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Human papillomavirus infection in women in Puerto Rico: Agreement between physician-versus self-collected anogenital specimens

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Abstract

Objective—To describe the prevalence and concordance between cervical and anal HPV infection and compare cervicovaginal and anal self-collection methods for HPV testing between physician and self-collected specimens in women in Puerto Rico.

Materials and Methods—Specimens for HPV-DNA testing were obtained from 100 women aged 18-34 years attending a general gynecology clinic for a routine Pap smear. HPV testing was performed using PCR MY09/MY11 primers. Positive samples were typed for 39 genotypes. Agreement between sampling methods was determined by % agreement and the kappa statistic.

Results—38.4% (38/99) of cervicovaginal and 33.7% (30/89) of anal physician-collected samples were HPV+, for the 39 genotypes evaluated; whereas, 35.1% (34/97) of cervicovaginal and 32.0% (31/97) of anal self-collected samples were positive. HPV-16 was the most common type identified in the cervix (8.3%, 8/97) and the anus (5.6%, 5/89) of physician-collected samples, with similar prevalence in self-collected samples. Concordance between cervical and anal HPV infection was high (>90%) for all HPV types evaluated. There was strong % agreement between physician and self-collected cervicovaginal and anal samples (>95% for all HPV types) and good-excellent agreement (kappa>0.60) for most HPV types.

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Conclusions—The clinic-based prevalence of anal and cervicovaginal HPV infection was high, with strong concordance between cervical and anal infection and good to excellent agreement between physician and self-collected samples. This study supports the feasibility of utilizing cervical and anal self-sampling methods in future population-based studies of HPV infection in PR, and as an HPV screening method in women.

Keywords

Human papillomavirus; anal cancer; cervical cancer; screening; self-sampling

Introduction

Persistent infection with certain types of human papillomavirus (HPV) is associated with cervical and anal cancer, accounting for 96% and 93% of these tumors, respectively [1]. In women, anal and cervical squamous intraepithelial lesions tend to occur concurrently or consecutively [2], an observation partially explained by the fact that anal and cervical HPV infections are strongly correlated [3,4] and that the histology of the anus is similar to that of the cervix, making them both prone to HPV carcinogenesis [5]. Although research documents concordance between anal and cervical HPV infection [4, 6], research in this area is still limited.

HPV testing, as primary screening [7] or as an adjunct to cytological screening for cervical cancer, has shown diagnostic advantage with a combined sensitivity for cervical intraepithelial neoplasia 2 and 3 of nearly 100% [8-10]. However, collection of cervicovaginal specimens by physicians continues to be a challenge in many settings [11]. Self-collected cervicovaginal specimens for HPV testing [12-15] and other sexually transmitted infections [16] as well as for cervical cancer screening [9] have been found to be a sensitive, convenient and acceptable method by women in studies worldwide. Cervicovaginal self-collection has been proposed as a cost-effective approach for cervical cancer screening and for research purposes [11]. Although HPV cervical self-sampling is less sensitive than clinician sampling [17], a recent meta-analysis showed that self-collected cervicovaginal samples had good screening accuracy for HPV DNA with an overall sensitivity of 74% and specificity of 88% for detecting cervical precancers [11].

Physician-collected samples for anal cytology have shown similar [18], or better [19] sensitivity to detect anal intraepithelial neoplasia compared to self-collected samples by men who have sex with men (MSM). Nonetheless, anal self-sampling techniques for HPV testing among MSM have shown excellent concordance with physician collected samples [18]. To our knowledge, no study has assessed the adequacy of anal self-sampling collection methods in women. Self-collected anal specimens may be suitable for use in HPV-related natural history studies and treatment and vaccine trials [18], as well as in the development of screening programs for anal cancer.

Although the diagnostic accuracy of cervicovaginal self-sampling specimen collection methods have been demonstrated in other populations, data among Hispanics remains scarce [17, 20], and absent for Puerto Rico (PR). In addition, information on the concordance of cervical and anal HPV infection is scarce and limited to studies in few populations [6]. This study describes the 1) overall and type-specific prevalence of cervicovaginal and anal HPV infection, the 2) concordance between cervical and anal HPV infection and 3) determines the agreement between self-collected and physician-collected cervical and anal specimens for HPV testing in a clinic-based sample of women in PR.

