572	
2	Negative	1349	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH06	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 06
English Text: HPV type 06	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1890	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH11	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 11
English Text: HPV type 11	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	5	5	
2	Negative	1916	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH16	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 16
English Text: HPV type 16	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	42	42	
2	Negative	1879	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH18	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 18
English Text: HPV type 18	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	20	20	
2	Negative	1901	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH26	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 26
English Text: HPV type 26	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	4	4	
2	Negative	1917	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH31	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 31

English Text: HPV type 31

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	24	24	
2	Negative	1897	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH33	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 33
English Text: HPV type 33	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	11	11	
2	Negative	1910	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH35	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 35
English Text: HPV type 35	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	17	17	
2	Negative	1904	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH39	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 39
English Text: HPV type 39	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	37	37	
2	Negative	1884	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH40	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 40
English Text: HPV type 40	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	12	12	
2	Negative	1909	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH42	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 42
English Text: HPV type 42	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1890	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH45	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 45
English Text: HPV type 45	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	16	16	
2	Negative	1905	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH51	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 51
English Text: HPV type 51	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	53	53	
2	Negative	1868	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH52	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 52
English Text: HPV type 52	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	53	53	
2	Negative	1868	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH53	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 53

English Text: HPV type 53

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	60	60	
2	Negative	1861	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH54	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 54
English Text: HPV type 54	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	45	45	
2	Negative	1876	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH55	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 55
English Text: HPV type 55	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1890	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH56	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 56

English Text: HPV type 56

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1890	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH58	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 58
English Text: HPV type 58	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	24	24	
2	Negative	1897	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH59	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 59
English Text: HPV type 59	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	42	42	
2	Negative	1879	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH61	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 61
English Text: HPV type 61	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	52	52	
2	Negative	1869	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH62	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 62
English Text: HPV type 62	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	60	60	
2	Negative	1861	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH64	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 64
English Text: HPV type 64	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	1	1	
2	Negative	1920	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH66	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 66
English Text: HPV type 66	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	43	43	
2	Negative	1878	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH67	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 67
English Text: HPV type 67	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	12	12	
2	Negative	1909	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH68	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 68
English Text: HPV type 68	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	19	19	
2	Negative	1902	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH69	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 69
English Text: HPV type 69	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	1	1	
2	Negative	1920	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH70	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 70

English Text: HPV type 70

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	14	14	
2	Negative	1907	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH71	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 71

English Text: HPV type 71

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	12	12	
2	Negative	1909	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH72	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 72
English Text: HPV type 72	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	12	12	
2	Negative	1909	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH73	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 73
English Text: HPV type 73	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	18	18	
2	Negative	1903	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH81	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 81

English Text: HPV type 81

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1890	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH82	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 82
English Text: HPV type 82	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	5	5	
2	Negative	1916	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH83	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 83
English Text: HPV type 83	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	43	43	
2	Negative	1878	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH84	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 84
English Text: HPV type 84	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	89	89	
2	Negative	1832	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDH89	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type 89

English Text: HPV type 89

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	46	46	
2	Negative	1875	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBDHPI	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	HPV type IS39
English Text: HPV type IS39	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	2	2	
2	Negative	1919	1921	
3	Inadequate	105	2026	
.	Missing	361	2387	

LBXNST	Target
	F(14 Yrs. to 59 Yrs.)
Hard Edits	**SAS Label**
	other HPV strip types

English Text: other HPV strip types

English Instructions:

Code or Value	Description	Count	Cumulative	Skip to Item
1 to 10	Range of Values	21	21	
.	Missing	2366	2387	