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Analysis of 14 Day Stability for Dry COPAN FLOQSwabs™: Self-Collected Vaginal Specimens Evaluated with the cobas® CT/NG Test

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Introduction & Objectives

Molecular testing methods to detect the presence of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) have become the standard of care as a result of increased analytic sensitivity, specificity, and rapid turn-around time compared to traditional culture methods. Following collection, swabs are often placed into liquid transport media, which increases their stability and allows for testing several weeks to months post collection. The use of dry swabs has been proposed to improve convenience of collection, and encourage screening in women at high risk of infection; however, it is essential that their stability be established through clinical studies.

Methods

The **cobas**® CT/NG Test is an FDA cleared in vitro nucleic acid amplification test for the qualitative detection of CT and/or NG. The test is approved for use with clinician-collected and patient-collected vaginal swab specimens in **cobas**® PCR Media, as well as other specimen types. To determine the suitability and stability of a dry swab collection method, **cobas**® CT/NG Test results using an FDA-cleared test process for self-collected vaginal swabs were compared to those collected with dry COPAN FLOQSwabs™ from women ages 18-25 years, and analyzed at days 0 and 14 following expression into cobas® PCR Media.

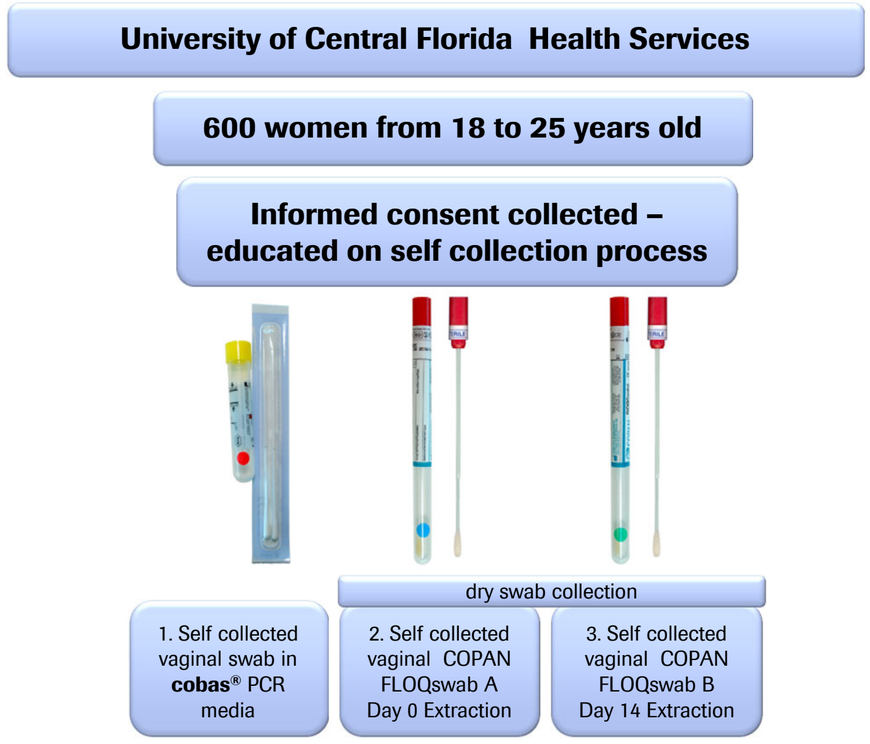

Figure 1. Sample collection scheme for clinical study participants

Figure 2. **cobas**® 4800 System (**cobas x** 480 and **cobas z** 480 instruments)

Results

Analysis at day 0 with the **cobas**® CT/NG Test identified 39/600 (6.5%) of self-collected swabs using cobas® PCR Media collection kits (FDA cleared protocol) as positive for CT, while 561/600 (93.5%) were negative for CT. NG analysis demonstrated positive results for 1/600 (0.16%), while 599/600 (99.8%) were negative for NG. Expression of swabs into **cobas**® PCR Media and analysis at day 14 demonstrated 99.8% overall concordance for CT results with positive findings in 39/600 (6.5%) specimens, while 561/600 (93.5%) were negative. NG results at day 14 were found to be 100% concordant with those of day 0 (1/600 positive, 599/600 negative).

Positive Samples for CT or NG with cobas

	Standard	Day 0	Day 14
CT	37/600 (6.2%)	39/600 (6.5%)	39/600 (6.5%)
NG	1/600 (0.16%)	1/600 (0.16%)	1/600 (0.16%)

Conclusions

These data support the use of COPAN FLOQSwabs™ for use with the **cobas**® CT/NG Test, and indicate suitable stability of at least 14 days from the time of collection.

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