

Human Papilloma Virus detection using self-collected vaginal versus clinician-collected cervical samples in women with a recent diagnosis of cervical dysplasia

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Background and aims:

Vaginal self-sampling is a promising alternative to increase women's participation to cervical cancer primary screening, through high-risk **Human Papilloma Virus (HPV)** detection, as well as allowing the diagnosis of other **Sexually Transmitted Infections (STI)**. The aim of this study was to evaluate detection of HPV and other STI in self-collected vaginal samples as compared to physician-collected cervical samples in women with a recent diagnosis of cervical dysplasia.

Methods:

Self-collected vaginal samples at point of care (POC) and physician administered cervical samples using FLOQSwabs™ (Copan, Italia) was collected from 30 women with a recent diagnosis of cervical dysplasia attending the Gynaecology Outpatients Clinic of San Gerardo Hospital, Monza, Italy.

All samples were transported dry to the Clinical Microbiology Laboratory of the University Milano-Bicocca and subsequently suspended in PreservCyt solution (Hologic) prior to nucleic acid extraction by NucliSENS®easyMAG (bioMérieux).

All samples were assessed for sample cellularity by CCR5 gene quantification, by real-time PCR and for the presence of HPV and STIs (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma hominis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, and *Ureaplasma parvum*), using Anyplex II HPV28 and STI-7 (Seegene).

Conclusions:

Cellularity of both self-collected vaginal and clinician-collected cervical samples using FLOQSwabs™ (Copan Italia) showed comparable results. HPV and STIs detection using Anyplex II HPV28 and STI-7 (Seegene) in self and clinician-collected samples showed a high degree of concordance. Preliminary data demonstrate promising results for the use of self-collected samples in cervical cancer and STI screening programs.

Results:

All samples had an adequate cellularity, with median values for self and clinician-collected samples of 1.70E+06 and 1.05E+07 cells/sample, respectively.

At least one HPV type was detected in 90% (27/30) of women's samples. Co-infections with multiple HPV types were shown in 40% of women, with HPV 16, 31, 53, being the most frequently detected genotypes. **Concordant HPV detection for at least one type was demonstrated in 100%** of self and clinician-collected samples. HPV-type specific concordant detection was observed in 86% of samples.

At least one STIs other than HPV was detected in 53.3% (16/30) of women's samples. **Concordant STIs detection was proved in 93.3% (28/30)** of self and clinician-collected samples.



SAMPLE	PAP TEST	PHYSICIAN ADMINISTERED CERVICAL SAMPLES				SELF-COLLECTED VAGINAL SAMPLES			
		HR	pHR	LR	STIs	HR	pHR	LR	STIs
M021	HSIL		53, 82		Up		53, 82	54, 69	Up
M012	HSIL	56, 59				56, 59			
M003	HSIL	16, 18			Up	16, 18			Up
M005	HSIL	52				52			
M004	HSIL	31				31			
M002	HSIL	16			Up	16			Up
M010	HSIL	NEG				NEG			
M020	HSIL		73				73		
M022	HSIL	NEG				NEG			
M018	LSIL	68	53		Up	68	53		Up
M015	LSIL	52, 68	53		Up	52, 68	53, 70		Up
M013	LSIL	58, 68	53			58, 68	53		
M009	LSIL	56				56			
M016	LSIL	68			Up	68			Up
M014	LSIL	51			Up	51			Up
M011	LSIL		53, 70		Up		53, 70		NEG
M001	LSIL		53				53		
M007	LSIL	39		42	Up	39		42	Up
M027	LSIL	16, 52, 68		54, 61	Uu	16, 52, 68			Uu
M028	LSIL		66				66		
M029	LSIL		66	54			66	54	
M030	LSIL	18, 31			Ct, Up	18, 31			Ct, Up
M006	ASC-H	31				31			
M008	ASC-H	16, 33, 39			Up	16, 33			Up
M017	ACG-US	31				31			
M019	ACG-US	NEG				NEG			
M024	ACG-US	16			Up	16			Ct, Up, Mh
M023	ASCUS	16			Up	16			Up
M025	ASCUS			54				54	
M026	ASCUS	16			Up	16			Up

Table 1. HPV and STIs detections in Self-collected vaginal and physician administered cervical samples. UP (*Ureaplasma Parvum*), UU (*Ureaplasma Urealyticum*), Ct (*Chlamydia trachomatis*) and Mh (*Mycoplasma hominis*)