

National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Human Papillomavirus (HPV) DNA - Vaginal Swab: Roche Linear Array (HPVSWR_I)

Data File: HPVSWR_I.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 as well as other anogenital cancers, and the “low-risk” types of HPV (e.g., HPV 6, 11) are associated 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 will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. Three HPV vaccines (Gardasil, Gardasil 9, and Cervarix) are licensed and recommended for use in females. Two vaccines are licensed and recommended for use in males (Gardasil and Gardasil 9). 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 a 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 to 59 years. Please see *Analytic Notes* about the release of data for adolescents aged 14-17 years.

Description of Laboratory Methodology

This assay used the 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 amplified essentially all HPV types found in the genital tract along with the human β -globin gene. After amplification, the samples were 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 were read by comparing the reaction pattern to the typing template. Samples that were negative for HPV and the β -globin control indicated lack of a suitable sample and were considered inadequate for interpretation (Linear Array HPV Genotyping Test

Application manual, 2008). Refer to the Laboratory Method Files section for a detailed description of the laboratory methods used.

Laboratory Method Files

[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.

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

Note: In the 2015-2016 cycle, Cobas HPV Swab High-Risk results (LBXHP2C) are being released separately in two new datasets: HPVSWC_I and HPVC_I_R. In the 2013-2014 cycle, LBXHP2C results were released with the Roche Linear Array results in datasets HPVSWR_H and HPVS_H_R.

Refer to the [2015-2016 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 [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).

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 \(RDC\)](#).

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

- Centers for Disease Control and Prevention. (2018). Healthy People 2010. Retrieved from https://www.cdc.gov/nchs/healthy_people/hp2010.htm
- Centers for Disease Control and Prevention. FDA licensure of quadrivalent human papillomavirus vaccine (HPV4, Gardasil) for use in males and guidance from the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 59:630-2.
- Linear Array HPV Genotyping Test (Application manual 04462268001) Roche Molecular Systems, Inc., Branchburg NJ, USA.
- Onyekwuluje et al. A real-time PCR assay for HPV52 detection and viral load quantification. Clin Lab. 2012;58:61-6.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name:	SEQN
SAS Label:	Respondent sequence number
English Text:	Respondent sequence number.
Target:	Females only 18 YEARS - 59 YEARS

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

Target: Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	764	764	
2	Negative	1094	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

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
Target: Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	1850	1850	
2	Negative	8	1858	
.	Missing	206	2064	

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
Target: Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	1826	1826	
2	Negative	32	1858	
.	Missing	206	2064	

LBDR06 - HPV type 6

Variable Name: LBDR06**SAS Label:** HPV type 6**English Text:** HPV type 6**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	21	21	
2	Negative	1837	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR11 - HPV type 11

Variable Name: LBDR11**SAS Label:** HPV type 11**English Text:** HPV type 11**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	2	2	
2	Negative	1856	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR16 - HPV type 16

Variable Name: LBDR16**SAS Label:** HPV type 16**English Text:** HPV type 16**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	41	41	
2	Negative	1817	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR18 - HPV type 18

Variable Name: LBDR18**SAS Label:** HPV type 18**English Text:** HPV type 18**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	22	22	
2	Negative	1836	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR26 - HPV type 26

Variable Name: LBDR26**SAS Label:** HPV type 26**English Text:** HPV type 26**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	6	6	
2	Negative	1852	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR31 - HPV type 31

Variable Name: LBDR31**SAS Label:** HPV type 31**English Text:** HPV type 31**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	19	19	
2	Negative	1839	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR33 - HPV type 33

Variable Name: LBDR33**SAS Label:** HPV type 33**English Text:** HPV type 33**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	11	11	
2	Negative	1847	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR35 - HPV type 35

Variable Name: LBDR35**SAS Label:** HPV type 35**English Text:** HPV type 35**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	33	33	
2	Negative	1825	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR39 - HPV type 39

Variable Name: LBDR39**SAS Label:** HPV type 39**English Text:** HPV type 39**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	49	49	
2	Negative	1809	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR40 - HPV type 40

Variable Name: LBDR40**SAS Label:** HPV type 40**English Text:** HPV type 40**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	19	19	
2	Negative	1839	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR42 - HPV type 42

Variable Name: LBDR42**SAS Label:** HPV type 42**English Text:** HPV type 42**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	35	35	
2	Negative	1823	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR45 - HPV type 45

