

Diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* with APTIMA Combo 2 Testing of Self-Collected Vaginal Samples Using Flocked Swabs and an ESwab Collection and Transport System

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ABSTRACT

Objectives: A significant number of infections with *C. trachomatis* [CT], and *N. gonorrhoeae* [GC] are asymptomatic, requiring screening with less invasive sampling. Flocked swabs [FS] and a universal transport media from Copan have been shown to enhance the analytical sensitivity endpoints for detection of CT and GC in contrived specimens using nucleic acid amplification assays. [J Clin Microbiol, 2006;44:1084]. The current studies compared swab types and media transport systems for self-collected vaginal swabs to diagnose CT and GC in a transient youth population.

Methods: Following testing of contrived specimens prepared in ESwab Media [ESM] and PBS to determine analytical sensitivity, a total of 291 women self-collected 3 vaginal swabs in a randomized fashion; an APTIMA swab [AS] into APTIMA buffer, a flocked swab [FS] into APTIMA buffer and the flocked swab of the ESwab [ES] kit into ESM containing Amies media [Copan]. The samples were tested within 48 hours for CT and GC in the APTIMA Combo 2 [AC2] assay [Gen-Probe]. A patient was considered positive for CT or GC if at least 2 of 3 swabs were positive for an infection.

Results: CT and GC laboratory strains as ten-fold dilutions in PBS or ESM [contrived samples] revealed equal analytical sensitivity endpoints, or were within a ten-fold difference for each organism. In the clinical trial the prevalences of infection were 12.7% [37/291] for CT, 3.1% [9/291] for GC, and 2.4% [7/291] for CT and GC together. All CT and GC infections were detected equally by the 3 sampling and transport systems, with 100% sensitivity and specificity. The majority of patients found it easy to self-collect 3 vaginal swabs.

Conclusions: Women can easily collect their own vaginal sample. Compared to the AC2 collection and transportation system, flocked swabs in APTIMA buffer and flocked ESwabs in ESM detected all of the patients infected with CT and/or GC. Flocked swabs placed into APTIMA buffer or the ESwab collection kit could be used for the diagnosis of CT or GC using the AC2 assay.

Specimen Testing:

- When received at the lab, a volume of 200µL from the ESwab media tube was removed and placed into the ACM tube prior to testing in the APTIMA Combo 2 assay.
- All three vaginal samples were tested by the APTIMA Combo 2 assay (Gen-Probe Incorporated) within 48 hours.
- A patient was considered positive for CT, GC if at least 2 of 3 samples were positive for a particular infection.



AS (GenProbe) FS (Copan)



ESwab (Flocked swab in 1mL Amies medium)

INTRODUCTION

- It has been well documented that reservoirs of infections caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* remain predominantly in the asymptomatic population.
- Undiagnosed infections may lead to upper tract complications such as endometritis and salpingitis leading to pelvic inflammatory disease, ectopic pregnancy, or tubal factor infertility.
- Screening programs involving less invasive sampling (FCU/ vaginal or vulvar swabs) as well as self sampling may be more compliant to patients.
- The ESwab collection and transport system (Copan) is a CE marked product that preserves nucleic acids and bacterial/viral antigens including CT/GC for both culture and molecular testing.

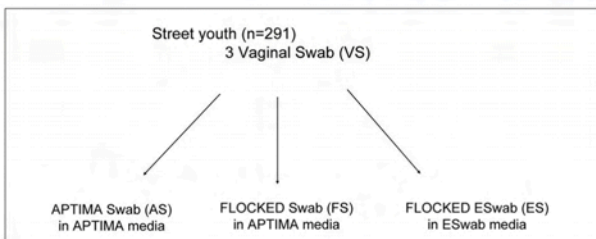
OBJECTIVES

- To compare the ESwab collection kit [Copan] to both APTIMA swab [AS] and the Flocked swab [FS] into ACM to diagnose CT and GC by APTIMA Combo 2 assay using self-collected vaginal samples.

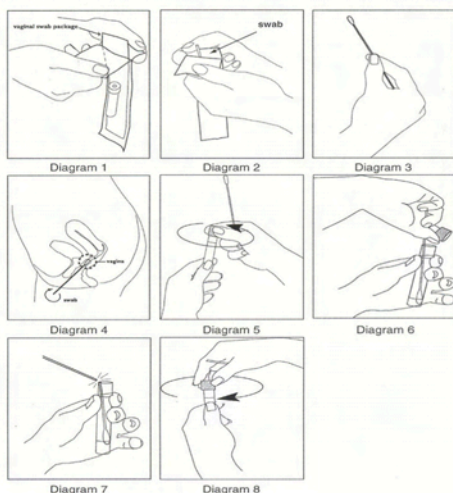
METHODS

Patient Recruitment:

- A total of 291 consenting women from an inner-city Youth Health Centre street-youth clinic had self-collected 3 vaginal swabs in a randomized fashion; an APTIMA swab [AS] into APTIMA buffer [STM], a flocked swab [FS, Copan Diagnostics Inc.] into APTIMA buffer and the flocked swab of an ESwab kit [ES] into ESwab media [Copan Diagnostics Inc.].



Each patient followed instructions shown graphically in an 8 step diagram.



RESULTS

Patient Demographics:

- Participants were aged 14-25 years old. They were predominantly asymptomatic (>80%), many were sexually assaulted at an early age (>50%), had a previous STD (>50%) and had multiple sex partners in the past two months.

% Prevalence of Infection

<i>Chlamydia trachomatis</i>	12.7 (37)
<i>Neisseria gonorrhoeae</i>	3.1 (9)
Dual Infections (CT and GC)	2.4 (7)

Infection rates in these street youth were high compared to non-street youth rates which are normally 6% for CT, 1.5% for GC but the rate of combined infection with both organisms was similar at 18%.

Detection of CT and GC in self-collected VS from 291 women

Organisms	Swab Types and Transport Systems		
	AS/ACM (%)	FS/ACM (%)	ES/ESM (%)
<i>C. trachomatis</i>	37/37 (100)	37/37 (100)	37/37 (100)
<i>N. gonorrhoeae</i>	9/9 (100)	9/9 (100)	9/9 (100)

- The analytical sensitivity of CT and GC ATCC strains were similar in AC media and ES media (10^3 for CT and 10^4 for GC).
- Most women found it easy to self-collect VS.

CONCLUSIONS

- In this study population, the youth diagnosed with CT and GC presented to the clinic were often asymptomatic.
- Women easily collected their own vaginal sample and preferred this procedure for the diagnosis of CT and GC.
- Flocked swabs in APTIMA buffer and flocked ESwab media detected the same patients infected with CT and/or GC as the AC2 collection and transportation system.