

National Health and Nutrition Examination Survey

2013-2014 Data Documentation, Codebook, and Frequencies

Human Papillomavirus (HPV) DNA - Vaginal Swab: Roche Cobas & Roche Linear Array (HPVSWR_H)

Data File: HPVSWR_H.xpt

First Published: December 2016

Last Revised: NA

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 other 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 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 girls and women. 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 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 and older were eligible. The public data file includes data for persons aged 18-59 years. Please see Analytic Notes about the release of data for adolescents aged 14-17 years.

Description of Laboratory Methodology

Roche Cobas HPV DNA Test

LBXHP2C (Cobas HPV Swab High Risk Result)

DNA extraction is performed with a modified protocol and the commercial QIAamp kit (Qiagen, Valencia, CA). Presence of high-risk HPV in the extracted patient DNA is determined with the Cobas Human Papillomavirus (HPV) Test. This qualitative in-vitro diagnostics test uses oligonucleotide probes labeled with four different fluorescent dyes. The primers target a DNA region of approximately 200 nucleotides within the polymorphic L1 region of the HPV genome to detect 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) in a single analysis. The test reports concurrently the presence of one or more of these types at clinically relevant infection levels, however the test has been modified from the FDA approved format (sample type and extraction) and results cannot be used clinically.

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 Linear Array Laboratory Procedure Manual](#) (December 2016)

[HPV Vaginal Swab Cobas High Risk Laboratory Procedure Manual](#) (December 2016)

Laboratory Quality Assurance and Monitoring

Vaginal swab specimens are processed, stored, and shipped to 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 are stored at room temperature until they are shipped to Chronic Viral Diseases Branch, Division of High-Consequence Pathogens and Pathology for analysis.

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. 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 quality assurance evaluation during unscheduled 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.

NCHS developed and distributed a quality control protocol for all the contract laboratories which outlined the use of Westgard rules when running NHANES 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 [2013 - 2014 Laboratory Data Overview](#) for general information on NHANES laboratory data.

Sample Weights

MEC exam sample weights should be used for analyses.

NHANES Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES [2013-2014 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 respondents 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.

Roche Cobas HPV DNA Test

The Roche Cobas HPV test is qualitative and only determines the presence or absence of high-risk HPV. If any analyte HPV 16, HPV 18 or Other High-risk is indicated as positive (POS) in the Cobas result file the result for the sample ID will be recorded as positive. If all of the HPV analytes are negative (NEG) in the Cobas result file the result for the sample ID will be recorded as negative. If any of the analytes are indicated as invalid in the Cobas result file, the DNA from that sample will be re-tested one time to obtain valid results. If the repeated result are still invalid the final result will be recorded as invalid.

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.

Detection Limits

Since this data is reported as qualitative data the use of lower LLODs is not applicable.

Data Access

The public release data file includes HPV data for participants aged 18–59. Data for youth aged 14–17 years are available through the [NCHS Research Data Center \(RDC\)](#).

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.
- 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.
Target:	Females only 18 YEARS - 59 YEARS

LBXHP2C - Cobas HPV Swab High Risk

Variable Name: LBXHP2C

SAS Label: Cobas HPV Swab High Risk

English Text: Cobas HPV Swab High Risk

Target: Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	409	409	
2	Negative	1528	1937	
3	Inadequate	58	1995	
.	Missing	169	2164	

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	852	852	
2	Negative	1133	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	1977	1977	
2	Negative	8	1985	
.	Missing	179	2164	

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	1931	1931	
2	Negative	54	1985	
.	Missing	179	2164	

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	20	20	
2	Negative	1965	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	5	5	
2	Negative	1980	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	62	62	
2	Negative	1923	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	33	33	
2	Negative	1952	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	3	3	
2	Negative	1982	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	32	32	
2	Negative	1953	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	12	12	
2	Negative	1973	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	30	30	
2	Negative	1955	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	53	53	
2	Negative	1932	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	13	13	
2	Negative	1972	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	39	39	
2	Negative	1946	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	45	45	
2	Negative	1940	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	68	68	
2	Negative	1917	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

LBDR52 - HPV type 52

Variable Name: LBDR52**SAS Label:** HPV type 52**English Text:** HPV type 51**Target:** Females only 18 YEARS - 59 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	60	60	
2	Negative	1925	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	123	123	
2	Negative	1862	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	102	102	
2	Negative	1883	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	59	59	
2	Negative	1926	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	42	42	
2	Negative	1943	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	32	32	
2	Negative	1953	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	50	50	
2	Negative	1935	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	109	109	
2	Negative	1876	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	135	135	
2	Negative	1850	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	1985	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	55	55	
2	Negative	1930	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	22	22	
2	Negative	1963	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	35	35	
2	Negative	1950	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	4	4	
2	Negative	1981	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	39	39	
2	Negative	1946	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	16	16	
2	Negative	1969	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	31	31	
2	Negative	1954	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	49	49	
2	Negative	1936	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	65	65	
2	Negative	1920	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	20	20	
2	Negative	1965	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	76	76	
2	Negative	1909	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	112	112	
2	Negative	1873	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	90	90	
2	Negative	1895	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	

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	10	10	
2	Negative	1975	1985	
3	Inadequate	10	1995	
.	Missing	169	2164	