Materials and Methods

Study population and data collection procedures

One-hundred consecutive non-institutionalized women aged 18-34 years-old attending the University of PR Gynecology Clinic for routine Pap smear screening between November 2007-June 2008, who completed an informed consent, were included. Women were ineligible if they were HIV-infected or cognitively or physically impaired. Participants completed a face-to-face interview on demographic, lifestyle and reproductive characteristics, and self-reported history of abnormal cervical cytology. Information on sexual practices was collected through a self-administered questionnaire using an Audio Computer Assisted Self-Interview (ACASI) system implemented using Questionnaire Development System (QDS) (Nova Research Co., Washington D.C.). Participants received HPV educational materials and monetary compensation upon study completion. Women positive for cervical high-risk HPV infection received post-counseling and referral for follow-up medical evaluation. This study was approved by the Institutional Review Board of the University of Puerto Rico Medical Sciences Campus.

Collection of Cervicovaginal and Anal Biological Specimens

Physician's specimen collection—After interview completion, participants underwent a pelvic examination and collection of biological specimens by a trained Obstetrician/Gynecologist. The study physician collected cervicovaginal and anal specimens for HPV-DNA using a Cytobrush® (CooperSurgical, Inc; Connecticut, USA) and Dacron swab, respectively. For the cervicovaginal collection, the cervix was sampled first and then the upper 1/3 of the vagina. Samples were placed in separate vials containing 1 mL Sample Transport Medium (STM) (Qiagen Inc; Duesseldorf, Germany).

Patient's self-collection of specimens—After the physician collected the specimens, patients were given verbal and written instructions for anal and cervicovaginal self-collection and a sterile collection kit containing written instructions for self-sampling (including a diagram of the female genital anatomy), two pairs of latex gloves, one Dacron swab, one Cytobrush®, two vials containing 1 mL STM, and 1 sealable plastic bag for disposal of sampling materials. In a private, well-lit room, women were instructed to wear latex gloves to remove the sterile Cytobrush®, to assume a comfortable position and insert the brush into the vagina as far as they could without losing the end [21]. They were asked to pull the brush half-way out the vagina, reinsert it, move it up and down 5 times, make 3 complete rotations at the cervix, immediately place it in the first STM vial containing the sample, and tightly close the bottle. After collecting the cervicovaginal sample, women were instructed to change gloves, remove the Dacron swab from the package and moisten it with tap water before inserting it 1 inch into the anal canal. They were asked to apply gentle pressure to the walls of the anal canal, and rotate the swab in spiral motion for 10-seconds before removing it [22], place it into the second vial of STM, and close the vial tightly. All specimens were stored at −70°C and shipped on dry ice to the University of California, San Francisco for HPV typing.

Analysis of Biological Specimens

HPV detection and typing—HPV typing was performed using L1 consensus primer polymerase chain reaction (PCR) with MY09/MY11 primers. After thawing, the samples were digested with Proteinase K (PK, Invitrogen) at a final concentration of 250 μg/ml at 56°C overnight. The PK was heat inactivated, and 200 μl was precipitated and suspended in 25 μl Tris-EDTA. Five microliters of sample were used for PCR amplification using the standard 40 cycle protocol [23]. PCR products from positive samples were typed by dot-blot hybridization using 39 individual type-specific probes, including oncogenic HPV types as

defined by IARC (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68) and non-oncogenic types (6/11, 26/69, 30, 32/42, 34, 53, 54, 57/2/27, 61, 62, 67, 68, 70, 71, 72, 73, 81, 82, 83, 84, 85, 76/87, 90/106, 97, 102/108, as well as 2 separate mixtures, mix1 contains 7/13/40/43/44/55/74/91, and mix2 contains 3/10/28/29/77/78/94 plus all those HPV types that hybridized only with the consensus probe) [24].

