National Health and Nutrition Examination Survey

2011-2012 Data Documentation, Codebook, and Frequencies

Human Papillomavirus (HPV) DNA - Vaginal Swab: Digene Hybrid Capture & Roche Linear Array (HPVSWR_G)

Data File: HPVSWR_G.xpt

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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) are associated with cervical cancer and the "low-risk" types (e.g., HPV 6, 11) 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 antibody) will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. Two HPV vaccines (Gardasil and Cervarix) are licensed and recommended for use in girls and women. One vaccine is licensed and recommended for use in males (Gardasil). In mid-2006, the Advisory Committee on Immunizations (ACIP), recommended routine vaccination of females aged 11 or 12 years and for those 13-26 years not previously vaccinated. In December, 2011 ACIP recommended routine vaccination of males aged 11 or 12 years and for those aged 13 through 21 years not previously vaccinated. As vaccine becomes more widely used, the national prevalence of HPV infection will be critical for evaluating vaccination strategies in the United States.

Eligible Sample

Examined female participants aged 14-59 years were eligible. This public data file includes data for examined participants aged 18-59 years. Please see *Analytic Notes* about the release of data for adolescents aged 14-17 years.

Description of Laboratory Methodology

Digene hc2 HPV DNA Test

LBXH2RL (Hybrid Capture high risk result)

The vaginal swab is extracted to obtain DNA. The DNA extracts are used in the Digene hc2 HPV DNA Test. This test, using Hybrid Capture 2 technology, is a nucleic acid hybridization microplate assay with signal amplification. It uses chemiluminescence for the qualitative detection of human papillomavirus (HPV) DNA in cervical specimens. The high-risk (HR) hc2 HPV DNA Test detects 13 HR HPV types: 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 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.

Roche Linear Array Assay

This assay uses Roche Linear Array HPV Genotyping test that is based on HPV L1 consensus polymerase chain reaction (PCR) with biotinylated PGMY09/11 primer sets. It also includes biotinylated β -globin primers as an internal control for sample amplification. The primer mix amplifies essentially all HPV types found in the genital tract along with the human β -globin gene. After amplification the samples are typed by hybridization to the 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, 89, and IS39) and for the positive β -globin control as well. Types are read by comparing the reaction pattern to the typing template. Samples that are negative for HPV and the β -globin control indicate lack of a suitable sample and are considered inadequate for interpretation.

Laboratory Method Files

HPV Vaginal Swab Digene High Risk Laboratory Procedure Manual (November 2018)

HPV Vaginal Swab Linear Array Laboratory Procedure Manual (November 2018)

Laboratory Quality Assurance and Monitoring

Vaginal swab samples were processed, stored and shipped to the Chronic Viral Diseases Branch, Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA for analysis.

The Digene hc2 HPV DNA Test is approved for clinical testing, but 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 and has been CLIA certified since August 2008. 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. The analytical methods are described in the **Description of the Laboratory Methodology** section.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Swabs were stored at room temperature until they were shipped to the National Center for Emerging and Zoonotic Infectious Diseases for testing.

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.

Progress reports containing any problems encountered during shipping or receipt of specimens, summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

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 2011-2012 Laboratory Data Overview for general information on NHANES laboratory data.

Sample Weights

MEC exam sample weights should be used for analyses.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2011-2012 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 Questionnaire data files contain socio-economic data, health indicators, and other related information collected during household interviews. Certain sensitive data on participants under 18 years of age (e.g., HPV typing results, sexual behavior variables) are not included in the public use files. These data may be requested as described in the NHANES guidelines.

The public release data file includes HPV vaginal swab data for participants aged 18-59. HPV vaginal swab data for youth aged 14-17 years are available through the NCHS Research Data Center (RDC).

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 (LBDRPCR) indicates if at least one type is positive (LBDRPCR=1), the sample is negative (LBDRPCR=2), the sample is inadequate (LBDRPCR=3), or the sample is missing (LBDRPCR=.).

If beta-globin is not present, both LBDRHP and LBDRLP are negative in the sample and no HPV type is detected, the sample is coded as "Inadequate".

If any of the types on the strips (LBDR06-LBDRPI) are positive, the sample is coded as positive. If all of the types on the strip are coded as negative, and beta-globin is detected (either LBDRHP or LBDRLP is positive) the sample is coded as negative.

