# 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  $\beta$ -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  $\beta$ -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  $\beta$ -globin control as well. Types were read by comparing the reaction pattern to the typing template.

Samples that were negative for HPV and the  $\beta$ -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

binary

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 I tem
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

E	ode or Value	Value Description	Count	Cumulative	Skip to I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
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 I tem
1	Positive	7	7	
2	Negative	1851	1858	
3	Inadequate	14	1872	
	Missing	192	2064	