Variable Name: LBDR45**SAS Label:** HPV type 45**English Text:** HPV type 45**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	29	29	
2	Negative	1829	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR51 - HPV type 51

Variable Name: LBDR51**SAS Label:** HPV type 51**English Text:** HPV type 51**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	54	54	
2	Negative	1804	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR52 - HPV type 52

Variable Name: LBDR52**SAS Label:** HPV type 52**English Text:** HPV type 52**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	68	68	
2	Negative	1790	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR53 - HPV type 53

Variable Name: LBDR53**SAS Label:** HPV type 53**English Text:** HPV type 53**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	98	98	
2	Negative	1760	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR54 - HPV type 54

Variable Name: LBDR54**SAS Label:** HPV type 54**English Text:** HPV type 54**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	98	98	
2	Negative	1760	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR55 - HPV type 55

Variable Name: LBDR55**SAS Label:** HPV type 55**English Text:** HPV type 55**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	49	49	
2	Negative	1809	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR56 - HPV type 56

Variable Name: LBDR56**SAS Label:** HPV type 56**English Text:** HPV type 56**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	24	24	
2	Negative	1834	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR58 - HPV type 58

Variable Name: LBDR58**SAS Label:** HPV type 58**English Text:** HPV type 58**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	35	35	
2	Negative	1823	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR59 - HPV type 59

Variable Name: LBDR59**SAS Label:** HPV type 59**English Text:** HPV type 59**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	40	40	
2	Negative	1818	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR61 - HPV type 61

Variable Name: LBDR61**SAS Label:** HPV type 61**English Text:** HPV type 61**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	97	97	
2	Negative	1761	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR62 - HPV type 62

Variable Name: LBDR62**SAS Label:** HPV type 62**English Text:** HPV type 62**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	99	99	
2	Negative	1759	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR64 - HPV type 64

Variable Name: LBDR64**SAS Label:** HPV type 64**English Text:** HPV type 64**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	0	0	
2	Negative	1858	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR66 - HPV type 66

Variable Name: LBDR66**SAS Label:** HPV type 66**English Text:** HPV type 66**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	52	52	
2	Negative	1806	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR67 - HPV type 67

Variable Name: LBDR67**SAS Label:** HPV type 67**English Text:** HPV type 67**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	11	11	
2	Negative	1847	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR68 - HPV type 68

Variable Name: LBDR68**SAS Label:** HPV type 68**English Text:** HPV type 68**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	30	30	
2	Negative	1828	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR69 - HPV type 69

Variable Name: LBDR69**SAS Label:** HPV type 69**English Text:** HPV type 69**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	5	5	
2	Negative	1853	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR70 - HPV type 70

Variable Name: LBDR70**SAS Label:** HPV type 70**English Text:** HPV type 70**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	54	54	
2	Negative	1804	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR71 - HPV type 71

Variable Name: LBDR71**SAS Label:** HPV type 71**English Text:** HPV type 71**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	17	17	
2	Negative	1841	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR72 - HPV type 72

Variable Name: LBDR72**SAS Label:** HPV type 72**English Text:** HPV type 72**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	38	38	
2	Negative	1820	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR73 - HPV type 73

Variable Name: LBDR73**SAS Label:** HPV type 73**English Text:** HPV type 73**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	23	23	
2	Negative	1835	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR81 - HPV type 81

Variable Name: LBDR81**SAS Label:** HPV type 81**English Text:** HPV type 81**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	63	63	
2	Negative	1795	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR82 - HPV type 82

Variable Name: LBDR82**SAS Label:** HPV type 82**English Text:** HPV type 82**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	8	8	
2	Negative	1850	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR83 - HPV type 83

Variable Name: LBDR83**SAS Label:** HPV type 83**English Text:** HPV type 83**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	78	78	
2	Negative	1780	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR84 - HPV type 84

Variable Name: LBDR84**SAS Label:** HPV type 84**English Text:** HPV type 84**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	84	84	
2	Negative	1774	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDR89 - HPV type 89

Variable Name: LBDR89**SAS Label:** HPV type 89**English Text:** HPV type 89**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	79	79	
2	Negative	1779	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	

LBDRPI - HPV type IS39

Variable Name: LBDRPI
SAS Label: HPV type IS39
English Text: HPV type IS39
Target: Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	7	7	
2	Negative	1851	1858	
3	Inadequate	14	1872	
.	Missing	192	2064	