Statistical analysis

Frequency distributions were used to describe the study population and the HPV-types detected in the anus and the cervicovaginal areas. Agreement between self-collected and physician-collected anal and cervicovaginal samples was calculated for specific oncogenic and non-oncogenic HPV types. The agreement between sampling methods was defined as the percentage of pairwise samples for which test results for detection of any HPV-DNA were identical. Differences between paired physician- and self-collected cervicovaginal and anal samples were assessed by the McNemar test. An unweighted kappa statistic was computed to compare the agreement between physician- and self-collected sampling methods for both cervicovaginal and anal samples. Percentages (%) agreement and kappa statistic were also used to determine the agreement between cervical and anal samples, both using self-collected and clinician collected samples. Using the physician-collected sample as the “reference standard”, we calculated the sensitivity and specificity of self-collection methods for HPV detection. Statistical analyses were performed using STATA/SE 11.0 (Stata Corporation, Collage Station, Texas).

Results

Study population

The mean age of participants was 26.4± 0.4 years, most were born in PR, and had completed at least high school education. Forty-six percent of women reported first sexual intercourse <18 years, 12.1% had ≥ 10 lifetime sexual partners and 19% had an abnormal Pap test result at study recruitment (Table 1).

Prevalence of HPV infection

Among satisfactory samples, 38.4% (38/99) of cervicovaginal and 33.7% (30/89) of anal physician-collected samples were HPV+, for the 39 genotypes evaluated; whereas, 35.1% (34/97) of cervicovaginal and 32.0% (31/97) of anal self-collected samples were positive. HPV-16 was the most common type identified in the cervix (8.3%, 8/97) and the anus (5.6%, 5/89) of physician-collected samples, with similar findings in self-collected samples. The most common HPV types identified in both the physician- and self-collected cervicovaginal samples were HPV-16, -53 and -90/106; whereas, the most common types in both physician and self-collected anal samples were HPV-16, -51, -56, and -90/106 (Table 2). Based on the 39 type-specific probes, no HPV infection was detected in 65.0% (63/97) of self- and in 61.6% (61/99) of physician-collected cervicovaginal samples, and in 61.9% (60/97) of self- and 66.3% (59/89) of physician-collected anal samples. Infection with one and multiple (2+) HPV types was detected respectively in 14.4% (14/97) and 20.6% (20/97) of self- and in 20.2% (20/99) and 18.2% (18/99) of physician-collected cervicovaginal samples, and in 19.6% (19/97) and 18.6% (18/97) of self- and 18.0% (16/89) and 15.8% (14/89) of physician-collected anal samples (data not shown).

Cervical and anal HPV infection concordance

Among samples satisfactory for both the cervix and the anus, the prevalence of co-infection ranged from 0% to 6%, depending on the HPV type evaluated; co-infection was highest for HPV-16. Concordance between cervical and anal HPV infection was high (% agreement

>90%), with good to excellent agreements (Kappa> 0.60) for most HPV types evaluated (Table 3).

Self-testing vs. Physician testing concordance

There was strong % agreement between physician and self-collected cervicovaginal and anal samples for all HPV types evaluated (>95% for all HPV types), with good to excellent kappa (>0.60) for most HPV types. No statistically significant differences between physician- and self-collected cervicovaginal and anal samples were observed. The HPV type specific estimates of sensitivity and specificity were also high for most HPV types (Tables 4 and 5). Kappa results for the anus were slightly lower than in the cervix.

Discussion

The current study increases our knowledge of anogenital HPV infection in PR and of the performance of self-sampling methods in PR. This information is relevant for the planning of future cancer screening programs and HPV-related studies in this population. Approximately half of the study population was positive for HPV infection in either the cervix or the anus. This result is consistent with population-based estimates of cervicovaginal HPV infection in US women aged 14-59 years (42.5%), based on self-collected samples [25], although higher than estimates of anal HPV infection, based on physician collected samples, among a clinic-based sample of Hawaiian women (27%) [4]. Furthermore, the high concordance between cervical and anal HPV infection is consistent with previous reports from a Hawaiian cohort study [4,6].

