

Performance of PreservCyt® Solution Specimens on the BD Viper™ System with XTR™ Technology Utilizing the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay

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ABSTRACT

INTRODUCTION: This study examined the performance of PreservCyt® liquid based cytology (LBC) medium on the BD Viper™ System with XTR™ Technology (BD Viper System with XTR) in extracted mode utilizing the BD ProbeTec *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay (CTQ). The objective was to examine the performance of the PreservCyt medium on the BD Viper System with XTR utilizing the CTQ/GCQ assays vs. the patient infected status (PIS).

METHODS: Eleven geographically diverse clinical sites enrolled 2071 subjects. Specimens were collected from symptomatic and asymptomatic females at family planning and OB/GYN clinics (low prevalence), and STD clinics (high prevalence).

Three randomly collected endocervical swabs (references) and a PreservCyt specimen were obtained. One BD ProbeTec ET dry swab was tested using the BD ProbeTec ET CT/GC/AC assay. One Gen-Probe APTIMA® swab was tested with the APTIMA Combo 2 (AC2) assay. The BD ProbeTec Q^x swab was tested utilizing the CTQ/GCQ assay. Each site collected and tested samples or referred the testing to one of the other clinical sites. BD ProbeTec Q^x specimens were sent to an external BD Viper test site.

The PreservCyt specimen was collected with either a broom or brush/spatula collection device, tested on the BD Viper System with XTR utilizing the BD ProbeTec CTQ/GCQ assays and compared to the PIS defined as the following: positive when there were at least two positive endocervical swab results from the nucleic acid amplification tests from the AC2, BD ProbeTec ET, or CTQ assays.

RESULTS:

| Symptomatic | N | Sensitivity | Specificity |
|--------------|-------------|------------------------|--------------------------|
| N | 1346 | 91.9% (68/74) | 99.8% (1270/1272) |
| Y | 725 | 96.7% (59/61) | 99.8% (663/664) |
| Total | 2071 | 94.1% (127/135) | 99.8% (1933/1936) |

In this study, 75% of the compliant subjects came from low prevalence clinics (4.0 - 6.5% for CT) while 25% came from STD clinics (12.3% average prevalence).

CONCLUSIONS: The PreservCyt CT performance showed excellent overall sensitivity and specificity compared to patient infectivity status.

INTRODUCTION

This study examined the performance of PreservCyt® Solution (Cytec Corporation) liquid based cytology medium on the BD Viper™ System with XTR™ Technology (BD Viper System with XTR) combined with the BD ProbeTec *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay (CTQ) and the BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (GCQ). The specimens were collected from April 2, 2008 through September 3, 2008 at family planning, OB/GYN and STD clinical settings. The objective of the study was to examine the performance of the PreservCyt medium on the BD Viper System with XTR utilizing the CTQ/GCQ assays vs. the patient infected status.

METHODS

Eleven geographically diverse Clinical Centers were requested to enroll a total of approximately 2000 patients. Specimens were collected from family planning clinics, OB/GYN offices, and from STD clinics with a prevalence range of 2.1-22.2%. Both symptomatic and asymptomatic females were included in the study.

Three endocervical swabs and a PreservCyt specimen were obtained from each subject. The three endocervical swabs were randomly collected before the PreservCyt vial with the exception of one site which collected the PreservCyt first per their internal protocol. One BD ProbeTec ET endocervical dry swab (reference) was processed and tested on the BD ProbeTec ET CT/GC/AC assays. The Gen-Probe swab was tested on the AC2 test. The BD ProbeTec Q^x endocervical swab was collected and tested on the BD Viper System with XTR. The three endocervical swabs served as the reference.

Each of the Clinical Centers collected samples, tested them on the BD ProbeTec ET CT/GC/AC and Aptima Combo 2 (AC2) testing, or the center referred their testing to one of the other clinical centers. BD ProbeTec Q^x specimens (endocervical swabs and PreservCyt specimens) were sent to one of three external BD Viper test sites.

The PreservCyt specimen was collected by the clinician with either a broom or brush/spatula collection device approved by the media manufacturer, tested on the BD Viper System with XTR in extracted mode utilizing the BD ProbeTec CTQ/GCQ assays and compared to the patient infected status (PIS) defined as the following:

- The patient infected status (PIS) was defined as positive when there were at least two positive endocervical swab results from the nucleic acid amplification tests from AC2, BD ProbeTec ET CT/GC/AC, or CTQ/GCQ assays.

RESULTS

Table 1. CTQ Assay Performance for PreservCyt Specimens by Symptomatic Status and Overall

| Symptomatic | N | Sensitivity | 95% C.I. | Specificity | 95% C.I. |
|--------------|-------------|------------------------|------------------------|--------------------------|-------------------------|
| Y | 1347 | 91.9% (68/74) | (83.2% - 97.0%) | 99.8% (1271/1273) | (99.4% - 100.0%) |
| N | 724 | 96.7% (59/61) | (88.7% - 99.6%) | 99.8% (662/663) | (99.2% - 100.0%) |
| Total | 2071 | 94.1% (127/135) | (88.7% - 97.4%) | 99.8% (1933/1936) | (99.5% - 100.0%) |

Table 2. Percent Enrollment for Compliant Subjects with PIS CT Results by Clinic Type with Combined Prevalence

| Clinic Type | | Number of Compliant Subjects with PIS CT Results | |
|-----------------|-----------------|--|-------------|
| Family Planning | Low Prevalence | 1184 (57.2%) | |
| | | 367 (17.7%) | |
| OB/GYN | High Prevalence | 520 (25.1%) | |
| STD | | 520 (25.1%) | |
| Total | | 2071 | 2071 |

Table 3. CTQ Assay Performance with PreservCyt Specimens vs. PIS – By Collection Clinic Type

| Clinic Type | Prevalence | N | Sensitivity | 95% C.I. | Specificity | 95% C.I. | PPV% | NPV% |
|-----------------|------------|-------------|---------------|-----------------|-------------------|------------------|--------|-------|
| Family Planning | 4.00% | 1184 | 95.7% (45/47) | (85.5% - 99.5%) | 99.8% (1135/1137) | (99.4% - 100.0%) | 95.2% | 99.8% |
| OB/GYN | 6.50% | 367 | 95.8% (23/24) | (78.9% - 99.9%) | 99.7% (342/343) | (98.4 - 100.0%) | 95.7% | 99.7% |
| STD | 12.30% | 520 | 92.2% (59/64) | (82.7% - 97.4%) | 100.0% (456/456) | (99.2% - 100.0%) | 100.0% | 98.9% |
| | | 2071 | | | | | | |

Table 4. Assay Performance by Low and High Prevalence Clinics Compared to PIS

| Clinic Type | Prevalence | N | Sensitivity | 95% C.I. | Specificity | 95% C.I. | PPV% | NPV% |
|--|------------|-------------|---------------|-----------------|-------------------|------------------|--------|-------|
| Low Prevalence: Family Planning OB/GYN | 4.60% | 1551 | 95.8% (68/71) | (88.1% - 99.1%) | 99.8% (1477/1480) | (99.4% - 100.0%) | 95.9% | 99.8% |
| High Prevalence: STD | 12.30% | 520 | 92.2% (59/64) | (82.7% - 97.4%) | 100.0% (456/456) | (99.2 - 100.0%) | 100.0% | 98.9% |
| | | 2071 | | | | | | |

CONCLUSION

The CTQ assay performance for PreservCyt specimens showed excellent overall sensitivity and specificity compared to PIS in both low and high prevalence clinical settings. Studies show that coupling CT testing with routine Pap testing can increase screening thereby reducing serious health consequences of this infection.