Variables LBDRHP through LBDRPI are from the RUO Roche Linear Array HPV typing assay, however LBDR52 also includes information from a type-specific assay for HPV 52. The Linear Array typing strip includes an XR probe that hybridizes with HPV 52 as well as HPV types 33, 35 and 58. Samples positive for the XR probe and 33, 35, or 58 require specific testing to confirm the presence of HPV 52 (Onyekwuluje et al., 2012).

Detection Limits

If data is qualitative, the use of lower limits of detection (LLODs) is not applicable.

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.

References

- 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.
- Hc2 HPV DNA Test Package Insert, Digene Corporation.
- Onyekwuluje JM, Steinau M, Swan DC, Unger ER. A real time PCR assay for HPV 52 detection and viral load quantification. Clin Lab 58:61-66, 2012.
- Steinau M, Swan DC, Unger ER. Type-specific reproducibility of the Roche Linear Array HPV genotyping test. J Clin Virol 2008; 42: 412-414.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name: SEQN

SAS Label: Respondent sequence number

English Text: Respondent sequence number.

LBDRPCR - Roche HPV linear array summary result

Variable Name: LBDRPCR

SAS Label: Roche HPV linear array summary result

English Text: Roche HPV linear array (LA) summary result

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	781	781	
2	Negative	986	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBXH2RL - Digene HPV Swab High Risk RLU/CB

Variable Name: LBXH2RL

SAS Label: Digene HPV Swab High Risk RLU/CB

English Text: Digene HPV Swab High Risk RLU/CB

Code or Value	Value Description	Count	Cumulative	Skip to Item
0.07 to 2449.91	Range of Values	1772	1772	
	Missing	223	1995	

LBDRHP - Roche LA high positive globin control

Variable Name: LBDRHP

SAS Label: Roche LA high positive globin control

English Text: Roche LA high positive globin control

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	1764	1764	
2	Negative	3	1767	
	Missing	228	1995	

LBDRLP - Roche LA low positive globin control

Variable Name: LBDRLP

SAS Label: Roche LA low positive globin control

English Text: Roche LA low positive globin control

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	1747	1747	
2	Negative	20	1767	
	Missing	228	1995	

LBDR06 - HPV type 6

Variable Name: LBDR06

SAS Label: HPV type 6

English Text: HPV type 6

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	30	30	
2	Negative	1737	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR11 - HPV type 11

Variable Name: LBDR11

SAS Label: HPV type 11

English Text: HPV type 11

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	4	4	
2	Negative	1763	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR16 - HPV type 16

Variable Name: LBDR16

SAS Label: HPV type 16

English Text: HPV type 16

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	67	67	
2	Negative	1700	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR18 - HPV type 18

Variable Name: LBDR18

SAS Label: HPV type 18

English Text: HPV type 18

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	31	31	
2	Negative	1736	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR26 - HPV type 26

Variable Name: LBDR26

SAS Label: HPV type 26

English Text: HPV type 26

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	3	3	
2	Negative	1764	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR31 - HPV type 31

Variable Name: LBDR31

SAS Label: HPV type 31
English Text: HPV type 31

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	27	27	
2	Negative	1740	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR33 - HPV type 33

Variable Name: LBDR33

SAS Label: HPV type 33

English Text: HPV type 33

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	7	7	
2	Negative	1760	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR35 - HPV type 35

Variable Name: LBDR35

SAS Label: HPV type 35

English Text: HPV type 35

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	36	36	
2	Negative	1731	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR39 - HPV type 39

Variable Name: LBDR39

SAS Label: HPV type 39

English Text: HPV type 39

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	47	47	
2	Negative	1720	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR40 - HPV type 40

Variable Name: LBDR40

SAS Label: HPV type 40

English Text: HPV type 40

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	20	20	
2	Negative	1747	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR42 - HPV type 42

Variable Name: LBDR42

SAS Label: HPV type 42

English Text: HPV type 42

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	54	54	
2	Negative	1713	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR45 - HPV type 45

Variable Name: LBDR45

SAS Label: HPV type 45

English Text: HPV type 45

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	43	43	
2	Negative	1724	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR51 - HPV type 51

