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Detection and Quantification of HIV-1 in Self-Collected Genital Swabs from Women Enrolled in a Clinical Trial in Chiang Rai, Thailand

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Background: Self-collected genital swabs (SCS) could provide useful information on daily genital shedding of HIV-1 and HSV-2. We evaluated SCS for HIV-1 and HSV-2 and compared them with same-day collected cervicovaginal lavages (CVL).

Methods: Women co-infected with HIV-1 and HSV-2 and enrolled in a clinical trial in Chiang Rai, Thailand, collected genital (combined vaginal, vulvar, perianal) swabs at home. Swabs were pre-saturated with DNA/RNA Protect™,* stored at 8 to 31°C as long as 7 days, then frozen at –70°C. Women also had 10-mL CVL collected in the clinic weekly. CVL (5 mL whole; 5 mL separated into supernatants and pellets) were frozen at –70°C. HIV-1 in SCS and CVL supernatants was quantitated using the Amplicor v 1.5 assay, where extraction was modified by the addition of dithiothreitol, and heating (SCS) or silica beads (CVL); lower limit of detection: 20 to 40 copies/reaction. HSV-2 was detected in whole CVL and SCS, extracted as above, by real-time polymerase chain reaction (RT-PCR); assay sensitivity was ~1 to 10 copies/ reaction. Correlations of 373 same-day samples were assessed using Pearson's *r*.

Results: HIV-1 was detected in 252 (67.6%) SCS and 208 (55.8%) CVL; HSV-2 was detected in 65 (17.4%) SCS and 39 (10.5%) CVL (see the table). Copy numbers of HIV-1 and HSV-2 (median, range), respectively, were: SCS (320, 40 to 26,897; 3.04 x 10^4, 80 to 2.41 x 10^8 /swab); CVL (225, 20 to 23,691; 5.40 x 10^2 , 40 to 1.59 x 10^7 /mL). Copy numbers were significantly correlated in concordantly HIV-1 positive (r =0.6, p <0.001) or HSV-2 positive (r = 0.5, p <0.001) samples.

Conclusions: HIV-1 and HSV-2 assessments from SCS are useful for studies evaluating viral genital shedding, since they facilitate frequent evaluation. These data suggest that, in women co-infected with HIV-1 and HSV-2, SCS may be more sensitive for detection of viral shedding than CVL. Differences in the findings may relate to sample type, specimen storage, dilution, method of extraction, or compartment tested.

SCS	HIV-1 Results in CVL N (%)*				HSV-2 Results in CVL N (%)*		
	Positive	Negative	Invalid**	Total	Positive	Negative	Total
Positive	183 (49.1)	66 (17.7)	3 (0.8)	252 (67.6)	32 (8.6)	33 (8.8)	65 (17.4)
Negative	22 (5.9)	95 (25.5)	0	117 (31.4)	7 (1.9)	301 (80.7)	308 (82.6)
Invalid**	3 (0.8)	1 (0.2)	0	4 (1.0)	0	0	0
Total	208 (55.8)	162 (43.4)	3 (0.8)	373 (100)	39 (10.5)	334 (89.5)	373 (100)

* number (percent) of specimens; **no internal control detected

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* The sample preservative, formerly called "DNA/RNA Protect™", is manufactured by Sierra Molecular Corporation and is available under the trade name GeneLock™. More information about GeneLock™.and the other AssayAssure™ technologies is available at www.sierramolecular.com.