

Comparing Flocked Swabs to Kit Swab for the Collection of Clinical Specimens for the Diagnosis of *Chlamydia trachomatis* Infections with the APTIMA Combo 2 Assay

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Abstract

Chlamydia trachomatis (CT) infections are one of the most common sexually transmitted diseases. It has been reported that, contrived specimens, prepared with flocked swabs (FS) inoculated with an ATCC strain of *Chlamydia trachomatis*, placed in the Gen-Probe APTIMA Combo 2 assay transport media and tested with the same assay. No interference was noted and was shown to enhanced the analytical of the assay.

Objectives: a) to compare the detection of CT and Neisseria gonorrhoeae (GC) nucleic acid in the Gen-Probe Aptima Combo 2 (AC2) assay from clinical specimens collected with Copan flocked swabs to clinical specimens collected with AC2 swabs and transport medium. b) To determine the CT prevalence in a low and a high risk patient population.

Methods: 400 patients were tested in this clinical study, 253 from a clinic with low risk patients and 147 from a clinic with high risk patients. 3 randomized cervical specimens were collected from each patient, one with the system in use at the collection centers, one with an AC2 swab and the other with a flocked swab. After collection, both the AC2 swab and the flocked swab were placed in separate tubes of AC2 specimen transport medium and sent to the testing laboratory. All samples in AC2 medium were tested with the Gen-Probe AC2 assay as per manufacturer procedure. Specimens collected from low risk patients were tested with the BD ProbeTec assay, the specimens collected from high risk patients were tested with the Nonogen CT real time PCR.

Results: In the low risk population 6 patients were found to be CT infected using the AC2 swabs and 6 with the flocked swabs. In the high risk population 22 were found to be CT infected using the AC2 swabs and 23 with the flocked swabs. None of the patients were infected with GC. All the Gen-Probe AC2 CT positives were confirmed with the Gen-Probe APTIMA CT assay. The flocked swabs detected 1 additional CT positive. The CT positivity rates were 2.37% (6/253) in the population of the low risk clinic, and 15.67% (23/147) in the population of the high risk clinic.

Conclusions: The Copan flocked swabs and AC2 swabs transported in the AC2 transport medium and tested with the Gen-Probe AC2 Assay detected almost the same number of CT positive patients; one more CT positive patient was detected with the flocked swabs. Flocked swabs placed into AC2 medium can be used for the diagnosis of CT or GC using the AC2 assay. The *Chlamydia trachomatis* prevalence rates were 2.3% in the low risk population and 15.67% in the high risk population.

Background

Chlamydia trachomatis (CT) infections are one of the most common sexually transmitted diseases. It has been reported that, contrived specimens, prepared with flocked swabs (FS) inoculated with an ATCC strain of *Chlamydia trachomatis*, placed in the Gen-Probe APTIMA Combo 2 assay transport media and tested with the same assay. No interference was noted and was shown to enhanced the analytical of the assay.



AC Swabs



Flocked Swabs

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b) To determine the CT prevalence in a low and a high risk patient population.

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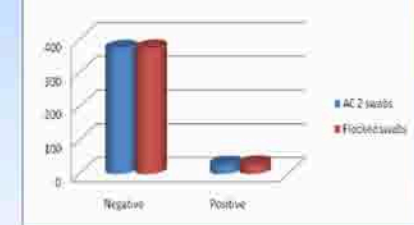
Results

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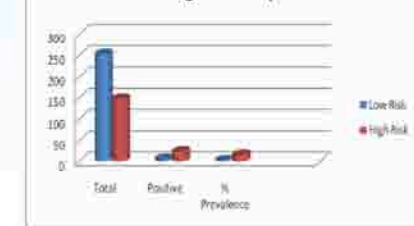
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The CT positivity rates were 2.37% (6/253) in the population of the low risk clinic, and 15.67% (23/147) in the population of the high risk clinic.

CT Positive with AC swabs vs Flocked Swabs



Chlamydia Positive and Prevalence in Low vs High Risk Population



Conclusions

The Copan flocked swabs and AC2 swabs transported in the AC2 transport medium and tested with the Gen-Probe AC2 Assay detected almost the same number of CT positive patients; one more CT positive patient was detected with the flocked swabs

Flocked swabs placed into AC2 medium can be used for the diagnosis of CT or GC using the AC2 assay.

The *Chlamydia trachomatis* prevalence rates were 2.3% in the low risk population and 15.67% in the high risk population.