Most studies have found good to strong agreement between self-collected and physician-collected cervicovaginal samples using Dacron/cotton swabs or Cytobrush® (κ=0.45-1.00) [11]. Consistent with previous studies, we found good to excellent agreement between self-collected and physician-collected cervicovaginal samples for most HPV types. Also as in previous studies, our results showed good sensitivity and high specificity of cervical self-sampling techniques, supporting their use for HPV screening. Our estimates of specificity and sensitivity for most HPV types fall between the ranges seen in previous studies, sensitivity: 56%-87% and specificity 84%-94% [11]. Similar to other studies, a larger number of HPV types were detected in cervicovaginal self-samples [9, 13, 21]. This result could be explained by the potential collection of HPV-infected cells from external genital sites, such as the vagina, through self-sampling.

Regarding anal sampling, our findings show a good to excellent agreement for most HPV types. These findings are consistent with those observed by Lampinen et al. [18], who reported a good to excellent agreement among self- and physician-collected anal HPV samples in MSM (kappa=0.62-0.83). Similar to the findings in the cervicovaginal samples, we observed high estimates of specificity and sensitivity for any HPV infection in the anal samples, and a larger number of HPV types in anal self-samples than in anal physician-collected samples.

Study limitations include a small clinic-based sample and high risk population (20% had abnormal Pap test results) that does not guarantee that results are generalizable to all women in PR. In fact, 20% of participants had an abnormal Pap at the time of study recruitment, which is even higher than prevalence estimates (13%) in young college women in the US [26]. Sample size for analyses was additionally reduced for some comparisons, as 3% and 13% of self-collected and physician-collected anal samples, respectively, were unsatisfactory. This may be explained by the fact that gynecologists do not routinely perform anal HPV sampling methods, which could have influenced them to be extra careful in sample collection and limiting their ability to collect an appropriate sample. Although the

population screened is younger than those at greater risk for cervical and anal cancer, they are the target for this study as they are young adults, population at highest risk for HPV infection. Despite these limitations, this study among a clinic-based sample of Hispanic females in PR shows the feasibility of using cervicovaginal and anal self-sampling procedures among young adult women in PR, and a high prevalence of anal and cervicovaginal HPV infection and co-infection in these anatomical sites, with a large variety of HPV types not covered by current vaccines. The good agreement between physician-collected and self-collected samples supports the feasibility of utilizing anogenital self-sampling methods in future population-based studies of HPV infection in PR and as an HPV screening method with collection of samples done at home or in a private setting [25]. Further research is warranted to better estimate the overall and type-specific prevalence of anogenital HPV infection in PR. These data that are relevant to better understand the burden of HPV infection and HPV-related conditions in PR, particularly given the high prevalence of HIV and anal sexual practices in PR [27, 28].

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Table 1

Characteristics of study participants (n=100)

	N (%)
Demographics	
Age (years)	
18-24	35 (35.0%)
25-29	37 (37.0%)
30-34	28 (28.0%)
Mean age (years) μ ± SD	26.4 (0.4)
Place of birth	
Puerto Rico	87 (87.0%)
United States	6 (6.0%)
Dominican Republic	7 (7.0%)
Education (years)	
≥ 12	87 (87.0%)
< 12	13 (13.0%)
Annual family income (n=79)	
≥ $20,000	36 (45.6%)
< $20,000	43 (54.4%)
Marital status (n=99)	
Single	60 (60.6%)
Married/Cohabitating	35 (35.4%)
Divorced/Separated/Widowed	4 (4.0%)
Health care coverage	
None	11 (11.0%)
Public insurance	42 (42.0%)
Private	47 (47.0%)
Gynecologic History	
Lifetime number of sexual partners (n=99)	
0-1	18 (18.2%)
2-9	69 (69.7%)
>10	12 (12.1%)
Number of sexual partners in the last 12 months	
0-1	71 (71.0%)
2-3	23 (23.0%)
>4	6 (6.0%)
Age at first sexual intercourse (years)	
<15	21 (21.0%)
16 to 17	25 (25.0%)
≥ 18	54 (54.0%)