Variable Name: LBDR51

SAS Label: HPV type 51

English Text: HPV type 51

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	70	70	
2	Negative	1697	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR52 - HPV type 52

Variable Name: LBDR52

SAS Label: HPV type 52

English Text: HPV type 51

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	65	65	
2	Negative	1702	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR53 - HPV type 53

Variable Name: LBDR53

SAS Label: HPV type 53

English Text: HPV type 53

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	96	96	
2	Negative	1671	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR54 - HPV type 54

Variable Name: LBDR54

SAS Label: HPV type 54

English Text: HPV type 54

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	77	77	
2	Negative	1690	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR55 - HPV type 55

Variable Name: LBDR55

SAS Label: HPV type 55

English Text: HPV type 55

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	45	45	
2	Negative	1722	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR56 - HPV type 56

Variable Name: LBDR56

SAS Label: HPV type 56

English Text: HPV type 56

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	36	36	
2	Negative	1731	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR58 - HPV type 58

Variable Name: LBDR58

SAS Label: HPV type 58

English Text: HPV type 58

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	38	38	
2	Negative	1729	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR59 - HPV type 59

Variable Name: LBDR59

SAS Label: HPV type 59

English Text: HPV type 59

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	53	53	
2	Negative	1714	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR61 - HPV type 61

Variable Name: LBDR61

SAS Label: HPV type 61

English Text: HPV type 61

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	112	112	
2	Negative	1655	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR62 - HPV type 62

Variable Name: LBDR62

SAS Label: HPV type 62

English Text: HPV type 62

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	98	98	
2	Negative	1669	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR64 - HPV type 64

Variable Name: LBDR64

SAS Label: HPV type 64

English Text: HPV type 64

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	1	1	
2	Negative	1766	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR66 - HPV type 66

Variable Name: LBDR66

SAS Label: HPV type 66

English Text: HPV type 66

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	50	50	
2	Negative	1717	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR67 - HPV type 67

Variable Name: LBDR67

SAS Label: HPV type 67

English Text: HPV type 67

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	21	21	
2	Negative	1746	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR68 - HPV type 68

Variable Name: LBDR68

SAS Label: HPV type 68

English Text: HPV type 68

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	34	34	
2	Negative	1733	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR69 - HPV type 69

Variable Name: LBDR69

SAS Label: HPV type 69

English Text: HPV type 69

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	7	7	
2	Negative	1760	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR70 - HPV type 70

Variable Name: LBDR70

SAS Label: HPV type 70

English Text: HPV type 70

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	54	54	
2	Negative	1713	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR71 - HPV type 71

Variable Name: LBDR71

SAS Label: HPV type 71
English Text: HPV type 71

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	22	22	
2	Negative	1745	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR72 - HPV type 72

Variable Name: LBDR72

SAS Label: HPV type 72

English Text: HPV type 72

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	33	33	
2	Negative	1734	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR73 - HPV type 73

Variable Name: LBDR73

SAS Label: HPV type 73

English Text: HPV type 73

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	37	37	
2	Negative	1730	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR81 - HPV type 81

Variable Name: LBDR81

SAS Label: HPV type 81

English Text: HPV type 81

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	44	44	
2	Negative	1723	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR82 - HPV type 82

Variable Name: LBDR82

SAS Label: HPV type 82

English Text: HPV type 82

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	12	12	
2	Negative	1755	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR83 - HPV type 83

Variable Name: LBDR83

SAS Label: HPV type 83

English Text: HPV type 83

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	71	71	
2	Negative	1696	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR84 - HPV type 84

Variable Name: LBDR84

SAS Label: HPV type 84

English Text: HPV type 84

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	84	84	
2	Negative	1683	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDR89 - HPV type 89

Variable Name: LBDR89

SAS Label: HPV type 89

English Text: HPV type 89

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	91	91	
2	Negative	1676	1767	
3	Inadequate	5	1772	
	Missing	223	1995	

LBDRPI - HPV type IS39

Variable Name: LBDRPI

SAS Label: HPV type IS39

English Text: HPV type IS39

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	3	3	
2	Negative	1764	1767	
3	Inadequate	5	1772	
	Missing	223	1995	