	N (%)
Parity (# live births)	
0	67 (67.0%)
1-2	23 (23.0%)
≥ 3	10 (10.0%)
History of STI *	
Yes	25 (25.0%)
No	75 (75.0%)
History of abnormal cervical cytology (n=95)	
Yes	41 (43.2%)
No	54 (56.8%)
Pap smear results at recruitment (n=92)	
Normal	74 (80.4%)
ASCUS	6 (6.5%)
LSIL	9 (9.8%)
HSIL	3 (3.3%)

* STI was defined as self-reported infection with HIV, hepatitis B, gonorrhea, syphilis, genital warts, genital herpes, thricomonas, bacterial vaginosis, HPV or Chlamydia.

Table 2

Specific HPV DNA Types identified by Self-Testing and Physician-Testing

	Anus[a]		Cervix[b]	
Prevalence	**Self-testing (n=97)**	**Physician-testing (n=89)**	**Self-testing (n=97)**	**Physician-testing (n=99)**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Vaccine specific HPV types				
6/11	3 (3.1)	2 (2.3)	3 (3.1)	3 (3.0)
16	4 (4.1)	5 (5.6)	8 (8.3)	9 (9.1)
18	2 (2.1)	1 (1.1)	2 (2.1)	2 (2.1)
Ten most common HPV types				
16	4 (4.1)	5 (5.6)	8 (8.3)	9 (9.1)
51	6 (6.2)	4 (4.5)	3 (3.0)	4 (4.0)
52	4 (4.1)	3 (3.4)	3 (3.0)	4 (4.0)
53	2 (2.1)	3 (3.4)	5 (5.1)	6 (6.1)
56	4 (4.1)	4 (4.5)	4 (4.0)	5 (5.1)
58	3 (3.1)	2 (2.3)	5 (5.1)	3 (3.0)
68	2 (2.1)	1 (1.1)	3 (3.0)	5 (5.1)
61	2 (2.1)	2 (2.3)	4 (4.0)	4 (4.0)
62	3 (3.1)	1 (1.1)	4 (4.0)	3 (3.0)
90/106	4 (4.1)	3 (3.4)	5 (5.2)	6 (6.1)
39 HPV type probes [c]	31 (32.0)	30 (33.7)	34 (35.1)	38 (38.4)
Overall [d]	51 (52.6)	48 (53.9)	47 (48.5)	45 (45.5)

[a] Anus: satisfactory results were obtained for 89 of the clinician-collected samples and for 97 of the self-collected samples.

[b] Cervix: satisfactory results were obtained for 99 of the clinician-collected samples and for 97 of the self-collected samples.

[c] Based on persons positive to any of the 39 type specific probes.

[d] Based on all persons positive with the consensus primers (positive to any HPV type).

Table 3

Concordance between cervical and anal HPV infection, for both self-collected and physician-collected swabs. *a*,*b*,*c*,*d*

	Self-sampling (n=94)			Clinician-sampling (n=88)		
	% co-infected	**% Agreement**	**Kappa**	**% co-infected**	**% Agreement**	**Kappa**
Oncogenic						
16	3.19	94.68	0.52	5.68	95.45	0.69
18	2.13	100.00	1.00	1.14	98.86	0.66
33	1.06	100.00	0.98	1.14	100.0	1.00
35	1.06	100.00	1.00	0.00	98.9	--
39	1.06	98.94	0.66	0.00	97.7	--
51	2.13	94.68	0.42	1.14	93.18	0.21
52	3.19	98.94	0.85	3.41	98.86	0.85
56	3.19	97.87	0.74	3.41	96.59	0.65
58	3.19	98.94	0.85	2.27	98.86	0.79
68	1.06	96.87	0.38	0.00	--	--
Non-Oncogenic						
HPV 6/11	2.13	97.87	0.66	2.27	98.86	0.79
53	2.13	96.81	0.56	2.27	94.32	0.42
54	0.00	97.87	--	1.14	98.86	0.66
57/2/27	1.06	97.87	0.49	1.06	98.86	0.66
61	2.13	97.87	0.66	2.27	97.73	0.66
62	2.13	97.87	0.66	1.14	97.73	0.49
66	1.06	100.00	1.00	0.00	--	--
70	0.00	97.87	--	0.00	95.59	--
73	2.13	98.94	0.79	2.27	98.86	0.79
81	1.06	97.87	0.49	0.00	95.45	--
84	2.13	98.94	0.79	1.14	97.73	0.49
86/87	0.00	97.87	--	0.00	96.59	--
90/106	3.19	96.81	0.65	2.13	94.32	0.42
Mix 1 (7, 13, 40, 43, 44, 55, 74, 91)	1.06	98.99	0.66	--	--	--
Total *e*	26.60	--	--	22.72	--	--

*a*These analyses were focused on women with satisfactory anal and cervical samples for each screening method (clinician, n=88; clinician, n=88).

*b*Other types analyzed that were not found on neither anal or cervical samples were HPV types 30,31, 59, 71, 72, 82, 83, 102/89, 26/69, 67, 85, 97 and mix 2 (3, 10, 28, 29, 77, 78, 94).

*c*Kappa calculated for HPV types who had at least one positive result in both cervix and anus.

[d] All McNemars test results were non-significant (p>0.05). McNemar test could not be estimated for types HPV types 18, 6/11, 73, 81 and 84 given that there were no discordant paired samples.

[e] Based on persons positive to any of the 39 type specific probes.

Table 4

Agreement of HPV infection in the anus: Self-Testing vs. Physician-Testing (n=87)[a,b,c,d]

	% Positive n (%)		Agreement			
	Self-testing	Physician-testing	% Agreement	Kappa	Sensitivity	Specificity
HPV types						
Oncogenic						
16	4 (4.6)	5 (5.1)	96.6	0.65	60.0	98.8
18	2 (2.3)	1 (1.1)	98.9	0.66	100.0	98.8
31	1 (1.1)	0 (0.0)	98.9	--	--	--
33	1 (1.1)	1 (1.1)	100.0	1.00	100.0	100.0
35	1 (1.1)	1 (1.1)	100.0	1.00	100.0	100.0
39	2 (2.3)	2 (2.3)	100.0	1.00	100.0	100.0
51	6 (6.9)	4 (4.6)	95.4	0.58	75.0	96.4
52	4 (4.5)	3 (3.4)	96.6	0.55	66.7	97.6
56	4 (4.6)	4 (4.6)	95.4	0.48	50.0	97.6
58	3 (3.4)	2 (2.3)	98.9	0.79	100.0	98.8
68	2 (2.3)	1 (1.1)	98.9	0.66	100.0	98.8
Non-oncogenic						
6/11	3 (3.4)	2 (2.3)	96.6	0.38	50.0	97.6
30	2 (2.3)	0 (0.0)	97.7	--	--	--
53	2 (2.3)	3 (3.4)	98.9	0.79	66.7	100.0
54	1 (1.1)	2 (2.3)	98.9	0.66	50.0	100.0
57/2/27	1 (1.1)	1 (1.1)	100.0	1.00	100.0	100.0
61	2 (2.3)	2 (2.3)	100.0	1.00	100	100.0
62	3 (3.4)	1 (1.1)	97.7	0.49	100.0	97.7
66	1 (1.1)	0 (0.0)	98.9	--	--	--
70	0 (0.0)	1 (1.1)	98.9	--	--	--
71	1 (1.1)	2 (2.3)	98.9	0.66	50.0	100.0
73	3 (3.4)	3 (3.4)	100.0	1.00	100.0	100.0
81	2 (2.3)	2 (2.3)	97.7	0.49	50.0	98.8
82	2 (2.3)	3 (3.4)	96.6	0.38	33.3	98.8
84	4 (4.6)	2 (2.3)	97.7	0.66	100.0	97.6
86/87	3 (3.4)	2 (2.3)	98.9	0.79	100.0	98.8
90/106	4 (4.6)	3 (3.4)	98.9	0.85	100.0	98.8
102/89	3 (3.4)	2 (2.3)	98.9	0.79	100.0	98.8
Mix 1 (7, 13, 40, 43, 44, 55, 74, 91)	2 (2.3)	0 (0.0)	98.0	--	--	--

[a] Anus: satisfactory results were obtained for 89 of the clinician-collected samples and for 97 of the self-collected samples, for a total of 87 samples with adequate results for both methods..

[b] Other types analyzed that were not found on anal samples were: 26/69, 32/42, 34, 45, 59, 67, 72, 83, 85, 97 and mix 2 (3, 10, 28, 29, 77, 78, 94).

[c] Kappa, sensitivity and specificity calculated for HPV types who had at least one positive result in each sampling method.

[d] All McNemars test results were non-significant ($p>0.05$). McNemar test could not be estimated for types HPV types 31, 33, 35, 57/2/27, 61, 73 and 82 given that there were no discordant paired samples.

Table 5

Agreement of HPV infection in the cervix: Self-Testing vs. Physician-Testing (n=96)[a,b,c,d]

	% Positive n (%)		Agreement			
	Self-testing	**Physician-testing**	**% Agreement**	**Kappa***	**Sensitivity***	**Specificity ***
Oncogenic						
16	8 (8.3)	8 (8.3)	97.9	0.86	87.5%	98.9%
18	2 (2.1)	2 (2.1)	100.0	1.00	100%	100%
33	0 (0.0)	1 (1.0)	99.0	--	--	--
35	1 (1.0)	0 (0.0)	99.0	--	--	--
39	1 (1.0)	0 (0.0)	99.0	--	--	--
45	0 (0.0)	1 (1.0)	99.0	--	--	--
51	3 (3.1)	4 (4.2)	99.0	0.85	75%	100%
52	3 (3.1)	4 (4.2)	96.9	0.56	50%	98.9%
56	4 (4.2)	5 (5.2)	96.9	0.65	60%	98.9%
58	5 (5.2)	3 (3.1)	97.9	0.74	100%	97.8%
68	3 (3.1)	5 (5.2)	97.9	0.74	60%	100%
Non-Oncogenic						
6/11	3 (3.1)	3 (3.1)	100.0	1.00	100%	100%
32/42	1 (1.0)	1 (1.0)	100.0	1.00	100%	100%
34	1 (1.0)	0 (0.0)	99.0	--	--	--
53	5 (5.2)	6 (6.3)	99.0	0.90	83.3%	100%
54	1 (1.0)	1 (1.0)	97.9	--	--	--
57/2/27	3 (3.1)	2 (2.1)	99.0	0.79	100.0	98.9
61	4 (4.2)	4 (4.2)	100.0	1.00	100%	100%
62	4 (4.2)	3 (3.1)	99.0	0.85	100%	98.9%
66	2 (2.1)	1 (1.0)	99.0	0.66	100%	98.9%
70	2 (2.1)	2 (2.1)	97.9	0.49	50%	98.9%
73	2 (2.1)	2 (2.1)	100.0	1.00	100	100
81	2 (2.1)	2 (2.1)	100.0	1.00	100	100
83	0 (0.0)	2 (2.1)	--	--	--	--
84	2 (2.1)	2 (2.1)	100.0	1.00	100	100
86/87	0 (0.0)	1 (1.0)	99.0	--	--	--
90/106	5 (5.2)	6 (6.3)	99.0	0.90	83.3	100.0
Mix 1 (7, 13, 40, 43, 44, 55, 74, 91)	1 (1.0)	0 (0.0)	99.0	--	--	--

[a]Cervix: satisfactory results were obtained for 99 of the clinician-collected samples and for 97 of the self-collected samples, for a total of 96 samples with adequate results for both methods

[b] Other types analyzed that were not found on cervical samples were: 30,31, 59, 71, 72, 102/89, 26/69, 67, 82, 85, 97 and mix 2 (3, 10, 28, 29, 77, 78, 94).

[c] Kappa, sensitivity and specificity calculated for HPV types who had at least one positive result in each sampling method.

[d] All estimated McNemars test results were non-significant (p>0.05). McNemar test could not be estimated for HPV types 32/42 and 83 given that there were no discordant paired samples.